



**A Critical Analysis of Evidence-Based Practice in Healthcare:  
The Case of Asthma Action Plans.**

**Submitted for Fulfilment of the Degree of PhD by Publication**

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## **Abstract**

Evidence-based practice is an integral part of multi-disciplinary healthcare, but its routine clinical implementation remains a challenge internationally. Written asthma action plans are an example of sub-optimal evidence-based practice because, despite being recommended, these plans are under-issued by health professionals and under-used by patients/carers. This thesis is a critical analysis of the generation and implementation of evidence in this area and provides fresh insight into this specific theory/practice gap.

This submission brings together, in five published papers, a body of work conducted by the candidate. Findings report that known barriers to action plan use (such as a lack of practitioner time) are symptomatic of deeper and more complex underlying factors. In particular, over-reliance on knowledge derived from randomised controlled trials and their systematic review, as the primary and sole source of evidence for healthcare practice, hindered the implementation of these plans. A lack of evidence reflecting the personal experience of using these plans in the real world, rather than in trial settings, contributed to a mismatch between what patients/carers want from asthma action plans and what they are currently being provided with by professionals. This submission illustrates the benefits of utilising a broader range of knowledge as a basis for clinical practice. The presented papers report how new and innovative research methodologies (including meta-ethnography and cross-study synthesis) can be used to synthesise individual studies reporting the personal experiences of patients and professionals and how such findings can then be used to better understand why interventions can be implemented in trial settings rather than everyday practice. Whilst these emerging approaches have great potential to contribute to evidence-based practice by, for example, strengthening the 'weight' of experiential knowledge, there

are methodological challenges which, whilst acknowledged, have yet to be fully addressed.

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1. Paper 1: Ring N, Malcolm C, Wyke S, MacGillivray S, Dixon D, Hoskins G, Pinnock H, Sheikh A. (2007) Promoting the use of Personal Asthma Action Plans: a systematic review. *Primary Care Respiratory Journal* 16(5):271-283.

2. Paper 2: Ring N., Pinnock H, Wilson C, Hoskins G, Jepson R, Wyke S, Sheikh A. (2011) Understanding what asthma plans mean: a linguistic analysis of terminology used in published texts. *Primary Care Respiratory Journal* 20(2) 170-177.
3. Paper 3: Ring N., P Jepson R, Hoskins G, Wilson C, Pinnock H, Sheikh A, Wyke S. (2011) Understanding what helps or hinders asthma action plan use: a systematic review and synthesis of the qualitative literature. *Patient Education and Counselling* 85(2) e131-e143.
4. Paper 4: Ring N, Jepson R, Ritchie K. (2011) Methods of synthesising qualitative research studies for health technology assessment. *International Journal of Technology Assessment in Healthcare* 27(4) 384-390.
5. Paper 5: Ring N, Jepson R, Pinnock H, Wilson C, Hoskins G, Wyke S, Sheikh A. (2012) Developing novel evidence-based interventions to promote asthma action plan use: a cross-study synthesis of evidence from randomised controlled trials and qualitative studies. *Trials* Nov 20;13: c216.

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Primary Care Respiratory Journal: Ring N, Malcolm C, Wyke S, MacGillivray S, Dixon D, Hoskins G, Pinnock H, Sheikh A. Promoting the use of Personal Asthma Action Plans: a systematic review. *Prim Care Respir J* 2007; 16 (5):271-283. DOI: <http://dx.doi.org/10.3132/pcrj.2007.00049>

Primary Care Respiratory Journal: Ring N, Pinnock H, Wilson C, Hoskins G, Jepson R, Wyke S, Sheikh A. Understanding what asthma plans mean: a linguistic analysis of terminology used in published texts. *Prim Care Respir J* 2011; 20 (2):170-177. DOI: <http://dx.doi.org/10.4104/pcrj.2011.00012>

## **Section 1: Background to submission:**

This PhD submission presents five papers focusing primarily, but not exclusively, on asthma action plans. Together, these papers represent a case study of evidence-based practice in the UK, specifically the use of action plans in asthma self-management, enabling critical re-examination of the generation and implementation of evidence in this particular area of healthcare.

This section outlines the two concepts of evidence-based practice and asthma action plans, setting the context for the submitted research papers and providing an overview of this PhD submission. Key issues are introduced below, but are discussed in-depth in later sections. The later sections also indicate how the five submitted papers have made a significant and original contribution to these two fields of knowledge.

### *1.1 An overview of evidence-based practice:*

The last generation has seen significant change in the context and delivery of United Kingdom (UK) healthcare practice. There has, for example, been a shift in the balance of care from hospital management of acute conditions to the primary care management of long-term chronic conditions with increased multi-disciplinary team-working and shared decision-making involving patients and carers (Scottish Government Social Research 2008; Scottish Government, NHS Scotland (NHSS) & COSLA 2009; NHSS 2010; NHS Education for Scotland (NES) 2012). There have also been strategic and policy directives heralding the introduction of key improvement initiatives such as clinical effectiveness, evidence-based practice (EBP) and clinical governance (Department of Health (DoH) 1998; Her Majesty's Stationery Office (HMSO) 1991; NHS Executive (NHSE) 1999; Scottish Executive Health Department (SEHD) 1999; Scottish Office Department of Health (SODoH) 1998). Although such initiatives were

introduced in the 1990s, they remain central to healthcare practice in the 2010s (NES 2012).

EBP can be defined as 'practice based on the most valid and reliable research findings, the judgement and experience of practitioners, and the views of clients (Parahoo 2006:468). Over the 20 years since its introduction in the 1990s, EBP has been embraced both by a succession of UK Governments and the various multi-disciplinary health professional bodies because of its perceived benefits, which include improvements in the quality of care, increased professional accountability and reduced clinical risk through reductions in the variations in clinical care (HMSO 1991; Sackett *et al.* 1996; SODoH 1997a; SODoH 1997b; DoH 1998; Harrison 1998; French 1999; NHSE 1999; SEHD 1999; French 2005; Jordan & Segrott 2008).

The concept of EBP is actually an umbrella term for various processes including the finding and critical appraisal of evidence (including research), its incorporation into clinical guidelines for practice, and evaluation of its implementation through, for example, clinical audit. It also includes other activities such as health technology assessment, which is the process used to determine whether new drugs, treatments and services should be introduced into mainstream use on the grounds of clinical and cost-effectiveness. To support EBP implementation there have also been many national and international initiatives to find, appraise and convert evidence into recommendations for clinical practice. Within Scotland, two such examples include the introduction of national multi-disciplinary clinical guidelines (in 1993) and nursing and midwifery Best Practice Statements (in 2003) (Scottish Intercollegiate Guideline Network (SIGN) 1995; Nursing & Midwifery Practice Development Unit 2002; Ring *et al.* 2005; Ring *et al.* 2006).

## 1.2 *EBP areas of debate and controversy:*

The introduction of EBP was not without controversy, and the literature was 'fraught with contradiction and dissent' (Rolfe & Gardener 2005:903). Reflecting the context of healthcare at the time, some initially saw EBP as a 'worrisome force' (Walker 2003:151). In the UK, such concerns arose because the governing Conservative party, in power since its election in 1979, had key objectives to make the public sector, including the NHS, more efficient and effective. To achieve this, a series of initiatives were implemented with the aim of 'managing clinical activity' (Ham 1991:3). These initiatives included the introduction of general managers to the NHS in the 1980s (Department of Health and Social Security 1983), and clinical audit, clinical effectiveness and EBP in the 1990s (SEHD 1999; Scottish Office & Clinical Resource and Audit Group (CRAG) 1993). As part of an agenda to modernise the NHS subsequent Labour Governments built on these early initiatives by, for example, ensuring patient treatment decisions were based on effectiveness data. Nevertheless, some perceived these initiatives as a means of rationing and containing costs in response to the ever increasing demand for healthcare (Harrison 1998; Upton 1999; Bradshaw 2000; Swinkels *et al.* 2002). There were also concerns amongst health professionals that such initiatives were a threat to their autonomy and decision-making (Harrison 1998), with some doctors regarding EBP as a 'dangerous innovation ... to serve cost cutters and suppress clinical freedom' (Sackett *et al.* 1996:71). Some also considered EBP would lead to 'cookbook' practice with professionals rigidly adhering to guideline recommendations, resulting in the loss of individualised care (DiCenso & Cullum 1998:38). Nonetheless, despite such initial concerns, the concept of EBP 'has swept the world ... like a new epidemic' (Bradshaw 2000:313) and is now part of mainstream health professional practice in the UK (Nursing and Midwifery Council (NMC) 2008; General Medical Council (GMC) 2009; Davies 2012), with its use expected by healthcare organisations (NHSS 2010). Yet, key areas of debate and controversy remain.

1.2.1 One area of discussion concerns the meaning of EBP itself. Within the literature, there are multiple definitions for EBP (French 2002) (see Table 1). Although some definitions are cited more frequently than others, there is a lack of consensus regarding an agreed definition. There are several reasons for this. First, there appears to be variation in the perceived purpose of EBP. For instance, some definitions consider EBP as supporting professionals with their clinical decision-making *generally* - providing 'best evidence' so 'best' decisions can be made (see Sackett *et al.* (1996) and Muir Gray (1997) - Table 1). Other definitions, reflecting the seminal 1970s work of Archie Cochrane (Cochrane 1972); regard EBP as supporting professionals with their clinical decision-making *specifically* through understanding the effectiveness of diagnostic and therapeutic procedures (for example, Harrison 1998). Second, EBP definitions vary in terms of their reference to patient involvement such as whether patients are consulted in this process (Muir Gray 1997; Dawes *et al.* 2005; Parahoo 2006) (Table 1). Third, although now a generic activity, EBP was derived from evidence-based *medicine* (EBM) (Sackett *et al.* 1996) and the concept adopted by the other healthcare disciplines, including nursing (Jutel 2008). As the original uni-disciplinary EBM has been applied in various multi-disciplinary contexts, including evidence-based healthcare, evidence-based nursing, evidence-based public health and evidence-based management, existing definitions of EBP have been modified and others have emerged.

**Table 1: Some definitions of evidence-based practice including evidence-based medicine and healthcare**

<i>Definition</i>	<i>Source, Year, Country &amp; Discipline(s)</i>	<i>Comments</i>
Evidence based <i>healthcare</i> : 'Is the conscientious use of current best evidence in making decisions about the care of individual patients or the delivery of health services. Current best evidence is up-to-date information from relevant, valid research about the effects of different forms of health care, the potential for harm from exposure to particular agents, the accuracy of diagnostic tests, and the predictive power of prognostic factors'	Attributed to Cochrane (1972) UK source but definition used globally. Initially medicine & epidemiology	This definition is cited on the Cochrane Collaboration website ( <a href="http://www.cochrane.org">www.cochrane.org</a> ) (accessed Jan. 2013). Although attributed to Cochrane (1972) neither the 1 <sup>st</sup> nor 2 <sup>nd</sup> edition of this seminal text (Cochrane 1989) cite this specific definition
An evidence-based health service is: 'a knowledge based health service in which clinical, managerial and policy decisions are based in sound information about research findings and scientific developments' (p1)	DoH (1995) England. Multi-disciplinary audience	
Evidence-based <i>medicine</i> (EBM): 'Is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research' (p71)	Sackett <i>et al.</i> (1996) Canada but used globally. Medicine but applied in other disciplines	This seminal definition is frequently cited across various healthcare disciplines, not just medicine. This definition is also cited on the Cochrane Collaboration website ( <a href="http://www.cochrane.org">www.cochrane.org</a> ) accessed Jan. 2013)
'Providing care to clients for which there is evidence of clinical effectiveness is the cornerstone of EBP. Evidence may come from research, audit, feedback from clients and expertise'	Royal College of Nursing (RCN) (1996) UK. Nursing	
Evidence based <i>healthcare</i> is: 'a discipline centred upon evidence-based decision-making about groups of patients, or populations, which may be manifest as evidence-based policy, purchasing or management' (p3)  Evidence based <i>clinical practice</i> : 'Is an approach to decision-making in which the clinician uses the best evidence available, in consultation with the patient, to decide upon the option which suits that patient best' (p9)  Evidence based <i>clinical practice</i> is 'the conscientious, explicit and judicious use of current best evidence when making decisions about individual patients' (p231)	Muir Gray (1997) UK but used globally. Quality/Management audience as well as health professionals	All 3 definitions are cited in the 1st (1997) & 2nd (2001) editions of Muir Gray's key book. In his chapter on EB <i>clinical practice</i> , all supporting references are for EB <i>medicine</i> with all citations from medical journals.  The 2 <sup>nd</sup> definition given here is cited on the Cochrane Collaboration website ( <a href="http://www.cochrane.org">www.cochrane.org</a> ) accessed Oct. 2012.
'Evidence based <i>healthcare</i> takes place when decisions that affect the care of patients are taken with due weight accorded to all valid, relevant information' (p1)	Hicks (1997) UK Healthcare generally & patients/carers	Source: Bandolier an independent journal of evidence based healthcare information
EBM: 'the doctrine that professional clinical practice ought to be based upon sound biomedical research evidence about the effectiveness of each diagnostic or therapeutic procedure' (p15)	Harrison (1998) UK Management & Policy	Paper (funded by KPMG) appeared in Policy & Politics journal. Definition of EBM used to define EBP in nursing paper (French 2005)

The systematic interconnecting of scientifically generated evidence with the tacit knowledge of the expert practitioner to achieve a change in particular practice for the benefit of a well-defined client/patient group' (p74)	French (1999) Nursing	Author based in Hong Kong but journal paper targets an international audience
'EBP ( <i>medicine, healthcare, nursing</i> ) is based upon epidemiological and bio-statistical principles of evaluating the efficacy and effectiveness of a clinical intervention, the evidence-based movement has had a significant impact on the way clinicians are encouraged to make decisions' (p460)	Kitson (2000) UK Nursing	Paper also notes that 'the principles of EB healthcare can be used to judge the appropriateness of nursing skill mixes as it can for interventions' (p460)
'EBP theoretically ensures that the individual doctor, nurse or therapist is applying knowledge based on sound research, with a good statistical likelihood of a successful outcome' (p1)	Dawes (2000) UK Medicine & management	Author was director of NHS Centre for EBM. Definition in a publication by the Health Service Journal aimed at NHS managers
'EBP is commonly a euphemism for information management, clinical judgement, professional practice development or managed care'	French (2002) Nursing Hong Kong	
Evidence-based <i>practice</i> 'requires that decisions about healthcare are based on the best available, current, valid and relevant evidence. These decisions should be made by those receiving care, informed by the tacit and explicit knowledge of those providing care, within the context of available resources' (p4)	Dawes <i>et al.</i> (2005) International Medicine & epidemiology	Paper 'proposes the concept of EBM be broadened to EBP to reflect the benefits of entire teams and organisations adopting a shared evidence-based approach' (p3)
'Practice based on the most valid and reliable research findings, the judgement and experience of practitioners and the views of clients' (p468)	Parahoo (2006) UK Nursing	
'Evidence-based practice is what the Sister says. ...Procedure that has to be followed in a certain way' (p445)	Rolfe <i>et al.</i> (2008) UK Nursing Management	Definition of EBP in quote from a nurse in a survey of understanding of EBP
'Evidence-based <i>clinical</i> practice or evidence-based <i>medicine</i> is: the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research' (p371) (Author attributes this definition to Sackett <i>et al.</i> (1996))	Muir Gray (2009) UK but used globally. Quality/Management audience and health professionals	Individual clinical expertise is considered to mean 'the proficiency and judgement that individual clinicians acquire through clinical experience and practice' (p371). (Author attributes this quote to Sackett <i>et al.</i> (1996))
'Evidence based <i>practice</i> : is supported by clear reasoning, taking into account the patient's or client's preferences and using your own judgement' (p7)	Aveyard & Sharp (2009) UK Health & social care	
Evidence based <i>clinical</i> practice: 'decisions about patient care based on the best research evidence available, rather than on personal opinions or common practice (which may not always be <i>evidence-based</i> )'	NICE, 2012 England Multi-disciplinary	Definition obtained from NICE website: <a href="http://www.nice.org.uk">www.nice.org.uk</a> (accessed 16/10/12). NICE guidelines manual appendix 2012
Evidence-based <i>practice</i> is: 'systematic search for and appraisal of best evidence; use of evidence for making clinical decisions, the evidence often provided by research; account taken of individual needs of patients, as well as research-based evidence; brings about changes in practice' (p2)	Davies (2012) UK Nursing & Allied Health Professionals (AHPs)	

Whilst the medical origins of EBP are recognised by the other health professions, such as in the nursing literature (Clarke 1999; Walker 2003; Rycroft-Malone *et al.* 2004b), the terms EBP and EBM are intertwined and often used inter-changeably. Some authors writing about EBP in nursing or multi-disciplinary healthcare support their arguments by citing sources from EBM, especially the work of Sackett *et al.* (1996) (including Traynor 2000; Romyn *et al.* 2003; French 2005; Leach 2006). Yet, interchangeable use of the terms EBP and EBM does not adequately acknowledge differences in the current roles of nurses, allied health professionals and doctors, as well as their need for different types of knowledge to underpin their practice. EBM primarily requires knowledge of intervention effectiveness, such as which analgesic works best. Whilst nurses and allied health professionals need such knowledge, this alone is not enough to support the full range of clinical decisions they need to make. Interchangeable use of the terms EBP and EBM also does not take into account differences in how the various healthcare professions developed historically as academic disciplines and in research. As such, what appear to be simply differences in terminology and 'labels' could be more than just semantics, potentially having real implications for the practical application of the principles of EBP by non-medical practitioners.

1.2.2 Another contested area is what constitutes 'evidence', especially 'best' evidence (Rycroft-Malone *et al.* 2004b; Rolfe *et al.* 2008), as 'best' is a value-laden term. For organisations responsible for producing clinical guidelines and health technology assessments, including SIGN and the National Institute for Health and Clinical Excellence (NICE), what constitutes 'best evidence' is explicitly defined in 'levels of evidence.' Levels of evidence (also known as the 'evidence hierarchy' or 'evidence pyramid') determine what 'weight' is attached to a particular source of evidence. The higher a particular piece of evidence is ranked, the more robust,

reliable and better quality it is perceived as a source from which to draw conclusions as a basis for recommended practice. For 'each step up' the hierarchy, the chances of bias are lessened (Kelly & Moore 2012:5). Evidence from the top levels is considered to provide stronger recommendations for practice than evidence from lower levels in the hierarchy.

Given the socio-political context of EBP and its perceived role in controlling costs in the NHS by promoting effectiveness and efficiency (Cochrane 1972), 'best' evidence was initially conceived as having a narrow focus, namely scientific research providing knowledge of intervention effectiveness in the medical areas of prevention, treatment and diagnosis (Cochrane 1972). This requires evidence derived from Randomised Controlled Trials (RCTs) as these objectively investigate efficacy and effectiveness of interventions, including new drugs and surgical techniques, in trial settings. Using statistics RCTs extrapolate their findings to the wider population.

The evidence hierarchy, as illustrated in Table 2, clearly favours this research methodology (O'Cathain *et al.* 2009) with RCTs, their systematic review and meta-analysis shown as the highest level of evidence (NICE 2009; BTS & SIGN 2012). With their high validity and low risk of error and bias (Mickenausch 2010), RCTs are seen as producing a 'scientific truth' (Mickenausch 2010:2), 'uncontaminated by human subjectivity and interpretation' (French 2005), about the effectiveness of new and existing interventions. RCTs have their 'snags' (Cochrane 1989:5); for instance bias has to be carefully guarded against and the technique is not always possible (or appropriate) for ethical reasons (Cochrane 1989). There have also been concerns about the lack of diversity amongst those conducting RCTs – a

<b>Table 2: Levels of Evidence</b>	
1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion
Source: (SIGN 2011).	
Notes: This evidence hierarchy is based on a grading system first reported in 1979 by Canadian doctors (Canadian Task Force 1979). These levels of evidence are used by SIGN and are a refinement of an earlier version (SIGN 1995).	

methodology traditionally associated with Western medical researchers. (This is now changing with a greater range of health professionals conducting RCTs globally, and Cochrane's observation that Catholics and Communists are 'against' RCTs (1989:24) no longer holds true). Nonetheless, the position of RCTs at the top of the evidence hierarchy has become consolidated over time and this is now generally regarded internationally as the 'gold standard' for research (Bradshaw 2000; Rycroft-Malone & Duff 2000; O'Cathain *et al.* 2009; Moher *et al.* 2010) and therefore evidence (Rycroft-Malone & Duff 2000; Nursing and Midwifery Audit Service 1998; Jordan & Segrott 2008).

1.2.3 The 'privileged' position of the RCT at the top of the evidence hierarchy (Clarke 1999; Dixon-Woods *et al.* 2006a) and as '*the* major evaluative tool' (Oakley

1989:27) in EBP is not without controversy. Some argue that the 'priority' given to such scientific and experimental research (Paley *et al.* 2007) has resulted in the 'relative neglect' of other forms of evidence (Rycroft-Malone *et al.* 2004b:83; Nutley *et al.* 2012). Whilst experimental research is valued for generating a specific type of knowledge for practice, such as understanding the effect a new drug has on individuals in a trial setting, research generating knowledge reflecting the views of those who should be using and/or administering that new drug in everyday life – that is, patients/carers and mainstream practitioners – has been under-valued, with 'little attention' paid to the 'contextual and cultural factors' of intervention studies (McCourt 2005:75). Yet, in many areas of clinical practice such knowledge is vital. For example, in public health it is not enough to simply know 'what works'. Evidence is also needed to understand 'what works' for whom, in what circumstances and when. In such circumstances, the evidence hierarchy (as shown in Table 2), which centres on biomedical research studies evaluating the effectiveness of interventions, becomes a 'difficult construct to apply' (Petticrew & Roberts 2003:527).

Evidence from RCTs and systematic reviews alone cannot provide answers across the full range of clinical and practice questions (Petticrew & Roberts 2003; Walach *et al.* 2006; Broom & Tovey 2007; Nutley *et al.* 2012). Different types of clinical questions need to be answered by different types of research studies. This requires 'methodological aptness' (Petticrew & Roberts 2003:528) and means that, in some circumstances, the 'best' study design according to the established evidence hierarchy may not be the most appropriate approach for generating the type of knowledge required.

It has therefore been argued that use of a single evidence hierarchy is 'at best a simplification and at worst a mistake' (Walach *et al.* 2006:9) and that a broader view of evidence is needed – one which better acknowledges the need to answer research questions which are not just about understanding intervention effectiveness. A circular model of evidence (Walach *et al.* 2006), typographies and evidence matrices (Petticrew & Roberts 2003; Nutley *et al.* 2012) have all been suggested as alternatives to the single evidence hierarchy, as better reflecting the complexity and multiplicity of research methods. However, the single evidence hierarchy continues to dominate in healthcare practice being 'employed rigorously' (Broom & Tovey 2007:553) within the fields of guideline development, health technology assessment and systematic reviewing.

1.2.4 Debate over the value and role of different research approaches – for example, experimental research and research capturing patients' views - in providing evidence as a basis for practice has been long-standing. This is because discussion about what constitutes 'best' evidence has traditionally been polarised by the existence of two 'contrasting paradigms' (Saks & Allsop 2013:19); that is, sets of beliefs governing the nature and generation of knowledge. These two paradigms - positivism and interpretivism - each have their own research approaches which in turn, determine their methods - including what data should be collected and how it should be analysed. Positivist research, which includes quantitative research methods such as RCTs and meta-analysis, has been the 'dominant force' in healthcare research (Saks & Allsop 2013:21), with interpretivist research using qualitative methods been conducted less often. Some of the features of quantitative and qualitative research and their advantages and disadvantages are summarised in Table 3.

<b>Table 3: Quantitative and qualitative research: a summary</b>	
<i>Quantitative research</i>	<i>Qualitative research</i>
<p><i>Features e.g.</i> Data are collected as numbers and statistically analysed Research is aimed at discovering facts about phenomena and making causal inferences Researchers are objective as they are outside the research process</p> <p><i>Advantages and disadvantages e.g.</i> Measures used should be valid and reliable The research process should be conducted rigorously and transparently - others should be able to replicate what was done Bias can be minimised Findings can be generalised to the wider population</p> <p>The world investigated in quantitative research e.g. in trials, is different from the real world Measures are 'artificial' constructs identified by the researcher and not real people in their everyday lives Quantitative research is not able to provide interpretation and meaning in a social context Knowledge is seen as cumulative being based on what has been researched before</p>	<p><i>Features e.g.</i> Data are collected in real life settings. Depth of data is critical. Data can be presented as narrative themes Research is aimed at understanding the subjective meaning of phenomena to those who experience them Research is not seen as taking place independently of the researcher e.g. it is not 'value neutral'</p> <p><i>Advantages and disadvantages e.g.</i> The research process can be flexible e.g. it can be iterative Data should be rich in subjective experience Methods are high on internal validity</p> <p>Researcher bias is potentially greater There are multiple possible qualitative research methods Findings may not be generalisable as they may be interpreted differently by different researchers Methods are not replicable by others Internal validity may be high but external validity is absent Knowledge is not seen as being cumulative</p>
Source: (Saks & Allsop 2013:22-28)	

Although there have been 'antagonisms' (Nutley *et al.* 2002:3) between the positivist and interpretivist paradigms and their respective research approaches, in the last decade debate has become less polarised with calls for a pluralist approach towards the generation of knowledge (Petticrew & Roberts 2003; Mays *et al.* 2005; Pearson 2005; Pearson *et al.* 2005). Consequently, instead of a

traditional 'either/or' approach to the two paradigms and their different research approaches, with researchers being either positivist or interpretivist, there is increasingly a shift towards researchers using methods from both paradigms, depending on the nature of their research question(s). For instance, the use of qualitative methods to obtain the views of patients within quantitative healthcare research, including in RCTs, health technology assessments and systematic reviews (Campbell *et al.* 2007; Medical Research Council (MRC) 2000; MRC 2008; Higgins & Green 2011; NHS Quality Improvement Scotland (NHS QIS) 2011), is now recommended. Using an approach which blends research methods from the different paradigms is also illustrated in the submitted papers.

1.2.5 Researchers conducting both positivist and interpretivist research either within a single study and/or throughout their careers is a relatively recent development in the history of health research and the legacy of polarised research paradigms and approaches is still apparent within EBP and the key debates. Of particular importance is the perceived role and value of qualitative research.

Qualitative research obtains personal insight and meaning into the 'real world', for example through interviews of patients/carers. Such research can offset concerns that the RCT form of science is unable to 'contextualise' its answers on an 'individual or social level' (Jutel 2008). Nevertheless, qualitative research is based on an alternative interpretive paradigm. From the perspective of the established evidence hierarchy, which reflects a positivist paradigm (see Table 2), research derived from qualitative methodologies is considered to be 'inferior' (Bradshaw 2000:315), because personal knowledge whether in the form of qualitative research findings and/or expert opinion (such as case studies) is perceived as 'idiosyncratic,

subject to bias and lacking in credibility' (Rycroft-Malone *et al.* 2004b:84). This means that ensuring the views, needs and preferences of patients/carers and professionals are 'heard' in the processes used to generate evidence - and evaluate its implementation - will be challenging to achieve whilst the personal perspective in the form of expert opinion and qualitative methodologies are considered to be 'tainted' with systematic error and lacking in validity (Mickenausch 2010:54) – the 'opposite' of RCTs and systematic reviews with their perceived low risk of error. Qualitative methodologies and expert opinion (whether from patients/carers living with a condition and/or the professionals caring for them), are therefore currently ranked low in the positivist evidence hierarchy, or are not included within such ranking systems, and are generally considered to be weak forms of evidence as a basis for practice.

1.2.6 This system for rating the levels of evidence, used by UK and international organisations, reflects the leading role of medicine, not just in the use of RCTs, but also in the development of the EBP movement from its inception to date. For instance, the seminal work of Archie Cochrane (Cochrane 1972), which preceded the introduction of EBP by two decades, informed EBP implementation internationally, and the world leading organisation conducting systematic reviews (the Cochrane Collaboration) is named after this British doctor. Another example is the Scottish (SIGN) guideline development programme, which was established as an initiative from the medical Royal Colleges.

When the concept of practice based on scientific evidence was first proposed in the 1970s (Cochrane 1972), research was much more established in medicine than in any of the other health disciplines, in the UK and internationally. When EBP was

introduced into mainstream UK healthcare in the early 1990s the positivist hierarchy of evidence, as illustrated in Table 2, reflected a tradition of empirical scientific research as practised almost exclusively by medical researchers. By the mid-1990s, the RCT had been in use for over 50 years in the medical profession (Streptomycin in Tuberculosis Trials Committee 1948) with UK medical researchers leading the way in use of this approach across the world (Cochrane 1989). University medical education had existed for decades, if not centuries, and research was part of this education (especially from the late 1800s). This was not the case for the other healthcare disciplines, which were not generally graduate professions and therefore lacked research capacity and capability. For instance, degree programmes in nursing (the largest healthcare discipline) were only introduced in Europe in the 1960s and until the 1990s these were only available for less than one per cent of student nurses qualifying each year (Sinclair 1984; Ring 2002). As a result when EBP was introduced nursing research (UK and worldwide) was at a 'low base' (Lacey 1994) and 'under-nourished' (Rafferty *et al.* 2003:833) with few researchers in nursing (United Kingdom Central Council for Nursing (UKCC) 1983; Bradshaw 2000) or the allied health professions (AHPs) (Swinkels *et al.* 2002). By the 1990s, although research in nursing and the AHPs was more established, RCTs in these disciplines were uncommon (Swinkels *et al.* 2002; Webb 2003; King & Thompson 2008)<sup>1</sup>. There were several reasons for this.

First, the differing nature of health professional roles - nurses and allied health professionals tend to have a caring role (rather than a curing one like doctors). RCTs, which produce data on intervention efficacy or effectiveness, are therefore not always the most appropriate type of evidence to underpin their practice

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<sup>1</sup> Lack of RCTs in the non-medical professions in the 1990s still has implications for EBP in the 2010s e.g. only 20% of Cochrane Systematic Reviews of RCTs are currently relevant to nurses (Guerden *et al.* 2012).

(Guerden *et al.* 2012). Instead, alternative forms of knowledge are required, including from interpretivist research methods. For nurses, it is generally more relevant to conduct research understanding what it is like to live with cancer pain (so nurses can better support patients and families) than it is to clinically trial new analgesics. Consequently, nurses have a long history of using qualitative research to understand the phenomena of interest to them and those they care for (Webb 2003), but are less likely to conduct RCTs (Hagell 1989; Nursing and Midwifery Audit Service (NMAS) 1998; Webb 2003).

Second, the historical development of the various health professions has influenced their professional research activity. The ability to produce a specialist body of knowledge through research is associated with professional status (Pyne 1992; Mulhall 1998; Bonell 1999; Upton 1999). In the 1980s and 90s, nursing and the allied health professions were in the process of moving from practice-based occupations, with apprentice style learning, to professions with academic disciplines. One of the arguments against nursing being a profession was that it lacked its own knowledge base relying on medical knowledge (Pyne 1992). For nursing to fulfil its aspiration of becoming a profession, it needed a 'distinct knowledge base' and there was a belief this should 'not be grounded in empirico-analytical science' like the medical profession (Hagell 1989:226). Such beliefs further reinforced the use of interpretivist research methods in nursing research.

Research and academic learning, whilst now regarded as essential within nursing and the allied health professionals, were controversial in the UK in the period preceding the introduction of EBP. There was a belief that such knowledge detracted from the acquisition of the necessary practical skills. There was

therefore a culture of anti-intellectualism within the emerging non-medical professions. Within nursing, this contributed to an 'anti-trial culture' (Cullum 1997:5) and a 'backlash' against quantitative research (Webb 2003:933) which reinforced the preference for nurses to participate in research approaches 'different' from those used by doctors (Cullum 1997) that is, to conduct qualitative rather than quantitative research so, as not to be seen as imitating medicine (Hagell 1989:229). (This led to concerns that nursing could become 'marginalised' (Bonell 1999:29) within the EBP movement).

In the 1980s, feminists also argued that RCTs were less 'suited' to the needs of women – whether patients or professionals (Hagell 1989; Oakley 1989). For example, it was argued that the predominantly female nursing and allied health professionals needed knowledge which enabled them to understand the personal experiences of their patients/clients (Hagell 1989), as opposed to data on intervention effectiveness. There were also concerns that 'what counts as knowledge was embedded within masculine values' (Oakley 1989:27) and that 'scientific knowledge was considered as the only legitimate knowledge because men had the power to label it as such' (Hagell 1989). Such arguments seem understandable given that until even the early 2000s, UK organisations leading the EBP agenda, such as the Department of Health and SIGN, were dominated by male doctors (DoH 1995; SIGN 2001). However, as, increasingly, patient values need to be incorporated into clinical decision-making (Dawes 2000), all health professionals now (regardless of gender) need knowledge derived from research other than RCTs and systematic reviews if 'clinically useful measures' are to be generated for practice (Dawes 2000:14). In addition, demographic changes in medicine mean women doctors will soon be in the majority in this profession (Dacre

2012), so the gender argument is less powerful today than it has been in previous decades.

EBP is central to contemporary practice and is likely to remain so in the future. Nonetheless, it is essential that it is understood within its historical context. As mentioned, terms such as EBP and EBM are used interchangeably; however, given the different research traditions within medicine, nursing and the allied health professionals, it is clear that synonymous use of these terms should be done so with caution. The current evidence hierarchy, by placing low value on qualitative research, also implicitly suggests that research which traditionally has been conducted by the predominantly female, non-medical healthcare disciplines is also of lower value than quantitative research methods historically carried out by male doctors. Whilst perceptions that scientific knowledge of (predominantly) male medical practitioners is more 'legitimate' than the alternative forms of knowledge primarily used by (predominantly) female non-medical health practitioners are associated with mid-20<sup>th</sup> century feminists, these perceptions originated much earlier. Such perceptions were present in the 1800s and earlier, when doctors themselves were professionalising and wanted to distance themselves from wise-women who were the 'ordinary practitioners of domestic medicine' (Chamberlain 1981). The debate regarding what constitutes knowledge and 'best' evidence in EBP has deep historical roots within the UK but this is often over-looked in contemporary discussions.

### 1.3 *EBP and the challenge of implementation*

The concept of EBP is underpinned by an assumption that evidence, such as guidelines, can be relatively easily and effectively implemented (Harrison 1998) in

routine practice. In reality, however, this is not always the case. Where there is evidence to underpin clinical practice, for example research which has been translated into guideline recommendations, this evidence is not always being used by practitioners. (One example of this is asthma action plans, discussed further below). Alternatively, where evidence is being used, it is not done so consistently, resulting in variations in care quality. Consequently, routinely getting more evidence into practice and over-coming the 'theory/practice gap' (Upton 1999; Bradshaw 2000; Swinkels *et al.* 2002)<sup>2</sup> has 'become a pre-occupation' of policy-makers and health service organisations (Nutley *et al.* 2002:6) since EBP was introduced.

The challenge of getting EBP implemented is a global one. It is also a multi-professional issue (Swinkels *et al.* 2002). Reducing the gap between recommended and actual practice in order to improve EBP implementation clinically has been the focus of much research, with specific attention on understanding barriers and facilitators to promoting its use. Internationally, many studies have reported barriers to the implementation in everyday clinical practice of evidence generally and research specifically. Some examples, from across the health professions and different countries, include Lai *et al.* (2010); Lyons *et al.* (2011) and Olsen *et al.* (2013). Particular barriers to the use of evidence include lack of time by professionals, lack of awareness of guidelines and other evidence, lack of resources, lack of leadership and/or authority to influence change, and lack of knowledge of research and statistics (Grimshaw & Russell 1994; Barnsteiner 1996; Cheater & Closs 1997; le May 1998; Grol & Grimshaw 2003; McKenna *et al.* 2004; Udod & Care 2004; Sherriff *et al.* 2007; Solomons & Spross 2010; Olsen *et al.* 2013). Difficulties in accessing and appraising evidence, including research, are

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<sup>2</sup> Alternative terms are knowledge into action and research utilisation.

also barriers to implementation (Lai *et al.* 2010; Lyons *et al.* 2011 Christie *et al.* 2012).

Conversely, EBP implementation is likely to occur when these same factors are present and acting as drivers for change (Gerrish *et al.* 2008; Solomons & Spross 2010); for example there being adequate resources and local leaders available to create a supportive organisational context. Getting evidence into practice also requires practitioners with positive attitudes and beliefs towards research (Squires *et al.* 2011; Gerrish *et al.* 2012), multi-disciplinary team-working, the presence of practice development facilitators and supportive colleagues (Yadav & Fealy 2012). Critically, successful implementation requires staff with the authority to make changes to practice and who are empowered to overcome organisational barriers preventing the use of evidence (Oranta *et al.* 2002; Gerrish *et al.* 2008; Chang *et al.* 2010).

Understanding the barriers to, and facilitators for, the use of evidence in practice has been widely researched over the years. It is therefore interesting to note that the barriers and facilitators first identified in the 1990s remain similar in the 2010s (Funk *et al.* 1995; Kerrison *et al.* 1999; Solomons & Spross 2010; Straka *et al.* 2012) and even where there is strategic support for EBP and national initiatives to promote use and overcome recognised barriers, 'patchy' implementation remains with local variations in care evident (Grol & Grimshaw 2003; Ring *et al.* 2006; Barratt 2008).

The 'struggle' (DiCenso & Cullum 1998:38) to get evidence (where it exists) into practice is a long-standing issue internationally and a major limitation of EBP. This is because potential clinical benefits for patients identified in research cannot be realised if evidence-based recommendations are not implemented in real-life. For example, if trial based evidence is later found to be un-implementable in every-day practice. Research reporting this gap between recommended practice and actual practice exists in different disciplines, countries and clinical conditions. One specific example of inadequate EBP implementation is in the promotion and use of asthma action plans.

#### 1.4 Asthma and asthma action plans

Asthma is a long-term condition (LTC). In developed countries such as the UK, the numbers of people living with LTC has increased considerably. The result is more people living at home who are managing their own LTC and/or caring for someone else's LTC. The clinical management of LTC generally – and asthma specifically - is a multidisciplinary topic but is of particular relevance to nurses, especially those working in primary care where most people with LTC are managed.

Asthma is a chronic inflammatory condition of the airways resulting in episodic periods of breathless, wheeze, cough and chest tightness (Global Initiative for Asthma (GINA) 2011). This condition is a 'significant burden' worldwide with approximately 300 million individuals affected (GINA 2011). In England alone in one year (2005), 32 million asthma related prescriptions were issued (Simpson & Sheikh 2010).

To help those with asthma manage their condition, asthma action plans are recommended globally as good asthma care within a programme of self-management education (GINA 2011; BTS & SIGN 2012). Asthma action plans are a written or electronic record detailing the personalised action required to be taken by a patient/parent in response to worsening asthma (Ring *et al.* 2007). Research evidence from RCTs and systematic review of RCTs indicates these plans can improve patient care, for example by reducing unplanned hospital admissions (Gibson *et al.* 2009). However, twenty years after their use was first recommended (BTS & Research Unit of the Royal Colleges of Physicians of London (RURCPL 1990), their implementation remains sub-optimal, with different research studies reporting they are under-promoted by health professionals and under-used by patients/carers internationally (Sulaiman *et al.* 2004; Hoskins *et al.* 2005; Gillies *et al.* 2006; Wiener-Ogilvie *et al.* 2007; Tan *et al.* 2009; Kaferle & Wimsatt 2012). Initiating and sustaining asthma action plan use therefore remains a clinical and strategic priority (DoH 2011; DoH 2012).

As mentioned, the theory/practice gap exists in many healthcare areas and is not specific to respiratory care and asthma action plans. The reasons for professionals not implementing evidence pertaining to asthma action plans are multi-factorial. Many of these reasons are similar to those reported for EBP initiatives generally (see section 1.3) including lack of clinical time and professional training as well as organisational barriers hindering their use. Other reasons, however, are specific to this topic, for example, action plans being perceived as irrelevant and/or suitable only for certain types of patients (Jones *et al.* 2000; Sulaiman *et al.* 2011). There are also practical barriers to asthma action plans use; for example, they need to be easily read and understood by patients (Bibb *et al.* 2007), which is not always the case for those with literacy problems, visual and/or hearing impairment and

language difficulties. There is also evidence that patients/carers experienced in managing their (or their child's) asthma believe they know what to do when asthma worsens and feel they do not need a written plan provided for them by health professionals (Asthma UK Scotland 2008; Ring *et al.* 2011).

## 1.5 Overview of this PhD submission

This PhD submission centres on five research papers which provide fresh insight into the theory/practice gap in the area of asthma action plan implementation. Specifically, it will be argued that known barriers to the use of these plans (such as a lack of clinical consultation time) are actually symptomatic of much deeper and more complex underlying factors which are hindering their implementation – factors which have previously been under-acknowledged as barriers to action plan implementation. This will highlight how limitations within the existing evidence have also been hindering the implementation of written asthma action plans.

Although this submission has a specific respiratory focus, the submitted work also has a wider relevance because the presented research papers report what is, in effect, an in-depth exploration of EBP, providing new insight into the contentious issues outlined above. The presented research on asthma action plans, as a case study for EBP generally, clearly highlights the limitations of RCTs and their systematic review as the primary or sole source of evidence for practice. This submission illustrates the benefits of utilising a broader range of evidence, especially qualitative research, in EBP because it provides knowledge of the personal experiences of those implementing evidence in the real world and not just trial settings. Such awareness has the potential to enable better understanding of why initiatives to promote EBP may be effective in RCT settings but not clinically.

Finally, the submitted papers also demonstrate new and innovative ways in which qualitative research can be used as a basis for practice especially the potential for the synthesis of individual qualitative studies to strengthen the 'weight' of evidence traditionally perceived as low 'value' according to the established evidence hierarchy.

## **Section 2: Introduction to submitted publications and candidate's contribution to this work**

2.1 This PhD submission presents five journal papers (see Box 1 for references) reporting a series of linked empirical studies aimed at better understanding what helps or hinders the promotion and/or use of personal asthma action plans in practice in order to improve their future implementation by professionals and patients. These individual studies/papers have been brought together, 'going beyond' their original aims and purposes to provide a better understanding of EBP specifically in the area of asthma action plans, but also in healthcare generally.

### **Box 1: Full references for submitted papers**

*Paper 1:* Promoting the use of Personal Asthma Action Plans: a systematic review. (2007) *Primary Care Respiratory Journal* 16(5):271-283. Authors: **Ring N**, Malcolm C, Wyke S, MacGillivray S, Dixon D, Hoskins G, Pinnock H, Sheikh A.

*Paper 2:* Understanding what asthma plans mean: a linguistic analysis of terminology used in published texts. (2011) *Primary Care Respiratory Journal* 20(2) 170-177. Authors: **Ring N**, Pinnock H, Wilson C, Hoskins G, Jepson R, Wyke S, Sheikh A.

*Paper 3:* Understanding what helps or hinders asthma action plan use: a systematic review and synthesis of the qualitative literature. (2011) *Patient Education and Counselling* 85(2) e131-e143. Authors: **Ring N**, Jepson R, Hoskins G, Wilson C, Pinnock H, Sheikh A, Wyke S.

*Paper 4:* Methods of synthesising qualitative research studies for health technology assessment. (2011) *International Journal of Technology Assessment in Healthcare*. 27(4) 384-390. Authors: **Ring N**, Jepson R, Ritchie K.

*Paper 5:* Developing novel evidence-based interventions to promote asthma action plan use: a cross-study synthesis of evidence from randomised controlled trials and qualitative studies. *Trials* (2012) 13:216. Authors: **Ring N**, Jepson R, Pinnock H, Wilson C, Hoskins G, Wyke S, Sheikh A.

2.2 Diagram 1 provides an overview of the order in which Papers 1-5 were published. These papers were published in five different, high quality, peer reviewed international journals (see Box 1) representing different fields – respiratory medicine, health education/promotion, health technology assessment and clinical trials. Further details on journal standing, including impact factors, are provided in Section 5.

The individual studies reported in these five papers were conducted over a six year period (2006-11) (see Diagram 1 for data collection dates). With one exception (Paper 1), these studies were conducted during the period of PhD registration. The studies were funded by Asthma UK Scotland and NHS Quality Improvement Scotland<sup>3</sup> (Paper 1), the Chief Scientist Office, Scotland, (Paper 3 and preliminary work for Paper 5) and NHS QIS (Paper 4).

Papers 1-3 and 5 report four research studies conducted in collaboration with colleagues from other academic institutions: Professor Aziz Sheikh and Dr Hilary Pinnock (the University of Edinburgh), Professor Sally Wyke (the University of Glasgow, formerly University of Stirling), Dr Gaylor Hoskins (University of Stirling, formerly the University of Dundee) and Dr. Ruth Jepson (University of Stirling). Within this team, I contributed most to these research studies and preparation of the related papers acting as lead grant applicant, principal investigator and lead author. Overall, I contributed in excess of 85% of the work associated with papers 1-3 and 5. For example, in Paper 1, except for searching of the electronic databases, I led on all the stages within the systematic review process, acting as lead researcher.

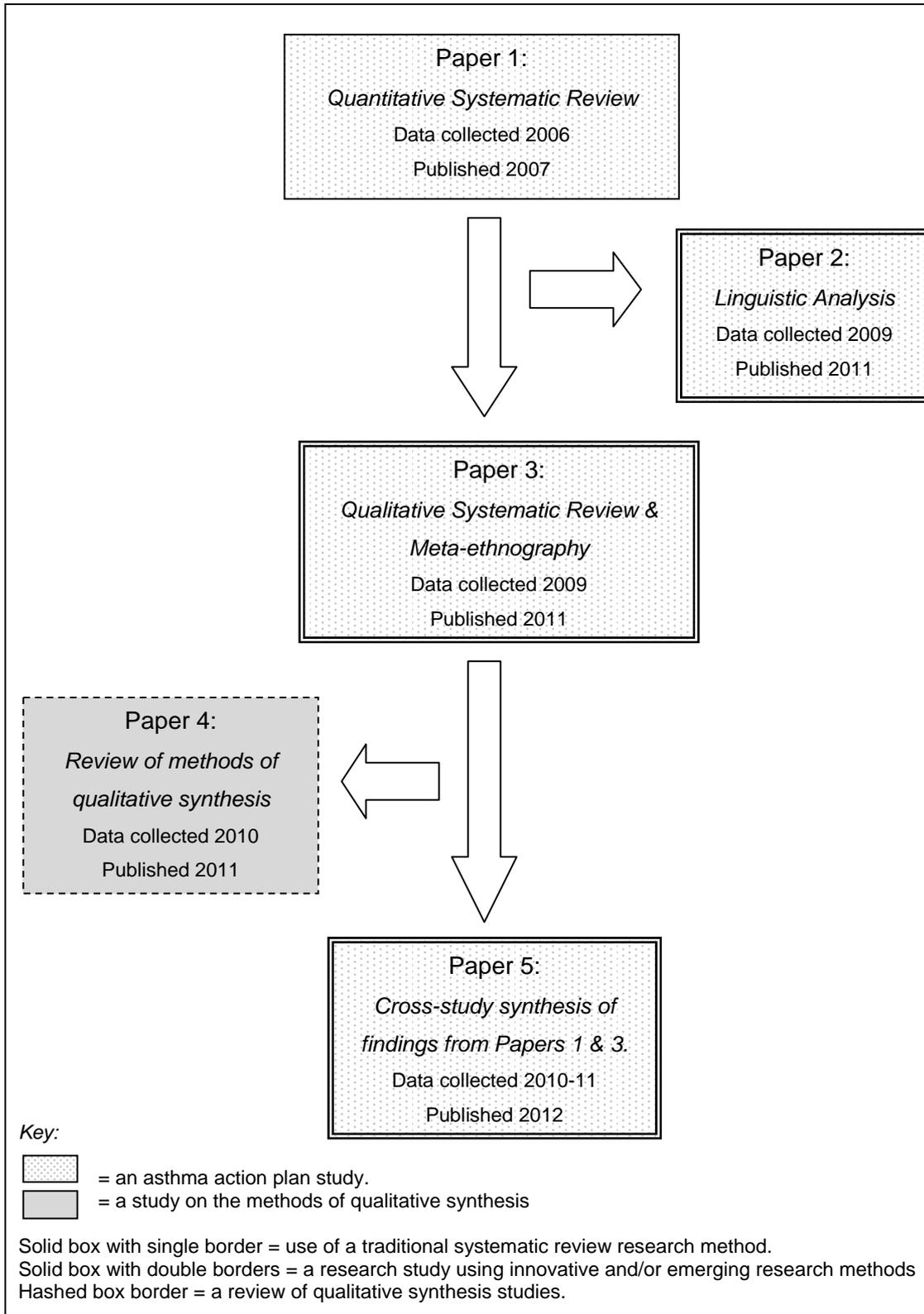
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<sup>3</sup> NHS Quality Improvement Scotland (NHS QIS) is now Healthcare Improvement Scotland (HIS).

Paper 4 was the result of a collaboration between myself, Dr. Ruth Jepson and Dr. Karen Ritchie from NHS QIS. In this paper, I contributed (50%) with Dr Jepson 45% and our NHS partner 5%.

Further details of my contribution to each study are provided in the individual papers. All studies were conducted and papers produced whilst I was employed as a lecturer at the University of Stirling.

**Diagram 1: An overview of the order of the individual research studies, publications and the relationship between the submitted papers.**



**Section 3: Summary of aims, objectives, methodology, methods, results, conclusions of submitted work and ethical issues.**

3.1 Summary of the five individual publications – aims, objectives, methodology, methods, results and conclusions

<p><i>Paper 1:</i> Promoting the use of Personal Asthma Action Plans: a systematic review. (2007) <i>Primary Care Respiratory Journal</i> 16(5):271-283.</p>
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*Aim:* To understand what helps or hinders the promotion and use of personal asthma action plans.

*Objectives:* To determine the most effective method to encourage health professionals to promote and for people with asthma to use asthma action plans.

*Methodology and methods:* Systematic review of quantitative evidence from RCTs published between 1960 and 2006. (See Appendix 1 for full study details). Briefly, to be included in the systematic review, studies had to be RCTs and report measures of action plan promotion by health professionals and/or use their use by patients (action plans need not be the primary focus of the original trial). Nine electronic databases were searched and lead asthma researchers internationally were also contacted for on-going and/or unpublished work. Included studies were quality assessed. Relevant data from included studies were extracted onto specially designed forms prior to analysis. Study characteristics such as participant numbers were analysed using Excel. Other data were analysed as a narrative synthesis.

*Results:* Fourteen RCTs met our study inclusion criteria. These RCTs included a broad range of interventions including postal prompts and educational initiatives. Only four studies reported data for actual action plan use. Generally interventions promoted the facilitation of action plans, such as more patients being issued with these, rather than their use. This review provided evidence of the benefit of organisational initiatives in promoting action plan use, for example systems to increase the number of patients having asthma reviews in primary care (Glasgow et al. 2003).

*Conclusions:* Primary care teams could promote the use of action plans through the implementation of proactive practice based organisational systems for asthma management. Further research is required to assess the effectiveness of interventions sustaining action plan use longer-term. Primary care teams should consider how such interventions could be incorporated into existing practices.

*Paper 2:* Understanding what asthma plans mean: a linguistic analysis of terminology used in published texts. (2011) *Primary Care Respiratory Journal* 20(2) 170-177.

*Aims:* To explore the extent of variation and inconsistencies in asthma plan terminology internationally and to understand how such issues have arisen over time.

*Objectives:*

- 1) To identify from the literature what terms are used for 'asthma plans', with what meaning, and in what context(s)
- 2) To propose a taxonomy of asthma plan terms and definitions.

*Methodology and methods:* Linguistic analysis of a selected body ('corpus') of asthma literature from 1989-2009. (See Appendix 2 for full details). Briefly, the six principles of Biber's model (Biber *et al.* 1998) were applied to the corpus to identify over-arching themes. Data were extracted using Excel and were analysed descriptively to form a narrative synthesis. Timelines for asthma plan terminology were also created.

*Results:* The corpus consisted of 84 sources (including seminal texts, guidelines, research papers) published between 1989 and 2009. A wide range of asthma plan terminology was evident, with terms such as 'action plans', 'self-management plans' and 'treatment plans' being applied inconsistently and synonymously. For individual patients the term 'asthma plan' can describe a clinically-determined list of prescribed medication, an agreed plan to guide self-management of changing symptoms, or a more holistic 'living with asthma' plan. In some contexts the term 'asthma plan' was also used to describe an organisational system of care.

*Conclusions:* A range of asthma plans exist on individual and organisational levels. Within the international literature, a plethora of terms for these different plans is used inconsistently and with varied meaning, resulting in ambiguity and confusion. This is a potential, but under-acknowledged, barrier to asthma plan implementation. A taxonomy of standardised terms and definitions for the different types and levels of asthma plans is therefore proposed.

*Paper 3:* Understanding what helps or hinders asthma action plan use: a systematic review and synthesis of the qualitative literature. (2011) *Patient Education and Counselling* 85(2) e131-e143.

*Aim:* To investigate barriers and/or facilitators to action plan use from the perspective of professionals who should be issuing them and patients/carers who should be using them.

*Objective:* To understand better what helps and/or hinders asthma action plan use from the professionals and patients/carers perspective.

*Methodology and methods:* Systematic review and qualitative synthesis (using meta-ethnography). (See Appendix 3 for full study details). Briefly, data were extracted onto specially designed forms. Data reporting participant findings and author themes and concepts were imported into NVivo (v8) and content analysed. Demographic and study details such as participant numbers were analysed using Excel. Qualitative data from the 'conceptually rich' papers (Malpass *et al.* 2009) were then analysed using refutational analysis and line of argument synthesis (Noblit & Hare 1988). Synthesis grids were also used to develop a new (third order) interpretation of these original studies (Noblit & Hare 1988).

*Results:* Nineteen studies (20 papers) were included in an analysis of patients/carers' and professionals' views. Seven main influences on action plan implementation were identified including perceived un-helpfulness and irrelevance of the plans. Translation and synthesis of the original authors' interpretations suggested that action plan promotion and use was influenced by professional and patient/carers' asthma beliefs and attitudes and patient/carer experiences of

managing asthma. Action plan use is hindered because professionals and patients/carers have different explanatory models of asthma, its management and their respective roles in the management process. Patients/carers, based on their experiential knowledge of their condition, perceive themselves as capable, effective in managing their asthma, but health professionals do not always share this view.

*Conclusion:* Professionally provided medically focused action plans that do not 'fit' with and incorporate the patients'/carers' views of asthma, and their management strategies, will continue to be under-utilised. Professionals need to develop a more patient-centred, partnership-based, approach to the joint development and review of action plans, recognising the experiential asthma knowledge of patients/carers.

*Paper 4:* Methods of synthesising qualitative research studies for health technology assessment. (2011) *International Journal of Technology Assessment in Healthcare*. 27(4) 384-390.

*Aim:* To better understand which methods for synthesising qualitative research are being used and with what focus.

*Objectives:*

- 1) To identify which methods for synthesising qualitative research have been most used in health research to-date
- 2) To determine which methods have a potential role in health technology assessment specifically.

*Methodology and methods:* To identify reviews conducted using the eight main methods for synthesizing qualitative studies, nine electronic databases were searched in 2010 using key terms including meta-ethnography and synthesis. Descriptive analysis and a summary table is used to group the identified reviews by their use of the eight methods, highlighting the methods used most generally and specifically in relation to health technology assessment topics. (See Appendix 4 for full study details).

*Results:* 107 reviews were identified using one of the eight main methods of qualitative synthesis. Four methods (meta-ethnography, meta-study, meta-summary, and thematic synthesis) have been most widely used and have a role within health technology assessment. Meta-ethnography is the leading method for synthesizing qualitative health research. Thematic synthesis is also useful for integrating qualitative and quantitative findings. Four other methods (critical interpretive synthesis, grounded theory synthesis, meta-interpretation, and cross-case analysis) have been under-used in health research and their potential in health technology assessments is currently under-developed.

*Conclusions:* Synthesizing individual qualitative studies has become increasingly common in recent years. There are many possible approaches for synthesizing qualitative studies and this range of methods can be confusing. Although this is still an emerging research discipline such an approach is one means of promoting the patient-centeredness of health technology assessments.

*Paper 5:* Developing novel evidence-based interventions to promote asthma action plan use: a cross-study synthesis of evidence from randomised controlled trials and qualitative studies. *Trials* (2012) 13:216.

*Aim:* To use findings from our meta-ethnography to re-interpret findings from our earlier systematic review of RCTs enabling a better understanding of how the benefits of action plans might be realised in trial settings but not clinically.

*Objective:* To integrate findings from our previously conducted quantitative and qualitative syntheses focusing on barriers and facilitators to asthma action plan implementation.

*Methodology and methods:* A two-stage cross-study synthesis. First, a theoretical model of action plan implementation was proposed, based on our synthesis of 19 qualitative studies, identifying elements which, if incorporated into future interventions could promote their use. Second, elements in our model of action plan implementation were used as a framework with which to secondary analyse the 14 RCTs previously reviewed. To do this, we assessed the strength to which the elements in our action plan model were present within the RCT interventions (i.e. 'strong', 'weak' or no presence) and with what effect. Matrices charted each element's presence and strength, facilitating analysis of element presence and measures of action plan implementation. (See Appendix 5 for full details).

*Results:* Four elements - professional education, patient/carer education, partnership working and communication (between patients/carers and professionals) - were identified in our model as likely to promote asthma plan use. Thirteen interventions reporting increased action plan promotion and/or use

contained all four elements, with two or more strongly present. One intervention reporting no effect on action plan implementation contained only weakly present elements. Only four interventions reported action plan measures relating specifically to the elements. Whilst important from the professional and patient/carer perspectives, the integral role of these elements in intervention delivery and their effect on study outcomes was under-acknowledged in these RCTs.

*Conclusions:* Our approach enabled a new interpretation to emerge of how action plan use can be promoted in trial settings but is harder to achieve in everyday practice. Evidence-based interventions better reflecting the realities of living with asthma and clinical practice are needed to promote action plan use. Our innovative approach identified the need for future interventions to strongly incorporate those elements contained in our model of action plan implementation. That is, effective professional and patient/carer communication and partnership working, facilitating the joint development of patient-centred action plans with professional *and* patient/carer education supporting development of these skills. There is now a need to further test such a complex intervention using a cluster trial design.

### 3.2: Ethical issues

Gaining ethical approval for healthcare research can be difficult to obtain as the process can be time-consuming and bureaucratic (van Teijlingen *et al.* 2008). NHS ethical approval was not required for these studies as data were collected through review of existing published studies. Also, whilst papers arising from these studies are included as part of this PhD submission, they were conducted within my role as a lecturer within the School of Nursing, Midwifery and Health – they were not conducted as a student research study *per se*. As such, School Research Ethics

Committee approval was not required either. Nonetheless, research governance requirements meant that as principal investigator I had a responsibility to conduct and manage these studies ethically (SEHD 2006; MRC 2012). That is, to ensure the studies were conducted transparently, with academic rigour, to ensure the results were of the highest quality and that funders' money was used appropriately. To that end several mechanisms were put in place to achieve this. For example, each study had a project steering group including members of the academic team and other stakeholders. During the research process two researchers worked independently and then collaboratively to ensure that all relevant studies were included and there was agreement for study decisions including identification of themes arising from the data, and an appropriate audit trail was created. (Ethical issues are discussed further in Section 7).

## **Section 4: Rationale for submitted publications and their interrelationship**

The background to the individual papers and their interrelationship is summarised below and illustrated in Diagram 1.

4.1 **Paper 1** reports a study which was conducted in response to a commissioning request by NHS QIS (now HIS) and Asthma UK (Scotland). These organisations had a joint priority to better understand the barriers and facilitators to asthma action plan use so they could make recommendations for practice, thereby improving future implementation of these plans which are internationally recommended as good asthma practice (GINA 2011; BTS & SIGN 2012). When Professor Wyke accepted this request and established the initial collaboration with the Universities of Edinburgh and Dundee, the programme of work which has since ensued – and is still on-going - was not anticipated.

On completion of this quantitative systematic review, findings indicated a need for further research. This was because whilst research from the 14 RCTs reviewed provided some evidence for increasing the promotion of action plans, especially their distribution to patients, there was a lack of trial evidence on how best to initiate and sustain their actual use amongst patients/carers. This resulted in an application by the team (led by me) to the Chief Scientist's Office (CSO) for Scotland for research monies to undertake a qualitative synthesis using meta-ethnography to investigate the topic from the perspective of those who should be issuing and/or using these plans.

Once the qualitative systematic review and meta-ethnography started it became very apparent that ambiguity and confusion regarding action plan terminology was a significant issue, with a variety of terms, such as 'action plan', 'self-management

plan' and 'asthma management plan' being used interchangeably and inconsistently. Although the team had previously commented on this issue in Paper 1 (Ring *et al.* 2007), during the qualitative literature searching process, the extent of the issue was found to be far greater than originally reported. It was found that if two authors used the same term, such as 'action plan', it was not always certain whether they were referring to the same concept with exactly the same meaning. This preliminary finding meant that, from necessity, before continuing further with the meta-ethnography the scope of ambiguity and confusing asthma plan terminology in the literature needed further investigation. This was done through linguistic analysis of a corpus of key asthma documents, including seminal research papers and early asthma guidelines. This work enabled us to propose a taxonomy of standardised terms and definitions for asthma plans, allowing us to 'anchor' our study terms prior to completion of the meta-ethnography. Findings from the linguistic analysis are reported in **Paper 2** and the qualitative systematic review and meta-ethnography in **Paper 3**.

Although CSO provided funding for the meta-ethnography, a condition of this funding was that we integrated findings from our two separate quantitative and qualitative syntheses (Papers 1 and 3). Such an approach was, and still is, an innovative and under-used method (see Section 6). At the time (2009), project funding deadlines meant it was only possible to report preliminary findings from this cross-study synthesis in our CSO project report and to establish that this approach was actually feasible. Consequently, the full scale integration of our qualitative and quantitative findings was completed during 2010-2011 (led by me on behalf of the team). Results of this cross-study synthesis, integrating findings from the quantitative and qualitative syntheses are reported in **Paper 5**.

4.2 Whilst the primary purpose of these studies and their resulting publications has been to better understand the promotion and use of asthma action plans, an unanticipated outcome has been in my use of innovative methods for synthesising qualitative studies. The acquisition of such specialist skills and knowledge has been timely as there has been a significant multi-disciplinary increase in the use of qualitative synthesis methods (see Section 6). This expertise resulted in an invitation for Dr. Jepson and me to collaborate with Dr. Karen Ritchie at NHS QIS in the production of a commissioned report on methods of qualitative synthesis for health technology assessment (NHS Quality Improvement Scotland 2011). On completion of this report, this team then undertook an additional small-scale (unfunded) review to systematically identify studies published to date using different methods of qualitative synthesis, reporting when, with what frequency and for what purpose these methods were used, and which were most suited to health technology assessment. As this study was conducted before the cross-study synthesis was completed its findings are presented in **Paper 4**.

## **Section 5: Journal standing, journal choice and reception of submitted papers**

### *5.1 Paper 1: Quantitative systematic review of RCTs (Ring et al. 2007)*

This paper was published in the Primary Care Respiratory Journal (PCRJ). PCRJ, as an established international journal specialising in respiratory care from a primary care perspective, was our target journal. This choice reflected our topic, target professional audience (practice nurses and general practitioners who are key in promoting action plans) and the primary care/general practice background of the research team. Although the PRCJ has a multi-disciplinary audience, it is primarily a medical journal and has a citation index of 2.61 (as at December 2012). Currently only about 25-30% of manuscripts submitted to PCRJ are accepted (source: [www.thepcrj.org](http://www.thepcrj.org) December 2012).

For Paper 1 to subsequently inform clinical practice and future research, it needed to be published in a journal specialising in respiratory care. As most asthma researchers are doctors and/or social scientists, Paper 1 had to appear in such a journal if it was to be perceived as a credible source of evidence to other researchers. So, although I have a nursing background, nursing journals were not considered by the team because they have lower impact ratings than medical journals, which could result in lower citation rates. Whilst there are higher ranking respiratory medicine journals than PCRJ, our study was a descriptive synthesis rather than meta-analysis (see Sections 1 and 6 for further details on meta-analysis in the evidence hierarchy) which meant these journals would be unlikely to accept this paper for publication. This reinforced PCRJ as an appropriate first choice journal.

As at December 2012, Paper 1 has received 18 citations including several international ones such as Singapore and America (Tan *et al.* 2009; Kaferle & Wimsatt 2012). Paper 1 also received a positive evaluation from DARE (the Database of Abstracts of Reviews of Effects), NHS Centre for Reviews and Dissemination (CRD) within the Cochrane Library. Each DARE abstract is a critical summary of individual systematic reviews assessing effectiveness of interventions with an assessment of the review's overall quality. A positive evaluation is important to ensure future citations by others and indicates a review meets the criteria for inclusion on DARE.

#### 5.2 *Paper 2: The linguistic analysis (Ring et al. 2011a)*

This paper was also published in the PCRJ but this was not our first choice journal. Paper 2, whilst a small scale study, highlighted a long-standing international problem of ambiguous and inconsistent asthma plan terminology – a problem that we reported was acting as an unacknowledged barrier to the implementation of such plans. As we identified that different types and levels of asthma plans existed, we also proposed a taxonomy of terms and standardised definitions. Paper 2 used linguistic analysis - an approach established in other academic disciplines – but which is an original and innovative method in healthcare research. Our first choice journal was Thorax (Impact Factor 8.4) but, disappointingly, our submitted manuscript was returned without reaching peer review. A revised manuscript was then submitted to Patient Education and Counseling but whilst reviewer comments were positive, the editor rejected the paper as not being a priority for publication. This paper was then submitted to PCRJ where it was accepted.

To-date (14/12/12), this paper has only received three citations, although two citations were from international asthma researchers (Australia and Canada).

Importantly, one of these citations (Reddel 2011) is a PCRJ Editorial featuring our findings and proposed taxonomy and states that 'what emerges is an embarrassment of confusion' in asthma plan terminology (Reddel 2011:116). The Editorial also recommends the need for international action to clarify terminology and prevent future confusion, arguing this issue is 'not pedantry' (Reddel 2011:116) because vague guidelines are less likely to be implemented by practitioners.

### 5.3 *Paper 3: Meta-ethnography (Ring et al. 2011b)*

This paper was published in Patient Education and Counseling (PEC) which is an established (early 1980s) interdisciplinary, international journal with a focus on patient education and health promotion. This journal was targeted as it aims to explore and understand educational, counselling and communication models in health care. As Paper 3 focuses on an aspect of health care (asthma) and reports a mismatch in professional and patient/carers views of asthma action plans and asthma management, which could adversely affect clinical communication, this was a relevant journal choice. Although the journal's rejection rate is in excess of 60% (source: [www.pec-journal.com/authorinfo](http://www.pec-journal.com/authorinfo) July 2012) PEC had previously published studies using meta-ethnography (Larun & Malteraud 2007), further supporting our decision to target this journal for Paper 3. The impact factor for PEC at December 2012 was 2.305.

Scopus (at 14/12/12) listed seven citations for Paper 3 including papers published in the Netherlands, Sweden, Norway and the UK. This number is expected to rise as it is known that this paper has been cited by other researchers in journal papers in preparation/press.

#### 5.4 *Paper 4: Review of methods of qualitative synthesis (Ring et al. 2011c)*

This paper was published in the *International Journal of Technology Assessment in Health Care* (IJTAHC). This journal - established in the mid-1980s - is a forum for those interested in the economic, social, ethical, medical and public health implications of health technology assessment. This journal, whilst of relevance to practising health professionals, is primarily aimed at those working in the specialist field of health technology assessment, including policy makers and guideline developers across the world. The journal's impact factor is 1.365 (July 2012). This was our target journal as the initial work (NHS QIS 2011) which led to this study was conducted primarily to be of interest to health technology assessors.

As at 01/12/12 Scopus listed no journal citations for this paper; however the authors are aware of the paper being cited in papers in preparation/press. Importantly, combined with the related peer reviewed report (NHS QIS 2011), this paper resulted in Dr. Jepson and I being contacted by a Cochrane Collaboration reviewer for specialist advice on qualitative synthesis. This led to us being acknowledged for providing methodological expertise in a recent Cochrane review (Jefferson *et al.* 2012). The related report on methods of qualitative synthesis (NHS QIS 2011) has also been positively received and is also being cited in academic papers internationally.

#### 5.5 *Paper 5: Cross-study synthesis (Ring et al. 2012)*

The 'ahead of print' online version of this paper appeared in the *Trials* journal in December 2012 so it is too early to expect citations in other publications. This is an international open access journal with an Impact Factor of 2.5. This paper reports on the cross-study synthesis of findings from our meta-ethnography with those from a systematic review of RCTs, and our findings provide new insight into the development and evaluation of RCTs generally. As a result, *Trials* was our primary

target journal. We were therefore delighted this paper was accepted following minor revisions. Reviewer comments for this paper were very positive with one international reviewer considering the content to be of 'outstanding merit'.

#### 5.6 Reception of these papers beyond publication and citations

In addition to these publications, all studies on which these papers are based have been disseminated through national and international conferences including, most recently, a presentation on methods of qualitative synthesis at a Medical Research Council conference (see also Appendix 6 – CV). Together the journal papers and conference presentations have increased my profile as a researcher in asthma self-management and as having an expertise in qualitative synthesis. This increased profile and credibility has resulted in invitations by researchers from other UK universities for me to collaborate with them on funding applications and related projects and to act as peer reviewer for high quality respiratory medicine journals (including Thorax IF 8.4, Respiratory Research IF 3.36) as well methodology journals (for example, BMC Medical Research Methodology IF 2.67).

## **Section 6: Critical reflection of research methodologies and methods**

Having outlined the five different research papers in Sections 2-5, this section critically reflects on their methodologies and methods. As full details of each study, including their strength and limitations, are provided in Papers 1-5, readers are referred to the relevant appendices before reading Section 6. Some of the issues addressed within the following sub-sections may have been included in the published papers, but perhaps not in detail due to the journal word count. Other issues, whilst relevant in the context of a PhD submission, may not have been included in Papers 1-5 at all as they may not have been relevant to the journal readership.

6.1 Paper 1 reports findings from a **systematic review of randomised controlled trials (RCTs)** assessing the effectiveness of asthma self-management interventions which included action plans as one of their components.

The overall concept of systematic review of interventions is clearly defined (see Table 4) and the methods for conducting<sup>4</sup> and reporting quantitative systematic reviews are well established (Moher *et al.* 2009; Higgins & Green 2011). The review process consists of several steps; including literature searching and screening, quality appraisal, data extraction/analysis and reporting. Importantly, good practice guidance for these different steps is available (Moher *et al.* 2009; Higgins & Green 2011): for example, having two researchers independently reviewing possible papers for inclusion then comparing the outcome of their screening; discussing areas of uncertainty and, where necessary, referring any disagreements to the wider team for arbitration. In ways such as these, the

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<sup>4</sup> The Cochrane Collaboration, launched in 1993, is internationally recognised as setting the standard for conducting systematic reviews of RCTs.

transparency and robustness of quantitative systematic review is considered one of its strengths, contributing to the quality assurance of this approach, differentiating systematic review from literature review (see Table 4) and placing systematic reviews at the top of the evidence hierarchy (Table 2).

<b>Table 4: Glossary of key terms and definitions</b>	
<b>Term</b>	<b>Definition</b>
Literature Review	An objective account of what has been written on a given subject. This should reflect prominent emerging themes and inform the conceptual framework of a study (Ryan 2007:738).
Systematic Reviews	<p>Research that summarises the evidence on a clearly formulated question according to a predefined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical meta-analysis' (NICE 2009).</p> <p>A review prepared with a systematic approach to minimising biases and random errors, and including components on materials and methods (Bowling 2009:470).</p>
Synthesis of evidence	<p>A generic term to describe methods used for summarising (comparing and contrasting) evidence into a clinically meaningful conclusion in order to answer a defined clinical question. This can include systematic review (with or without meta-analysis), and qualitative and narrative summaries. (NICE 2009) (Accessed 16/10/12).</p> <p>'The collation, combination and summary of the findings of individual studies included in the systematic review .... can be done quantitatively ..or if formal pooling of results is inappropriate, through a narrative approach. As well as drawing results together, synthesis should consider the strength of evidence, explore whether any observed effects are consistent across studies, and investigate possible reasons for any inconsistencies. This enables reliable conclusions to be drawn from the assembled body of evidence' (Centre for Reviews and Dissemination 2009:45).</p>

On reflection, this study was relatively straightforward to complete because the research team included experienced Cochrane systematic reviewers and whilst I was new to this methodology, I had existing skills in documentary analysis gained through earlier research (Ring 2002). By adopting good practice for systematic reviews of RCTs (Moher *et al.* 2009; Higgins & Green 2011) we know this study was conducted using the appropriate methodology and that the correct methods were applied. Having two researchers working separately and then collaboratively meant that, as a new systematic reviewer, I could work independently, acquiring

the specialist research skills, yet have my work openly scrutinised by colleagues checking for accuracy and critically reviewing my decisions.

On completion of the other related studies, it is now possible to reflect more critically on this research approach - identifying the following issues:

#### 6.1.1 *The small number of RCTs included in this systematic review.*

Although our electronic database searches identified 7993 possible papers, only 14 RCTs finally met our inclusion criteria (Figure 1, Paper 1). It could therefore be argued that only 14 relevant RCTs were identified because our study inclusion criteria were too narrow.

Our inclusion criteria were designed to reflect the nature of our research question – that is, included RCTs had to provide data reporting barriers and/or facilitators to action plan use in practice. In anticipation that we might only find a small number of relevant published trials, studies for inclusion in this review were not exclusively limited to those which had been published. Our literature search was extended to identify possible unpublished and on-going ones as well. This was done by me identifying internationally recognised asthma researchers and respiratory organisations and then contacting them to request such information. The search for un-published and on-going studies is seen as one means of minimising, or avoiding, publication bias in systematic review, which is a threat to validity. Although a thorough search was carried out to identify and contact relevant individuals and organisations, no new additional studies were identified through this route. Given this study was only of six months duration, this additional search for un-published and on-going RCTs, was resource intensive for no yield (see Paper 1). Whilst Cochrane systematic reviews require the most comprehensive searches for studies meeting the eligibility criteria, and identifying unpublished and on-going

studies may be expected (Higgins & Green 2011), our experience here suggests that for those conducting non-Cochrane reviews in the future, careful consideration should be given as to whether un-published studies should be searched for because of the additional resource requirements.

Including non-randomised trials would have increased the number of studies in our systematic review by as much as 15 (See Figure 1, Paper 1). Data from non-RCTs would have helped us answer our research question by supplementing the findings from RCTs (Higgins & Green 2011) and, depending on the importance of study findings, identifying areas where future RCTs might be possible and would be worth conducting as a matter of priority. However, according to the evidence levels (see Section 1) including non-controlled studies would have reduced the perceived strength and 'weight' of our final systematic review findings because they are considered as having greater potential for bias (Higgins & Green 2011). Given that extending our inclusion criteria to include all trials – not just RCTs – would also have required additional resources (time and money), the decision was made to focus solely on RCTs in this systematic review.

#### 6.1.2 *Quality of included RCTs*

The published RCTs in our systematic review were also notable because they were assessed as generally being of poor quality; that is, at high risk of performance, detection and/or attrition bias (Ring *et al.* 2007). Appraisal of the methodological quality of included studies in a systematic review is recommended practice as it enables assessment of the risk of bias (Higgins & Green 2011). We quality assessed included studies against criteria contained within the Cochrane handbook current at the time<sup>5</sup> (Higgins & Green 2005) and identified that only one (Glasgow

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<sup>5</sup> This version (4) has now been superseded and the quality criteria we assessed against replaced with a two-part tool covering seven domains of risk (Higgins & Green 2011).

*et al.* 2003) of the 14 RCTs we reviewed was of the highest quality (Grade A) with low risk of bias whilst 10 others were low quality (Grade C) with high risk of bias (see Appendix 1). There were various reasons why these RCTs were assessed as low quality, for example no double blind recruitment, but the low quality of the RCTs we reviewed 'weakened' the strength of our findings because although we had conducted a rigorous and robust systematic review our recommendations for practice were based on relatively poor quality trials.

According to the evidence hierarchy shown in Section 1, RCTs are the highest form of evidence. Yet, on critically reviewing those RCTs in our systematic review, it is clear that many trials, even those published in high impact factor journals, are flawed in terms of their conducted methods and/or study reporting. One of our included RCTs (Homer *et al.* 2005) was so poorly conducted that more patients in the control group were found to have asthma action plans post-intervention than those in the study group, which suggested contamination between these two groups during the study (Homer *et al.* 2005). Such contamination between study groups, by introducing bias, is a fundamental flaw in RCT methodology, meaning this particular intervention was considered as having no effect. Nonetheless, this RCT was published and is frequently cited, for example in asthma guidelines (BTS & SIGN 2012). To-date, this poor quality RCT with a high risk of bias (Homer *et al.* 2005) has been cited 58 times; whereas the highest quality RCT with low risk of bias (Glasgow *et al.* 2003) included in our systematic review has only received 33 citations (Scopus at 29/08/12). This almost double rate of citations for the poorly conducted RCT (Homer *et al.* 2005) compared to the well conducted one (Glasgow *et al.* 2003) could be explained because its atypical results are frequently reported as an 'exception' to other studies. Alternatively, poorer quality studies may report larger effect sizes than would otherwise be expected, producing more sensational results, again increasing the frequency of their citations. Although not an RCT, the

now discredited research reporting a link between MMR vaccines and autism is such an example of poor research being widely cited.

### 6.1.3 *Action plan data were not reported and/or were under-reported in RCTs*

In our literature search we identified 42 potentially appropriate RCTs with action plans in their interventions but 27 of these did not report any action plan data, such as the number of plans issued (Ring *et al.* 2007), and were subsequently excluded from our review. This relatively high number of RCTs with action plans included in their interventions, but which did not report any action plan data in their journal publications, is noteworthy given that these plans were first recommended in 1989 as good asthma care (Woolcock *et al.* 1989) and the earliest RCT included in our systematic review was conducted in 1993 (Yoon *et al.* 1993). So, it could be argued that RCTs with action plans in their asthma interventions – at least those conducted in the 2000s - should have been measuring the effect of their intervention on action plan implementation, given these plans were internationally recommended yet were known to be under-used in practice. Our systematic review therefore identified opportunities in RCT research which could have been used to further develop understanding of action plan implementation. These opportunities were missed because, as identified by the 27 RCTs we excluded, the effect of interventions on action plan use was either not recorded or were not considered a priority for reporting within the restricted word count of journal publications.

Amongst the 14 RCTs included in our systematic review which did provide action plan data, such information was limited (Ring *et al.* 2007). Studies frequently only reported data for the number of patients *with* action plans rather than the numbers actually *using* them. Also, amongst the 14 RCTs reporting action plan data, such measures were not homogeneous because various different terms were used to

refer to the same or similar action plan measures. For example, some studies reported how many patients were 'issued' with action plans whilst others reported the numbers 'owning' or 'having' action plans. Generally, action plan measures such as 'owned' were not defined in an RCT; and/or where similar action plan measures were used, these were reported at different time intervals such as four or six weeks post-intervention. Such variation in action plan measures meant that statistical meta-analysis amongst sub-groups of papers was therefore not possible and we could only report our findings in a descriptive analysis. A consequence of this was that although we had conducted a rigorous, high quality systematic review, the lack of meta-analysis reduced the strength of evidence generated from our study in terms of the evidence hierarchy (see Section 1): especially because the RCTs included in our review were generally at high risk of bias (Ring *et al.* 2007). Lack of a meta-analysis also had implications for the publication of this paper (see Section 5) as the highest impact respiratory journals were unlikely to publish our systematic review without such statistical analysis. It also meant that whilst we received a positive evaluation from DARE (see Section 5), we were unlikely to be given their highest level of endorsement as we could only report our findings as a narrative synthesis.

6.2 Paper 2 reports findings from a **linguistic analysis** of asthma plan terminology. Briefly, linguistic analysis involves systematically and critically analysing a body (corpus) of texts to facilitate understanding of authors' use of words through, for example, analysis of the frequency with which terms are used, how and where words are located and the meaning of different terms (Biber *et al.* 1998).

### 6.2.1 *Linguistic analysis in asthma plan research*

In comparison to Paper 1, the linguistic analysis was challenging to conduct for two reasons. First, the study was unplanned and conducted in response to difficulties which arose during the literature searching phase of our meta-ethnography. Although we had been aware that various asthma plan terms were used inconsistently and interchangeably prior to starting our meta-ethnography (Ring *et al.* 2007), we had not appreciated the extent of this issue and/or the impact it would have on our ability to complete this research. Specifically, confusion regarding the meaning of various asthma plan terms, including 'action plan' and 'self-management plan,' was hindering our ability to identify relevant papers for inclusion in our qualitative systematic review. So, before we could complete the literature searching phase of our meta-ethnography, we had to better understand the various asthma plan terms to be certain we were synthesising the appropriate studies. This meant that, although our meta-ethnography was funded, this linguistic analysis was unfunded and had to be completed within existing resources. Not only did this require many extra hours for all involved, it constrained our study design to what was feasible in the time available. Whilst this study is limited because it is relatively small scale (our corpus of texts only included 84 items), we did have more than enough data to fulfil our research objectives (Section 3).

Second, this study was challenging methodologically because linguistic analysis, whilst an established approach in other academic disciplines, is rare in health research; so this represents an original approach in respiratory research specifically, and healthcare research generally. Fortunately, one of my supervisors (JP) was familiar with linguistic analysis and recognised the potential for this methodology to help us better understand asthma plan terminology. This study was informed by Biber's principles of linguistic analysis (Biber *et al.* 1998). Although unfamiliar with this model, I had relevant skills gained from conducting our

systematic review which I could apply to this study. Given that the corpus of texts analysed in this study covered the period 1989-2010, many of the items we analysed were archival, so my earlier historical nursing research (Ring 2002) experience was also pertinent. Experience of critically analysing discourse in written texts and awareness of the need to contextualise archival sources in their historical period was especially useful. In practice, much of this linguistic analysis was historical research - this may not be the case in other health topics - as we needed to develop an asthma plan time-line identifying and tracking the various terms chronologically to understand how meaning had evolved over time and in different countries. Whilst using a new methodology was initially daunting, I was confident I could conduct a good quality, rigorous study through applying my existing research skills to these new methods.

Importantly, I understood the context of this research study. We were conducting a qualitative study, using an approach which was novel in health research, and would be disseminating our findings to a target audience (respiratory specialists) likely to be more receptive to evidence derived from positivist research, considering it to be more robust. As principal investigator, I decided that we needed to adopt, where possible, quantitative systematic reviewing 'good practice' in relation to what was, in effect, a qualitative study. Whilst such processes may not be required for linguistic analyses carried out in other academic disciplines, we were aware that such processes are seen as enhancing methodological quality in healthcare systematic reviews. If this study was to be published it would be reviewed by healthcare researchers, and so we adopted a blended approach fusing the principles of Biber's linguistic analysis (Biber *et al.* 1998) with established quantitative systematic review processes, where possible. Our rationale for this approach was pragmatic - we anticipated that journal reviewers may be unfamiliar with linguistic analysis but familiar with established systematic review processes.

Journal reviewers might therefore regard the application of established systematic review processes in this novel project as an indication of overall study quality and rigour, thereby increasing our chances of this paper being published.

### 6.2.2 *Linguistic analysis in healthcare research – strengths and limitations*

We used linguistic analysis to investigate asthma plan terminology and it was effective in providing us with new understanding of the topic. Specifically, this approach gave us objective evidence to support our previous observations (Ring *et al.* 2007) that inconsistent and interchangeable use of asthma plan terms was a significant problem and that the resulting confusion and ambiguity was an unacknowledged barrier to action plan implementation. Knowledge derived from our linguistic analysis also enabled us to propose a taxonomy for the various asthma plans with standardised terms and definitions (see Paper 2). This framework, by anchoring our search terms, was used to guide our meta-ethnography literature search, thereby increasing sensitivity and specificity of this process. On reflection, linguistic analysis was an inspired methodological choice for this study as our findings overall make a unique contribution to the asthma plan body of knowledge (see Section 7 for details).

Based on our experiences, we would suggest that linguistic analysis has a potential application in healthcare research more widely; for example, areas such as: 'self-care'/'self-management' and 'patient involvement'/'public involvement'. Such terms are often used interchangeably even though these concepts have evolved over time and their meaning (and therefore application) may also vary internationally according to differences in healthcare provision between countries.

Those planning on using linguistic analysis in healthcare research should, however, consider possible limitations of this approach. Researchers need to have the

necessary skills and knowledge to conduct this work and/or be supervised by someone experienced in using this alternative methodology. Additionally, as an innovative research methodology in a healthcare context, publication may be more difficult in certain journals. Although our findings, and the taxonomy, are highly relevant to practitioners and researchers internationally, the highest ranking respiratory journals are medical ones and, as such, traditionally publish RCTs and meta-analyses. Dominance of this evidence hierarchy in such journals has created a 'hierarchy of methods' in which qualitative methodologies are lower ranking (O'Cathain *et al.* 2009:6), even when they provide original insight not otherwise available – such as with this study. The challenge of getting others to see the 'worth' of qualitative research is recognised and has been described for such researchers as 'swimming against the tide' of prevailing views (O'Cathain *et al.* 2009:6). This was the case for our linguistic analysis. The paper was declined by two journals before being accepted – disappointingly, our target journal (Thorax) did not even submit it for peer review. Consequently, it took nearly two years for our findings to be published in PCRJ (delaying my PhD progression). Although this is a specialist respiratory journal it has a much lower impact factor (2.61) than our target journal (8.3), which may also have contributed to the lower rate of citations for this paper (see Section 5). As a team we knew that getting this study published in a high impact respiratory journal would be difficult and, as lead author, I had the final choice in identifying our target journal. Having since become a reviewer for such journals, including Thorax, it is only now that I have fully realised how strong the tide we were swimming against was for this paper and this unusual health research methodology. Currently, even getting traditional qualitative studies published, such as those using interviews, is difficult as such approaches are still 'novel' for some of these journals (personal e-mail communication from Thorax journal, 2012).

6.3 Paper 3 reports findings from a **qualitative systematic review and synthesis** of published studies indicating what helps or hinders the promotion of asthma action plans by health professionals and their use by patients/carers.

Although the synthesis of qualitative studies is being used increasingly in healthcare, it is still a relatively new approach (Ring *et al.* 2011); and whilst the concept of synthesising individual qualitative studies is established in nursing research, it is a more recent development in multi-disciplinary and medical healthcare research. Synthesising qualitative studies is an emerging research methodology and multiple methods already exist (Dixon-Woods *et al.* 2004; NHS QIS 2011; Ring *et al.* 2011). Different methods exist because qualitative research can be conducted for different purposes - some methods are used for bringing together only qualitative studies whereas others are for combining qualitative and quantitative research (Dixon-Woods *et al.* 2004; NHS QIS 2011; Ring *et al.* 2011). The availability of different methods also reflects the many reasons why qualitative synthesis may be conducted; for example some researchers may want to generate theory, others may want to answer a specific clinical question or understand a social phenomenon or the effect of a clinical intervention (NHS QIS 2011).

Whilst synthesising qualitative research is in its infancy, literature in this field is already confusing, and has been referred to as 'knitting smoke' (Downie 2008:4). This is because there is no single approach, and the many different methods have similar names such as meta-study, meta-synthesis and meta-narrative (NHS QIS 2011). Another factor contributing to confusion in this area is that researchers conducting qualitative synthesis often 'borrow' and adapt methods from the various different approaches but do not always explicitly state what these adaptations have been (Dixon-Woods *et al.* 2004:418). In an attempt to make sense of the different approaches, a detailed critique of qualitative synthesis generally, and a discussion

of eight main methods (including their underpinning theory and main uses), is provided in the guide on this topic which I co-authored with Dr. Jepson for NHS QIS (NHS QIS 2011).

From amongst the many possible methods of qualitative synthesis, **meta-ethnography** emerged as the leading approach in the 2000s (Dixon-Woods *et al.* 2007) and has since consolidated its position as the most commonly used method for synthesising qualitative studies in healthcare research (Ring *et al.* 2011). The research team chose meta-ethnography as our methodology for study 3 (Paper 3) because of the theoretical guidance and seminal papers available describing this approach which could guide our work (Noblit & Hare 1988; Pound *et al.* 2005) and because a team member (Dr. Jepson) had previous experience of this process.

The principles of meta-ethnography were developed in the 1980s (Noblit & Hare 1988) for use in education research but have since been applied to various healthcare research questions, for example in understanding medicine taking, chronic fatigue, living with depression (Pound *et al.* 2005; Larun & Malteraud 2007; Malpass *et al.* 2009). Meta-ethnography should produce a synthesis, presenting a new 'third level' interpretation of the existing research (Noblit & Hare 1988). The 'third order' synthesis provided by the synthesisers should over-arch the 'second order' interpretation which the original authors made of their reported participants' views; which in turn, over-arches the 'first order' interpretations of their participants' personal experiences (Noblit & Hare 1988).

Using meta-ethnography, themes or concepts in individual but similar studies can be brought together through a process of iterative translation, producing a new 'line of argument' (Noblit & Hare 1988). In this way, individually analysed studies can be integrated into a 'whole' by synthesising their 'similarities and differences' (Noblit

& Hare 1988) to present a fresh interpretation of what helps or hinders action plan promotion and use. Full details of our methods are provided in Paper 3. Reflecting critically on this study, two key points emerge (Sections 6.3.1-6.3.2).

### 6.3.1 *Applying quantitative systematic review practices to meta-ethnography*

Again, we adopted established quantitative systematic review practices within our meta-ethnography, especially processes for identifying included studies, reporting the outcomes of literature searching and extracting data (Moher *et al.* 2009; Higgins & Green 2011). As meta-ethnography was originally developed for education research (Noblit & Hare 1988) and not as a method of systematic review (Candy 2011), these processes are not required. Nevertheless, recognising that we were using a relatively new approach within a health research context, we considered it appropriate to do so. For example, the concept of two researchers working independently and then collaboratively to compare findings would be expected by certain researchers as an indicator of research quality including those reviewing for medical journals. Although not required within the original meta-ethnography approach (Noblit & Hare 1988), we also critically appraised our included studies, which is standard practice in Cochrane systematic reviews (Higgins & Green 2011), as a means of assessing bias. The issue of quality assessing qualitative studies is a controversial one (Dixon-Woods *et al.* 2004; Dixon-Woods *et al.* 2006a; NHS QIS 2011) with no agreed approach. However, one benefit of quality assessing our included qualitative studies was that this critical appraisal gave us detailed understanding of the strengths and weaknesses of the individual studies. It enabled us to identify which studies had data of the necessary depth and richness for synthesis. We did not use the outcome of our quality assessments as a means to exclude studies from our meta-ethnography because there is currently no validated method for doing so (Atkins *et al.* 2008).

Many qualitative researchers would though be critical of us applying such quantitative systematic review processes to a qualitative study, because in doing so positivist research methodologies would be 'contaminating' what should be a purely interpretive qualitative synthesis. Despite such potential criticism, we believe our approach was a necessary and pragmatic one. Qualitative research is criticised for its perceived subjectivity (Saks & Allsop 2013); so for us, applying established processes for literature searching and reporting, albeit taken from a quantitative review context, increased the transparency of our methods, reducing the possibility of bias. Having two researchers checking every stage of our meta-ethnography, meant our research processes, and findings as they emerged, were subject to enhanced scrutiny. We believe adopting such processes to the systematic review stages of this meta-ethnography was a strength of our study and enhanced the rigour of this methodology. This approach increased our confidence in our early findings - the reporting of our first and second order findings (see 6.3.3 and Paper 3 for details) - ensuring we had a solid platform from which to proceed to the generation of our final synthesis.

### 6.3.2 *Synthesising diverse qualitative studies to produce a new interpretation*

Generating the new third order interpretation in meta-ethnography is challenging as it is less clear from the existing literature (Noblit & Hare 1988) how this should be done. This final stage is also inductive, intuitive and iterative. For us, having different researchers working independently and then in pairs, during the different study stages meant several individuals in the research team had in-depth knowledge of these studies. This ensured that during the development of our third order constructs (see Paper 3), preliminary findings produced by me, the lead researcher, could be more effectively challenged by other team members, ensuring that our overall synthesis was indeed 'grounded' in, and emerged from, the original

studies (Dixon-Woods *et al.* 2006a). Such critical scrutiny of our emerging third order interpretation was also an important means of reducing bias in this study.

Crucially, this extra (third) level of analysis differentiates meta-ethnography from other forms of 'synthesis' which only summarise the first and second order constructs and do not provide this new higher level interpretation. Unfortunately, within the literature the term 'synthesis' is used inconsistently resulting in ambiguity regarding the exact nature of the 'synthesis' conducted. The definitions of evidence synthesis shown in Table 4 (section 6.1) are an example of this, referring to summation of studies and not the generation of third order findings as described here. Integrative reviews are also frequently reported as 'syntheses', yet they report 'summarising data' (Esteves *et al.* 2012); and many cite their theoretical underpinning as a source which considers 'synthesis' to be analysis of quantitative data (Cooper 1989). Consequently, readers are often unclear regarding what type of 'synthesis' has been conducted in an integrative review without reading full papers.

In our meta-ethnography, we both summarised the first and second order findings as reported in the original studies and provided an additional layer of new insight and interpretation. We therefore conducted an 'aggregative synthesis' (summarising original findings) *and* an 'interpretive synthesis' in which we 'subsumed' original findings into a new theoretical structure (Dixon-Woods *et al.* 2006a:36-37). Unfortunately, once we critically reviewed the 19 included studies, it became apparent that some studies lacked the necessary 'conceptual richness' for generating third level constructs. To avoid losing any data we adapted the original principles of meta-ethnography (Noblit & Hare 1988) by content analysing the participant views and author findings of all included studies to identify emerging themes. Such an approach, whilst unorthodox, enabled us to bring findings from all

19 individual studies together and increase our understanding of the topic, even though our third level constructs were produced by synthesising only a sub-group of eight conceptually rich papers.

6.3.3 Reflecting on this qualitative systematic review and meta-ethnography, it could be criticised by both qualitative *and* quantitative researchers. Meta-ethnography enables researchers to bring together a number of qualitative studies which can be diverse in terms of methodologies and methods. Some qualitative researchers would criticise such an approach, arguing that studies conducted from different epistemological bases cannot be brought together because of 'irreconcilable differences' in data collection and analysis (Dixon-Woods *et al.* 2001:131; Dixon-Woods *et al.* 2004). For example, there may be differences in data interpretation and presentation between studies being synthesised where researchers in one study may have analysed data using a feminist approach whilst researchers in another study may have adopted a different theoretical perspective (NHS QIS 2011).

There are, however, other potential criticisms of qualitative synthesis. For instance, the studies we brought together were conducted over an 11 year period in five different countries. Given the importance of context on the personal experience of participants in qualitative studies (Dixon-Woods *et al.* 2004), it could be argued that data from studies conducted in different time periods and in different healthcare systems should not be pooled. In my opinion, however, the converse applies; that is, when the 'same' themes arise from studies conducted in different countries and time periods, the weight of these findings are strengthened. It also needs to be recognised that the influence of context and different time periods on study outcomes is a factor which can impact on quantitative systematic review and meta-analysis findings too (Nutley *et al.* 2012); for instance where a change in strategic

policy has altered the social context of an intervention and may have affected its resulting outcomes. One such example is where the banning of alcohol consumption in public places may have been a factor in the effectiveness of built environmental interventions in reducing the fear of crime (Lorenc *et al.* 2013).

Another potential criticism is that qualitative data that is rich in depth and insight is reduced into 'chunks' of text through extracting data from the original studies before bringing extracted findings together in the overall synthesis. Many purist qualitative researchers would consider the application of such reductionist research methods to interpretive methodologies as unacceptable because data were 'fragmented' (Saks & Allsop 2013:26) and the 'integrity' of individual studies lost (Mays *et al.* 2005). We would argue, however, that breaking down individual studies in such ways and then re-building them into a new cohesive new third order interpretation, justified this approach because of the new knowledge created.

Positivist researchers might dismiss the knowledge resulting from meta-ethnography because of the low position of expert opinion and qualitative studies in the evidence hierarchy (Table 2 and Section 1). Our primary reason for bringing together these different qualitative studies was pragmatic – we needed to answer our specific asthma plan research question; that is, what helps or hinders action plan implementation – a research question which was still predominantly unanswered by our systematic review of RCTs.

As expected from qualitative research generally, our meta-ethnography produced findings rich in personal meaning (Saks & Allsop 2013). For us, this qualitative methodological approach and our particular methods paid dividends in terms of the wealth of insight obtained compared to that gained from our equivalent RCT study. (Section 7 discusses this in detail). Importantly, despite potential criticisms of our

approach, this study had major benefits for us in terms of understanding from the personal perspective the implementation of action plans in everyday rather than trial settings. According to the evidence hierarchy expert opinion (in this case the views of those who should be issuing and/or using action plans in real life) would rank low as a form of knowledge, especially as reported in individual qualitative studies. Meta-ethnography by bringing expert views together from many studies collectively increases the weight of such findings, effectively generating new knowledge for practice. Unfortunately, the potential benefits from knowledge generated by meta-ethnography from this, and other, qualitative synthesis approaches which produce new higher order interpretations, and not just summaries of studies, are not currently recognised in the existing evidence hierarchy (Table 2).

6.4 Paper 4 reports on a **systematic review** of studies published using the different methods of qualitative synthesis.

In this study, we adopted standard systematic review processes, albeit we were focusing on reviewing research methods rather than clinical topics. The specific focus of this paper also meant that meta-analysis was not possible, so our findings are presented as a narrative summary of the different methods with a descriptive analysis. For example, we categorised the different approaches by quantifying them according to the number of published studies identified using each. Again, we adopted the expected good practices for systematic reviewing (Higgins & Green 2011), such as having two researchers working independently and then collaboratively to review the outcome of their literature screening.

In hindsight, this was the easiest study completed as part of this PhD submission for several reasons. First, we were using a well-established research methodology.

Second, I had the necessary skills, acquired from the earlier studies, to conduct it, and I was working with Dr. Jepson an experienced Cochrane systematic reviewer. Third, we were a small team - only three researchers from two different institutions (University of Stirling and our NHS partner, QIS). As this was a follow up study to a larger project (NHS QIS 2011) effective team-working was already in place with a shared understanding regarding our methodological approach.

#### 6.4.1 *Strengths and limitations of our approach*

This was an unfunded study so we had limited resources with which to conduct it. This meant that once we had identified through our literature search possible studies using qualitative synthesis, we were only able to review their titles and abstracts to identify which method they used – without funding we could not retrieve and analyse the full papers to obtain specific details. Given the discussion above regarding inconsistent use of the term ‘synthesis’ in the literature, this is a limitation of our study. Nonetheless, by critically analysing paper titles and abstracts we were able to clearly demonstrate that whilst the synthesis of qualitative studies is emerging as a methodology, it has been under-used to date and its potential as a means of generating evidence for practice is only starting to be realised. For example, it has currently only been used to understand a relatively small range of clinical conditions (see Supplementary Table 1, Paper 4). Importantly, this review provided us with objective data indicating that meta-ethnography was the leading approach in qualitative synthesis. However, whilst its use is increasingly common, with less than 70 such studies identified (Ring *et al.* 2011) this approach could still be considered as being in its infancy. As we only reviewed article titles and abstracts, it could be argued we under-identified previously published studies using meta-ethnography. That said, of the eight approaches for synthesising qualitative studies focused on in Paper 4, this one is the least ambiguous to search for because of its distinctive name, theoretical

underpinning and 'third order' constructs (Noblit & Hare 1988). We are therefore confident in our reporting of this particular finding and in knowing that our meta-ethnography on action plans is a relatively early published example of this methodology.

#### 6.4.2 *Areas for future development*

During our review of titles and abstracts we noted that researchers were applying the original principles of meta-ethnography (Noblit & Hare 1988) in different ways. There are two possible reasons for this. First, despite the availability of theoretical guidance on meta-ethnography (Noblit & Hare 1988) and some seminal worked examples (Britten *et al.* 2002; Pound *et al.* 2005) there is a lack of detailed guidance on how to conduct meta-ethnography, especially when producing the third level synthesis. Second, as this approach was developed in one discipline and applied to another, it is also possible that health researchers are, from necessity, adapting it to better suit the requirements of their clinical contexts. This indicates an urgent need for further critical in-depth analysis of the meta-ethnographies identified in this study (using systematic review methodology) to determine how, and in what ways, the original principles of meta-ethnography are being adapted (Noblit & Hare 1988). Such work could also be used to provide recommendations for how meta-ethnography might be practically applied in future health research.

#### 6.5 Paper 5 details our **cross-study synthesis of qualitative and quantitative review findings.**

Paper 5 reports an innovative method for integrating findings from our two separately conducted reviews. This was a challenging, complex and time consuming process as our novel approach was ground breaking.

### 6.5.1 *Differentiating cross-study synthesis*

Our cross-study synthesis was, in effect, secondary analysis of the 14 RCTs previously systematically reviewed in Paper 1, using our findings from Paper 3. To do this, we needed a method which would enable us to bring these two sets of findings together. Although there are other approaches for integrating qualitative and quantitative review findings to better understand interventions (Harden *et al.* 2004; Thomas *et al.* 2004) these did not ‘fit’ with our study research objectives (see Section 3.1). For example, some of these studies used qualitative synthesis findings to make recommendations for public health initiatives which were then integrated with RCT interventions and their effectiveness data (Harden *et al.* 2004; Thomas *et al.* 2004). Other methods for integrating qualitative and quantitative research, including critical interpretive synthesis (Dixon-Woods *et al.* 2006a; Dixon-Woods *et al.* 2006b), were also not appropriate for our study because the integration of mixed research methods was done in one single systematic review – rather than two.<sup>6</sup> Importantly, these other approaches integrated the qualitative and quantitative research concurrently (Harden *et al.* 2004; Thomas *et al.* 2004) whereas, we retrospectively integrated findings from two separate previously conducted studies.

We named our innovative approach - ‘cross-study synthesis’.<sup>7</sup> By doing so we could potentially add further confusion to this research field because multiple forms of ‘synthesis’ (Dixon-Woods *et al.* 2005; NHS QIS 2011; Ring *et al.* 2011) already exist, and introducing another form of synthesis means there is now even more ‘smoke to knit’ (Downie 2008)! However, for pragmatic reasons we felt it was important to differentiate our novel approach from other methods for integrating

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<sup>6</sup> Candy *et al.* (2011) also integrated two separately conducted systematic reviews retrospectively using matrices to map recommendations derived from qualitative studies to RCT interventions. Our study differs from this one for several reasons including our higher level of qualitative synthesis and the extent to which we re-interrogated our RCTs.

<sup>7</sup> We did so having checked Medline to determine whether ‘cross-study synthesis’ was already in use with a specific meaning and could not therefore be applied to our approach.

qualitative and quantitative reviews findings. In particular, literature in this research field is complex with a wide array of possible approaches, many with similar sounding names. Ambiguous terminology abounds, so finding relevant studies can be difficult – even for those familiar with the field. Giving our approach a succinct distinctive, unambiguous name provided clarity which should make this study easily identifiable by others in the future.

### 6.5.2 *Developing our framework for secondary analysis of RCTs*

Our first challenge was to devise a framework which could be used to integrate our two sets of findings rigorously. To do this, we went beyond our reported meta-ethnography findings to develop a model for action plan implementation derived from the perspective of professionals and patients/carers (see Paper 5). Model development was inductive and involved incorporating the facilitators identified in Paper 3 as promoting action plan use, such as professional education, as essential elements in our model (see Paper 5, Diagram 2). Model development was informed by the various multi-disciplinary perspectives within the team (general practice, practice and public health nurses) and the wider literature, including shared decision-making. Through discussion and several iterations we produced a model which ‘made sense’ of the situation and which we could then apply to the previously reviewed RCTs. That is, we could map whether the essential elements in our qualitatively derived model were components within these RCTs and, if so, to what extent they were present and what effect their presence had on action plan implementation. This approach provided us with a novel framework which enabled secondary analysis of these 14 previously reviewed RCTs, allowing the development of a more nuanced appreciation of why action plan implementation was possible in research settings but not in clinical practice. This original approach enabled us to better understand the ‘individual situation’ of action plan implementation in these trials and how this could correspond with everyday

settings, an aspect of RCTs which is usually absent and is a criticism of that methodology (Mickenausch 2010:2; Saks & Allsop 2013).

This was a novel approach so it was critical that we ensured our study was conducted rigorously and to a high standard, and that bias was minimised where possible. We also needed to clearly articulate our processes so they could be replicated (or adapted) by others in the future. One strategy for achieving this was to adopt, where possible, previously used research methods. From quantitative systematic reviewing we adopted the principle of having two researchers checking data extraction and assessment outcomes, including whether elements in our model were contained within the RCTs re-analysed and to what extent. We also used matrix mapping, which was used effectively in the public health approach to integrate qualitative and quantitative systematic review findings (Harden *et al.* 2004; Thomas *et al.* 2004) as a method for mapping our elements to RCT interventions.

### 6.5.3 *Limitations and strengths of our cross-study synthesis*

Our approach could be criticised in several ways. First, because it is based on a model of action plan implementation which, within the time and resources available, we were unable to externally validate with professionals and patients. This is however, a possible area for future research. Second, those who oppose the synthesis of individual qualitative studies generally would likely be critical of an approach which then integrated these findings with those from quantitative research.

Third, assessment of whether elements from our model were contained within the 14 RCTs previously systematically reviewed, and in what strength, was based on our retrospective interpretation of the original trial intervention descriptions.

Determining whether elements such as professional/patient communication and partnership working were components within these 14 RCT interventions should have been relatively straightforward as it would be expected such elements would be components within these asthma self-management interventions. However, this was not the case and the interventions in these 14 RCT interventions were generally poorly described in terms of the asthma consultation between professionals and patients, especially the nature of the clinical communication and whether, for example, patients were involved in the development and review of their asthma plans (see Paper 5). Assessing element presence, and strength of presence, was therefore the most challenging part of our cross-study synthesis.

The issue of inadequate intervention description is now widely recognised in the literature and the need for more detailed trial descriptions in future has already been called for, including suggestions for improving intervention reporting (Abraham & Michie 2008; Boutron *et al.* 2008; Glasziou *et al.* 2008). (This issue is discussed further in Paper 5 and Section 8). However, until intervention description improves in published studies it is possible that future studies using cross-study synthesis may experience similar difficulties and will also be required to base their assessment of intervention components on their subjective interpretation of intervention descriptions rather than objective information available from trial protocols and/or original researchers. Our response to this lack of intervention description, resulting in assessment of elements being based on our interpretation, was to reduce bias as much as possible. We did this through various methods including developing inter-rater guidance for the researchers to use when assessing elements (see Paper 5) and ensuring all decisions about elements were made by two researchers and that all element assessment outcomes were recorded in our study database.

Once we discovered the paucity of intervention descriptions in these 14 RCTs, we contacted original researchers to ask for further intervention details. Initial attempts to gain this extra information were unsuccessful and as this was an unfunded study we were unable to more actively pursue this line of inquiry within the resources available. On reflection, it is interesting to compare the poor response we had from original authors to requests for additional information in this study compared to the good response to our request for details of on-going and un-published studies in Paper 1. Obtaining additional information may have been difficult in this case because so much time had passed between our request and these original studies taking place; for example, the earliest RCT we reviewed was conducted in 1993 (Yoon *et al.* 1993). Alternatively, original authors contacted may have perceived our request for information as criticism of their initial research. We have since discovered that others have reported similar difficulties in obtaining additional details about previously conducted interventions in order to integrate qualitative and quantitative findings (Candy 2011), so those using cross-study synthesis in future may need to specifically consider this issue during their project planning.

Despite the above limitations, using our theoretical model as a novel alternative framework for secondary analysis of these 14 interventions studies meant we were able to re-assess them from a fresh perspective, gaining new insight into how these interventions worked in their trial setting. When we reported findings from our systematic review of RCTs, we initially thought this study had provided us with very limited understanding of what helps or hinders action plan implementation. However, by re-interrogating them through the framework derived from our qualitative synthesis findings, we were able to discover so much more about these RCTs and how their interventions operated. As such, bringing together our qualitative and quantitative findings meant we were able to delve deeper into these earlier RCTs, generating new knowledge for asthma plan research and practice.

(See Section 7 for details). We therefore believe that this novel approach demonstrates the potential benefits to be derived from this type of cross-study synthesis in future.

#### 6.6 *Ethical issues:*

Although these five studies were guided by current principles of good research practice (SEHD 2006; MRC 2012) (see also Section 3.2), none of them required NHS ethical approval. This was an advantage and a disadvantage. The disadvantage was that I could have completed my doctoral studies without personally experiencing the NHS research ethics and governance processes, including the Integrated Research Application System (IRAS), which are fundamental to so many health research studies. The advantage was that NHS ethical approval processes are criticised for being time-consuming and bureaucratic (van Teijlingen *et al.* 2008). Not requiring NHS ethical approval for these studies meant I could focus my resources on doing the actual studies rather than writing about what I was planning to do in an ethics application - this was especially important given that some of these five studies were unfunded.

If ethical approval had been required for these studies, it would have constrained what was feasible – less would have been achievable given I would have needed to spend several months completing the necessary paperwork for the different studies. Not requiring ethical approval meant I could devote my time to conducting an ambitious programme of work using existing methodologies (quantitative systematic review and meta-ethnography), adapting other methodologies (linguistic analysis) to a healthcare context and developing a novel approach for integrating qualitative and quantitative review findings (cross-study synthesis).

## **Section 7: Critical review of the significant and original contribution the submitted work makes to the field of written asthma action plans**

The submitted papers report five separately conducted studies, each using different research approaches. These papers have resulted in a coherent body of knowledge relating to asthma self-management – specifically the promotion and/or use of asthma action plans – and evidence based practice. The significant and original contribution of this work in the fields of asthma action plans and EBP is discussed in this and the following section, respectively,

7.1. In hindsight, the systematic review of RCTs (**Paper 1**) contributed least in terms of better understanding the promotion or use of action plans and how to increase their implementation. This study did provide evidence of the type of interventions effective in getting more written action plans *issued* to patients/carers, such as organisational systems for asthma review (Glasgow *et al.* 2003); but it provided very little insight into how to effectively get more of these plans actually *used*.

As discussed in Section 6, this study revealed how the RCTs included in this review, and many of those considered for inclusion, missed opportunities to add to the evidence base in this area because they did not measure and/or report action plan data. Given these RCTs were conducted many years after action plans were first recommended internationally, this was a significant omission from these trials, reducing the number of RCTs meeting our inclusion criteria and which could then be aggregated. Additionally, amongst those RCTs which did provide action plan data, this information was basic, often simply reporting the number of patients/carers with these plans rather than also using them. Where RCTs reported action plan data, they did so using various measures at different time

intervals meaning meta-analysis was not possible. Importantly, whilst RCTs and their systematic review have supremacy in the evidence hierarchy and are considered a 'cornerstone' in the EBP movement (Dixon-Woods *et al.* 2006a:27), our study identified, that in the case of asthma action plans, the RCTs we reviewed were generally poor quality with high risk of bias. So what is argued to be strength of RCTs as a form of evidence, namely their objectivity and low risk of bias (Mickenausch 2010), was not generally the case in the studies we reviewed.

RCTs have traditionally focused on measuring intervention efficacy in trial settings rather than their implementation in everyday care settings – as such, RCT trial settings can be criticised for being 'artificial' (Saks & Allsop 2013:24) and divorced from the reality of practice. To offset such criticisms, RCT methodology is evolving – moving beyond its traditional narrow focus of intervention efficacy - towards the use of pragmatic trials (Cesar *et al.* 2004; Brahmajee *et al.* 2008; Maclure 2009; Oxman *et al.* 2009) enabling assessment of intervention effectiveness in everyday settings. The RCTs included in this systematic review reflect such changes and also illustrate how complex interventions have become. For example, in the self-management interventions included in this review, action plans were just one of their many components. It is therefore possible that for these complex interventions, measuring and reporting data for all their contributing parts was just too difficult, especially as action plan use could not be controlled in the trial setting since it was the responsibility of the patient and would take place in the real world.

Whilst written action plans are recommended as good asthma care (GINA 2011; BTS & SIGN 2012) and they were included as components of the asthma self-management interventions we reviewed, their measurement and reporting were not considered a priority by these trial researchers. Under-recognition of the need to fully measure action plan implementation – that is, report on the number of patients

with action plans *and* using them – may have arisen because individuals in these RCT research teams were not promoting written asthma plans in their own clinical practice and therefore did not ‘see’ the relevance of doing so in their trials. In reality, it is nurses rather than doctors who issue and review asthma action plans at long-term condition clinics, especially in primary care where most patients with asthma are managed, but few of the RCTs we reviewed involved nurses within their intervention(s) or as members of the research team. The under-representation of this professional group is an important omission in the RCTs included – or considered for inclusion - in our systematic review and may explain why the RCTs we reviewed placed so little emphasis on measuring the effect of interventions in promoting action plan use. Researchers conducting these RCTs may not have fully appreciated the need to measure and report action plan implementation because it was a nursing role and their RCTs lacked nursing involvement in their planning and delivery. This reiterates the importance of researchers fully understanding the context of their interventions (Wells *et al.* 2012) and recognising that whilst their interventions have a research setting, they also have a real-world clinical setting and that effective implementation needs to occur in both contexts if an intervention is to benefit patients longer-term.

7.1.1 On completion of this systematic review, it was our intention to use these results to inform development of a future trial intervention aimed at improving asthma action plan use in primary care, but our limited findings meant this was not possible at that point. This systematic review therefore made an important contribution to the field of written asthma action plan implementation by providing objective evidence that RCT data alone were not enough to answer our research question of which type(s) of interventions helped and/or hindered action plan implementation. In line with the guidance on the development and evaluation of complex interventions (MRC 2000; Campbell *et al.* 2007; MRC 2008), this study

identified the urgent need for us to adopt a broader more inclusive approach to gathering evidence for this area of practice; specifically, to explore the qualitative literature reporting personal views of action plan implementation in practice through the use of innovative and emerging methodologies.

To have proceeded to intervention development without this qualitative work would have resulted in us developing a new intervention similar to those previously trialled - one which over-emphasised the organisational components, such as the delivery of new asthma clinics, and under-emphasised the inter-personal components, for example, how patients/parents and professionals work together at these clinics to jointly develop meaningful patient/parent-centred asthma plans. Now the intervention we develop will be informed by the views of patients/parents and professionals and our proposed model, so should be more relevant to their needs and more likely to support asthma plan implementation in clinical practice. So, whilst this study provided little evidence on how to encourage the actual use of action plans longer-term, Paper 1 is significant as it became the foundation for a programme of research aimed at better understanding barriers and facilitators to action plan implementation.

7.2 The linguistic analysis (**Paper 2**) study was conducted in response to inconsistent and ambiguous use of asthma plan terminology which caused difficulties during the literature searching for our meta-ethnography. Although Paper 2 reports a relatively small scale study, its findings make a significant contribution to the field of asthma action plans.

As detailed in Section 6, these findings allowed us to track the historical development of asthma plan terms to determine what terms were being used globally, in what context, at what time and with what meaning. This linguistic

analysis objectively demonstrated not just the wide array of asthma plan terms – much wider than had previously been acknowledged – but also how few of the texts we reviewed in this study specifically defined what they meant when they referred to such plans in their texts, contributing to uncertainty and ambiguity in meaning.

Linguistic analysis highlighted how asthma plan terms have evolved and changed since they were first recommended over 30 years ago. In fact, it would have been surprising if such terms had remained unchanged in that time and that differences in meaning did not exist internationally, reflecting different healthcare systems. This paper highlighted that whilst the terms ‘action plans’ and ‘self-management plans’ are now used interchangeably, when these plans were first introduced there were clear differences between them regarding the level of patient involvement (BTS & Research Unit of the Royal Colleges of Physicians of London (RURCPL) 1990; Woolcock *et al.* 1989). In the UK, for example, ‘self-management plans’ were initially recommended with clear patient involvement in their development and review (BTS & RURCPL 1990). By comparison, Australian ‘asthma action plans’ were explicitly a medical initiative with these plans given to patients by their doctors (Woolcock *et al.* 1989). This means that whilst these terms are now used synonymously, there may be underlying differences in their meaning and interpretation, especially regarding the level of patient involvement. Findings from this study identified the urgent need for clarification in this area and enabled us to propose standardised definitions of terms and an international taxonomy for the different types and levels of asthma plans (see Paper 5).

Linguistic analysis also demonstrates that there may be fundamental differences between asthma plans issued in trial and/or clinical settings – even if they share the same format, they could differ in their delivery; for example, the level of partnership

working between patients and practitioners. Our analysis indicates that the exact meaning of a particular asthma plan term cannot therefore be assumed from its name. So, an 'action plan' may be jointly developed between patients and professionals in one study but be developed by health professionals and simply given to patients in another. This finding has several implications. First, mainstream practitioners wanting to promote in their practice 'action plans' which have been effectively trialled in an RCT may not be exactly replicating what was used in the trial setting, resulting in sub-optimal clinical implementation of these plans. Second, there are implications for those conducting research evaluating asthma plan implementation. If health professionals offer patients *action plans* but researchers evaluate the use of *self-management plans*, figures reporting action plan use may be lower than in reality as patients mistakenly believe the researchers are referring to a different concept. Differences in terminology and meaning also have implications for those combining studies - whether qualitative or quantitative; aggregative or interpretive synthesis - because it cannot be assumed that the same or similar terms and concepts are static and that meaning is shared across different disciplines, countries and time periods.

7.3 The **meta-ethnography** study (Paper 3), unlike our initial RCT systematic review, provided many more answers to our research question regarding what helps and/or hinders the promotion and use of action plans. Whereas in the RCT systematic review, we got very little information on how to initiate and sustain action plan use, meta-ethnography offered new insight from the perspective of those professionals who should be issuing these plans and patients/carers who should be using them.

Using meta-ethnography to synthesise individual qualitative studies revealed that action plans were not always seen as helpful or relevant by patients/carers or

professionals. Importantly, their use is currently hindered because patients/parents and professionals act upon the basis of different models which inform their understandings of what asthma is, how it can/should be managed and their roles within this process. For instance, patients/parents see asthma as an intermittent episodic condition, rather than a chronic condition which needs to be prevented. As such, patients/carers frequently use asthma inhalers differently from how these are prescribed by professionals, often experimenting with lower doses. These differences mean that professionals often provide medically focused action plans that do not 'fit' with the patients'/carers' views of asthma, their asthma management strategies and/or needs. Certain facilitators for action plan use were identified; including effective communication and partnership working during clinical asthma consultations. These facilitators appear to help patients/carers and professionals to understand each other's models of asthma and encourage the joint development of action plans more 'fit for purpose', taking into account patients'/carers' own self-management strategies and the wider consequences of living with asthma. These findings therefore make a significant contribution to our understanding of why action plan implementation has been sub-optimal for so long internationally.

Our findings are also of particular importance because they resonate with an earlier qualitative study reporting the views of patients, doctors and nurses about 'guided self-management plans<sup>8</sup> for asthma' (Jones *et al.* 2000). This study, published over a decade ago in the British Medical Journal (Impact Factor 14.09), reported that most patients interviewed considered self-management plans were 'largely irrelevant to them' and that most professionals 'opposed their use' (Jones *et al.* 2000:1507). It also noted a 'gulf between the professionals' concept of the "responsible asthma patient" and the patients' view requiring the need for more patient centred, patient negotiated plans if they are to be more successfully used in

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<sup>8</sup> This is an alternative term for asthma action plan.

the future. Importantly, this study highlighted that neither patients nor professionals were 'enthusiastic' about the concept of asthma plans (Jones *et al.* 2000). This paper (Jones *et al.* 2000) was, however, controversial at the time, generating considerable discussion in the journal's letter pages. For example, it was argued that the authors' conclusions were 'unsupported by the evidence' (Partridge *et al.* 2001), their 'methods may have biased the outcome of their study' (Cleland & Moffat 2001) and their findings 'may not accurately reflect attitudes towards [these] plans' (Cleland & Moffat 2001). Over a decade later, our meta-ethnography clearly supports the findings from this earlier standalone qualitative study (Jones *et al.* 2000) – especially the need for such plans to be patient-centred and not designed or delivered on the medical model of asthma care.

7.3.1 Significantly, the meta-ethnography process highlighted just how much was known already about asthma management, including action plan use/non-use, within the qualitative literature. We identified a considerable volume of pertinent studies providing a wealth of knowledge derived from the personal views of patients/carers and professionals, providing insight into, and explanation of, the under-utilisation of asthma plans. What is striking though is that this evidence did not appear to have informed the development and evaluation of RCTs incorporating these plans. Meta-ethnography therefore made an important contribution to knowledge in this area in two main ways.

First, meta-ethnography, by bringing findings from several individual studies together collectively, strengthened their 'weight' as evidence, helping to offset some of the criticisms of qualitative research. Qualitative research is, for example, criticised because of the small number of participants in each study (Saks & Allsop 2013) who are often 'hand-picked' from a localised and un-representative (Parahoo 2012:80) 'narrow base' (Saks & Allsop 2013:28). By comparison, our meta-

ethnography included 785 patients/carers and professionals from five countries over an 11 year period, providing a greater range of participant views than would be possible in a single qualitative study.

Second, by going beyond the original author (second order) interpretations of their findings to present our new higher level (third order) interpretation (Noblit & Hare 1988), our meta-ethnography also enhanced the value of these single studies providing additional insight into action plan use not available to the original authors based on their study findings alone. So, despite being recommended internationally as good asthma care, meta-ethnography revealed that the potential for action plan implementation is limited by the differing views of patients/carers and professionals. For example, professionals think action plans should *not* be given to new patients, whereas patients consider the newly diagnosed (or their parents/carers) as those who would benefit from these plans as they have not built up the necessary experiential knowledge of asthma management and need professional guidance (Ring *et al.* 2011a). Previously known barriers to action plans, including their perceived irrelevance, selective issuing of them by professionals and lack of time during clinical consultations (Jones *et al.* 2000; Ring *et al.* 2011b; Sulaiman *et al.* 2011), are therefore symptomatic of deeper and more complex issues associated with fundamental differences between patients/carers and professionals concerning the meaning of asthma, its management and the role of asthma plans.

The under-promotion and under-use of action plans is long-standing. It seems that the considerable body of evidence derived from individual qualitative studies - reporting the expert opinion of those who should be issuing and/or using these plans - was over-looked. Although this knowledge could have made a substantial contribution to understanding this specific theory/practice gap, opportunities to do

so appeared to have been lost because such evidence is perceived unfavourably in the prevailing evidence hierarchy. For instance, our finding that patients/carers 'see' asthma and its management differently to professionals and develop their own asthma expertise and self-management strategies emphasised the importance of jointly developed and negotiated action plans – yet this aspect was not generally considered in the RCTs reviewed in Paper 1. Such differences also suggest that, for action plan implementation to increase, behavioural change is needed from patients/carers *and* professionals. Again, amongst the reviewed RCTs most interventions focused exclusively on providing patient/carer education rather than professional education as well.

Qualitative evidence is regarded by some to be subjective, unscientific and at high risk of bias (Parahoo 2006). However, it could be argued that this perception resulted in this type of knowledge being 'dismissed' by those who consider that the only 'true' evidence for practice can come from scientific research such as RCTs. Unfortunately, one consequence of this is that by ignoring the views of patients/carers and professionals, barriers to action plan use which could have been addressed within trial interventions, making these plans more relevant to patients' needs, remained. This illustrates how, in certain circumstances and certain research questions, the evidence hierarchy (as shown in Table 2) should be 'inverted', with qualitative research 'on the top rung' (Petticrew & Roberts 2003:528) rather than RCTs and their systematic review.

7.4 Our systematic review of published studies using different methods of qualitative synthesis (**Paper 4**) contributes to our knowledge of asthma plans by demonstrating how innovative our meta-ethnography was in healthcare generally and respiratory care and long-term conditions management specifically. This paper highlighted how few studies had been published using such an approach.

Importantly, it also provided evidence of the originality of our cross-study synthesis by indicating that our approach was ground-breaking in integrating qualitative and quantitative review findings to better understand trial interventions. Although we suspected these two studies were innovative, it was important to have objective evidence of this to cite in future publications and grant applications.

The needs, preferences and experiences of patients/carers should be taken into account by service providers, policy makers (Facey 2010) and those designing and evaluating RCTs (MRC 2000; Campbell *et al.* 2007; MRC 2008). Paper 3 illustrates that qualitative synthesis could have a key role in achieving this, and our asthma plan research demonstrates the consequences of researchers not taking into adequate account the views of service users. Specifically, over-looking qualitative evidence as a source of knowledge resulted in researchers and professionals promoting action plans that are not congruent with what patients/carers need or want, hindering their implementation in clinical practice. There are, however, two key barriers to the use of qualitative synthesis.

First, dominance of an evidence hierarchy which reflects the positivist approach to research - assessing whether 'something works' (Dixon-Woods *et al.* 2006a) - has resulted in a situation where qualitative research and expert opinion is undervalued as a source of evidence, especially when derived from single studies and case reports. This might explain why asthma plans were first introduced in the late 1980s (Woolcock *et al.* 1989), were included in asthma self-management RCTs from the early 1990s (Yoon *et al.* 1993), but the first research reporting the views of patients and professionals who should be implementing these plans was only published in 2000 (Jones *et al.* 2000) to mixed reviews. Our meta-ethnography was conducted almost a decade later.

Second, whilst qualitative synthesis has great potential to generate knowledge reflecting the patient and carer perspective, the various methodologies are still emerging. Different possible approaches and confusing terminology exist, meaning this field is complex and 'muddy'. Even for those familiar with the literature, it is often difficult to understand the different approaches and how they should be used. This could therefore act as a barrier limiting the potential for qualitative synthesis to promote awareness of the views and needs of professionals delivering interventions and patients/carers receiving them. (This is discussed more in Section 8).

7.5 It could be argued that **Paper 5**, our cross-study synthesis of quantitative and qualitative review findings, makes the most significant and original contribution to knowledge in the field of asthma plans.

As noted earlier, our systematic review of RCTs provided limited knowledge of how best to promote action plan implementation. Cross-study synthesis through integrating our qualitative and quantitative review findings provided us with an opportunity to 'un-lock' the 14 RCTs previously systematically reviewed. Cross-study synthesis did this by providing us with an alternative framework with which to re-analyse these RCTs, enabling a new understanding to emerge of how the promotion and/or use of action plans can be effectively increased in research settings but is harder to achieve in clinical practice.

Using our model of action plan implementation, derived from the qualitative evidence, we were able to identify and then critically re-examine the role of essential elements (such as partnership working and effective communication) in promoting action plan implementation in these trials. Specifically, we reported that these essential elements were components of these interventions and were likely

to have been 'active ingredients' (MRC 2000) in promoting their effectiveness. That said, their facilitative role in the delivery of these interventions was often invisible because these elements were not routinely and/or explicitly identified as intervention components, and their effect on intervention effectiveness not measured. This omission meant it was unclear how professionals delivering these interventions interacted with their patients/carers during their consultations – a process we now understand from the qualitative literature to be critically important in practice.

Contextual factors 'shape or co-construct' interventions (Wells *et al.* 2012:15). Our cross-study synthesis findings, by highlighting the importance of the individual context (that is, the clinical interaction between patients/carers and health professionals), provided us with a more in-depth understanding of intervention delivery in these 14 RCTs. The RCTs generally over-emphasised the organisational context of their interventions, including the setting of an intervention and frequency of its delivery, but under-emphasised how action plans were actually issued, such as whether individual patients/carers were encouraged to participate in developing their plans. Yet barriers to change exist at individual and organisational levels (Grol & Grimshaw 2003), so both these contexts need to be equally acknowledged if action plan implementation is to be encouraged in practice. This means that organisational systems to increase the issuing of action plans, including regular systems for asthma review (Glasgow *et al.* 2003) and postal prompts (Kemple & Rogers 2003), are required as well as mechanisms to promote effective patient/carer and professional partnership working so action plans can be jointly negotiated, to become more relevant to the needs of those who should be using them.

Findings reported in Paper 5 have implications for practitioners and researchers in several ways. First, without RCTs specifically detailing the nature of the individual clinical contexts in which their action plans were issued, practitioners will be unlikely to replicate in their day-to-day practice the same conditions as were available within the RCT settings, resulting in sub-optimal action plan implementation. Cross-study synthesis articulated the importance of the 'unseen' components (Abraham & Michie 2008) within these action plan and asthma self-management interventions; that is, the communication and partnership working style of those delivering the intervention. Our findings reinforced the need for researchers to fully detail such 'hidden' intervention components within their trial descriptions; in particular ensuring that intervention descriptions focus not just on the 'who, what and how' of intervention delivery but also the 'in what way' – see Paper 5 for further information. Second, creating the appropriate individual contexts for promoting implementation, that is clinical consultations in which actions plans can be better tailored to patient needs, requires education for patients/carers *and* education of doctors and nurses. More research is required in this area because, to-date, asthma educational initiatives evaluated in RCTs have disproportionately focused on delivering education targeted at only patients and carers. For us as a research team, knowledge gained from our cross-study synthesis and our qualitatively derived model for action plan implementation has provided us with a more 'coherent and efficient approach to planning' (Sutton 2009) our future intervention and feasibility study. Findings from our earlier studies have 'strengthened' development of our planned future intervention and its subsequent evaluation (Audrey 2011). This preparatory work has clarified the full nature of the components of our future action plan intervention and identified a more comprehensive range of process and outcome measures needed to evaluate the effectiveness of such an intervention.

7.6 Overall summary of action plan knowledge generated from these studies:

This complex programme of work used established and innovative methodologies for generating evidence for clinical practice and can be summarised as follows:

Asthma action plans are recommended as good asthma care internationally (GINA 2011; BTS & SIGN 2012) but, action plans are under-promoted by health professionals and under-utilised by patients (Sulaiman *et al.* 2004; Hoskins *et al.* 2005; Gillies *et al.* 2006; Wiener-Ogilvie *et al.* 2007; Tan *et al.* 2009). Our RCT based systematic review reported a lack of high quality quantitative evidence about how best to encourage the use of these plans by patients/carers (Ring *et al.* 2007). Findings did provide some insight into how best to promote action plans, however this evidence was often limited; for example quantification of the number of patients with action plans rather than also providing data on use of these plans (Ring *et al.* 2007). Results also indicated that whilst most people with asthma are managed by nurses, especially in primary care, there was a lack of trial based evidence regarding the promotion of asthma plans by nurses. So whilst RCTs and their systematic review are considered the highest form of evidence for practice (Table 2), this study illustrated how little information can actually be provided by these methodologies.

Our qualitative findings derived from meta-ethnography (Ring *et al.* 2011b) and linguistic analysis (Ring *et al.* 2011a) challenged trial based findings in several ways. First, the taxonomy of standardised terms proposed through linguistic analysis (Ring *et al.* 2011a) acknowledges that asthma plans can exist at different levels (individual and organisational), and with varying degrees of patient involvement and shared decision-making. This study also clearly highlighted the extent of ambiguity regarding the meaning of terms such as 'action plans', 'self-management plans' and 'asthma management plans'; identifying the

interchangeable and inconsistent use of such terms internationally. This ambiguity of meaning has implications for research and practice. Practitioners cannot assume the 'action plans' they are implementing - whilst of a similar format to those used successfully in a trial setting – are actually the same. For researchers, differences in meaning between asthma plans mean they must explicitly define the type of asthma plan included within their interventions and ensure they are comparing 'like with like' when conducting future systematic reviews (qualitative or quantitative).

Second, whilst considerable effort has been focused on encouraging the use of action plans, the qualitative literature clearly highlights that medically focused action plans are not 'fit for purpose', as they do not reflect the patients/carers models of asthma and their personal management strategies (Ring *et al.* 2011b). Whilst professionals may see asthma as a long-term condition which needs daily prevention, patients/carers see asthma as an intermittent condition which requires episodic treatment. The existence of different explanatory models means it is critical that action plans are jointly developed (and reviewed) to ensure their content better reflect the needs of patients/carers. Meta-ethnography also identified the importance of the 'softer' unseen elements of an intervention, particularly communication and partnership working between patients and professionals, which may in fact be the 'active ingredient' in an intervention's effectiveness. Unfortunately, the importance of these elements has generally been under-acknowledged to date in quantitative research studies (Ring *et al.* 2012).

7.6.1 On completion of these studies it appears that over-reliance on positivist research as the main source of evidence built an incomplete picture of the barriers and facilitators to action plan implementation. Research derived from trial settings and systematic reviews generated knowledge about the type of interventions likely

to be effective in promoting action plan use but did not provide personal insight into the use of these plans in real world settings. Whilst 'top level' quantitative research from the evidence hierarchy identified organisational interventions effective in increasing the number of action plans issued (Glasgow *et al.* 2003; Kemple & Rogers 2003) and the format of these written plans (Gibson & Powell 2004), it has been qualitative research reporting the views of patients/carers and professionals - 'low level' evidence according to the hierarchy – which has provided deeper knowledge of under-recognised barriers to their use. Findings from qualitative research suggest that sub-optimal use of action plans in practice will continue whilst a mismatch remains between what patients/carers want from these plans and what they are provided with by professionals. Suggested formats for written action plans, derived from RCT evidence (Gibson & Powell 2004), are therefore unlikely to improve future use of these plans until professionals are provided with complementary information derived from other sources of evidence regarding how these plans should actually be delivered during their consultations.

7.6.2 Back in 2006, our systematic review of RCTs was intended to be a six month, one-off study, leading directly to a feasibility study of an intervention for promoting action plans in primary care. Instead, this was the start of a programme of work in asthma plan research which is still on-going. In line with the Medical Research Council guidance for the development and evaluation of interventions (MRC 2000; MRC 2008), we finally have a more complete picture of the type of intervention we need to develop, and the study measures we need to evaluate. Importantly, our evidence now consists of knowledge gained from quantitative and qualitative studies, so we now have a comprehensive understanding of the components of our complex intervention within the context of our theoretical model of action plan implementation. This means that, whilst we will set our intervention within an organisational system of regular asthma review, we will also ensure there

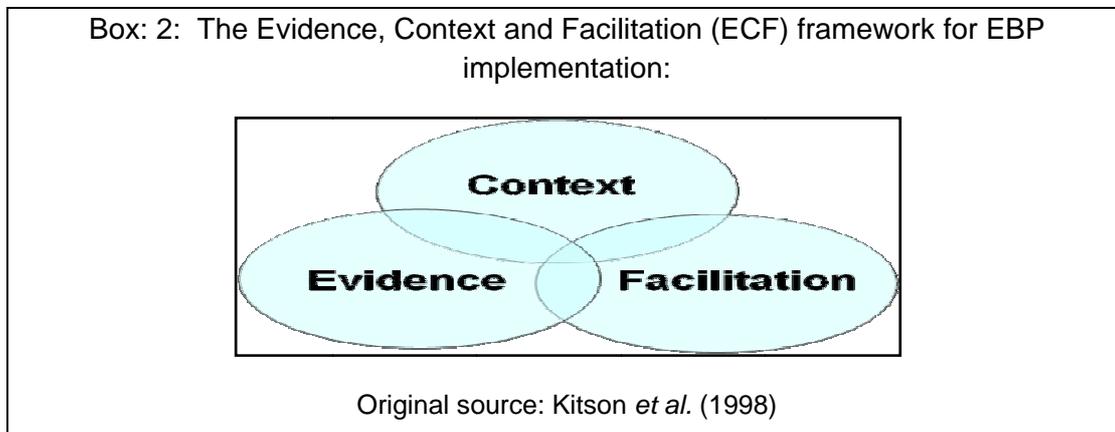
is education targeted towards professionals and patients/carers to ensure that the action plans are jointly developed and better suited to the needs of patients/carers. Work on a grant application for a feasibility study of such an intervention is now under way (led by Dr. Hoskins and myself on behalf of the research team) and is anticipated to be a three year study.

**Section 8: Critical review of the significant and original contribution the work makes to the field of evidence-based practice.**

The overall principles of EBP have been accepted by the multi-disciplinary health professions as an integral part of practice (for example in nursing (NMC 2008)), but twenty years after the concept was first introduced EBP continues to be a complex practice issue. Implementing EBP across the different healthcare sectors remains difficult and challenging internationally. The gap between recommended and actual practice in asthma action plans is just one example of this. By acting as a case study, the submitted papers and this programme of research on asthma action plans provide a unique opportunity for in-depth analysis of EBP, making a significant and original contribution to understanding current debates and issues. To provide a structure for this critical review of EBP, a model or conceptual framework is required.

The conceptual framework used as the basis for this analysis was first proposed by nurses for healthcare quality purposes in the 1990s (Kitson *et al.* 1998). Although there are other conceptual frameworks and models of EBP implementation available, this particular framework is recognised as having good construct and face validity (Rycroft-Malone & Bucknall 2010). From my own experience, as a nurse with a background in clinical effectiveness and quality improvement, I knew from previous use of this framework that it does 'accord with people's experiences of trying to implement evidence into practice' (Rycroft-Malone & Bucknall 2010:131). This particular conceptual framework is also 'flexible enough to be applied in different settings' and 'amenable for use in studies using different methodological approaches' (Rycroft-Malone & Bucknall 2010:131), making it well-suited for use in this specific analytical setting.

Since its original publication, the conceptual framework for EBP implementation proposed by Kitson *et al.* (1998) has been refined, further developed (Rycroft-Malone *et al.* 2002b, Rycroft-Malone *et al.* 2004a) and researched (for example, Seers *et al.* 2012). Nonetheless, its original principles have remained constant – that is, successful implementation is represented as a function of the nature of the evidence, the quality of the context of implementation and the appropriateness of approaches to facilitation’ (Kitson *et al.* 1998, Rycroft-Malone & Bucknall 2010:108) (see Box 2).



For the purposes of this critical review, I used the original principles of this conceptual framework (Kitson *et al.* 1998) as the foundations for my analysis, but make reference to the more recent refinements to this work as necessary.

Successful EBP implementation therefore requires these three over-lapping elements: evidence, context and facilitation (Kitson *et al.* 1998). When each element is mapped to a continuum from ‘low’ to ‘high’ (see Box 3 for details) and found to be sitting at the ‘high’ end of the continuum, EBP implementation is more likely (Kitson *et al.* 1998); that is, where the evidence for practice is strong, where the clinical context is receptive to change, and there is facilitation available to support change (Kitson *et al.* 1998). Although there is a perception that the most

important element in the implementation of EBP is the evidence, all three elements are critical and this asthma action plan research has enabled a fresh perspective of the three elements to emerge.

<b>Box 3: Details of evidence, context and facilitation in the ECF framework*</b>		
<i>Element</i>	<i>Low</i>	<i>High</i>
<b>Evidence e.g.</b> Research Clinical experience Patient preferences	Anecdotal evidence Expert opinion divided Patients not involved	RCT, Systematic reviews, guidelines Expert consensus Partnership working
<b>Context e.g.</b> Culture Leadership Measurement	Task driven, low morale Poor leadership &/or team working No feedback e.g. audit and/or performance review	Learning organisation, patient centred Clear roles, effective teams, clear leadership Routine feedback e.g. audit, peer review internally and externally
<b>Facilitation e.g.</b> Characteristics Role Style	Low respect, credibility Lack of clarity e.g. authority, change agenda Inflexible and inappropriate	Respect, credibility Clear authority, change agenda etc. Flexible, consistent and appropriate support and presence.
Sources: Kitson <i>et al.</i> (1998); Rycroft-Malone <i>et al.</i> (2004a). Note: *in subsequent papers this framework is referred to as PARIHS (Promoting Action on Research Implementation in Health Services) (Rycroft-Malone <i>et al.</i> 2002b).		

### 8.1 *The context of EBP in the UK*

'Context' in terms of this EBP framework is defined as: 'the environment or setting in which the proposed change is to be implemented' (Kitson *et al.* 1998:150; McCormack *et al.* 2002:96) and consists of three sub-elements:

- Prevailing culture
- Nature of human relationships as summarised through leadership roles; and
- Organisation's approach to routine monitoring of systems and measurements' (Kitson *et al.* 1998:154).

*What asthma plan research tells us about the context of EBP?*

8.1.1 A central strand of EBP is the development and implementation of clinical guidelines (Grimshaw & Russell 1994; Batstone & Edwards 1996; Cheater & Closs 1997; Harrison 1998; Rycroft-Malone & Duff 2000; Grol & Grimshaw 2003), including those recommending the use of action plans in asthma management (GINA 2011; BTS & SIGN 2012). Since EBP and the first asthma guidelines were introduced, the context of UK healthcare has become increasingly complex. There have, since the 1980s/1990s, also been significant changes in the clinical environment in which UK healthcare is delivered. For example, care settings have changed, with a reduction in acute hospital care provision, the closure of large long-stay institutions and increased primary care provision. Traditional role boundaries have also altered, with an increasing focus on multi-disciplinary teams supported by initiatives such as the introduction of non-medical prescribing. Such changes in the organisational context(s) of UK healthcare have implications for the contemporary implementation of EBP.

Reflecting today (in the 2010s) on the context for EBP, it seems the clinical setting for EBP implementation was originally perceived as occurring within relatively unified and tightly controlled in-patient settings, mainly hospitals. In the 1990s, when the majority of healthcare was provided in secondary settings, this perception was valid but it is not the case in the 2010s where clinical contexts are now much more diverse and include patients' homes – where health professionals have little, if any control. Equally, although the concept of EBP originated in medicine, it is now applied generically to all the other health care disciplines. Consequently, in the UK EBP is not being implemented in a single healthcare context and instead is being implemented simultaneously in multiple clinical contexts; with various organisational cultures, including public and private sectors; and across the full range of healthcare disciplines and teams. Not only have the organisational

contexts in which EBP is to be implemented become more diverse, EBP has expanded its reach far beyond its initial focus on drug treatments, surgical interventions and diagnostic procedures, to include all aspects of the care pathway, all clinical conditions (acute and chronic) and all patient groups. Even though the prevailing culture within the UK and other developed countries is that the concept of EBP in healthcare is a 'common sense aspiration' (Harrison 1998:15) and a 'good thing' for patients and practitioners, under-recognition of the huge variety of clinical contexts may help explain why, in reality, getting evidence into practice has been so difficult to achieve.

Conventional RCT methodology – assessing efficacy of single interventions in controlled research settings such as a respiratory ward or laboratory - was clearly better aligned to the 1990s perception of a more homogeneous healthcare context than it is to the multiple healthcare settings of the 2010s. The heterogeneous nature of today's clinical context(s) in which EBP needs to be implemented reinforces the importance of researchers fully understanding and recognising the context(s) of their interventions (Wells *et al.* 2012), and supports the need for change in the RCT methodology itself which is currently on-going; that is, the move away from trials of efficacy of single treatments or procedures (Cesar *et al.* 2004; Brahmajee *et al.* 2008) and 'specialist experiments with specialised populations' (Maclure 2009:476) towards pragmatic trials which conduct and evaluate the effectiveness of 'real world tests' on 'real world populations' (Maclure 2009:476). It could be argued that such pragmatic trials should be better able to provide data that reflects the multiple contexts of contemporary clinical practice, increasing the potential for such evidence subsequently being implemented.

8.1.2 EBP implementation requires supportive organisational and individual contexts (Grol & Grimshaw 2003). Given the historical background to EBP, with

successive Governments modernising the NHS through increasing efficiencies and effectiveness, this organisational context is clear within the ECF framework (see Box 3) and is exemplified by the focus on performance monitoring and measurement (SODoH 1996; Kitson *et al.* 1998; Rycroft-Malone *et al.* 2004a; Dawes *et al.* 2005). Whilst cost and clinical-effectiveness remain central to UK Government health policy in the 2010s, other drivers influencing the context of EBP implementation have emerged since the 1990s. Of particular importance is the patient involvement and shared decision-making agenda (Coulter 2011) and its impact on the individual context of care.

The ECF framework make references to the need for patient-centredness and partnership working (Rycroft-Malone *et al.* 2004a) but these terms do not necessarily imply shared decision-making. Some early definitions of EBP (see Table 1) also regarded the individual context of EBP as requiring active professional involvement and passive patient/carer involvement, with health professionals 'making decisions *about*' patients (Sackett *et al.* 1996). When EBP was introduced, patients were primarily considered recipients, such as receiving the type of hip replacement recommended by the doctor as proven to last the longest; whereas now patients/carers need to be partners in deciding whether such specific orthopaedic intervention is indeed most appropriate for their circumstances.

Patient empowerment has been seen as 'complicating the translation of evidence into practice' (Reilly 2004:992) because it brings an extra dimension to an already challenging process. Nonetheless, this cultural shift towards a context of individual patient involvement and shared decision-making is an extremely important, but often over-looked, factor in EBP implementation; especially in the care of long-term conditions, such as asthma, in which patients/carers are required to (self-)manage

and take responsibility for their own health. The self-management context of care is increasingly common, meaning EBP implementation is now a matter for health professionals and patients/carers. Where long-term conditions like asthma are concerned, there is therefore an individual clinical context of EBP implementation such as asthma consultations with health professionals; but there is also an individual *non-clinical* context, as patients/carers are expected to implement the recommended evidence in their own homes. Contexts for the implementation of asthma plans are now 'infinite' (McCormack *et al.* 2001:96).

Failure to recognise the full extent and diversity of the organisational and individual contexts of EBP can hinder its implementation. This is illustrated in the case of asthma plans. Our research identified that this medically led initiative contributed to sub-optimal action plan implementation because there had been inadequate recognition of the individual contexts and the need for active patient/carer involvement. Consequently, despite the benefits of these plans in trial settings (Gibson *et al.* 2009), they are under-used in practice because they do not meet the needs of patients/carers. So, whilst organisational contexts such as Health Boards or general practices have been receptive towards action plan implementation, individuals – whether practitioners or patients/carers – have been less conducive to this change.

## 8.2 *Facilitation of EBP*

In terms of EBP implementation, facilitation has focused on providing support to 'help people change their attitudes, habits, skills, ways of thinking and working' towards meeting 'desired outcomes' (Kitson *et al.* 1998:152). Facilitating EBP is therefore about 'enabling' and 'making easier' the process of implementation (Kitson *et al.* 1998:152; Harvey *et al.* 2002:579) in practice.

*What asthma plan research tells us about the facilitation of EBP?*

8.2.1 The critical role of individuals in facilitating EBP has always been recognised; but as leaders, change agents and performance monitors within their organisational contexts (Kitson *et al.* 1998:151). Since EBP was introduced, the primary role of individual facilitators (including clinical leaders, practice development and clinical effectiveness staff) has been directed towards changing organisations - enabling staff to work 'within and across role and structural boundaries' in their clinical teams (Kitson *et al.* 1998:151). Changing professional behaviour in this way was seen as essential because EBP was intended to modernise UK healthcare delivery and promote cultural shift (Batstone & Edwards 1996). As a result, strong leadership and performance management were vital. Facilitation was therefore targeted towards helping health professionals acquire skills in literature searching, critical appraisal and clinical audit. This was seen as a priority for supporting EBP implementation because these skills were needed to produce clinical guidelines and evaluate their use (Grimshaw & Russell 1994; University of Dundee & CRAG 1994; NHSE 1998; Adams 1999; Bradshaw 2000; Cranston 2002; Reilly 2004; Sherriff *et al.* 2007).

This type of facilitation, whilst needed, only addresses the organisational context of EBP implementation - facilitation is also required to change the individual context, especially the clinical behaviour of individual professionals. This is because clinical decision-making is no longer about health professionals making decisions '*for* rather than *with* patients' (Coulter 2011). The clinical consultation is at the heart of EBP (Barratt 2008), and practitioners need to be skilled in obtaining the views of patients/carers and sharing decisions (Parahoo 2006; Barratt 2008). Many professionals need help to acquire these new skills if EBP is to be fully supported. Our research on action plans shows this training need was not always recognised or considered. Facilitation for health professionals, where provided, was usually

directed at ensuring they were aware of the asthma guidelines, had the relevant skills in diagnosis and treatment, could access the required resources (including a supply of action plans) and were able to measure guideline implementation. Organisational interventions facilitating the promotion of action plan use did not generally also facilitate change within the individual clinical consultations, such as encouraging effective patient/professional communication and partnership working. Amongst the RCTs we reviewed, where interventions did facilitate organisational *and* individual change their intervention descriptions were such that only the organisational facilitation was described: the individual facilitation aspects were over-looked (Ring *et al.* 2012). Features of a new asthma clinic would therefore be detailed, but not the features of the actual clinical interaction between patients and professionals; such as how they communicated and whether action plans were jointly developed. This omission meant that mainstream practitioners setting up a new asthma clinic, effective in a trial, would be able to replicate the necessary organisational change but would be unlikely to replicate the necessary individual change within their clinical consultations, as these components of the original trial intervention were not detailed.

8.2.2 This asthma work programme also identified that nurses were under-represented amongst the leaders generating knowledge in the field of respiratory care generally, and asthma plans specifically - whether as researchers and/or guideline developers.

Despite the central role of nurses in the delivery of asthma care, their disproportionately low presence in the research studies we reviewed (reasons for this are discussed in Section 1) is likely to have contributed to the sub-optimal implementation of asthma plans in several ways. First, with few nurses as active partners in these research studies, the pool of nurses able to subsequently act as

clinical facilitators was reduced. More nurse researchers in this area could have encouraged their peers to better engage with the relevant research, for instance through publishing in nursing journals and liaising with clinical leaders, thereby encouraging the necessary change in attitude and ways of working (Kitson *et al.* 1998) required to promote action plan use. Second, research relating to asthma plans was generally produced by research teams led by doctors and/or social scientists. Research conducted in this area may not have provided nurses with the knowledge they needed to effectively facilitate asthma plan use in their practice. The resulting evidence may therefore not have resonated with nurses enough to encourage them to change their practice, especially as there was a lack of 'high' ranked research evidence which could then be translated into the asthma guidelines as recommendations for nursing practice specifically.

### 8.3 *Evidence*

What constitutes 'best' evidence has been widely debated for many years and the scientific basis of EBP, for instance the 'strength and nature' of different types of evidence can be assessed and 'weighted' (Kitson *et al.* 1998:150), has been criticised as one of the 'serious naiveties' of this concept (Harrison 1998:15).

#### *What asthma plan research tells us about the nature of evidence in EBP?*

Despite issues of debate (see Section 1), within the EBP movement 'best' evidence is currently considered to be RCTs, systematic reviews and meta-analysis (see Table 2). Given initial Government support for EBP as a means of reducing 'inefficient and ineffective clinical procedures' (SODoH 1996) it is understandable that the RCT and its systematic review have had a primary role in generating knowledge because these provided 'population based results' of effectiveness (Lockwood 2004; Mickenautsch 2010) for large groups of patients with low risk of bias, including which drug or treatment had the best results. Importantly, such

knowledge could also be relatively easily incorporated into guidelines and health technology assessments.

Our asthma plan research, by acting as a case study of EBP, demonstrated that relying on RCTs and their systematic review as the primary type of evidence is no longer sufficient in the 2010s given the changing nature of EBP and the context of UK healthcare. This asthma plan research exemplifies the circumstances in which other forms of evidence may be more appropriate than RCTs and their systematic review for answering specific research questions. Our work therefore demonstrates, in a number of ways, why a pluralist approach to evidence is required (Nutley *et al.* 2002; Petticrew & Roberts 2003; Mays *et al.* 2005; Pearson 2005). First, it illustrates the limitations of the RCT methodology in generating evidence for practice. Second, it identifies the importance of utilising a broader range of evidence, across all levels of the hierarchy, not just those at the top. In particular, this work supports the need to consider research methods according to their ability to answer specific clinical and practice questions rather than according to their position in a hierarchy (Walach *et al.* 2006).

### 8.3.1 Limitations of the RCT methodology

RCTs are seen as the 'gold standard' for evaluating the effectiveness of interventions (Bradshaw 2000; O'Cathain *et al.* 2000; Aveyard & Sharp 2009; Moher *et al.* 2010; Audrey 2011). In reality, the standard of published RCTs is variable. Amongst the small number of RCTs ( $n=14$ ) we critically reviewed, most had issues associated with how they were conducted which reduced their overall study quality; for example, double blind allocation was not possible (Ring *et al.* 2007). As a result, their risk of bias was high, as factors other than the intervention could have contributed to the study outcomes (Saks & Allsop 2013).

The RCTs we critically reviewed were all complex interventions of asthma self-management, and action plans were only one component of them. When comparing these 14 interventions to one of the earliest clinical trials on streptomycin treatment of tuberculosis<sup>9</sup> (Streptomycin in Tuberculosis Trials Committee 1948) it is apparent how much this methodology has evolved. In this early RCT, the young patients were all restricted to bed rest for six months in treatment centres, so the trial setting was tightly controlled. Trial outcomes including death and radiological improvement were also easily measurable. By comparison, the RCTs in our systematic review were conducted in various settings; including hospitals, general practices, schools, community centres and online. Trial process and outcome measures in these RCTs were also more challenging to assess - for example action plan use by patients.

RCTs will continue to have a central role in the generation of knowledge for particular research questions, especially where there is a need for objective findings of effectiveness. Increasingly, however, this methodology is being used to evaluate ever more complex interventions with greater diversity of participants, settings and trial outcome measures. The 14 RCTs we reviewed suggest that as interventions become more complex, meeting the highest quality standards may be less achievable, as controlling bias in such studies will become more challenging. Future pragmatic trials may produce findings that are more generalisable to the wider population; however their internal validity may be 'compromised' to achieve this (Wells *et al.* 2012:15). This would have implications for the quality assessment of RCTs and guideline development, which are core activities within EBP. Presently, RCT evidence is considered to be strongest and most reliable where bias is lowest, increasing confidence in an intervention's effects (Guyatt *et al.* 2008)

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<sup>9</sup> This study of 107 patients aged 15-30 all with the similar type of disease (which could not be treated any other way). Study compared streptomycin plus bed rest with bed rest alone in the treatment of tuberculosis.

- the stronger the perceived quality of an RCT and its findings, the higher the grade of guideline recommendation for practice. If, increasingly, complex and pragmatic RCTs are less able to achieve 1\*\*/1\* evidence ratings (see Table 2), their resulting guideline recommendations will be graded lower. Although the grade of guideline recommendation denotes the strength of underpinning evidence, not the clinical importance (BTS & SIGN 2012), it is possible lower graded guideline recommendations will be less likely to be implemented, especially when healthcare budgets are constrained.

Another factor limiting the contribution of RCTs to EBP is their inadequate description of their interventions. In most of the RCTs we reviewed, their intervention descriptions were so poor it was unclear exactly what any intervention consisted of and how it was conducted (Ring *et al.* 2007; Ring *et al.* 2012), thereby reducing the ability of others to reproduce these interventions with the same effect (Saks & Allsop 2013). As discussed in Paper 5, an RCT study may report on the *how*, *why* and *when* of intervention implementation, but not *in what way*; that is, how practitioners actually engaged with their patients/clients. In our trial based systematic review, although we noted that these interventions were poorly described (Ring *et al.* 2007) it was not until we had completed the cross-study synthesis (Ring *et al.* 2012) that we fully appreciated the extent of this problem. The issue of inadequate trial reporting is now widely recognised in the literature, with recommendations being made as to how intervention descriptions can be improved in future (Perera *et al.* 2007; Abraham & Michie 2008; Boutron *et al.* 2008; Glasziou *et al.* 2010) – this issue is expanded upon in Paper 5.

Inadequate trial intervention descriptions are, however, an unacknowledged barrier to the implementation of EBP because this reduces the ability of mainstream practitioners to replicate interventions shown to be effective in trials in their own

practice. The evidence hierarchy does not include the quality of intervention description as a criterion against which evidence strength and level is assessed. This means that whilst a 1\*\* RCT with low risk of bias will be used as the basis for the strongest practice recommendations within a clinical guideline; in reality the potential for that intervention to be implemented in real-life will be severely limited because practitioners will be unable to exactly replicate its delivery without explicit intervention details. It is therefore possible that a high rated 1\*\*/1\* intervention with low risk of bias translated into a Grade A guideline recommendation may not result in improved patient care because mainstream practitioners cannot reproduce the trial settings for that intervention in their practice with the same results.

### 8.3.2 Using qualitative research as evidence

Increasingly, evidence derived from RCTs is being criticised for not providing an 'absolute truth' (because, for example, RCT participants are carefully selected from a particular patient population) and for 'devaluing' other types of knowledge (Mickenausch 2010), including that derived from the expert opinion of professionals or patients/carers. In essence, RCTs devalue those forms of evidence which provide the 'evidence of me' in EBP (Lockwood 2004:1033).

In the case of asthma action plans, RCT evidence provided only a partial truth to understanding barriers and facilitators to their implementation. This meant that, if we had relied solely on RCT evidence as the basis for developing our intervention to promote action plan use in primary care, we would inadvertently have developed an intervention 'out of tune' with the needs of those who would be receiving it. Our intervention would have focused on the organisational aspects of implementation - the type of action plan and system(s) for regular asthma - overlooking the individual context of implementation; namely the clinical interaction between patients/carers and professionals.

The value of qualitative research in the development of trial interventions is recommended (MRC 2000; Campbell *et al.* 2007; MRC 2008) as a means of strengthening interventions and enhancing their future evaluation (Audrey 2011). Our experience re-affirms the essential importance of researchers using different sources of evidence during the development of complex interventions (MRC 2000; Campbell *et al.* 2007; MRC 2008). Specifically, our case study identifies how evidence currently in 'low' positions within the established hierarchy - levels 3 and 4 (see Table 2) – can be used with great effect to generate original insight and meaning, through the synthesis of single qualitative research studies or by integrating qualitative and quantitative synthesis findings. Such approaches can ensure the views of those delivering or receiving health services are captured, and that knowledge used to inform intervention development. There are, however, challenges to be faced by researchers in gathering such knowledge. These include additional research costs and the extra time required to reach intervention development – practical issues which are currently under-acknowledged in the literature. There are also more complex and methodological challenges associated with the use of evidence generated from qualitative synthesis which could seriously limit its potential contribution to the EBP movement.

Critically, qualitative synthesis is an emerging research methodology. Based on my experience in this area,<sup>10</sup> the field of qualitative synthesis can be daunting, even to those familiar with the area. Unlike the systematic review of quantitative studies where there is relative consensus on the best way to conduct such research (Higgins & Green 2011), there are many methodologies for synthesising qualitative studies and for bringing together qualitative and quantitative research. These different approaches have similar names and purposes. They often overlap,

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<sup>10</sup> Two meta-ethnographies (Paper 1 and one on paediatric long-term conditions), a guide on methods of qualitative synthesis (NHS QIS 2011) and the study reported in Paper 4.

adopting methods from each other (NHS QIS 2011), and creating methodological 'mash-ups'. Even for experienced qualitative synthesisers it can be difficult to differentiate between these approaches without referring to source documents. Consequently, in qualitative synthesis the literature field is currently not just muddy - it is a quagmire!

Various authors have tried to make sense of the literature, producing guidance documents identifying key approaches, each with their theoretical sources and seminal worked examples (Dixon-Woods *et al.* 2004; Dixon-Woods *et al.* 2005; Barnett-Page & Thomas 2009; NHS QIS 2011). Nevertheless, this emerging field remains complicated. The many (confusing) methods of qualitative synthesis act as a barrier to the full utilisation of such approaches as a means of generating evidence for practice. That said, it is possible that, once the field becomes more established, methodologies used less often in health research (such as meta-interpretation (Weed 2005; Weed 2007) may 'fall out' of use resulting in fewer approaches with more clearly differentiated methods and purposes. To clarify the situation, others have also proposed developing a taxonomy of 'less traditional knowledge synthesis methods' (Kastner *et al.* 2012:2). This should be beneficial to those wanting to use such approaches in future, enabling researchers to more easily match their research question to the most appropriate approach (Kastner *et al.* 2012). Clarity resulting from such developments may also mean that, in future, researchers are less likely to adapt methods to suit their particular study because they will be more confident they are using the most appropriate method in the right way. 'Taking better stock' of existing methods of qualitative synthesis may also assist in identifying where other new methods may be required to fully maximise the utility of qualitative evidence in future.

As well as confusion regarding the many methodological approaches for synthesising qualitative studies, there is also inconsistency and ambiguity regarding what is meant by the term 'synthesis' (see Section 6.3.3 for details). Too often within the literature, 'synthesis' is simply a summation of findings and themes from original studies. This creates a perception that the synthesis of qualitative evidence is simply aggregating existing studies; whereas, in the case of meta-ethnography, an extra tier of analytical and conceptual interpretation is also provided. Ambiguity regarding the meaning of synthesis could limit the potential contribution to EBP of those methodologies which do provide new higher order interpretations, 'going beyond' the primary reported findings. This is because the credibility of such approaches will be under-mined if it becomes commonly perceived that 'synthesis' is simply a summation of earlier findings rather than a new interpretation. This could result in the findings of those studies which do provide a higher level of interpretation being over-looked and 'down-graded' in terms of their significance and importance because they are perceived as standard literature reviews.

Meta-ethnography is leading the field as the most used (or most published!) approach to qualitative synthesis (see also Section 6) (Dixon-Woods *et al.* 2005; Ring *et al.* 2011). It is the most distinguishable approach within this field because of its distinctive name, underpinning theory and its different levels of interpretation (first, second, and third order constructs) (Noblit & Hare 1988). However, in our research for Paper 4 we identified an urgent need for further critical in-depth analysis (using systematic review methodology) of the practice of this approach. This is because; from amongst the many published meta-ethnographies we identified, there were notable differences in how researchers adapted the original principles of meta-ethnography (Noblit & Hare 1988) for use in health research. Consequently, this has led others to report that meta-ethnography 'cannot, at

present, be regarded as a standardised approach capable of application in a routinised way' (Campbell *et al.* 2011). It is therefore critical, at this relatively early point in the use of meta-ethnography in healthcare research, to determine how, and in what ways, the original principles of meta-ethnography are being adapted (Noblit & Hare 1988) and/or used. For example, how frequently are meta-ethnographers applying standard quantitative systematic review processes during their literature searching and reporting? How are they 'drawing' data from separate studies together? Such specific knowledge would indicate where the original theoretical guidance on meta-ethnography, which is now over 30 years old, (Noblit & Hare 1988) could be adapted providing detailed practical recommendations for its use in the 2010s and beyond. Such guidance is essential in reducing variations in how meta-ethnography is being conducted in healthcare research, reduce confusion and enhance the credibility of this methodology.

As the field of qualitative studies continues to emerge, new practical challenges which urgently need addressed continue to surface. One such issue relates to the updating of previously conducted qualitative syntheses, including how and when to do so. This is an important issue for three reasons. First, it is possible that two research teams synthesising the same studies and using similar methods may come to different interpretations of the original data because of their different professional and academic backgrounds. Second, any significant change which had occurred between an original review and its update, for instance a shift in social policy between these two time periods, would need to be identified and the possible impact, if any, on findings considered by reviewers. Third, whilst additional qualitative studies may have been published in a particular field, updating a meta-ethnography to include these studies might show 'saturation' has been reached in terms of knowledge generation and that no new theoretical development is possible (Campbell *et al.* 2011). As such, researchers updating a

meta-ethnography might find many new studies, but as these all confirm previous findings new third order constructs and interpretation may not be possible. Such issues are only now starting to surface as qualitative synthesis establishes itself as a method of generating knowledge. Nonetheless, these issues will need to be addressed to avoid qualitative syntheses being regarded as processes which produce findings of variable quality and rigour and which may, as a result, limit their contribution to EBP because they are regarded as poor sources of knowledge.

Taking a pragmatic approach to the synthesis of qualitative studies as a means of generating knowledge, standard good practice used in quantitative systematic review processes should be applied to the systematic review and synthesis of qualitative studies. This includes having two researchers working independently and then collaboratively to compare their work, and using standard processes for reporting literature searching outcomes (Moher *et al.* 2009; Higgins & Greens 2011). Such a recommendation may, however, be controversial to some qualitative researchers who would be uncomfortable at the application of quantitative methods to qualitative research. Nonetheless, if the synthesis of qualitative studies is to be seen as a credible research process, it needs conducted to the highest standard with bias minimised where possible and its processes open to scrutiny. It is therefore essential that researchers are explicit and transparent about their methods, including their literature searching processes and how they developed their new interpretation.

### 8.3.3 Integrating qualitative and quantitative review findings

Using qualitative evidence to improve the 'relevance and utility' of systematic reviews and health technology assessments has only 'recently received recognition' (Higgins & Green 2011). Integrating qualitative synthesis findings with trial interventions to better understand their implementation is therefore innovative

and ground-breaking. This is a fledgling approach and currently only a few published examples are available (Harden *et al.* 2004; Thomas *et al.* 2004). Some researchers may consider combining qualitative and quantitative findings as 'philosophically impossible' (Dixon-Woods *et al.* 2004) but, in our experience, this was feasible and effective in contributing new insight. For us, bringing together findings from qualitative and quantitative systematic reviews enabled us to understand why interventions to promote action plans work better in trial settings rather than in practice. Combining qualitative and quantitative findings is an exciting development with huge potential in terms of generating evidence for practice. This approach has, however, major challenges which need to be overcome if its potential is to be fully utilised in EBP.

Although integrating qualitative and quantitative review findings is an area which is in its infancy, several different approaches have already appeared (Harden *et al.* 2004; Thomas *et al.* 2004; Candy 2011; Ring *et al.* 2012). It is therefore important that lessons are learned from the field of qualitative synthesis in order to avoid – or at least minimise – similar development of methodological confusion and mash-ups. If the integration of qualitative and quantitative review findings is to contribute to the generation of evidence and help understand the implementation of EBP, it is vital that this field emerges in a more 'organised' fashion than the field of qualitative synthesis. Achieving this will be a challenge, and requires the commitment of individual researchers/teams as well as research organisations.

The contribution of novel approaches for integrating qualitative and quantitative review findings to the EBP movement will also be hampered by poor trial intervention descriptions. Until intervention descriptions improve, researchers using approaches such as cross-study synthesis to understand trial interventions will be forced to re-analyse trial interventions based on their interpretation of a

trial's components rather than on explicit trial descriptions as provided by original authors. Recommendations to improve intervention descriptions are available (Perera *et al.* 2007; Abraham & Michie 2008; Boutron *et al.* 2008; Glasziou *et al.* 2010), and when applied to *current and future* trials, integrating qualitative and quantitative review findings should become easier. However, the issue of poor intervention descriptions in *previously* conducted trials will remain problematic. One strategy for overcoming this problem is to contact original authors for additional details of their interventions. As noted in Section 6, this approach may not always be successful.

#### 8.3.4 The current evidence hierarchy and 'low' ranking evidence

The submitted papers on asthma plan research demonstrate that the views of those who should be implementing and receiving EBP need to be captured, and this evidence acted upon if its use is to be maximised. Our work exemplifies how evidence from the 'lower' end of the hierarchy derived from expert opinion (patients/carers and professionals) can make a substantial and original contribution to the generation of knowledge, either through the synthesis of individual studies and/or their integration with quantitative findings. There are, however, key barriers to the use of such approaches which need to be addressed.

There needs to be a shift towards more positive attitudes regarding the value of qualitative research within the EBP process. It is clear from the literature that this cultural shift has begun. Leading research organisations now support the use of qualitative research in systematic review processes (Higgins & Green 2011) and in the development of complex interventions (MRC 2000; Campbell *et al.* 2007; MRC 2008). However, as some individuals and organisations have traditionally considered qualitative research as evidence 'beyond the pale' (Dixon-Woods *et al.* 2001), and there are concerns regarding the rigour and value of qualitative

research (Audrey 2011; Higgins & Green 2011) whether single or synthesised studies, further cultural transition is needed to overcome embedded 'signs of resistance' to the inclusion of qualitative methods as 'equal partners' in research (Audrey 2011). To help achieve such change there is an urgent need for high impact healthcare journals, especially medical journals, to recognise the worth of qualitative and mixed methods research, publishing more such studies (O'Cathain *et al.* 2009). Organisations such as the Cochrane Collaboration, whilst committed to including more qualitative research in their systematic reviews (Higgins & Green 2011), need to do more to acknowledge such approaches as a matter of urgency; for example, by including terms such as 'qualitative', 'synthesis', and 'meta-ethnography' within their glossary (Cochrane Collaboration 2012).

Such changes are, however, not enough whilst the evidence hierarchy (as outlined in Table 2) which currently underpins EBP under-values traditional qualitative research *and* does not acknowledge the new methodologies of qualitative synthesis or the integration of qualitative and quantitative review findings. As long as a single unchanged evidence hierarchy continues to dominate within the EBP movement, giving primacy to RCTs, systematic reviews and meta-analyses, the views of patients/carers and professionals are unlikely to be adequately reflected in future guidelines and health technology assessments. For example, the current single evidence hierarchy assesses the quality and strength of evidence using criteria which reflect quantitative research design, including factors that might bias estimates of treatment effects (Guyatt *et al.* 2008), criteria which are not appropriate for use with qualitative research, resulting in its consistently low position in the hierarchy.

Multiple hierarchies and typographies of knowledge have been proposed as a means of acknowledging more diverse types of evidence (Petticrew & Roberts

2003; Nairn 2012; Nutley *et al.* 2012), including qualitative research. Use of alternatives to the single evidence hierarchy, such as evidence matrices (Petticrew & Roberts 2003; Nutley *et al.* 2012), would be beneficial in increasing the perceived value of qualitative research as a means of answering specific research questions. However, even if these are adopted there are still key issues which need to be addressed regarding the standard of qualitative research evidence. In particular, diversity in qualitative methodology generally, and lack of consensus regarding what constitutes a 'good' qualitative study specifically (Dixon-Woods *et al.* 2004), means assessing the quality of single studies was contentious, even prior to the emergence of innovative methods for synthesising qualitative studies and integrating findings with quantitative reviews (which have complicated this matter even further). Nonetheless, there are rudimentary criteria which can be used to assess such work. 'Syntheses' conducted by multi-disciplinary teams producing new third order interpretations should be rated higher than studies by solo researchers which simply summarise earlier findings. Again, studies with clear aims, explicitly described methods and transparent decision-making processes, enabling others to replicate their processes (Mays *et al.* 2005) should be considered more robust and higher quality than those which do not meet these criteria.

#### 8.4 *What the ECF framework tells us about asthma action plan implementation?*

According to the ECF framework, when the three elements of evidence, context and facilitation are mapped onto a continuum from 'low' to 'high', if they are situated towards the 'higher' end of that continuum, EBP implementation is more likely to occur.

When first embarking on our research, all three of these elements appeared to be at the higher end of the continuum, increasing the likelihood of action plan

implementation. That is, the evidence for action plans was strong; being derived from RCTs and Cochrane systematic reviews, and this evidence was included as recommendations within national and international guidelines. The context supporting action plan implementation was conducive to their use in the UK and internationally; for example, action plans were a priority for NHS implementation in Scotland. Facilitation promoting the use of action plans was also available nationally; for instance NHS QIS was funding our initial trial based systematic review to identify what helped and/or hindered action plan implementation. Whilst this suggested that the conditions for action plan implementation were 'right', research clearly indicated that action plan implementation was not happening in everyday practice in the UK and overseas (Sulaiman *et al.* 2004; Hoskins *et al.* 2005; Gillies *et al.* 2006; Wiener-Ogilvie *et al.* 2007; Tan *et al.* 2009; Kaferle & Wimsatt 2012).

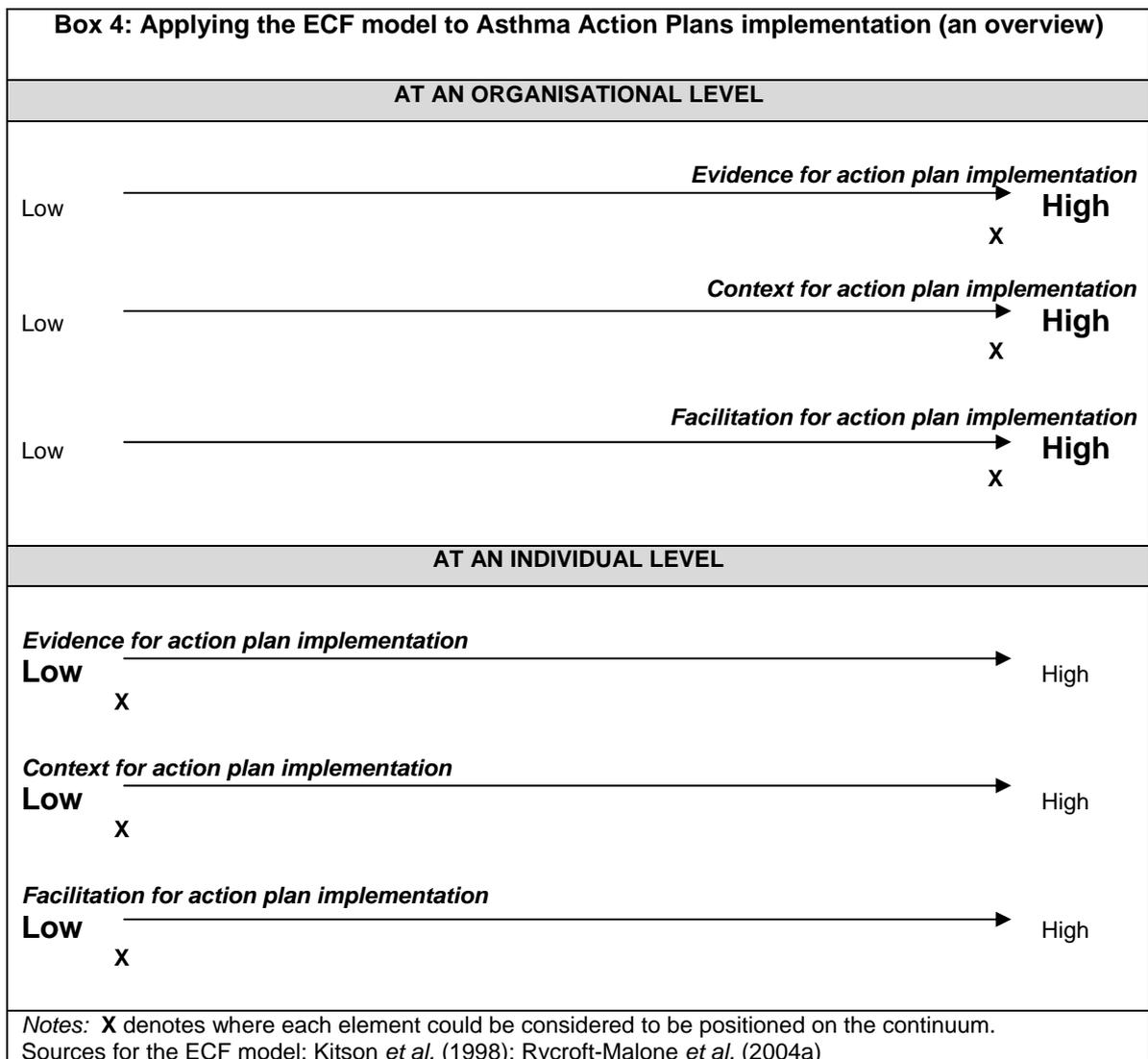
Critically reflecting on action plan implementation in terms of the ECF framework, it is now possible to see that whilst these three elements were high on their respective continuum, this was at an organisation level. From the perspective of individual patients/carers and professionals the picture was much less positive, with all three elements at the lower end of their continuum (see Box 4). In these circumstances, strong evidence, context and facilitation at an organisational level were therefore not enough to encourage successful action plan implementation at the level of individual patients/carers and professionals. For instance, organisational change may have increased opportunities for action plans to be issued, such as new asthma clinics being established, but this did not necessarily change individual consultation styles, thereby enabling action plans to be jointly developed and become more patient-focused, increasing their relevance and use. Consequently, the appropriateness of individual contexts for action plan implementation 'lagged behind' organisational readiness for change, resulting in

sub-optimal implementation in this specific area of EBP. Using the ECF framework to critically analyse the implementation of asthma action plans highlights that increasing use of these plans in future requires action targeted at enabling the three elements of evidence, context and facilitation at the level of individual patients and practitioners to move towards the higher end of the continuum, better reflecting the current position of these elements at the organisational level. Table 5 provides more detail about how such a shift could be achieved, identifying existing barriers to action plan implementation and factors which, if addressed, could enable the promotion and use of these plans in future.

Most importantly, it appears that practitioners were under-promoting these plans, and patients/carers were under-using them, because the evidence supporting their use contained in guidelines derived from RCTs and their systematic review did not adequately reflect their needs, wants and preferences. In this case study, high ranking evidence according to the hierarchy, was not enough to encourage the use of these plans in everyday practice because it did not adequately reflect the personal perspectives of those who should be using it. Our asthma plan research provides empirical evidence to support a revised and updated version of the ECF framework<sup>11</sup> which states that the successful implementation of EBP occurs when 'evidence is robust *and matches* professional consensus and patient needs and experiences' (Rycroft-Malone *et al.* 2002a:41).

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<sup>11</sup> The original conceptual framework and initially revised version were devised through conceptual analysis rather than empirical research. Research has since been conducted and is still on-going – see introduction to Section 8 for more details.



Our research highlights that a major and under-acknowledged barrier to action plan implementation is the limited nature of the evidence itself. RCTs, systematic reviews and their meta-analysis, whilst scientifically robust, did not match with the needs and experiences of those who should be using that evidence. Whilst this type of evidence was useful for practice, it was only one piece in the jigsaw of knowledge required to support action plan implementation – on its own it did not provide the full picture.

<b>Box 5: Applying the ECF model to Asthma Action Plans implementation (detailed view)</b>	
<b>ORGANISATIONAL LEVELS</b>	
<i>Element</i>	<i>Element Position on Continuum = High</i>
<i>Evidence</i>	<p>e.g.</p> <ul style="list-style-type: none"> <li>- RCTs and systematic reviews, including from Cochrane, were available so evidence was strong according to the evidence hierarchy shown in Table 2</li> <li>- International and national guidelines recommended the use of asthma action plans</li> <li>- The views and preferences of national organisations, patient bodies and experts in the field (especially doctors and medical researchers) were supportive of action plan use at a strategic level</li> </ul>
<i>Context</i>	<p>e.g.</p> <ul style="list-style-type: none"> <li>- Nationally and at Health Board level the NHS context and organisational culture(s) supported the implementation of clinical guidelines generally – this includes respiratory guidelines action plans specifically</li> <li>- Professional organisations, e.g. the Royal College of Nursing, require their members to engage with evidence generally e.g. to use clinical guidelines such as asthma ones</li> <li>- National leadership was available and this supported action plan use</li> <li>- The measurement of guideline implementation has been encouraged generally. The national Quality and Outcomes Framework (QOF) (NHS Confederation &amp; British Medical Association 2007) also supports annual asthma checks for patients in primary care</li> </ul>
<i>Facilitation</i>	<ul style="list-style-type: none"> <li>- Practical support from national and local bodies was present to support action plans e.g. money was available to fund related research and copies of action plans were available such as from Asthma UK</li> <li>- Respiratory Managed Clinical Networks facilitated asthma guideline implementation locally</li> <li>- Organisations also supported development of individual practitioner skills e.g. in clinical audit</li> </ul>
<b>INDIVIDUAL LEVELS</b>	
<i>Element</i>	<i>Continuum Position = Low</i>
<i>Evidence</i>	<p>e.g.</p> <ul style="list-style-type: none"> <li>- Research reflecting the views of those who should be issuing and/or using action plans in real life had not been sufficiently acknowledged e.g. such evidence had not adequately filtered into the RCTs, guidelines etc. Consequently action plans are not currently fit for purpose. There needs to be greater recognition given in guideline development to the value of research evidence which is currently perceived as low value in the established single evidence hierarchy. This could be addressed through the use of evidence matrices</li> <li>- Given the primary role of nurses in action plan promotion and review there has not been enough nursing focused research</li> </ul>
<i>Context</i>	<p>e.g.</p> <ul style="list-style-type: none"> <li>- Individual practitioners are expected to engage with evidence but there is so much evidence for practice and so many guidelines available generally that action plans not always seen as a priority for action</li> <li>- There has been inadequate recognition given to the clinical interaction as the critical context for action plan implementation and the need for greater partnership between patients/carers and professionals</li> <li>- Asthma plans are most likely to be promoted by nurses but nursing leadership has been low profile (or even missing) from this initiative e.g. respiratory guideline development and the research agenda are disproportionately led by non-nurses</li> <li>- To-date practitioner measurement of action plan implementation e.g. via clinical audit has been ad hoc</li> <li>- The QOF (NHS Confederation &amp; British Medical Association 2007) encourages annual asthma reviews and reporting of their uptake but this does not include action plan promotion and use. QOF asthma criteria are task orientated and not amenable to the development/review of action plans in annual asthma checks</li> </ul>
<i>Facilitation</i>	<p>e.g.</p> <ul style="list-style-type: none"> <li>- Inadequate attention had been given to facilitating change of individual professionals e.g. helping them to share decision making. Individual practitioners need facilitation, for example to enable them to identify the asthma self management strategies of their patients and incorporate this knowledge into the joint development of action plans with patients/carers</li> </ul>
Sources: (Kitson <i>et al.</i> 1998; Rycroft-Malone <i>et al.</i> 2004a)	

## Section 9: Conclusions

Our asthma plan case study focuses on the generation and use of evidence in one clinical area. Critically reflecting on this work several key themes emerge.

First, the concept of EBP has not remained static since its introduction over two decades ago – it has evolved, and is still evolving. EBP originated as a uni-disciplinary medical initiative aimed at modernising health care through improving effectiveness and efficiency. EBM was a simpler process in terms of its scope than contemporary EBP. It had a narrow focus, being ‘only applicable to parts of the NHS’, primarily medicine and epidemiology, especially areas of diagnosis and therapy rather than health ‘care’ generally (Cochrane 1972:2-3). Within EBM there was also relative agreement that RCTs, systematic reviews and meta-analysis provided the most appropriate type of clinical evidence because they generated knowledge about which drugs and surgical techniques were most likely to be effective with large groups of patients. Importantly, these research methods were reasonably well established and accepted within the medical profession and, because these types of studies can be quality assessed and ranked, findings could be relatively easily translated into guideline recommendations for practice.

EBP is a multi-disciplinary concept focusing on *all* aspects of care delivery in a multitude of contexts, across all disciplines. Patients/carers are now expected to have an active role in this process. EBP’s sphere has extended far beyond the diagnosis and treatment of acute conditions, such as hip fracture, to include the (self-)management of long-term diseases and conditions as varied as asthma, obesity and learning disabilities. To underpin practice in such hugely diverse areas, knowledge is needed which is much broader than just knowing the efficacy of drugs and therapies. Contemporary EBP in healthcare generally, not just

asthma care specifically, is therefore a much more complex process than it was originally intended to be, making implementation more challenging.

Second, the historically polarised debate over what constitutes best evidence and 'whose evidence trumps whose' (Jutel 2008:420) has over-shadowed the changing nature of EBP and the need for evidence better suited to patients/carers and professionals. As guideline development and health technology assessments need to be informed by the views and preferences of patients/carers and professionals, knowledge needs to be derived from qualitative and quantitative research. The case of asthma action plans indicates how over-reliance on research ranked high in the evidence hierarchy, namely RCTs and their systematic review has contributed to the production of knowledge which does not adequately resonate with the full range of health professionals and patients/carers who should be using that evidence, thus contributing to sub-optimal use of these plans.

Whilst the concept of EBP has evolved, the evidence hierarchy has remained static, continuing to reflect the knowledge requirements of EBM rather than EBP. The dominant status of the current evidence hierarchy is, however, being challenged, not least because the traditional quantitative and qualitative research approaches underpinning the hierarchy are themselves evolving. Qualitative research is changing through the emergence of methods to synthesise individual studies and to integrate qualitative and quantitative review findings, all of which increases the 'weight' of forms of evidence previously considered 'low' value. The supremacy of single trials of interventions, measuring efficacy with restricted study populations in tightly controlled settings (Maclure 2009), is also being challenged by changes in the RCT methodology towards the use of more complex, pragmatic trials with 'real' participants in 'real world' settings. However, the established single evidence hierarchy does not adequately reflect such research developments. The

use of evidence matrices would therefore be beneficial as an alternative to the single evidence hierarchy.

Third, successful EBP implementation requires strong evidence, context and facilitation. The focus of EBP has been disproportionately on evidence - its generation, appraisal and translation into practice via guidelines and other forms such as care pathways. Context and facilitation have, by comparison, received less attention, and their focus has been mainly directed towards changing organisations and how they operate rather than also changing the behaviour of individual professionals and patients/carers in their clinical interactions. Whilst helping practitioners to acquire practical skills such as clinical audit has been necessary in the past, EBP implementation in the 2010s also requires professionals with skills in patient partnership working and shared decision-making – skills relating directly to the individual context of clinical care. The need to balance the organisational *and* individual requirements of contemporary EBP implementation reflects the different dimensions of healthcare quality improvement identified decades ago (Maxwell 1984). As far back as the 1960s, interpersonal care was highlighted alongside organisational and technical factors as necessary for improving clinical effectiveness and efficiency (Donabedian 1966). Our action plan case study suggests that the individual and interpersonal dimensions of EBP may have 'got lost' in strategic health agendas aiming to increase effectiveness and efficiency through primarily improving the quality of technical care and organisational delivery.

Finally, these five submitted papers represent a case study of the generation and implementation of evidence in just one area of practice. Although there are other examples demonstrating unique insight into clinical care obtained through using diverse sources of evidence - insight not available from quantitative evidence alone

(Glasby & Beresford 2006) - our case study has been more extensive and novel. This is because we used existing methodologies (systematic review) as well as new and innovative approaches (meta-ethnography, linguistic analysis and cross-study synthesis) to work with quantitative and qualitative evidence in a more flexible, creative and integrated way. Further case studies are, however, required to determine whether the benefits derived from using a wider range of evidence as a basis for practice, which we found here, are also evident in other clinical areas.

Having completed our work, it now seems that previously acknowledged barriers to the use of asthma action plans, including lack of time, leadership and ability to access the evidence, are symptomatic of deeper underlying and more complex barriers to their implementation - barriers relating to what constitutes 'best' evidence for practice and the meaning of EBP.

Asthma action plans and their implementation are an example of contemporary EBP. Action plans are intended to support patients in the self-care of a long-term condition. This requires multi-disciplinary, and active patient, involvement with a broad range of supporting evidence including that which incorporates patients' views. Yet the original idea of asthma action plans was a medically led initiative, primarily aimed at treating acute asthma episodes and preventing hospital admissions amongst patients with more severe asthma. Action plans pre-date the introduction of EBP and shared decision-making; and they are firmly rooted in the concept of EBM, in which the 'best' evidence to support the use of these plans in practice is RCTs and systematic reviews. As our asthma work demonstrates, whilst this evidence is useful, it is not enough. Over-reliance on such quantitative evidence has contributed to a mismatch between what patients/carers want from asthma action plans and what they are currently being provided with by professionals. This mismatch is indicative of the tensions which exist between the

contemporary practice of *EBP* and its historical foundations in *EBM*. At the heart of this tension is the evidence hierarchy which remains rooted in the principles of *EBM*, out of alignment with contemporary *EBP* perceptions and practice. Such unresolved tension is currently an un-recognised barrier to the implementation of asthma action plans in practice.

## Section 10: References

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## Appendices

1. Paper 1: Ring et al. (2007) Promoting the use of Personal Asthma Action Plans: a systematic review. *Primary Care Respiratory Journal* 16(5):271-283.
2. Paper 2: Ring N., Pinnock H, Wilson C, Hoskins G, Jepson R, Wyke S, Sheikh A. (2011) Understanding what asthma plans mean: a linguistic analysis of terminology used in published texts. *Primary Care Respiratory Journal* 20(2) 170-177.
3. Paper 3: Ring N., P Jepson R, Hoskins G, Wilson C, Pinnock H, Sheikh A, Wyke S. (2011) Understanding what helps or hinders asthma action plan use: a systematic review and synthesis of the qualitative literature. *Patient Education and Counselling* 85(2) e131-e143.
4. Paper 4: Ring N, Jepson R, Ritchie K. (2011) Methods of synthesising qualitative research studies for health technology assessment. *International Journal of Technology Assessment in Healthcare*. 27(4) 384-390.
5. Paper 5: Ring N, Jepson R, Pinnock H, Wilson C, Hoskins G, Wyke S, Sheikh A. (2012) Developing novel evidence-based interventions to promote asthma action plan use: a cross-study synthesis of evidence from randomised controlled trials and qualitative studies. *Trials*, Nov. 13: c216.

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