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Complete List of Authors:	Sholl, Sarah; University of Dundee, Centre for Medical Education; Edinburgh Napier University, School of Business Ajjawi, Rola; Deakin University, Centre for Research in Assessment and Digital Learning Allbutt, Helen; NHS Education for Scotland, Planning and Corporate Governance Butler, Jane; Health Education Kent, Surrey and Sussex Jindal-Snape, Divya; University of Dundee, School of Education and Social Work Morrison, Jill; University of Glasgow, General Practice & Primary Care Rees, Charlotte; Monash University, Faculty of Medicine, Nursing & Health Sciences
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Title:

Balancing student/trainee learning with the delivery of patient care in the healthcare workplace: protocol for realist synthesis

Sarah Sholl¹, Rola Ajjawi², Helen Allbutt³, Jane Butler⁴, Divya Jindal-Snape⁵, Jill Morrison⁶, Charlotte Rees⁷

Corresponding Author:

Dr Sarah Sholl
Centre for Medical Education
University of Dundee
Mackenzie Building
Kirsty Semple Way
Dundee
DD2 4BF
Tel: +44 (0)1382 318984
Email: s.sholl@dundee.ac.uk

Author affiliations:

¹Centre for Medical Education, University of Dundee, Dundee, UK

²Centre for Research in Assessment and Digital Learning, Deakin University, Geelong, Australia

³Planning and Corporate Governance, NHS Education for Scotland, Edinburgh, UK

⁴Health Education Kent, Surrey and Sussex, Crawley, UK

⁵School of Education and Social Work, University of Dundee, Dundee, UK

⁶Institute of Health and Wellbeing, College of Medical, Veterinary and Life Sciences, University of Glasgow, Glasgow, UK

⁷HealthPEER (Health Professions Education and Education Research), Faculty of Medicine, Nursing and Health Sciences, Monash University, Melbourne, Australia

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ABSTRACT

Introduction

Dennis et al. recently conducted a national survey to explore medical education research priorities in Scotland. The identified themes and their underlying priority areas can be linked to current medical education drivers in the United Kingdom. The top priority area rated by stakeholders was: 'Understanding how to balance service and training conflicts'. Despite its perceived importance, a preliminary scoping exercise revealed the least activity with respect to published literature reviews. This protocol has therefore been developed to guide a body of work so as to understand how patient care, other service demands, and student/trainee learning can be simultaneously facilitated within the healthcare workplace.

Methods and Analysis

The review will identify key interventions designed to balance patient care and student/trainee learning, and try to understand how and why such interventions produce their effects. Our research questions seek to address the ways in which identified interventions enable balanced patient care-trainee learning within the healthcare workplace, for whom, why and under what circumstances. Pawson's five stages for undertaking a realist review underpin this protocol. We will: (1) clarify the scope of the review by identifying relevant interventions and existing programme theories, understanding how interventions act to produce their intended outcomes; (2) search for empirical evidence from 1998 (the introduction of the European Working Time Directive) on UK multidisciplinary team working concerning these interventions, theories and outcomes; (3) assess the quality of studies; (4) extract data; and (5) synthesise data, drawing conclusions.

Ethics and Dissemination

Formal ethical review is not required for this realist review. These findings should provide important understanding of how workplace-based interventions influence the balance of trainee learning and service provision. They should benefit various stakeholders involved in workplace-based learning interventions, and should continue to inform the research agenda for medical education in the United Kingdom.

Strengths and Limitations

- Realist synthesis allows a flexible approach and explanatory focus on situations in potentially complex environments. It enables the inclusion of a wide range of evidence sources. The variety of disciplinary backgrounds which the authors represent will contribute to the validity of the findings.
- The generation of inclusion criteria for assessment puts inevitable limits on the scope of data to be assessed and consequently the conclusions that will be drawn. Recommendations may not be generalisable.

INTRODUCTION

Medical education research priorities

In 2014, Dennis *et al.*[1] conducted a national survey in order to explore the priorities for medical education research in Scotland as perceived by a variety of stakeholders. The priority setting exercise identified twenty-one priority areas for Scottish medical education research, falling into five broad themes: (1) The culture of learning together in the workplace; (2) Enhancing and valuing the role of educators; (3) Curriculum integration and innovation; (4) Bridging the gap between assessment and feedback; (5) Building a resilient workforce.

These research themes and their underlying priority areas can be linked to current medical education drivers in the United Kingdom (e.g. *Tomorrow's Doctors*,[2] the *Shape of Training* review,[3] and *Promoting Excellence: standards for medical education and training*[4]). The reasons given by participants for prioritising items included patient safety, quality of care, investing in the future, policy/political agendas, and evidence-based education.[1]

A preliminary scoping exercise for literature reviews relevant to the identified priority areas was conducted between January and March 2015 using MEDLINE, EMBASE and Google Scholar. This elicited 157 reviews published from 1995 to 2014, 97% of which were characterised by their authors as 'systematic' or 'narrative'. Figure 1 shows the wide variation in literature review activity across the different priority areas.

The top priority area rated by stakeholders in Dennis *et al.*[1] was: 'Understanding how to balance service and training conflicts', concerning 'the pressures that exist or are perceived to exist between the delivery of service to patients and the provision of training.' [1] Despite it being rated as the top priority area, the preliminary literature search revealed the least activity with respect to already published literature reviews (see Figure 1).

<Insert figure 1 here>

Challenges of evaluating complex interventions in the workplace

The balance of service delivery and education operates within a complex environment. It is present in a variety of care contexts, it involves different stakeholders (e.g. members of multidisciplinary teams, patients, managers etc.), and the dynamic of the balance will vary between sites (e.g. different models of care in different regions) and at different times of the day, week, and year, depending on demand.[5] Interventions such as protected study time are dependent both on these variations and on the ways in which such interventions are implemented.[6] The factors affecting this balance are similarly complex and dynamic, although many of the factors themselves (such as protected learning time, workplace learning culture and capacity/capability) appear to be common across healthcare settings.[1,5]

Narrative reviews summarise a range of material in order to construct holistic conclusions informed by a combination of the research team's own experience and drawing on existing theories.[8] Robustly conducted narrative reviews can be useful depending on their intended purposes, but they are commonly criticised from a positivist perspective as being

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3 vulnerable to bias.[7,9,10] Systematic reviews involve “empirical evidence that fits pre-
4 specified eligibility criteria in order to answer a specific research question”. [11] They can be
5 useful for assessing simple interventions, employing robust and replicable methods, and
6 providing a comprehensive review of available peer-reviewed literature.[9,12,13] By
7 focussing only on peer-reviewed literature, however, we risk missing out on potentially
8 valuable information collected by other means such as grey literature. The scoping exercise
9 mentioned previously has also indicated that much of the literature dealing with the
10 balance of service and training conflicts appears to be embedded in papers with different
11 primary foci, such as occupational stress or evaluation of clinical teaching.
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15 A realist review would be suitable for more complex interventions such as those
16 encountered in healthcare, affording us an explanatory focus and the ability to include a
17 wide range of evidence sources (including primary qualitative and quantitative research,
18 secondary research, and grey literature).[14] The realist approach described by Pawson *et*
19 *al.* enables us to develop theories that consider the context-mechanism-outcome (C-M-O)
20 approach [15], i.e. how these contexts mobilise resources through which interventions (such
21 as protected time) work or do not work and their ability to promote the balance of service
22 delivery and training. It is worth noting here that the C-M-O approach is not necessarily a
23 linear one, even though it is ultimately expressed as such; for example, interventions may
24 work in more than one way in a particular context, or a programme theory may be based on
25 an existing outcome. Despite realist reviews not being able to cover every eventuality, they
26 are able to shed light on complex situations and to provide contextual explanations, which
27 are arguably more useful in a healthcare policy-making context.[15]
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31 **Aim and Research Questions**

32 This study aims to understand how patient care and trainee learning can be simultaneously
33 facilitated within the healthcare workplace. It will identify key complex interventions
34 designed to balance patient care and trainee learning, and try to understand how and in
35 what circumstances such interventions produce their effects. Our research questions
36 therefore seek to address the ways in which identified interventions enable balanced
37 patient care-trainee learning within the healthcare workplace, for whom, why and under
38 what circumstances.
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42 **METHODS AND ANALYSIS**

43 **Study design**

44 Pawson *et al.*[15] describe five stages for undertaking a realist review, which have been
45 used to underpin the design of this study. Since the review process is iterative, it may not
46 necessarily follow this linear progression neatly:
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50 **1** – Clarify the scope of the review by identifying: a) relevant interventions; and b) existing
51 programme theories, so as to understand how these interventions act to produce their
52 intended outcomes. The scoping exercise mentioned above generated a number of possible
53 search terms which could be used both to refine the purpose of the review and as the basis
54 for formulating key theories, and may help to address the issue that much of the research in
55 this area is embedded in other literature.[16-18] These search terms include: (1) protected
56 study time; (2) workplace-based learning (or workplace learning); (3) workplace-based
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assessment (or workplace assessment); (4) clinical learning environment; (5) clinical placement; (6) supervised learning events; (7) bedside teaching encounters; (8) continuing professional development; (9) barriers/facilitators to learning; (10) interprofessional/multiprofessional learning; (11) capacity and capability; (12) workforce planning; (13) cost effectiveness; (14) organisational need; (15) context-sensitive learning.

2 – Search for empirical evidence concerning these interventions, theories and outcomes. Note that evidence may be supportive, contradictory, or may act to modify the theories identified in stage 1. It is anticipated that the search strategy will involve: (1) Searching for peer-reviewed literature using electronic databases e.g. Medline, CINAHL, Web of Science, Scopus; (2) Snowballing and citation tracking; (3) Grey literature searching (e.g. National Health Service/healthcare regulator reports and reviews, policy documents etc.)

Terminology will initially be refined using MeSH to ensure a systematic and comprehensive search of the literature. The authors have elected to start with Medline and to use the list of search terms arising from the initial scoping exercise in order to elicit the MeSH terms that will be used. A similar strategy will be employed for CINAHL, which uses a similar control language but with a different set of descriptors. The resulting list of search terms will then be used for those databases requiring a free text approach, such as Scopus and Web of Science.

Since all of the papers identified during the scoping exercise employed a UK-wide focus, and since many of the factors considered to influence the balance of service and education are common to all regions of the UK, the proposed review will be UK-wide. Whilst the findings may have relevance to other national health systems, studies involving them will be excluded from this review as different health systems may be influenced by different contextual factors such as healthcare funding and educational pathways.

Postgraduate education tends to be workplace-based and often involves interprofessional learning; therefore the proposed review will include multidisciplinary teams as well as individual learning, rather than being limited to doctors only, particularly since we are seeking to understand in which circumstances (i.e. for which ‘populations’) mechanisms are effective.[19-23] See Box 1 for a brief timeline of relevant NHS milestones, which allowed us to choose an appropriate timescale for the literature search.

Box 1. Timeline of relevant NHS milestones informing the literature search timeframe

1990	NHS & Community Care Act[24] – health authorities manage own budgets
1991	NHS Trusts established following NHS Community Care Act
1997	Scottish white paper: Designed to Care[25] – 47 Trusts become 28; integration of services; managed clinical networks
1998	European Working Time Directive (EWTD)[26] introduced for all except junior doctors
1999	NHS Scotland control handed over to Scottish Government
2002	NHS Education for Scotland established
2004	EWTD extended to cover junior doctors
	Abolition of NHS Trusts by NHS Reform (Scotland) Act[27]

2008	Lord Darzi report: Our NHS, Our Future[28] Scottish Patient Safety Programme
2009	GMC report: Tomorrow's Doctors[2]
2012	2020 Vision and Strategic Narrative[29]
2013	Greenaway report: Shape of Training[3]

Since 'time' was the most frequently cited influencing factor in the twenty-five studies found in the scoping exercise, it is proposed that the literature search be conducted from 1998, the introduction of the European Working Time Directive.

3 – Assess quality of studies

Relevant studies will be those that inform the development of the programme theory (i.e. how, why and in what circumstances an intervention works to bring about an outcome).[14,30] Initial assessment of relevance will be carried out by reviewing abstracts using preliminary inclusion/exclusion criteria. Any ambiguities at this stage will be checked by an additional researcher. Depending on the quantity of studies found, it is likely that a two-stage review process will be carried out; firstly to identify the main interventions that are relevant, and then to prioritise one or two interventions which will be the focus of the main study. Ten to twenty-five percent of the papers will also be double-checked and discussed by additional researchers, along with a number of papers previously excluded (for quality control purposes).[30] Assessment of rigour will follow the same process, this time employing a review of the whole paper. The application of inclusion/exclusion criteria will be an iterative process, as will be the testing and refinement of programme theories that are generated during this stage.

4 – Extract data

Realist review data is characterised by annotation rather than list extraction.[14,30] Relevant data from documents will be highlighted and annotated using a combination of ATLAS.ti and Excel software, and a preliminary coding framework will be established by a team of researchers to facilitate data synthesis in the next stage. Discussion of the data between researchers allows continuation of the testing and refinement of programme theories at this stage.

5 – Synthesise data and draw conclusions

The purpose of the realist review should drive the process of synthesis.[15] Relevant annotated evidence is used to test each aspect of the programme theory (or theories). The process of synthesis includes the following considerations:[30] (1) Reconciling and consolidating contradictory evidence – evidence which does not support a theory can enable useful insights about its implementation;[14] (2) Consideration of the relative methodological strengths/weaknesses of evidence; (3) Findings of one study that may allow insights into another; (4) Maintenance of the context of evidence sources when drawing conclusions and presenting findings. See Box 2 for an understanding of how internal and external validity will be addressed.

Box 2. How internal and external validity will be addressed

<u>Construct validity</u>	- by using multiple sources of evidence (data triangulation)
<u>Internal validity</u>	- by pattern matching (relating several different pieces of information from the study to a theoretical concept)
<u>External validity</u>	- by employing theory in the study design and by testing empirical evidence against programme theory

DISSEMINATION

Results will be written up according to RAMESES publication standards[14] and disseminated via the Scottish Medical Education Research Consortium (<http://www.smerc.org.uk>) at conferences and in peer-reviewed journals, and to NHS Education for Scotland, Health Education England (in particular Postgraduate Deans), regulatory and professional bodies etc. These findings will provide important insights into how workplace-based interventions influence the balance of service delivery and education. They will benefit multiple stakeholders involved in developing, implementing and receiving workplace-based learning interventions, and will continue to inform the medical and health professions education research agenda for the UK.

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Author contributions:

SS and CR were responsible for project conception. SS wrote the first draft of the manuscript. All authors contributed to protocol development, and critically reviewed and refined the manuscript. All authors read and approved the final manuscript.

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1
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4 Research Consortium (SMERC).
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8 **Competing interests:**

9 None declared
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11 **Legends:**

12 Figure 1 – Literature reviews pertaining to each of the 21 priority areas identified in the
13 priority-setting exercise by Dennis *et al.*[1] Note that some literature reviews are relevant to
14 more than one priority area. (a) Vertical integration of undergraduate and postgraduate
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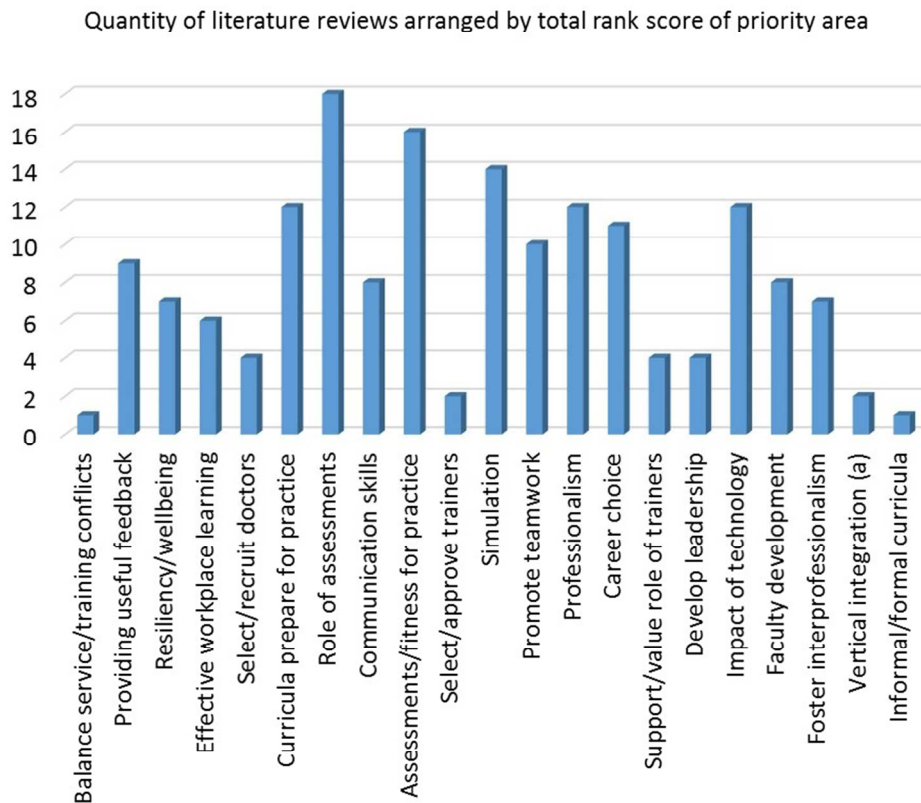


Figure 1 – Literature reviews pertaining to each of the 21 priority areas identified in the priority-setting exercise by Dennis et al.[1] Note that some literature reviews are relevant to more than one priority area.
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Sarah Sholl¹, Rola Ajjawi², Helen Allbutt³, Jane Butler⁴, Divya Jindal-Snape⁵, Jill Morrison⁶, Charlotte Rees⁷

Corresponding Author:

Dr Sarah Sholl
Centre for Medical Education
University of Dundee
Mackenzie Building
Kirsty Semple Way
Dundee
DD2 4BF
Tel: +44 (0)1382 318984
Email: s.sholl@dundee.ac.uk

Author affiliations:

¹Centre for Medical Education, University of Dundee, Dundee, UK

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ABSTRACT

Introduction

Dennis et al. recently conducted a national survey to explore medical education research priorities in Scotland. The identified themes and underlying priority areas can be linked to current medical education drivers in the United Kingdom. The top priority area rated by stakeholders was: 'Understanding how to balance service and training conflicts'. Despite its perceived importance, a preliminary scoping exercise revealed the least activity with respect to published literature reviews. This protocol has therefore been developed to guide a body of work so as to understand how patient care, other service demands, and student/trainee learning can be simultaneously facilitated within the healthcare workplace.

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INTRODUCTION

Medical education research priorities

In 2014, Dennis *et al.*[1] conducted a national survey in order to explore the priorities for medical education research in Scotland as perceived by a variety of stakeholders. The priority setting exercise identified twenty-one priority areas for Scottish medical education research, falling into five broad research themes: (1) The culture of learning together in the workplace; (2) Enhancing and valuing the role of educators; (3) Curriculum integration and innovation; (4) Bridging the gap between assessment and feedback; (5) Building a resilient workforce. These themes and their underlying priority areas can be linked to current medical education drivers in the United Kingdom (e.g. *Tomorrow's Doctors*,[2] the *Shape of Training* review,[3] and *Promoting Excellence: standards for medical education and training*[4]). The reasons given by participants for prioritising items included patient safety, quality of care, investing in the future, policy/political agendas, and evidence-based education.[1]

The top priority area rated by stakeholders was 'Understanding how to balance service and training conflicts', concerning 'the pressures that exist or are perceived to exist between the delivery of service to patients and the provision of training.'[1] However, a preliminary scoping exercise to identify literature reviews relevant to the priority areas revealed the least activity in this area. Figure 1 shows the wide variation in literature review activity across the different priority areas. It was therefore decided to proceed with a literature review for the top-rated priority area.

Figure 1 here

Challenges of evaluating complex interventions in the workplace

The balance of service delivery and education operates within a complex environment. It is present in a variety of care contexts, it involves different stakeholders (e.g. members of multidisciplinary teams, patients, managers etc.), and the dynamic of the balance will vary between sites (e.g. different models of care in different regions) and at different times of the day, week, and year, depending on demand.[5] Interventions such as protected study time are dependent both on these variations and on the ways in which such interventions are implemented.[6] The factors affecting this balance are similarly complex and dynamic, although many of the factors themselves (such as workplace learning culture and capacity/capability) appear to be common across healthcare settings.[1,5]

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20 complex situations and to provide contextual explanations, which are arguably more useful
21 in a healthcare policy-making context.[15]
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25 **Research Questions and Aim**

26 The research questions arising from the scoping exercise were as follows:

27 How can the delivery of service to patients and of training be simultaneously facilitated in
28 the healthcare workplace?

29 What are the key complex interventions which are designed to help achieve/maintain this
30 balance?

31 In what ways do successful interventions enable this balance within the healthcare
32 workplace, and in what context?
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36 Our study therefore aims to address the ways in which identified interventions enable
37 balanced patient care-trainee learning within the healthcare workplace, for whom, why and
38 under what circumstances.
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40 **METHODS AND ANALYSIS**

41 **Study design**

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environment; (5) clinical placement; (6) supervised learning events; (7) bedside teaching encounters; (8) continuing professional development; (9) barriers/facilitators to learning; (10) interprofessional/multiprofessional learning; (11) capacity and capability; (12) workforce planning; (13) cost effectiveness; (14) organisational need; (15) context-sensitive learning. A number of possible programme theories were considered when developing the protocol, and it was decided that it would be better to start reviewing the identified literature before developing specific candidate theories for testing.

2 – Search for empirical evidence concerning these interventions, theories and outcomes. Note that evidence may be supportive, contradictory, or may act to modify the theories identified in stage 1. It is anticipated that the search strategy will involve: (1) Searching for peer-reviewed literature using electronic databases; (2) Snowballing and citation tracking; (3) Grey literature searching. See Box 1 for a summary of the types of literature and sources to be searched.

<i>Type of literature</i>	<i>Sources</i>
Journal articles	Searching databases <i>ERIC, Scopus, CINAHL, Web of Science, and PsychInfo</i> ; checking the reference lists of included papers and contacting authors where appropriate.
Grey literature	Publications from the <i>General Medical Council, Health and Care Professions Council, Nursing and Midwifery Council etc.</i>
UK websites	e.g. <i>NHS Education for Scotland, Health Education England, Royal Colleges of Physicians/Nursing/Midwifery etc.</i>

Box 1. Summary of types of literature and sources to be searched

Terminology will initially be refined using Medical Subject Headings (MeSH) to ensure a systematic and comprehensive search of the literature. The authors have elected to start with Medline and to use the list of search terms arising from the initial scoping exercise in order to elicit the MeSH terms that will be used. A similar strategy will be employed for CINAHL, which uses a similar control language but with a different set of descriptors. The resulting list of search terms will then be used for those databases requiring a free text approach, such as Scopus and Web of Science. Box 2 summarises the type and detail of inclusion criteria to be used, which are explained in more detail below.

<i>Type</i>	<i>Criterion</i>
Topic	Literature should relate directly to one or more of the research questions (see earlier).
Recency	Literature published from 1998 onwards (see also Box 3).
Geographic spread	Literature should relate to studies carried out in the United Kingdom.

Box 2. Inclusion criteria

Since all of the papers identified during the scoping exercise employed a UK-wide focus, and since many of the factors considered to influence the balance of service and education are common to all regions of the UK, the proposed review will be UK-wide. Whilst the findings may have relevance to other national health systems, studies involving them will be excluded from this review as different health systems may be influenced by different

contextual factors such as healthcare funding and educational pathways. This is not to say that mechanisms identified in other countries would not be helpful to those in the UK healthcare workplace however; they may indeed be transferable in this context.

Postgraduate education tends to be workplace-based and often involves interprofessional learning; therefore the proposed review will include multidisciplinary teams as well as individual learning, rather than being limited to doctors only, particularly since we are seeking to understand in which circumstances (i.e. for which ‘populations’) mechanisms are effective.[19-23] These populations include students (i.e. those who have not yet gained their initial qualification but who undergo some of their training as part of a team in the healthcare workplace) and trainees (i.e. individuals post-qualification but not yet at the end of their training). See Box 3 for a brief timeline of relevant NHS milestones, which allowed us to choose an appropriate timescale for the literature search.

1990	NHS & Community Care Act – health authorities manage own budgets
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Box 3. Timeline of relevant NHS milestones informing the literature search timeframe

Since ‘time’ was the most frequently cited influencing factor in the twenty-five studies found in the scoping exercise, it is proposed that the literature search be conducted from 1998, the introduction of the European Working Time Directive.

3 – Assess quality of studies

Literature will be assessed for relevance and rigour according to RAMESES publication standards [14].

Relevance – papers will be screened first for relevance, i.e. those which “provide data that inform programme theory development and refinement”. [14,30] Initial assessment of relevance will be carried out by reviewing abstracts using preliminary inclusion criteria. Any ambiguities at this stage will be checked by an additional researcher. Depending on the quantity of studies found, it is likely that a two-stage review process will be carried out; firstly to identify the main interventions that are relevant, and then to prioritise one or two interventions which will be the focus of the main study. Double-checking will be carried out and discussed for 10-25% of the citations, along with a number of papers previously excluded (for quality control purposes).[30]

Rigour - assessment of rigour will follow the same process, this time employing a review of the whole paper, to determine “whether the methods used to generate the relevant data are credible and trustworthy”.^[30] Any differences will be resolved between the two analysts through negotiation and if this is not possible, then a third analyst will be brought in to adjudicate. The application of inclusion/exclusion criteria will be an iterative process, as will be the testing and refinement of programme theories that are generated during this stage. Figure 2 shows a summary of the searching and selection process.

Figure 2 here

4 – Extract and analyse data

Realist review data is characterised by annotation rather than list extraction,^[14,30] and a thematic approach will be adopted here. The process of analysis will pursue the following iterative progression: (1) Reading a sample of the data to identify codes for contexts, mechanisms and outcomes; (2) Developing a coding framework including descriptive elements and more analytic C-M-O configurations; (3) Applying the coding framework to the rest of the data; and (4) Interrogating the codes using ATLAS.ti software in order to look for patterns and organise codes. Discussion of the data between researchers allows continuation of the testing and refinement of programme theories at this stage.

5 – Synthesise data and draw conclusions

The purpose of the realist review should drive the process of synthesis.^[15] Relevant annotated evidence will be used to test each aspect of the programme theory (or theories). The process of synthesis will include the following considerations:^[30] (1) Reconciling and consolidating contradictory evidence – evidence which does not support a theory can enable useful insights about its implementation;^[14] (2) Consideration of the relative methodological strengths/weaknesses of evidence; (3) Findings of one study that may allow insights into another; (4) Maintenance of the context of evidence sources when drawing conclusions and presenting findings. See Box 4 for an understanding of how internal and external validity will be addressed.

<u>Construct validity</u>	- by using multiple sources of evidence (data triangulation)
<u>Internal validity</u>	- by pattern matching (relating several different pieces of information from the study to a theoretical concept)
<u>External validity</u>	- by employing theory in the study design and by testing empirical evidence against programme theory

Box 4. How internal and external validity will be addressed

The research team is multidisciplinary in background, including clinically-qualified individuals, social scientists, healthcare education researchers and managers. We anticipate that this broad range of experience will lend itself to a more comprehensive interpretation of the data.

DISSEMINATION

Results will be written up according to RAMESES publication standards^[14] and disseminated via the Scottish Medical Education Research Consortium

(<http://www.smerc.org.uk>) at conferences and in peer-reviewed journals, and to NHS Education for Scotland, Health Education England (in particular Postgraduate Deans), regulatory and professional bodies etc. These findings will provide important insights into how workplace-based interventions influence the balance of service delivery and education. They will benefit multiple stakeholders involved in developing, implementing and receiving workplace-based learning interventions, and will continue to inform the medical and health professions education research agenda for the UK.

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33 **Author contributions:**

34 SS and CR were responsible for project conception. SS, RA, HA, JB, DJS, JM and CR
35 contributed to protocol development. SS carried out the initial scoping exercise and wrote
36 the first draft of the manuscript. RA, HA, JB, DJS, JM and CR critically reviewed and refined
37 the manuscript. SS wrote the final draft. All authors read and approved the final manuscript.

38
39
40 **Funding statement:**

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43
44 **Competing interests:** None declared.
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Figure 1 – Literature reviews pertaining to each of the 21 priority areas identified in the priority-setting exercise by Dennis et al.[1] Note that some literature reviews are relevant to more than one priority area.
(a) Vertical integration of undergraduate and postgraduate curricula

Peer review only

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Figure 2 – PRISMA diagram of the searching and selection process

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BMJ Open

Balancing student/trainee learning with the delivery of patient care in the healthcare workplace: protocol for realist synthesis

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Title:

Balancing student/trainee learning with the delivery of patient care in the healthcare workplace: protocol for realist synthesis

Sarah Sholl¹, Rola Ajjawi², Helen Allbutt³, Jane Butler⁴, Divya Jindal-Snape⁵, Jill Morrison⁶, Charlotte Rees⁷

Corresponding Author:

Dr Sarah Sholl
Centre for Medical Education
University of Dundee
Mackenzie Building
Kirsty Semple Way
Dundee
DD2 4BF
Tel: +44 (0)1382 318984
Email: s.sholl@dundee.ac.uk

Author affiliations:

¹Centre for Medical Education, University of Dundee, Dundee, UK

²Centre for Research in Assessment and Digital Learning, Deakin University, Melbourne, Australia

³Planning and Corporate Governance, NHS Education for Scotland, Edinburgh, UK

⁴Health Education Kent, Surrey and Sussex, Crawley, UK

⁵School of Education and Social Work, University of Dundee, Dundee, UK

⁶Institute of Health and Wellbeing, College of Medical, Veterinary and Life Sciences, University of Glasgow, Glasgow, UK

⁷HealthPEER (Health Professions Education and Education Research), Faculty of Medicine, Nursing and Health Sciences, Monash University, Melbourne, Australia

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ABSTRACT

Introduction

A national survey was recently conducted to explore medical education research priorities in Scotland. The identified themes and underlying priority areas can be linked to current medical education drivers in the United Kingdom. The top priority area rated by stakeholders was: 'Understanding how to balance service and training conflicts'. Despite its perceived importance, a preliminary scoping exercise revealed the least activity with respect to published literature reviews. This protocol has therefore been developed so as to understand how patient care, other service demands, and student/trainee learning can be simultaneously facilitated within the healthcare workplace.

The review will identify key interventions designed to balance patient care and student/trainee learning, to understand how and why such interventions produce their effects. Our research questions seek to address how identified interventions enable balanced patient care-trainee learning within the healthcare workplace, for whom, why and under what circumstances.

Methods and Analysis

Pawson's five stages for undertaking a realist review underpin this protocol. These stages may progress in a non-linear fashion due to the iterative nature of the review process. We will: (1) clarify the scope of the review, identifying relevant interventions and existing programme theories, understanding how interventions act to produce their intended outcomes; (2) search journal articles and grey literature for empirical evidence from 1998 (introduction of the European Working Time Directive) on UK multidisciplinary team working concerning these interventions, theories and outcomes, using databases such as ERIC, Scopus and CINAHL; (3) assess study quality; (4) extract data; and (5) synthesise data, drawing conclusions.

Ethics and Dissemination

Formal ethical review is not required. These findings should provide important understanding of how workplace-based interventions influence the balance of trainee learning and service provision. They should benefit various stakeholders involved in workplace-based learning interventions, and inform the medical education research agenda in the UK.

Strengths and limitations of this study

- Realist synthesis is well suited to evaluation of complex interventions in the healthcare workplace
- The use of grey literature enables data triangulation from multiple sources
- Multidisciplinary research team lends broad experience and more comprehensive data interpretation
- Choice of search terms may limit material included in the review
- Geographic search area limited to the UK

INTRODUCTION

Medical education research priorities

In 2014, Dennis *et al.*[1] conducted a national survey in order to explore the priorities for medical education research in Scotland as perceived by a variety of stakeholders. The priority setting exercise identified twenty-one priority areas for Scottish medical education research, falling into five broad research themes: (1) The culture of learning together in the workplace; (2) Enhancing and valuing the role of educators; (3) Curriculum integration and innovation; (4) Bridging the gap between assessment and feedback; (5) Building a resilient workforce. These themes and their underlying priority areas can be linked to current medical education drivers in the United Kingdom (e.g. *Tomorrow's Doctors*,[2] the *Shape of Training* review,[3] and *Promoting Excellence: standards for medical education and training*[4]). The reasons given by participants for prioritising items included patient safety, quality of care, investing in the future, policy/political agendas, and evidence-based education.[1]

The top priority area rated by stakeholders was 'Understanding how to balance service and training conflicts', concerning 'the pressures that exist or are perceived to exist between the delivery of service to patients and the provision of training.'[1] However, a preliminary scoping exercise to identify literature reviews relevant to the priority areas revealed the least activity in this area. Figure 1 shows the wide variation in literature review activity across the different priority areas. It was therefore decided to proceed with a literature review for the top-rated priority area.

Figure 1 here

Challenges of evaluating complex interventions in the workplace

The balance of service delivery and education operates within a complex environment. It is present in a variety of care contexts, it involves different stakeholders (e.g. members of multidisciplinary teams, patients, managers etc.), and the dynamic of the balance will vary between sites (e.g. different models of care in different regions) and at different times of the day, week, and year, depending on demand.[5] Interventions such as protected study time are dependent both on these variations and on the ways in which such interventions are implemented.[6] The factors affecting this balance are similarly complex and dynamic, although many of the factors themselves (such as workplace learning culture and capacity/capability) appear to be common across healthcare settings.[1,5]

Narrative reviews summarise a range of material in order to construct holistic conclusions informed by a combination of the research team's own experience and drawing on existing theories.[7] Robustly conducted narrative reviews can be useful depending on their intended purposes, but they are commonly criticised from a positivist perspective as being vulnerable to bias.[8-10] Systematic reviews involve "empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question".[11] They can be useful for assessing simple interventions, employing robust and replicable methods, and providing a comprehensive review of available peer-reviewed literature.[9,12,13] By focussing only on peer-reviewed literature, however, we risk missing out on potentially valuable information collected by other means such as grey literature (i.e. that which lies

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3 outside academic or commercial publication). The scoping exercise mentioned previously
4 has also indicated that much of the literature dealing with the balance of service and
5 training conflicts appears to be embedded in papers with different primary foci, such as
6 occupational stress or evaluation of clinical teaching.
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9 A realist review would be suitable for more complex interventions such as those
10 encountered in healthcare, affording us an explanatory focus and the ability to include a
11 wide range of evidence sources (including primary qualitative and quantitative research,
12 secondary research, and grey literature).[14] The realist approach described by Pawson *et*
13 *al.* enables us to develop theories that consider the context-mechanism-outcome (C-M-O)
14 approach [15], i.e. how these contexts mobilise resources through which interventions work
15 or do not work and their ability to promote the balance of service delivery and training. It is
16 worth noting here that the C-M-O approach is not necessarily a linear one, even though it is
17 ultimately expressed as such; for example, interventions may work in more than one way in
18 a particular context, or a programme theory may be based on an existing outcome. Despite
19 realist reviews not being able to cover every eventuality, they are able to shed light on
20 complex situations and to provide contextual explanations, which are arguably more useful
21 in a healthcare policy-making context.[15]
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25 **Research Questions and Aim**

26 The research questions arising from the scoping exercise were as follows:

27 How can the delivery of service to patients and of training be simultaneously facilitated in
28 the healthcare workplace?

29 What are the key complex interventions which are designed to help achieve/maintain this
30 balance?

31 In what ways do successful interventions enable this balance within the healthcare
32 workplace, and in what context?
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36 Our study therefore aims to address the ways in which identified interventions enable
37 balanced patient care-trainee learning within the healthcare workplace, for whom, why and
38 under what circumstances.
39

40 **METHODS AND ANALYSIS**

41 **Study design**

42 Pawson *et al.*[15] describe five stages for undertaking a realist review, which have been
43 used to underpin the design of this study. Since the review process is iterative, it may not
44 necessarily follow this linear progression neatly:
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49 **1** – Clarify the scope of the review by identifying: a) relevant interventions; and b) existing
50 programme theories, so as to understand how these interventions act to produce their
51 intended outcomes. The scoping exercise mentioned above generated a number of possible
52 search terms which could be used both to refine the purpose of the review and as the basis
53 for formulating key theories, and may help to address the issue that much of the research in
54 this area is embedded in other literature.[16-18] These search terms (and derivations
55 thereof) include: (1) protected study time; (2) workplace-based learning (or workplace
56 learning); (3) workplace-based assessment (or workplace assessment); (4) clinical learning
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environment; (5) clinical placement; (6) supervised learning events; (7) bedside teaching encounters; (8) continuing professional development; (9) barriers/facilitators to learning; (10) interprofessional/multiprofessional learning; (11) capacity and capability; (12) workforce planning; (13) cost effectiveness; (14) organisational need; (15) context-sensitive learning.

A number of possible programme theories were considered when developing the protocol, and based on the scoping exercise a speculative candidate theory was identified as follows: protected learning time can be an effective intervention for postgraduate medical trainee in the primary care setting in the quest to balance the requirements of service delivery and of training depending on logistical pressures, learner motivation and attitude and the social environment. The mechanism is possibly due to access to education and perceived valuing/leadership.

2 – Search for empirical evidence concerning these interventions, theories and outcomes. Note that evidence may be supportive, contradictory, or may act to modify the theories identified in stage 1. It is anticipated that the search strategy will involve: (1) Searching for peer-reviewed literature using electronic databases; (2) Snowballing and citation tracking; (3) Grey literature searching. See Box 1 for a summary of the types of literature and sources to be searched.

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18 *Figure 2 here*
19

20 21 **4 – Extract and analyse data**

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23 thematic approach will be adopted here. The process of analysis will pursue the following
24 iterative progression: (1) Reading a sample of the data to identify codes for contexts,
25 mechanisms and outcomes; (2) Developing a coding framework including descriptive
26 elements and more analytic C-M-O configurations; (3) Applying the coding framework to the
27 rest of the data; and (4) Interrogating the codes using ATLAS.ti software in order to look for
28 patterns and organise codes. Discussion of the data between researchers allows
29 continuation of the testing and refinement of programme theories at this stage.
30

31 32 **5 – Synthesise data and draw conclusions**

33 The purpose of the realist review should drive the process of synthesis.[15] Relevant
34 annotated evidence will be used to test each aspect of the programme theory (or theories).
35 The process of synthesis will include the following considerations:[30] (1) Reconciling and
36 consolidating contradictory evidence – evidence which does not support a theory can
37 enable useful insights about its implementation;[14] (2) Consideration of the relative
38 methodological strengths/weaknesses of evidence; (3) Findings of one study that may allow
39 insights into another; (4) Maintenance of the context of evidence sources when drawing
40 conclusions and presenting findings. See Box 4 for an understanding of how internal and
41 external validity will be addressed.
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<u>Construct validity</u>	- by using multiple sources of evidence (data triangulation)
<u>Internal validity</u>	- by pattern matching (relating several different pieces of information from the study to a theoretical concept)
<u>External validity</u>	- by employing theory in the study design and by testing empirical evidence against programme theory

45 46 47 48 49 50 51 52 **Box 4. How internal and external validity will be addressed**

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54 The research team is multidisciplinary in background, including clinically-qualified
55 individuals, social scientists, healthcare education researchers and managers. We anticipate
56 that this broad range of experience will lend itself to a more comprehensive interpretation
57 of the data.
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DISSEMINATION

Results will be written up according to RAMESES publication standards[14] and disseminated via the Scottish Medical Education Research Consortium (<http://www.smerc.org.uk>) at conferences and in peer-reviewed journals, and to NHS Education for Scotland, Health Education England (in particular Postgraduate Deans), regulatory and professional bodies etc. These findings will provide important insights into how workplace-based interventions influence the balance of service delivery and education. They will benefit multiple stakeholders involved in developing, implementing and receiving workplace-based learning interventions, and will continue to inform the medical and health professions education research agenda for the UK.

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Author contributions:

40 SS and CR were responsible for project conception. SS, RA, HA, JB, DJS, JM and CR
41 contributed to protocol development. SS carried out the initial scoping exercise and wrote
42 the first draft of the manuscript. RA, HA, JB, DJS, JM and CR critically reviewed and refined
43 the manuscript. SS wrote the final draft. All authors read and approved the final manuscript.
44
45

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51 **Competing interests:** None declared.
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Figure 1 – Literature reviews pertaining to each of the 21 priority areas identified in the priority-setting exercise by Dennis et al.[1] Note that some literature reviews are relevant to more than one priority area.
(a) Vertical integration of undergraduate and postgraduate curricula

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Figure 2 – PRISMA diagram of the searching and selection process

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