

1 **Influence of external contextual factors on the implementation of**
2 **health and social care interventions into practice within or across**
3 **countries – A protocol for a ‘best fit’ framework synthesis**

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49 **Abstract**

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51 **Background**

52 The widespread implementation of interventions is often hindered by a decline and variability
53 in effectiveness across implementation sites. It is anticipated that variations in the
54 characteristics of the external context in different sites, such as the political and funding
55 environment, socio-cultural context, physical environment, or population demographics can
56 influence implementation outcome. However, there is only a limited understanding about
57 which and how external contextual factors influence implementation. We aim at developing a
58 comprehensive framework conceptualising the influence of external contextual factors on
59 implementation, particularly when spreading health and social care interventions within or
60 across countries.

61

62 **Methods**

63 The review will use the 'best fit' framework synthesis approach. In the first stage of the
64 review we will examine existing frameworks, models, concepts and theories on external
65 contextual factors and their influence on implementation from a variety of sectors and
66 disciplines including health and social care, education, environmental studies, and
67 international development fields. The resulting a-priori meta-framework will be tested and
68 refined in the second review stage by analysing evidence from empirical studies focusing on
69 the implementation of health and social care interventions within or across countries.

70 Searches will be conducted in bibliographic databases such as MEDLINE, ERIC, HMIC, and
71 IBSS, grey literature sources and on relevant websites. We will also search reference lists,
72 relevant journals, perform citation searches, and ask experts in the field. There is no
73 restriction to study type, setting, intervention type or implementation strategy to enable
74 obtaining a broad and in-depth knowledge from various sources of evidence.

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77 **Discussion**

78 The review will lead to a comprehensive framework for understanding the influence of
79 external contextual factors on implementation, particularly when spreading health and social
80 care interventions within or across countries. The framework is anticipated to help identify
81 factors explaining the decline and variability in effectiveness of interventions and assessing
82 the prospects of implementation effectiveness, when spreading interventions. We do not
83 intend to only develop another stand-alone implementation framework but one that can be
84 used in conjunction with existing frameworks. The framework can be honed and validated in
85 future empirical research.

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87 **Systematic review registration**

88 PROSPERO CRD42018084485

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91 **Keywords**

92 Implementation, innovation, context, spread, diffusion, scale-up, healthcare, social care,
93 framework, theory, 'best fit' synthesis

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100 **Background**

101 Despite many promising interventions being developed their implementation into everyday
102 practice is limited [1]. The process of translating research findings into widespread practice
103 can be described in four phases: (1) basic research discoveries, (2) tests of interventions in
104 trials, (3) implementation in pilot projects in single organisations, and (4) the spread to
105 several organisations and locations for the benefit of the whole population [2]. In the last
106 phase, the widespread implementation across several implementation sites is often hindered
107 by a decline in effect and variability in effectiveness across sites [3]. This leads to large parts
108 of the population not equally or not rapidly benefitting from new or improved interventions [4].

109

110 It is anticipated that variations in the characteristics of the external context in different
111 implementation sites can influence the implementation outcome. Such characteristics could
112 be differences in legal, political and funding environments, health system organisation,
113 socio-cultural contexts, the demographics of the served population, inter-organisational
114 networks, power dynamics, historical developments, or physical environment and location.
115 However, there is currently only a limited understanding about which and how external
116 contextual factors influence the implementation of health and social care interventions,
117 particularly when spreading interventions within or across countries [5].

118

119 Fewer studies have examined the influence of external contextual factors on implementation,
120 compared to other factors such as the internal, i.e. intra-organisational context, or the
121 content of an intervention [6]. The conceptualisation of what constitutes external contextual
122 factors already varies considerably. This makes it difficult to establish what impact the
123 external contextual factors would have. Some external contextual factors are specified in
124 existing implementation science frameworks, for example, Greenhalgh et al.'s conceptual
125 model of the Diffusion of Innovations in Service Organizations [7], the Consolidated
126 Framework for Implementation Research (CFIR) by Damschroder and colleagues [8], the

127 Exploration, Preparation, Implementation, Sustainment model (EPIS) by Aarons et al. [9], the
128 Context and Implementation of Complex Interventions framework (CICI) by Pfadenhauer and
129 colleagues [10] and Watson and colleagues' definition of the external implementation context
130 [11]. All these frameworks encompass different, but also overlapping, external contextual
131 factors and they vary considerably in their conceptualisation. Further, these studies'
132 underlying methodological approaches and evidence bases for developing the frameworks
133 differ noticeably. We will build upon this growing understanding of external implementation
134 context and aim at systematically deriving a comprehensive framework of how external
135 context is influencing the implementation of health and social care interventions, especially
136 when spreading interventions within and across countries.

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138

139 **Methods/Design**

140 The systematic review protocol is registered in the PROSPERO international prospective
141 register of systematic reviews (CRD42018084485). It was written according to the Preferred
142 Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P)
143 guideline recommended for systematic review protocols [12]. The PRISMA-P checklist is
144 included in Additional File 1.

145

146 **Review design**

147 The review will follow the 'best fit' framework synthesis approach developed by Carroll et al.
148 which is especially suited to develop a comprehensive framework based on existing
149 evidence [13] (Figure 1). The best fit approach allows for either identifying an appropriate (or
150 best fit) framework from the published literature to guide the thematic synthesis of evidence
151 from empirical studies or for generating a new meta-framework by systematically searching
152 for and synthesising published frameworks. We chose the latter approach as we did not

153 deem any published framework to be comprehensive in terms of focusing on external
154 implementation context.

155

156 The review is divided into two stages. Stage 1 (framework review) will follow the BeHEMOTH
157 (Behaviour of interest, health context, exclusions, models or theories) approach to
158 systematically identify theories, models, frameworks and concepts of external
159 implementation context in the scientific and grey literature from different sectors and
160 disciplines [14]. Frameworks, theories, models and concepts identified in stage 1 will be
161 synthesised in an a-priori meta-framework using thematic analysis [15]. Stage 2 (empirical
162 study review) will apply a systematic search and purposeful sampling approach to identify
163 information-rich empirical studies of health and social care interventions implemented into
164 practice within or across countries. Evidence from stage 2 will be coded against the a-priori
165 meta-framework generated in stage 1. Emerging themes from empirical studies that cannot
166 be coded against the a-priori meta-framework will be incorporated into the meta-framework.
167 The result of the review will be a refined framework on the influence of external contextual
168 factors on implementation. This new framework can subsequently be honed and validated in
169 future empirical research.

170

171 Figure 1: Two-stage review design following the 'best fit' framework synthesis approach,
172 based on Carroll et al. [13]

173

174 Legend Figure 1: The review applies a two-stage process. In the first stage we will review
175 existing frameworks, models, concepts and theories (stage 1 - framework review). Concepts
176 for external implementation context will be synthesised in an a-priori meta-framework. In the
177 second stage, we will test and refine the a-priori meta-framework by analysing evidence from
178 empirical studies that focus on the implementation of health and social care interventions
179 into practice within or across countries (stage 2 - empirical study review). The concepts
180 derived from both reviews will be synthesised into a final framework.

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Aims of the study

The primary aim of the review is to understand which and how external contextual factors influence the implementation of health and social care interventions into practice within or across countries. Each of the two consecutive review stages has specific review questions:

- Stage 1 (framework review):
How are external contextual factors that influence the implementation of interventions into practice conceptualised within existing theory?

- Stage 2 (empirical study review):
 1. How are external contextual factors influencing the implementation of health and social care interventions into practice within or across countries?

 2. What is the evidence on this influence regarding
 - a) the characteristics of the implementation process at different levels (i.e. micro, meso, macro levels), the involved stakeholders, the internal context of an organisation, and the intervention?
 - b) implementation outcomes?
 - c) Different types of interventions and different types of implementation strategies?
 - d) the implementation of interventions spreading internationally from one country to another compared to interventions spreading within the same country?

208 **Eligibility criteria**

209 Types of studies

210 In the framework review (stage 1) we will include studies that focus on exploring, testing or
211 developing frameworks, theories, concepts or models of the implementation of interventions.
212 Studies describing statistical or technical, care or disease models will be excluded. The
213 review will not be restricted to study type and will include, for example, experimental and
214 non-experimental studies, quantitative, qualitative and mixed methods studies, hybrid
215 implementation studies, process evaluations and conceptual studies.

216

217 In the empirical study review (stage 2) we will include primary studies analysing qualitative
218 empirical data of the implementation of interventions. We will exclude non-empirical studies
219 and studies not analysing the implementation of interventions, e.g., studies only analysing
220 the effectiveness of interventions. The review will be restricted to studies presenting
221 qualitative evidence from, for example, qualitative and mixed methods studies, hybrid
222 implementation studies, and process evaluations.

223

224 Domain

225 In the framework review (stage 1) we will include studies set in any non-profit public or
226 private service domain such as health care, public health, social care, education,
227 environment, public administration, and international development fields. We will not only
228 focus on studies set in the health and social care domain in this review stage but seek to
229 include evidence from other domains such as education or international development that
230 might be transferrable to the health and social care domain.

231

232 In the empirical study review (stage 2), studies focusing on interventions implemented in a
233 non-profit public or private health and social care domain will be included. Studies set in for-
234 profit businesses in the private domain will be excluded in both review stages.

235

236

237 Participants

238 We will include studies in both review stages that focus on participants in a practice setting,
239 including (a) service users, i.e., members of the public who might be using the intervention,
240 patients, carers and people from organisations that represent service users; and/or (b)
241 service providers, including professionals and managers. Studies focusing only on
242 participants in a policy or research setting will be excluded.

243

244 Intervention

245 In both review stages we will include studies focusing on active intervention implementation.
246 We will exclude studies focusing only on the stages of passive diffusion and dissemination of
247 interventions [7]. Further, studies focusing purely on utilisation or transfer of knowledge
248 instead of the implementation of tangible practices or interventions will be excluded.

249

250 In the empirical study review (stage 2) we will include studies describing the active
251 implementation of a health or social care intervention within or across countries. We will
252 exclude pilot implementation studies and planned but not yet implemented interventions. We
253 will include studies only focusing on interventions targeting delivery arrangements of
254 healthcare defined according to the Effective Practice and Organisation of Care (EPOC)
255 taxonomy [16]. As we only focus on practice settings (i.e. in primary, secondary, voluntary,
256 community care settings), studies only describing financial and governance arrangements
257 will be excluded from our review. Social care interventions are defined as the provision of

258 social work, personal care, protection or social support services to children or adults (or their
259 carers) in need or at risk, or adults with needs arising from disability, illness, old age or
260 poverty. They include working with individuals, small groups or communities and cover
261 services provided by public bodies, the voluntary sector or accessed on a self-funded basis
262 by the public. We will only include health and social care interventions that improve service
263 user or provider outcomes, or the quality of services. We will exclude studies set in a non-
264 health or non-social care domain, defined as interventions that are implemented in another
265 domain, e.g., education, and that are not delivered by health or social care professionals.
266 We will exclude studies focusing on the implementation of an intervention only in one single
267 site without it having been spread to other implementation sites. We define a site by
268 geographic location in order to capture the influence of different external contexts.

269

270 In both reviews, there will be no restriction regarding the type of intervention, type of
271 implementation strategy [17], or level of implementation (i.e., micro, meso, macro level).

272

273 Context

274 In both review stages we will include studies focusing on one or more external contextual
275 factors which can be defined as characteristics of the setting surrounding an organisation in
276 which the implementation takes place [7, 11]. Such external contextual factors could be, for
277 example, legal, political and funding environments, health system organisation, socio-cultural
278 contexts, the demographics of the served population, inter-organisational networks, power
279 dynamics, historical developments, or physical environment and location. Studies focusing
280 only on characteristics of the implementation process itself, the internal (intra-organisational)
281 context, the stakeholders involved in the implementation process, or the implemented
282 intervention will be excluded.

283

284 Outcomes

285 In the empirical study review (stage 2) we will include studies describing the influence of
286 external contextual factors on implementation outcome, ideally as defined by Proctor et al.
287 [18] (Table 1). We will also include studies if they refer to other implementation outcomes,
288 such as the utilisation of an intervention.

289

290 Table 1 Implementation outcome measures included in the review

Implementation outcome	Definition according to Proctor et al. [18]
Acceptability	Perception among implementation stakeholders that a given intervention is agreeable, palatable, or satisfactory.
Adoption	Intention, initial decision, or action to attempt to employ an intervention.
Appropriateness	Perceived fit, relevance, or compatibility of the intervention for a given practice setting, provider, or consumer; and/or perceived fit of the intervention to address a particular issue or problem.
Costs	Cost impact of an implementation effort.
Feasibility	Extent to which an intervention can be successfully used or carried out within a given setting.
Fidelity	Degree to which an intervention is implemented as it was intended in the original protocol or by the programme developers.

Penetration	Integration of an intervention within a service setting.
Sustainability	Extent to which a newly implemented intervention is maintained or institutionalised within a service setting's ongoing, stable operations.

291

292 **Search strategy**

293 For the framework review (stage 1), the search is following the iterative BeHEMOTH
 294 (Behaviour of interest, health context, exclusions, models or theories) strategy which was
 295 developed by Booth and Carroll for the systematic identification of frameworks, models,
 296 concepts, and theories from the literature [14]. Carroll et al. proposed to follow this strategy
 297 for the first stage of a best fit framework synthesis [13]. The BeHEMOTH strategy comprises
 298 the following steps: (1) Identifying theory from existing internal reference databases, (2)
 299 systematic database searches combining behaviour of interest (implementation) and context
 300 (external context) with terms for models or theory, (3) searches for named theories to identify
 301 key citations and (4) citation searches for identified theories in combination with the
 302 behaviour of interest.

303

304 For the systematic database search (step 2 of the BeHEMOTH strategy), we will combine
 305 generic and specific free text and database thesaurus terms for implementation, e.g.,
 306 implementation, adoption, knowledge transfer, with terms for external context, e.g., external
 307 context, outer setting, structural environment, and terms for theories, models, concepts and
 308 frameworks. An example of the proposed search strategy for MEDLINE (via Ovid) can be
 309 found in Additional File 2. The search covering scientific and grey literature will be performed
 310 in the following databases:

- 311 • Business Source Complete (from date of inception),

- 312 • CINAHL (Cumulative Index to Nursing and Allied Health) (from date of inception),
- 313 • Embase (from 1947),
- 314 • ERIC (Education Resources Information Center) (from date of inception),
- 315 • Global Health (from 1973),
- 316 • HMIC (Health Management Information Consortium) (from 1979),
- 317 • IBSS (International Bibliography of the Social Sciences) (from 1951),
- 318 • MEDLINE (from 1946),
- 319 • ProQuest Dissertations and Theses Global (from date of inception)
- 320 • PsycINFO (from 1806),
- 321 • SCOPUS (from 2004),
- 322 • Social Policy and Practice (from date of inception), and
- 323 • Web of Science (from 1900).

324

325 In the empirical study review (stage 2), the database search is combining generic and
326 specific free text and database thesaurus terms for external contextual factors with terms for
327 implementation, and terms for spread within or across countries, e.g., spread, scale-up,
328 cross-country, multi-site. The search strategy for this review stage will additionally be
329 informed by the results of the framework review (stage 1), e.g., regarding terms for external
330 contextual factors. The search covering scientific and grey literature will be performed in the
331 following databases:

- 332 • CINAHL (Cumulative Index to Nursing and Allied Health) (from date of inception),
- 333 • Embase (from 1947),
- 334 • HMIC (Health Management Information Centre) (from 1979),
- 335 • IBSS (International Bibliography of the Social Sciences) (from 1951),
- 336 • MEDLINE (from 1946),
- 337 • ProQuest Dissertations and Theses Global (from date of inception)

- 338 • PsycINFO (from 1806), and
- 339 • Social Policy and Practice (from date of inception).

340

341 Besides searching electronic databases, we will hand-search reference lists of included
342 articles and perform citation searches of included articles and authors to identify further
343 publications linked to included studies. We will also perform citation searches for the theories
344 identified in the framework review (stage 1) in combination with terms for health and social
345 care interventions spread within or across countries. Further, we will search Google Scholar
346 to cross-check that we have not missed any relevant publications.

347

348 For both reviews, we will search the grey literature databases GreyLit and OpenGrey. We
349 will also hand-search websites of relevant institutions and organisations such as the World
350 Health Organization, King’s Fund, and the Health Foundation and relevant journals in which
351 key articles were published, such as Implementation Science. In addition, we will ask experts
352 in the field to identify any unpublished and ongoing work. Both reviews are restricted to
353 publications in the English language. We will not apply any restrictions towards population,
354 place, study type, and publication year. We will include any publication type except for
355 conference abstracts and study protocols.

356

357 **Study selection, data extraction & analysis**

358

359 Selection

360 In both reviews, citations will be managed using Rayyan [19] and EndNote X9. Pairs of
361 reviewers will independently screen the title and abstract of records and full-texts for
362 inclusion (e.g., AZ (100%) + LB (30%), ES (20%), JO (10%), AB (10%), JS (10%)).

363 Disagreements will be resolved by group discussion and consensus in the review team. We

364 will calculate inter-rater reliability midway and at the end of the screening process to ensure
365 consistency between the reviewers. We aim to improve the inter-rater reliability after the first
366 calculation by refining the inclusion criteria in the review team.

367

368 In the empirical study review (stage 2), we follow the threefold purposeful sampling approach
369 applied by Benoot and colleagues [20]. We chose this approach as the authors had a similar
370 literature synthesis objective in that they aimed at constructing and refining a theory. From
371 the eligible studies identified in the systematic search, we intend to select a sample of rich
372 cases providing in-depth information to answer research questions 2 a-d (intensity
373 sampling). We also apply a maximum variation sampling approach and a disconfirming
374 sampling approach to allow for refining the external context concepts in the a-priori meta-
375 framework developed in stage 1. Based on the extracted data from eligible studies (see
376 below), we will first select information-rich studies based on the density of information
377 provided to answer research questions 2a-d and the quality and clarity of the studies
378 (intensity sampling). We will then select studies that vary as much as possible from each
379 other, for example, in study design, conceptual lens, implementation level, intervention type,
380 implementation outcome, and the described concepts of external context (maximum
381 variation sampling). In the last step, we will identify studies describing diverging concepts of
382 external context and conceptual lenses (disconfirming sampling). Publications on the same
383 study will be merged. Sampling of articles will be done by one reviewer (e.g., AZ) and
384 discussed and agreed upon with another reviewer (e.g., LB). Disagreements will be resolved
385 by group discussion and consensus within the review team.

386

387 Data extraction and analysis

388 In the framework review (stage 1) we will develop an a-priori meta-framework using thematic
389 analysis of the included frameworks, concepts, theories and models to identify

390 commonalities and differences [13]. Themes will be supported by descriptions or definitions
391 from the included studies if such detail is provided. Key concepts identified in stage 1 will
392 inform the construction of the data extraction form for the empirical study review (stage 2).

393

394 In the empirical study review (stage 2), the data extraction form for coding empirical studies
395 will include basic information on the studies and specific information related to research
396 questions 2 a-d such as study title, first author name, publication year, study design, study
397 country/countries, setting, study participants/stakeholders (e.g., service providers, service
398 users), intervention, implementation strategy, level of implementation (macro, meso, micro),
399 implementation outcomes, and if the spread of the intervention was within or across
400 countries. Furthermore, it will include information on external context concepts and the
401 applied conceptual lens. Finally, the data extraction form includes quality assessment criteria
402 (see below). The data extraction form will be piloted independently by two reviewers (e.g.,
403 AZ, LB) on a sample of the studies and jointly agreed upon by all review team members.
404 Once all appropriate data has been mapped deductively to the meta-framework a separate
405 inductive process of thematic analysis will be used to accommodate any remaining data
406 against new concepts within an augmented framework. One reviewer (e.g., AZ) will extract
407 data and perform the thematic analyses, with a second reviewer (e.g., LB) validating the
408 results by independently extracting and analysing data from a sample of the studies. Results
409 will be discussed with all members of the review team. Disagreements will be resolved by
410 group discussion and consensus within the review team.

411

412 **Quality assessment**

413 We will assess the internal validity of individual empirical studies, focusing on how the
414 design and conduct of each study has been reported following the quality appraisal
415 approach suggested for the best fit synthesis approach by Carroll et al. [13, 21]. We will

416 classify studies according to the number of quality criteria they meet. If a study meets two or
417 more quality criteria it will be rated as being of adequate quality. If only one or no quality
418 criterion is met the study will be rated as being of inadequate quality. We will perform a
419 qualitative sensitivity analysis following the synthesis stage (see below) to assess how each
420 individual study contributes to the final synthesis and how studies that were rated inadequate
421 in terms of quality are contributing to the synthesis and how exclusion of inadequate studies
422 would affect the synthesis.

423

424 The conceptual framework derived from the synthesis (see below) will be assessed for risk
425 of bias in terms of selection and reporting of the evidence used to generate the framework.
426 We will explore, for example, any unexplained absence of themes (e.g., differences between
427 the a-priori meta-framework and the final framework), the absence of negative or
428 disconfirming evidence, and the sensitivity to variables such as design, setting, participants,
429 or frequency of reported themes in included studies [13]. The analysis of the differences
430 between the two frameworks is also a test for a form of publication bias of the included
431 empirical studies in stage 2, if themes are not reported in the empirical studies that were
432 included in the a-priori meta-framework.

433

434 **Data synthesis**

435 Based on the concepts and themes identified from the two linked review stages we will
436 derive a new final framework [13]. In a first step, the themes identified from conceptual
437 frameworks in stage 1 and from the empirical data in stage 2 will be incorporated within a
438 new framework. In a second step, the evidence will be revisited to include relationships
439 between framework themes. This process will result in a conceptual diagram and a narrative
440 supporting the diagram that refers to the included studies.

441

442 **Amendments to the protocol**

443 Any amendments to the protocol will be documented. Records in the PROSPERO database
444 will be updated when important changes are introduced. All amendments to the protocol will
445 be described and explained in the publication of the review results.

446

447

448 **Discussion**

449

450 The review will lead to a comprehensive framework on the influence of external contextual
451 factors on the implementation of interventions in health and social care practice, especially
452 with a focus on interventions that spread within or across countries. The framework is
453 anticipated to help identify reasons and factors explaining the decline and variability in
454 effectiveness of an intervention and also assess the prospects of implementation
455 effectiveness when spreading interventions. By improving the spread of interventions, a
456 larger proportion of the population can more quickly and more equally benefit from new or
457 improved services. The framework can be validated and honed through future empirical
458 research.

459

460 We are aware of the vast number of existing frameworks in the field of implementation
461 science [22]. This will be the first framework providing a consolidated conceptualisation of
462 external implementation context and it can be applied when the focus of a study or
463 implementation project is to understand external implementation context. However, we do
464 not only intend to develop another stand-alone framework but a framework that can be used
465 in conjunction with existing implementation theories, models, and frameworks. The new
466 framework can contribute a deeper, broader and consolidated conceptualisation of the factor
467 “external context” that is included in other existing frameworks. Another critique of the large
468 number of existing frameworks is the lack of applicability or actual application [23]. By

469 following a thorough, systematic approach deriving evidence from not only the theoretical but
470 empirical literature, we are aiming at developing a framework that is applicable in practice as
471 it is based in evidence derived from implementation practice. Further, many determinant
472 frameworks such as the one proposed here, are criticised for simply listing determinants but
473 not reflecting on the connections between determinants or the mechanisms that link
474 determinants with implementation outcomes [23]. Through review stage 2, we intend to
475 derive the necessary level of detail from empirical studies to enrich the framework and make
476 connections and causal links visible.

477

478 We chose the best fit approach as it has shown to be suitable for the structured and
479 transparent development of a framework based on synthesising existing evidence. The
480 approach and especially the development of meta-frameworks have been suggested as a
481 useful evidence synthesis approach for the field of quality improvement and implementation
482 [15]. With its two-stage approach, it allows us to not only compile evidence from existing
483 theory into a meta-framework but enhance the framework's comprehensiveness and
484 representativeness with additional evidence from empirical studies.

485

486 We are aiming to develop a comprehensive framework covering a variety of external
487 contextual factors at multiple levels ranging, for example, from political and funding
488 environments and inter-organisational networks to population characteristics, physical
489 environments and historical developments. To achieve this, we decided to keep the
490 framework review (stage 1) broad to include a wide range of existing frameworks, models,
491 concepts and theories from different sectors and disciplines such as education,
492 management, environmental studies and international development. Studies from these
493 areas might contain useful concepts of external context applicable to the implementation of
494 health and social care interventions. Further, we will follow a broad search strategy covering
495 a large amount of scientific and grey literature sources and covering published and
496 unpublished work. We will not restrict the review to any type of evidence or study design.

497 There is also no restriction regarding, for example, a specific type of intervention, setting or
498 implementation strategy. This strategy will enable us to obtain a broad knowledge of external
499 contextual factors and their influence on implementation processes and outcomes.
500 Nevertheless, the quality of studies and their impact on the findings will be evaluated through
501 the quality assessment and sensitivity analysis.

502

503 Our broad approach in the review poses the risk of a large number of potentially eligible
504 studies and an unfeasible workload during the screening and data analysis process. We
505 have therefore chosen to restrict the database search for the stage 1 review by focusing on
506 studies that contain the terms for framework, model, theory or concept in the title only. We
507 will limit the risk of missing relevant studies by applying several additional search steps,
508 including searching for grey literature, citation search, hand-searching references and
509 relevant journals, and asking experts in the field.

510

511 Furthermore, we have chosen to focus the stage 2 review to qualitative empirical studies
512 describing health and social care interventions that spread within or across countries. This
513 allows us to capture empirical studies with a higher potential to describe the impact of
514 external contextual factors on implementation compared to studies focusing on single
515 implementation sites. In addition, the stage 2 review is not restricted to a certain group of
516 interventions or implementation strategies enabling us to still capture a broad range of
517 external contextual factors and their influence on implementation. The threefold purposeful
518 sampling approach also helps us to gather both, in-depth and comprehensive information on
519 the role of external contextual factors.

520

521 We have appointed an international external advisory board for quality assurance including
522 academic experts in health and social care, contextual factors, implementation and the best
523 fit review methodology. Additionally, we have appointed professional and service user/carer
524 representatives with the aim of including perspectives beyond those of researchers. The

525 professional representative was appointed based on expertise in spreading or adopting
526 health and/or social care interventions transferred from elsewhere. The service users/carers
527 have been appointed to provide their perspective on and experience with factors affecting
528 their use of newly implemented health and social care interventions. The advisory board was
529 and will be consulted and asked to comment on the review methodology and (preliminary)
530 results, the protocol, publication manuscripts, and for any specific queries arising during the
531 review process.

532

533

534 **List of abbreviations**

535 BeHEMOTH = Behaviour of interest, health context, exclusions, models or theories

536 CFIR = Consolidated Framework for Implementation Research

537 CICI = Context and Implementation of Complex Interventions

538 CINAHL = Cumulative Index to Nursing and Allied Health

539 EPIS = Exploration, Preparation, Implementation, Sustainment

540 EPOC = Effective Practice and Organisation of Care

541 ERIC = Education Resources Information Center

542 GreyLit = Grey Literature Report

543 HMIC = Health Management Information Consortium

544 IBSS = International Bibliography of the Social Sciences

545 PRISMA-P = Preferred Reporting Items for Systematic Reviews and Meta-Analyses

546 Protocols

547 PROSPERO = International prospective register of systematic reviews

548

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550 **Declarations**

551

552 **Ethics approval and consent to participate**

553 Not applicable

554

555 **Consent for publication**

556 Not applicable

557

558 **Availability of data and material**

559 Not applicable

560

561 **Competing interests**

562 The authors declare that they have no competing interests.

563

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579 Health and Social Care.

580

581 **Authors' contributions**

582 AZ and LB conceived the study. AZ wrote the first draft of the protocol. All authors were
583 involved in developing the eligibility criteria. AZ and LB set up the search strategy and
584 accomplished preliminary searches. All authors contributed to subsequent drafts of the
585 protocol and read and approved the final manuscript.

586

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592 London, UK; Prof Jim Dearing, Michigan University, East Lansing, USA; Clare Evans,
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597

598

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668 **Additional files**

- 669 • Additional file 1, pdf, Prisma-P 2015 checklist
- 670 • Additional file 2, pdf, Search strategy – Framework review (review stage 1) –
671 MEDLINE (OVID)

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673

Stage 1

Systematic identification of frameworks, concepts, models, theories
(from different sectors and disciplines)



Generate a-priory meta-framework using thematic analysis

Stage 2

Systematic and purposeful identification of empirical studies (focussing on health and social care interventions that spread within or across countries)



Extract basic study data and assess study quality



Code evidence from empirical studies against a-priory meta-framework



Refine meta-framework based on thematic analysis of evidence from empirical studies that cannot be coded against framework



Framework on the influence of external contextual factors on the implementation of health and social care interventions into practice that spread within or across countries

Additional file 1

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	n.a.
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	4
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1-2
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	1, 24
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	19
Support:			
Sources	5a	Indicate sources of financial or other support for the review	23-24
Sponsor	5b	Provide name for the review funder and/or sponsor	23-24
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	23-24
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	5-6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	8

METHODS

Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	9-13
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	13-15
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Add. File 2
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	16
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	15-16
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	16-17
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	17
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	12-13
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	17-18
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	n.a.
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	n.a.
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	n.a.
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	18
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	18
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	n.a.

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Additional File 2

Search strategy - Framework review (review stage 1) - MEDLINE (OVID)

1. translational medical research.sh
2. evidence based practice.sh
3. diffusion of innovation.sh
4. knowledge utili*.ab,ti
5. knowledge mobili*.ab,ti
6. knowledge transfer*.ab,ti
7. knowledge translat*.ab,ti
8. implement*.ab,ti
9. adopt*.ab,ti
10. research utili*.ab,ti
11. spread*.ab,ti
12. scale-up.ab,ti
13. scaling-up.ab,ti

14. external context*.ab,ti
15. external environment*.ab,ti
16. outer context*.ab,ti
17. outer setting*.ab,ti
18. structural context*.ab,ti
19. structural environment*.ab,ti
20. wider context*.ab,ti
21. wider environment*.ab,ti
22. wider setting*.ab,ti
23. broader context*.ab,ti
24. broader environment*.ab,ti
25. macro-level.ab,ti
26. micro-level.ab,ti
27. system-level.ab,ti
28. local context*.ab,ti
29. local environment*.ab,ti
30. regional context*.ab,ti
31. regional environment*.ab,ti
32. national context*.ab,ti
33. national environment*.ab,ti

34. framework*.ab,ti
35. concept*.ab,ti
36. theor*.ab,ti
37. model*.ab,ti

38. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13

39. 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
or 29 or 30 or 31 or 32 or 33

40. 34 or 35 or 36 or 37

41. 38 and 39 and 40