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Applying an analytical framework to map the impact of electronic data sharing on quality of care and safety: protocol for a systematic review

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Applying an analytical framework to map the impact of electronic data sharing on quality of care and safety: protocol for a systematic review

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3 **31 Abstract**
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8 **33** Introduction: Providing patients with access to Electronic health records (EHR) has emerged as a
9 **34** promising solution to improve quality of care and safety. However, there is a considerable gap between
10 **35** the predicted and demonstrated benefits of these interventions. As the efforts to develop and implement
11 **36** EHR-based data sharing platforms mature and scale up worldwide, there is a need to evaluate the impact
12 **37** of these interventions and to weigh their relative risks and benefits, in order to inform evidence-based
13 **38** health policies. The aim of this work is to systematically characterise and appraise the demonstrated
14 **39** benefits of EHR-based data sharing interventions, by mapping them across the six domains of quality of
15 **40** care of the Institute of Medicine analytical framework (i.e. patient-centredness, effectiveness, efficiency,
16 **41** timeliness, equity and safety).
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25 **43** Methods and analysis: CINAHL, Cochrane, Embase, HMIC, Medline/PubMed and PsycINFO databases
26 **44** will be searched from January 1997 to August 2017. Primary outcomes will include measures related with
27 **45** the six domains of quality of care of the IOM analytical framework (i.e. patient-centredness,
28 **46** effectiveness, efficiency, timeliness, equity and safety). Valid studies will be assessed for their quality
29 **47** using the Cochrane Risk of Bias Tool by two independent researchers and disagreements will be resolved
30 **48** by a third person. A narrative synthesis will be conducted for all the included studies. The body of
31 **49** evidence will be summarised in a Summary of Findings table and the strength of the body of evidence
32 **50** will be assessed according to the GRADE criteria. Results will be used to develop a comprehensive
33 **51** framework of the demonstrated benefits of EHR-based data sharing interventions, and subgroup analysis
34 **52** will be performed by domain of quality of care domain and by time scale (i.e. short-, medium- or long-
35 **53** term impact). This protocol was registered in PROSPERO (CRD42017070092).
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45 **55** Ethics and dissemination: Not applicable.
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61 **Strengths and limitations of this study**

- 62 • Comprehensive characterisation of EHR-based interventions used to share medical data with patients
- 63 • Summary and appraisal of existing evidence on the potential benefits EHR-based data sharing
64 interventions, grouped by domain of quality of care and by time scale (*i.e.* short-, medium- or long-
65 term impact)
- 66 • Development of a framework to customise informed decisions in health policies
- 67 • Expected limitations include the heterogenous nature of the outcomes assessed and the potentially
68 reduced sample size in subgroup analyses, which may negatively impact the statistical power in data
69 synthesis.

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87 Introduction

88 Although patients have had the legal right to access their health records since 1998, access to paper-based
89 health records is mediated by health professionals and data controllers, through a cumbersome procedural
90 process (1). Additionally, as health information is fragmented between different organisations and levels
91 of care, data access requests are often unable to provide a comprehensive health history record (2, 3).

92 In the last decade, electronic health records (EHRs), have emerged as a promising solution to enhance
93 patients' access to centralised medical information (4). The adoption of EHRs by primary care practices,
94 hospitals and other healthcare organizations has steadily increased in the last years. In England, the
95 percentage of General Practice surgeries that allowed patients to access their medical records online
96 increased from 3% to 97% between April 2014 and February 2016 (5). Various EHR-based platforms are
97 currently used to share health information with patients, including direct online access, with or without
98 patient-provider communication systems (6, 7) and health maintenance reminders (8, 9). As these efforts
99 mature and scale up worldwide, there is a need to evaluate the impact of EHR-based data sharing
100 interventions, in order to weigh their relative risks and benefits and inform evidence-based health policies.

101 The Institute of Medicine (IOM) identified six domains of health care quality: patient-centredness,
102 effectiveness, efficiency, timeliness, equity and safety (10). Patient-centredness ensures that the care
103 provided respects and responds to individual patient preferences, needs and values, thus incorporating
104 them in clinical decisions (10, 11) Health care shall provide evidence-based services, which can be
105 ultimately expressed as improvements in health outcomes (*i.e.* effectiveness) (12), while ensuring that
106 potential harms are avoided (*i.e.* patient safety). Other aspects of quality of delivery of care include the
107 minimisation of the waste of human, physical or economical resources (*i.e.* efficiency), the reduction of
108 waits and harmful delays (*i.e.* timeliness) and the reduction of avoidable differences on the delivery of
109 care between different groups of health care users (*i.e.* equity) (10, 13, 14).

110 Providing patients with access to their health records has been linked to theorised benefits in four major
111 domains of health care quality: patient-centredness, effectiveness, safety and efficiency (15-17).
112 However, despite the growing body of evidence on the theorised benefits of EHR-data sharing with
113 patients on these domains, there is still a considerable gap between the predicted and demonstrated
114 benefits of these interventions (18).

115 In order to analyse the effect of providing patients access to their medical records on quality outcomes,
116 Davis-Giardina T. et al performed a systematic review including studies published between 1970 and
117 2012 (19). According to this work, a limited amount of evidence suggests that access to medical records

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3 118 improves patient satisfaction and enhances patient-provider communication (19). Similarly, a systematic
4 119 review from de Lusignan *et al.* reported that providing patients online access to their EHR increased
5 120 convenience and satisfaction (20).

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8 121 Conversely, no clear benefits were found on effectiveness (19). Until 2012, only a few studies evaluated
9 122 the impact on effectiveness studies, most focussing on type 2 diabetes and with inconsistent results.
10 123 Tenforde *et al* showed that providing access to medical records was associated with lower glycated
11 124 haemoglobin A1C values (21); however, no significant effect was found in three other studies assessing
12 125 diabetes-specific effectiveness measure (22, 23). One of the limitations of this review consists in the
13 126 inclusion of studies evaluating both EHR and non-EHR based interventions - and this heterogeneity might
14 127 mask potential EHR-specific potential benefits. Furthermore, as pointed by the authors, the paucity of
15 128 papers published up to that date resulted in a tendency to include small and methodologically less robust
16 129 studies, thus increasing the risk of selective reporting and/or publication bias (19). Mold F. *et al* also
17 130 performed a systematic review assessing the impact of providing patients with access to their EHRs;
18 131 based in studies published between 1999 and 2012, this work found a positive influence in patient safety
19 132 (24).

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22 133 However, the authors were unable to find a consistent beneficial effect on efficiency measures (*i.e.*
23 134 number of face-to-face visits and telephone appointments) in both reviews (24) (19). While some studies
24 135 reported an increase in the number of face-to-face consultations (6,25), others document a decrease (9,26-
25 136 27). Similarly, inconsistent results were found regarding the impact on telephone consultations: only one
26 137 study reported a decline in the total number (28), whilst six other studies reported either no change or an
27 138 increase (7, 25-27, 29, 30). It is important to note, however, that most of the included studies assessing
28 139 efficiency measures included in this review showed a high risk of bias, mostly related to either unclear or
29 140 absent blinding methods (24).

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32 141 The landmark reviews of Mold F. *et al* (24) and Davis-Giardina T. *et al* (19) provide a comprehensive
33 142 characterisation of the literature published until 2012, highlighting the paucity and the scientific
34 143 limitations of the evidence published until that date. Although both were unable to demonstrate clear
35 144 benefits on efficiency and effectiveness measures, resources continue being allocated to EHR-based data
36 145 sharing interventions and platforms, renewing the interest on this evidence gap. As consequence of these
37 146 efforts, it is plausible that studies performed in the last 5 years can provide further clarification for this
38 147 evidence gap. Furthermore, these reviews do not address other domains of quality of care, as timeliness or
39 148 equity.

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3 149 This review will expand on the above-mentioned work, in order to identify recent methodological and
4 scientific progress until June 2017. Following the PRISMA-P checklist as guidance (31), we propose a
5 150 systematic and reproducible strategy to query the literature on the demonstrated benefits of EHR-based
6 151 data sharing and present the results in a comprehensive framework of health care quality measures.
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10 153 **Research aims**

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12 154 The main objectives of this review are: 1) to systematically characterise EHR-based data sharing
13 155 interventions published between 2000-2017; 2) to assess the demonstrated benefits of these interventions
14 156 on patient-centredness, effectiveness, safety, efficiency, timeliness and equity, compared to usual care (no
15 157 intervention). As secondary aim, we will develop a conceptual model integrating the contribution of
16 158 these interventions in short-, medium- and long-term perspectives (Figure 1).
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23 160 **Methods and analysis**

25 161 *Search strategy*

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27 162 The search strategy will be performed using resources that enhance methodological transparency and
28 163 improve the reproducibility of the results and evidence synthesis. A search of the literature from the last
29 164 20 years (January 1997 – August 2017) will be performed on CINAHL, Cochrane, Embase, HMIC,
30 165 Medline/PubMed and PsycINFO. Search strings (Table 1) will combine free terms and controlled
31 166 vocabulary, whenever supported. Language restrictions will be applied and articles in English will be
32 167 included. The reference lists of relevant articles will also be screened to ensure all eligible studies are
33 168 captured. Authors of protocols potentially meeting inclusion criteria will be contacted to provide further
34 169 information about the progress of the corresponding trial.
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43 171 *Study selection criteria*

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45 172 A summary of the participants, interventions, comparators and outcomes (PICO) considered, as well as
46 173 the type of studies included, is provided in Table 2.

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48 174 The systematic review will focus on studies on adult subjects, including both patients and carers (mean
49 175 age of study sample ≥ 16 years). The systematic review does not focus on a particular disease area or
50 176 health system setting as it intends to comprehensively characterise the scope of EHR-based interventions.
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3 177 Studies describing EHR-based data sharing interventions, either isolated or as part of a multicomponent
4 178 interventions, will be included. "*EHR-based data sharing intervention*" will be defined as a data sharing
5 179 intervention involving: 1) web-based patient access to EHR; 2) EHR-based health reminders / messaging
6 180 or 3) online patient-provider communication systems (health information exchange platforms). Studies
7 181 focusing on health reminders only (not EHR-based) or appointment reminders will not be considered. The
8 182 comparator will be 'no intervention' (*e.g.* usual care).

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13 183 Primary outcomes will include any measure related to a) patient-centredness (*e.g.* patient-reported
14 184 experience measures (PREMs), b) effectiveness (*e.g.* health outcomes); c) patient safety (*e.g.*
15 185 identification of medication discrepancies); d) efficiency (*e.g.* economic evaluation measures and proxies;
16 186 including service costs, number of consultations/admissions, e) timeliness (*e.g.* waiting lists, time-to-
17 187 treatment) and f) equity (*e.g.* discrepancies in quality measures between different groups of patients).
18 188 Studies that only report cognitive outcomes (*e.g.* intent), motivational outcomes or other subjective
19 189 psychological measures will be excluded. The types of study considered in this systematic review will be
20 190 a) randomised controlled trials; b) cluster randomised trials; c) quasi-experimental studies; d) case-control
21 191 studies and e) cohort studies. Systematic reviews will also be included to ensure that relevant articles will
22 192 be captured from their respective reference lists.

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31 32 194 *Screening and data extraction*

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34 195 Quantitative studies will be independently assessed by three reviewers and reported using the
35 196 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-P) flow
36 197 diagram (31). Initial screening of studies will be based on the information contained in their titles
37 198 and abstracts and will be conducted by two independent investigators. Full-paper screening will
38 199 be conducted by the same independent investigators. Cohen's kappa will be used to measure
39 200 inter-coder agreement in each screening phase. When there are doubts regarding inclusion or
40 201 exclusion, a third investigator will be involved in the decision. Two independent investigators
41 202 will extract information from the included studies into a standardized form. The data collected
42 203 for each study will include: name of the first author, year of publication, technology, intervention
43 204 components and characteristics, study duration, participants' and setting characteristics,
44 205 outcomes and retention rates. Two investigators will review the abstraction form for consistency.
45 206 Disagreements will be resolved by a third investigator.

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3 208 *Quality assessment*
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5 209 Valid studies will then be assessed for their quality using the Cochrane Risk of Bias Tool (32), that
6 210 assesses the following study-level aspects: a) randomisation sequence allocation; b) allocation
7 211 concealment; c) blinding; d) completeness of outcome data and e) selective outcome reporting. Two
8 212 independent reviewers will score the selected studies and disagreements will be resolved by a third
9 213 person.
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16 215 *Descriptive analysis and meta-analysis*
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18 216 A narrative synthesis will be conducted for all the included studies. Parallel-group trials that are deemed
19 217 comparable in relevant ways will be pooled together for a summary effect. Whenever possible,
20 218 continuous and dichotomous outcomes will be pooled together for meta-analysis purposes. All effect sizes
21 219 will be transformed into a common metric, in order to make them comparable across studies — the bias-
22 220 corrected standardized difference in means (Hedges' g) — classified as positive when in favor of the
23 221 intervention and negative when in favor of the control. Heterogeneity will be assessed using I^2 . The
24 222 presence of publication bias will be evaluated by use of a funnel plot and the Duval and Tweedie's trim
25 223 and fill method (33).
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31 224 We will also explore the cause of any observed statistical heterogeneity using subgroup analysis. Planned
32 225 subgroup analysis will be performed by domain of quality of care, time scale (*i.e.* short-, medium- or
33 226 long-term impact) and risk of bias (low *versus* high, as assessed by the Cochrane Risk of Bias Tool) (32).
34 227 Depending on the amount of information retrieved, subgroup analysis will also be performed for specific
35 228 diseases. The body of evidence will be summarised in a Summary of Findings table and the strength of
36 229 the body of evidence will be assessed according to GRADE criteria (34).
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44 231 *Amendments*
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46 232 Any amendments to this protocol will be documented with reference to saved searches and analysis
47 233 methods, which will be recorded in bibliographic databases (Ovid), Endnote, and Excel templates for data
48 234 collection and synthesis.
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236 Discussion

237 As the implementation of EHR-based data sharing interventions scales up worldwide, the systematic
238 evaluation of the impact of such interventions emerges as a priority research topic.

239 One of the strengths of the proposed study is to apply a reproducible and transparent procedure for
240 systematic review of the literature. In this protocol, we clearly describe the types of studies, participants,
241 interventions, and outcomes that will be included, as well as the data sources, search strategy, data
242 extraction methods (including quality assessment) and methods of combining data (35). By publishing the
243 research protocol, we reinforce the clarity of the strategy and minimise the risk of bias, namely selective
244 outcome reporting (32). Second, we will focus solely on the impact of EHR-based studies, increasing the
245 sensitivity to detect specific benefits of this type of intervention. Third, for the first time, we aim to
246 comprehensively evaluate the benefits of these interventions in a wide range of domains of quality of
247 care, as defined by the IOM. This framework shall provide high-level information to inform, support and
248 customise decisions in health policies.

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250 Potential limitations of this study include the heterogeneity of measures and outcomes evaluated and the
251 potentially reduced number of studies in subgroup analyses, which may negatively influence the statistical
252 power in data synthesis.

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5 266 **Acknowledgements**6
7 267 We thank Jacqueline Cousins (information specialist at Imperial College London) for the support
8
9 268 improving the composition of the search terms and procedural aspects of the search strategy.10
11 26912
13 270 **Ethics and dissemination**14
15 271 Not applicable.16
17 27218
19
20 273 **Authors' contributions**21
22 274 ALN, AC and EKM conceptualised this research. ALN, AC and LL designed the protocol. ALN and LF
23
24 275 defined the concepts and search items. EKM and AD contributed to the conceptualisation and commented
25
26 276 on the multiple versions of the protocol. The manuscript was written by ALN with contributions from all
27
28 277 authors.29
30 27831
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36 281 Research (NIHR) Patient Safety Translation Research Centre. The views of the authors do not
37
38 282 necessarily reflect those of the NHS, NIHR or the Department of Health.39
40 28341
42 284 **Competing interests' statement**43
44 285 We declare no conflict(s) of interest associated with this research.45
46 28647
48 287 **Data sharing statement**49
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51 288 No additional data relevant to this protocol are available for distribution. All relevant data and search
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53 289 terms are published in this manuscript.

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292 **Table 1. Concepts and search items**

| Database | Search items |
|---|---|
| CINAHL via EBSCO | <ol style="list-style-type: none"> 1. (((electronic* or online or on-line or digital*) N1 (health record* or medical record* or personal record* or patient record*)) or EHR# or EMR# or ephr#) 2. ((information or data) N4 (shar* or exchange*)) or HIE or HIEs or access*) 3. #1 and #2 4. (((experience or satisfaction) N4 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 5. (effectiveness or health outcome*) 6. (patient N1 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss* 7. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number N1 appointment*) or (number adj2 admission*) or (number N1 telephone visit*)) 8. waiting lists or timeliness or time-to-treatment 9. health equity 10. #4 or #5 or #6 or #7 or #8 or #9 13. 3 and 10 |
| Cochrane via url: http://onlinelibrary.wiley.com/cochranelibrary/search/advanced | <ol style="list-style-type: none"> 1. (((electronic* or online or on-line or digital*) near/1 (health record* or medical record* or personal record* or patient record*)) or EHR or EHRs or EMR or EMRs or ephr or ephrs) 2. Electronic Health Records [MesH] 3. #1 or #2 4. (((information or data) near/4 (shar* or exchange*)) or HIE or HIES or access*) 5. Information Dissemination [MesH] 6. #4 or #5 7. #3 and #6 8. (((experience or satisfaction) near/4 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 9. (effectiveness or health outcome*) 10. (patient near/1 safety) or (patient near/1 harm) or safety manag* or accident prevent* or error* or medication reconcil* 11. (efficiency or economic* or cost* or expenditure* or charge* or fee* or (number near/1 appointment*) or (number near/1 admission*) or (number near/1 telephone visit*)) 12. time-to-treatment or timeliness |

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| | <p>13. waiting lists [MesH] 14. health equity [MesH] 15. #8 or #9 or #10 or #11 or #12 or #13 or #14 17. 7 and 15</p> |
| Embase via Ovid | <p>1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?) 2. Electronic health record/ 3. 1 or 2 4. (((information or data) adj5 (shar* or exchang*)) or HIE*2 or access*) 5. Information dissemination/ 6. 4 or 5 7. 3 and 6 8. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 9. (effectiveness or health outcome*) 10. (patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss* 11. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or (number adj2 telephone visit*)) 12. waiting list* or time to treatment/ or timeliness 13. health equity/ 14. 8 or 9 or 10 11 or 12 or 13 15. 7 and 14</p> |
| HMIC via Ovid | <p>1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?) 2. Electronic patient records/ 3. 1 or 2 4. (((information or data) adj5 (shar* or exchang*)) or HIE*2 or access*) 5. Information exchange/ 6. 4 or 5 7. 3 and 6 8. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 9. (effectiveness or health outcome*) 10. (patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss* 11. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or</p> |

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| | <p>(number adj2 telephone visit*))</p> <p>12. waiting lists/ or patient waiting time or timeliness</p> <p>13. health inequalities/ or equity</p> <p>14. 8 or 9 or 10 or 11 or 12 or 13</p> <p>15. 7 and 14</p> |
| Medline via Ovid | <p>1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?)</p> <p>2. Electronic Health Records/</p> <p>3. 1 or 2</p> <p>4. (((information or data) adj5 (shar* or exchange*)) or HIE*2 or access*)</p> <p>5. Information Dissemination/</p> <p>6. 4 or 5</p> <p>7. 3 and 6</p> <p>8. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*)</p> <p>9. (effectiveness or health outcome*)</p> <p>10. ((patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss*)</p> <p>11. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or (number adj2 telephone visit*))</p> <p>12. Waiting Lists/ or Time-to-treatment/ or timeliness</p> <p>13. Health Equity/</p> <p>14. 8 or 9 or 10 or 11 or 12 or 13 15. 7 and 14</p> |
| PsycINFO via Ovid | <p>1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?)</p> <p>2. (((information or data) adj5 (shar* or exchange*)) or HIE*2 or access*)</p> <p>3. 1 and 2</p> <p>4. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*)</p> <p>5. (effectiveness or health outcome*)</p> <p>6. (patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss*</p> <p>7. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or (number adj2 telephone visit*))</p> <p>8. waiting list* or time-to-treatment or timeliness</p> <p>9. equity or health disparities/</p> <p>10. 4 or 5 or 6 or 7 or 8 or 9</p> <p>11. 3 and 10</p> |

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3 293 Search themes (facets) and terms derived for each theme relating to the use of EHR and predicted benefits
4 294 (patient experience, effectiveness and efficiency)
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| Table 2. Inclusion and exclusion criteria | | |
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| | Inclusion criteria | Exclusion criteria |
| Population | Adult subjects (patients and carers) | Individuals 16 years of age and under (e.g. mean age of study sample <16) |
| Intervention | Electronic health record-based interventions, including: <ul style="list-style-type: none"> • Patient access to EHR • EHR-based reminders / messaging • Unidirectional or bidirectional online patient-provider communication systems (care information exchange platforms); | <ul style="list-style-type: none"> • Health reminders only |
| Comparison | No intervention (e.g. usual care) | |
| Outcome | Any measure related to a) patient-centredness (e.g. PREMs), b) effectiveness (e.g. health outcomes); c) patient safety (e.g. identification of medication discrepancies); d) efficiency (e.g. economic evaluation measures and proxies; including service costs, number of consultations/admissions, e) timeliness (e.g. waiting lists, time-to-treatment) or f) equity (e.g. discrepancies in quality measures between different groups of patients). | Studies that only report cognitive outcomes (e.g. intention to), motivational outcomes or other subjective psychological measures |
| Study type | Randomised controlled trials, cluster randomised trials, quasi-experimental, case-control, cohort studies, systematic reviews | |

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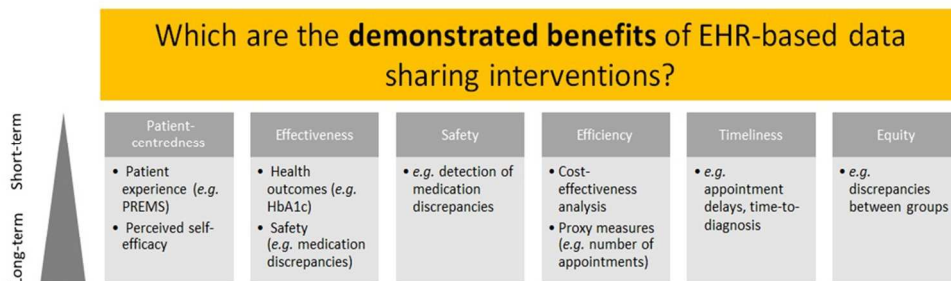


Figure 1. Conceptual model

338x190mm (96 x 96 DPI)

Review only

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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 | Page |
|-----------------------------------|---------|---|----------------|
| ADMINISTRATIVE INFORMATION | | | |
| Title: | | | |
| Identification | 1a | Identify the report as a protocol of a systematic review | 1, 2, 8, 9, 10 |
| Update | 1b | If the protocol is for an update of a previous systematic review, identify as such | Not applicable |
| Registration | 2 | If registered, provide the name of the registry (such as PROSPERO) and registration number | 2 |
| Authors: | | | |
| Contact | 3a | Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author | 1 |
| Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review | 10 |
| 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 | Not applicable |
| Support: | | | |
| Sources | 5a | Indicate sources of financial or other support for the review | 10 |
| Sponsor | 5b | Provide name for the review funder and/or sponsor | 10 |
| Role of sponsor or funder | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol | 10 |
| INTRODUCTION | | | |
| Rationale | 6 | Describe the rationale for the review in the context of what is already known | 3 |
| Objectives | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) | 6 |
| 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 | 6,14 |
| 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 | 6 |
| 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 | 6, 12-16 |

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|------------------------------------|-----|--|---|
| Study records: | | | |
| Data management | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review | 7 |
| 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) | 7 |
| 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 | 7 |
| 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 | 7 |
| Outcomes and prioritization | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale | 6 |
| 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 | 6 |
| Data synthesis | 15a | Describe criteria under which study data will be quantitatively synthesised | 6 |
| | 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) | 7 |
| | 15c | Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) | 7 |
| | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | 7 |
| Meta-bias(es) | 16 | Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) | 7 |
| Confidence in cumulative evidence | 17 | Describe how the strength of the body of evidence will be assessed (such as GRADE) | 7 |

*** 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.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

Impact of sharing electronic health records with patients on the quality and safety of care: a systematic review and narrative synthesis protocol

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Manuscripts

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4 1 **Impact of sharing electronic health records with patients**
5 2 **on the quality and safety of care:**
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7 3 **a systematic review and narrative synthesis protocol**
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52 28 **Keywords [MeSH terms]:** Electronic Health Records, Patient Access to Records, Patient-Centered Care,
53 29 Quality of Health Care, Patient Safety
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55 30 **Word count:** 2145 words
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3 **31 Abstract**
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8 **33** Introduction: Providing patients with access to Electronic Health Records (EHR) has emerged as a
9 **34** promising solution to improve quality of care and safety. However, there is a considerable gap between
10 **35** the predicted and demonstrated impact of these interventions. As the efforts to develop and implement
11 **36** EHR-based data sharing platforms mature and scale up worldwide, there is a need to evaluate the impact
12 **37** of these interventions and to weigh their relative risks and benefits, in order to inform evidence-based
13 **38** health policies. The aim of this work is to systematically characterise and appraise the demonstrated
14 **39** benefits and risks of sharing EHR with patients, by mapping them across the six domains of quality of
15 **40** care of the Institute of Medicine (IOM) analytical framework (*i.e.* patient-centredness, effectiveness,
16 **41** efficiency, timeliness, equity and safety).
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23 **42**

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25 **43** Methods and analysis: CINAHL, Cochrane, Embase, HMIC, Medline/PubMed and PsycINFO databases
26 **44** will be searched from January 1997 to August 2017. Primary outcomes will include measures related with
27 **45** the six domains of quality of care of the IOM analytical framework (*i.e.* patient-centredness,
28 **46** effectiveness, efficiency, timeliness, equity and safety). Valid studies will be assessed for their quality by
29 **47** two independent researchers, using the Cochrane Risk of Bias Tool, the ROBINS-I tool and the
30 **48** Drummond's checklist. A narrative synthesis will be conducted for all included studies. Subgroup
31 **49** analysis will be performed by domain of quality of care domain and by time scale (*i.e.* short-, medium- or
32 **50** long-term impact). The body of evidence will be summarised in a Summary of Findings table and the
33 **51** strength of the body of evidence will be assessed according to the GRADE criteria. This protocol was
34 **52** registered in PROSPERO (CRD42017070092).
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54 Ethics and dissemination: Findings will be disseminated widely through peer-reviewed publication and
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3 **61 Strengths and limitations of this study**
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- 5 62 • Comprehensive characterisation of interventions sharing EHR with patients
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7 63 • Summary and appraisal of existing evidence on the potential benefits and risks of these interventions,
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9 64 grouped by domain of quality of care
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11 65 • Map the contribution of these interventions in short-, medium- and long-term time frames, in order to
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13 66 customise informed decisions in health policies
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15 67 • Expected limitations include the heterogenous nature of the outcomes assessed and the potentially
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17 68 reduced sample size in subgroup analyses, which may negatively impact the statistical power in data
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19 69 synthesis.
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91 Introduction

92 Although, in England, patients have had the legal right to access their health records since 1998, access to
93 paper-based health records is mediated by health professionals and data controllers, through a
94 cumbersome procedural process [1]. Additionally, as health information is fragmented between different
95 organisations and levels of care, data access requests are often unable to provide a comprehensive health
96 history record [2, 3].

97 In the last decade, electronic health records (EHR), have emerged as a promising solution to enhance
98 patients' access to centralised medical information [4]. The adoption of EHR by primary care practices,
99 hospitals and other healthcare organizations has steadily increased in the last years. In England, the
100 percentage of General Practice surgeries that allowed patients to access their medical records online
101 increased from 3% to 97% between April 2014 and February 2016 [5]. Patients' willingness and ability to
102 access their health information through web portals is influenced by both individual (*i.e.* age, ethnicity,
103 education level, health literacy and health status) and by health care delivery factors (*i.e.* provider
104 endorsement and portal usability) [6, 7]. Various EHR-based platforms are currently used to share health
105 information with patients, including direct online access, with or without patient-provider communication
106 systems [8, 9] and health maintenance reminders [10, 11]. As these efforts mature and scale up
107 worldwide, there is a need to evaluate the impact of interventions sharing EHR with patients, in order to
108 weigh their relative risks and benefits and inform evidence-based health policies.

109 The Institute of Medicine (IOM) identified six domains of health care quality: patient-centredness,
110 effectiveness, efficiency, timeliness, equity and safety [12]. Patient-centredness ensures that the care
111 provided respects and responds to individual patient preferences, needs and values, thus incorporating
112 these in clinical decisions [12, 13]. Health care shall provide evidence-based services, which can be
113 ultimately expressed as improvements in health outcomes (*i.e.* effectiveness) [14], while ensuring patient
114 safety (*i.e.* prevention of errors and adverse effects associated with health care) [12]. Other aspects of
115 quality of delivery of care include the minimisation of the waste of human, physical or economical
116 resources (*i.e.* efficiency), the reduction of waits and harmful delays (*i.e.* timeliness) and the reduction of
117 avoidable differences on the delivery of care between different groups of health care users (*i.e.* equity)
118 [12, 15, 16].

119 Providing patients with access to their health records has been linked to theorised benefits in four major
120 domains of health care quality: patient-centredness, effectiveness, safety and efficiency [17-19].
121 However, despite the growing body of evidence on the theorised benefits of sharing EHR with patients on

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3 122 these domains, there is still a considerable gap between the predicted and demonstrated benefits of these
4 123 interventions [20].

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7 124 In order to analyse the effect of providing patients access to their medical records on quality outcomes,
8 125 Davis-Giardina T. *et al* performed a systematic review including studies published between 1970 and
9 126 2012 [21]. According to this work, a limited amount of evidence suggests that access to medical records
11 127 improves patient satisfaction and enhances patient-provider communication [21]. Similarly, a systematic
13 128 review from de Lusignan *et al.* reported that providing patients online access to their EHR increased
14 129 convenience and satisfaction [22]. These findings are in line with the model proposed by Otte-Trojel T. *et*
15 130 *al*, according to which sharing EHR with patients can improve both patient-provider communication and
16 131 patient satisfaction, by increasing continuity of care and patient convenience, respectively [23].

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20 132 Conversely, no clear benefits were found on effectiveness [21]. Until 2012, only a few studies evaluated
21 133 the impact on effectiveness studies, most focusing on type 2 diabetes and with inconsistent results.
22 134 Tenforde *et al* showed that providing access to medical records was associated with lower glycated
23 135 haemoglobin A1c values [24]; however, no significant effect was found in three other studies assessing
24 136 diabetes-specific effectiveness measures [25, 26]. One of the limitations of this review consists in the
25 137 inclusion of studies evaluating the impact of sharing both electronic and paper-based health records - and
26 138 this heterogeneity might mask potential specific benefits and risks of sharing EHR with patients.
27 139 Furthermore, as pointed by the authors, the paucity of papers published up to that date resulted in a
28 140 tendency to include small and methodologically less robust studies, thus increasing the risk of selective
29 141 reporting and/or publication bias [21]. Mold F. *et al* also performed a systematic review assessing the
30 142 impact of providing patients with access to their EHR; based in studies published between 1999 and 2012,
31 143 this work found a positive influence in patient safety [27].

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33 144 However, the authors were unable to find a consistent beneficial effect on efficiency measures (*i.e.*
34 145 number of face-to-face visits and telephone appointments) in both reviews [21, 27]. While some studies
35 146 reported an increase in the number of face-to-face consultations [8, 28] , others document a decrease [11,
36 147 29, 30]. Similarly, inconsistent results were found regarding the impact on telephone consultations: only
37 148 one study reported a decline in the total number [31], whilst six other studies reported either no change or
38 149 an increase [9, 28-30, 32, 33]. It is important to note, however, that most of the included studies assessing
39 150 efficiency measures included in this review showed a high risk of bias, mostly related to either unclear or
40 151 absent blinding methods [27].

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42 152 The landmark reviews of Mold F. *et al* [27], Davis-Giardina T. *et al* [21], Ammenwerth E. *et al* [34] and
43 153 Goldweig CL *et al* [7] provide a comprehensive characterisation of the literature published until 2013,
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3 154 highlighting the paucity and the scientific limitations of the evidence published until that date. Although
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5 155 these reviews were unable to demonstrate clear benefits on efficiency and effectiveness measures, the
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7 156 debates around patients' rights and data ownership in the digital era, and the need to improve patient-
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9 157 centredness of health care delivery have acted as strong drivers to allocate resources to interventions and
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11 158 platforms aiming to share EHR with patients. As consequence of these efforts, it is plausible that studies
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13 159 performed in the last 5 years can provide further clarification for this evidence gap.

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15 160 Furthermore, systematic reviews performed to the date do not address all domains of quality of care; in
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17 161 particular, the impact of sharing EHR with patients on timeliness or equity has not been addressed [7, 21,
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19 162 27, 34, 35]. This is a particularly relevant gap in knowledge, given that interventions aimed at improving
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21 163 the quality of care do not necessarily improve all specific domains, and may even have a deleterious
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23 164 effect in some of them.

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25 165 This review will expand on the above-mentioned work, in order to identify recent methodological and
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27 166 scientific progress until June 2017. Following the PRISMA-P checklist as guidance [36], we propose a
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29 167 systematic and reproducible strategy to query the literature on the demonstrated benefits and risks of
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31 168 sharing EHR with patients and map these results in a comprehensive framework of health care quality
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36 37 171 **Research aims**

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39 172 The main objectives of this review are: 1) to systematically characterise interventions sharing EHR with
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41 173 patients; and 2) to assess the demonstrated risks and benefits of these interventions on patient-
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43 174 centredness, effectiveness, safety, efficiency, timeliness and equity, compared to usual care (no
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45 175 intervention). As secondary aim, we will map the contribution of these interventions in short-, medium-
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47 176 and long-term timeframes (Figure 1).

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50 51 178 **Methods and analysis**

52 53 179 *Search strategy*

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55 180 The search strategy will be performed using resources that enhance methodological transparency and
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57 181 improve the reproducibility of the results and evidence synthesis. A search of the literature from the last
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59 182 20 years (January 1997 – August 2017) will be performed on CINAHL, Cochrane, Embase, HMIC,
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183 Medline/PubMed and PsycINFO. Search strings (Table 1) will combine free terms and controlled

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3 184 vocabulary, whenever supported. We will also search grey literature sources, including registrations in the
4 185 International Prospective Register of Systematic Reviews (PROSPERO), reports of relevant stakeholder
5 186 organisations (NHS Digital, AMIA, eHealth at WHO, International Society for Telemedicine and
6 187 eHealth), and conference proceedings (last 5 years) of several related conferences (American Medical
7 188 Informatics Association [AMIA], MedInfo, Medicine 2.0, Medicine X), in order to identify possible
8 189 additional studies that meet the inclusion criteria. Language restrictions will be applied and only articles
9 190 in English will be included.
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17 192 *Study selection criteria*

19 193 A summary of the participants, interventions, comparators and outcomes (PICO) considered, as well as
20 194 the type of studies included, is provided in Table 2.

23 195 The systematic review will focus on studies on adult subjects, including both patients and carers (mean
24 196 age of study sample ≥ 16 years). The systematic review does not focus on a particular disease area or
25 197 health system setting as it intends to comprehensively characterise the scope of interventions sharing EHR
26 198 with patients.
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30 199 Studies assessing the impact of sharing EHR with patients, either isolated or as part of a multicomponent
31 200 intervention, will be included. Included interventions will comprise: 1) web-based patient access to EHR;
32 201 2) EHR-based health reminders / messaging or 3) online patient-provider communication systems (health
33 202 information exchange platforms). Studies focusing on health reminders only (not EHR-based) or
34 203 appointment reminders will not be considered. The comparator will be 'no intervention' (e.g. usual care).
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39 204 Primary outcomes will include any measure related to a) patient-centredness (e.g. patient-reported
40 205 experience measures (PREMs), b) effectiveness (e.g. health outcomes); c) patient safety (e.g.
41 206 identification of medication discrepancies); d) efficiency (e.g. economic evaluation measures and proxies;
42 207 including service costs, number of consultations/admissions, e) timeliness (e.g. waiting lists, time-to-
43 208 treatment) and f) equity (e.g. discrepancies in quality measures between different groups of patients)
44 209 (Figure 1). Studies that only report cognitive outcomes (e.g. intent), motivational outcomes or other
45 210 subjective psychological measures will be excluded. The types of study considered in this systematic
46 211 review will be a) randomised controlled trials; b) cluster randomised trials; c) quasi-experimental studies;
47 212 d) case-control studies, e) cohort studies and f) cost-effectiveness studies. The reference lists of
48 213 systematic reviews identified in this search will also be screened to ensure all eligible studies are
49 214 captured.
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3 215 *Screening and data extraction*
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5 216 Quantitative studies will be independently assessed by three reviewers and reported using the
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7 217 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-P) flow
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9 218 diagram [36]. Initial screening of studies will be based on the information contained in their titles
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11 219 and abstracts and will be conducted by two independent investigators. Full-paper screening will
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13 220 be conducted by the same independent investigators. Cohen's kappa will be used to measure
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15 221 inter-coder agreement in each screening phase. When there are doubts regarding inclusion or
16
17 222 exclusion, a third investigator will be involved in the decision. Two independent investigators
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19 223 will extract information from the included studies into a standardized form. The data collected
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21 224 for each study will include: name of the first author, year of publication, technology, intervention
22
23 225 components and characteristics, study duration, participants' and setting characteristics,
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25 226 outcomes and retention rates. Two investigators will review the abstraction form for consistency.
26
27 227 Disagreements will be resolved by a third investigator.
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29 229 *Quality assessment*
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31 230 The quality of randomised controlled trials and cluster randomized trials will be assessed using the
32
33 231 Cochrane Risk of Bias Tool [37], that assesses the following study-level aspects: a) randomisation
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35 232 sequence allocation; b) allocation concealment; c) blinding; d) completeness of outcome data and e)
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37 233 selective outcome reporting. The quality of non-randomised intervention studies (*i.e.* case control, cohort,
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39 234 quasi-experimental) will be appraised using the ROBINS-I tool, which assesses bias due to a)
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41 235 confounding, b) selection of participants, c) classification of interventions, d) deviations from intended
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43 236 interventions, e) missing data, f) measurement of outcomes and g) selection of reported results [38]. For
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45 237 cost-effectiveness studies, the Drummond's checklist for assessing economic evaluations will be used
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47 238 [39]. Two independent reviewers will score the selected studies and disagreements will be resolved by a
48
49 239 third person.

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51 240 The risk of bias for each outcome across individual studies will be summarised as a narrative statement,
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53 241 and supported by a risk of bias table. A review-level narrative summary of the risk of bias will also be
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55 242 provided.
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3 245 *Descriptive analysis and meta-analysis*
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5 246 Planned subgroup analysis will be performed by domain of quality of care (IOM framework) and by time
6 247 scale (*i.e.* short-, medium- or long-term impact). For studies with a high or unclear risk of bias, defined as
7 248 high or unclear risk in 50% or more of the quality assessment outcomes, a narrative description of the risk
8 249 of bias will be provided. Risk of bias assessments will be incorporated into synthesis by performing
9 250 sensitivity analysis (*i.e.* limiting to studies at lowest risk of bias in a secondary analysis). Depending on
10 251 the amount of information retrieved, subgroup analysis will also be performed for specific diseases.

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15 252 A narrative synthesis will be conducted for all the included studies. Parallel-group trials that are deemed
16 253 comparable in relevant ways will be pooled together for a summary effect. Whenever possible,
17 254 continuous and dichotomous outcomes will be pooled together for meta-analysis purposes. All effect sizes
18 255 will be transformed into a common metric, in order to make them comparable across studies — the bias-
19 256 corrected standardized difference in means (Hedges' g) — classified as positive when in favor of the
20 257 intervention and negative when in favor of the control. Heterogeneity will be assessed using I^2 . The
21 258 presence of publication bias will be evaluated by use of a funnel plot and the Duval and Tweedie's trim
22 259 and fill method [40].

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29 260 The body of evidence will be summarised in a Summary of Findings table and the strength of the body of
30 261 evidence will be assessed according to GRADE criteria [41].
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35 263 *Patient and public involvement*
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37 264 Our research question emerged from the implementation evaluation of the Care Information Exchange
38 265 (CIE), a pilot web portal/patient-controlled EHR happening across a 2.4 million population in North West
39 266 London. CIE implementation evaluation was shaped by its steering group, which included lay partners,
40 267 and their perspectives reinforced that our research question was relevant and aligned with
41 268 patients' interest.

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44 269 Patients were not directly involved in the design of this study. As this is a protocol for a systematic
45 270 review and no participant recruitment will take place, their involvement on the recruitment and
46 271 dissemination of findings to participants was not applicable.

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49 272 However, patient partners will be included in the interpretation of our results, in the co-development of a
50 273 dissemination strategy, and in summarising the research findings into lay summaries and reports, in order
51 274 to raise awareness and stimulate public participation on this topic.
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3 276 *Amendments*
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5 277 Any amendments to this protocol will be documented with reference to saved searches and analysis
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7 278 methods, which will be recorded in bibliographic databases (Ovid), Endnote, and Excel templates for data
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9 279 collection and synthesis.
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281 Discussion

282 As the implementation of interventions to share EHR with patients scales up worldwide, the systematic
283 evaluation of their impact emerges as a priority research topic.

284 One of the strengths of the proposed study is to apply a reproducible and transparent procedure for
285 systematic review of the literature. In this protocol, we clearly describe the types of studies, participants,
286 interventions, and outcomes that will be included, as well as the data sources, search strategy, data
287 extraction methods (including quality assessment) and methods of combining data [42]. By publishing the
288 research protocol, we reinforce the clarity of the strategy and minimise the risk of bias, namely selective
289 outcome reporting [37]. Second, we will focus solely on the impact of EHR-based studies, increasing the
290 sensitivity to detect specific benefits of this type of intervention. Third, for the first time, we aim to
291 comprehensively evaluate both the benefits and risks of these interventions in a wide range of domains of
292 quality of care, as defined by the IOM, and in diverse time frames. This results shall provide high-level
293 information to inform, support and customise decisions in health policies.

294 Potential limitations of this study include the heterogeneity of measures and outcomes evaluated and the
295 potentially reduced number of studies in subgroup analyses, which may negatively influence the statistical
296 power in data synthesis.

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3 **311 Acknowledgements**
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13
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15 319 Research (NIHR) Patient Safety Translation Research Centre) for the useful discussions around public
16
17 320 and patient involvement.
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22 **322 Ethics and dissemination**
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24 323 Not applicable.
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28 **325 Authors' contributions**
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31 326 ALN, AC and EKM conceptualised this research. ALN, AC and LL designed the protocol. ALN and LF
32 327 defined the concepts and search items. EKM and AD contributed to the conceptualisation and commented
33
34 328 on the multiple versions of the protocol. The manuscript was written by ALN with contributions from all
35
36 329 authors.
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44
45 334 those of the NHS, NIHR or the Department of Health.
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50 **336 Competing interests' statement**
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52 337 We declare no conflict(s) of interest associated with this research.
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339 **Data sharing statement**

340 No additional data relevant to this protocol are available for distribution. All relevant data and search
341 terms are published in this manuscript.

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For peer review only

343 **Table 1. Concepts and search items**

| Database | Search items |
|---|--|
| CINAHL via EBSCO | <ol style="list-style-type: none"> 1. (((electronic* or online or on-line or digital*) N1 (health record* or medical record* or personal record* or patient record*)) or EHR# or EMR# or ephr#) 2. ((information or data) N4 (shar* or exchange*)) or HIE or HIEs or access*) 3. #1 and #2 4. (((experience or satisfaction) N4 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 5.(effectiveness or health outcome*) 6. (patient N1 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss* 7. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number N1 appointment*) or (number adj2 admission*) or (number N1 telephone visit*)) 8. waiting lists or timeliness or time-to-treatment 9. health equity 10. #4 or #5 or #6 or #7 or #8 or #9 13. 3 and 10 |
| Cochrane via url: http://onlinelibrary.wiley.com/cochranelibrary/search/advanced | <ol style="list-style-type: none"> 1. (((electronic* or online or on-line or digital*) near/1 (health record* or medical record* or personal record* or patient record*)) or EHR or EHRs or EMR or EMRs or ephr or ephrs) 2. Electronic Health Records [MesH] 3. #1 or #2 4. (((information or data) near/4 (shar* or exchange*)) or HIE or HIES or access*) 5. Information Dissemination [MesH] 6. #4 or #5 7. #3 and #6 8. (((experience or satisfaction) near/4 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 9. (effectiveness or health outcome*) 10. (patient near/1 safety) or (patient near/1 harm) or safety manag* or accident prevent* or error* or medication reconcil* 11. (efficiency or economic* or cost* or expenditure* or charge* or fee* or (number near/1 appointment*) or (number near/1 admission*) or (number near/1 telephone visit*)) 12. time-to-treatment or timeliness 13. waiting lists [MesH] 14. health equity [MesH] 15. #8 or #9 or #10 or #11 or #12 or #13 or #14 |

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|--|--|
| <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31</p> <p>Embase via Ovid</p> | <p>17. 7 and 15</p> <p>1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?)</p> <p>2. Electronic health record/</p> <p>3. 1 or 2</p> <p>4. (((information or data) adj5 (shar* or exchang*)) or HIE*2 or access*)</p> <p>5. Information dissemination/</p> <p>6. 4 or 5</p> <p>7. 3 and 6</p> <p>8. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*)</p> <p>9. (effectiveness or health outcome*) 10. (patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss*</p> <p>11. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or (number adj2 telephone visit*))</p> <p>12. waiting list* or time to treatment/ or timeliness</p> <p>13. health equity/</p> <p>14. 8 or 9 or 10 11 or 12 or 13</p> <p>15. 7 and 14</p> |
| <p>32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60</p> <p>HMIC via Ovid</p> | <p>1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?)</p> <p>2. Electronic patient records/</p> <p>3. 1 or 2</p> <p>4. (((information or data) adj5 (shar* or exchang*)) or HIE*2 or access*)</p> <p>5. Information exchange/</p> <p>6. 4 or 5</p> <p>7. 3 and 6</p> <p>8. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*)</p> <p>9. (effectiveness or health outcome*) 10. (patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss*</p> <p>11. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or (number adj2 telephone visit*))</p> <p>12. waiting lists/ or patient waiting time or timeliness</p> <p>13. health inequalities/ or equity</p> |

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|--------------------------|---|
| | <p>14. 8 or 9 or 10 or 11 or 12 or 13 15. 7 and 14</p> |
| Medline via Ovid | <p>1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?) 2. Electronic Health Records/ 3. 1 or 2 4. (((information or data) adj5 (shar* or exchang*)) or HIE*2 or access* 5. Information Dissemination/ 6. 4 or 5 7. 3 and 6 8. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 9. (effectiveness or health outcome*) 10. ((patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss*) 11. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or (number adj2 telephone visit*)) 12. Waiting Lists/ or Time-to-treatment/ or timeliness 13. Health Equity/ 14. 8 or 9 or 10 or 11 or 12 or 13 15. 7 and 14</p> |
| PsycINFO via Ovid | <p>1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?) 2. (((information or data) adj5 (shar* or exchang*)) or HIE*2 or access* 3. 1 and 2 4. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 5. (effectiveness or health outcome*) 6. (patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss* 7. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or (number adj2 telephone visit*)) 8. waiting list* or time-to-treatment or timeliness 9. equity or health disparities/ 10. 4 or 5 or 6 or 7 or 8 or 9 11. 3 and 10</p> |

344 Search themes (facets) and terms derived for each theme relating to the use of EHR and predicted benefits
345 (patient experience, effectiveness and efficiency)

Table 2. Inclusion and exclusion criteria

| | Inclusion criteria | Exclusion criteria |
|---------------------|--|---|
| Population | Adult subjects (patients and carers) | Individuals 16 years of age and under (e.g. mean age of study sample <16) |
| Intervention | Electronic health record-based interventions, including: <ul style="list-style-type: none"> • Patient access to EHR • EHR-based reminders / messaging • Unidirectional or bidirectional online patient-provider communication systems (care information exchange platforms); | <ul style="list-style-type: none"> • Health reminders only |
| Comparison | No intervention (e.g. usual care) | |
| Outcome | Any measure related to a) patient-centredness (e.g. PREMs), b) effectiveness (e.g. health outcomes); c) patient safety (e.g. identification of medication discrepancies); d) efficiency (e.g. economic evaluation measures and proxies; including service costs, number of consultations/admissions, e) timeliness (e.g. waiting lists, time-to-treatment) or f) equity (e.g. discrepancies in quality measures between different groups of patients). | Studies that only report cognitive outcomes (e.g. intention to), motivational outcomes or other subjective psychological measures |
| Study type | Randomised controlled trials, cluster randomised trials, quasi-experimental, case-control, cohort studies, cost-effectiveness | |

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3 440 42. Silagy, C.A., P. Middleton, and S. Hopewell, *Publishing protocols of systematic reviews: comparing what was done to what was planned*. Journal of the American Medical Association,
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5 442 2002. **287**(21): p. 2831-4.
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3 445 **Figure Legends**
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5 446 **Figure 1. Mapping the demonstrated benefits and risks of sharing EHR with patients across the six**
6 **domains of quality of care, as defined by the Institute of Medicine analytical framework.**
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8 448 Subgroup analysis will be performed by domain of quality of care domain and by time scale.
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For peer review only

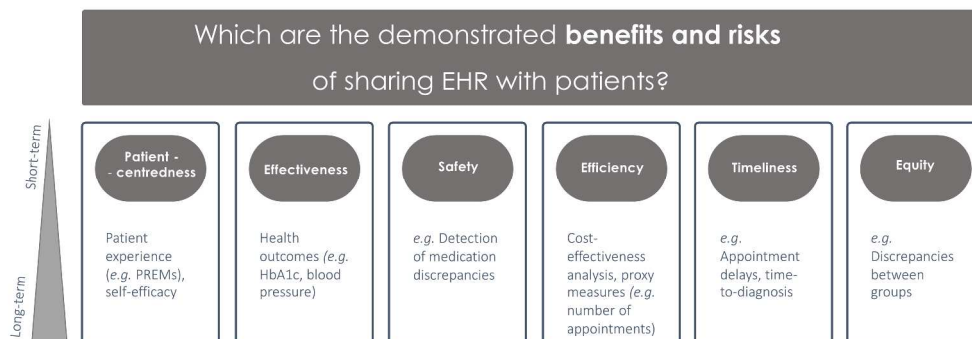


Figure 1. Mapping the demonstrated benefits and risks of sharing EHR with patients across the six domains of quality of care, as defined by the Institute of Medicine analytical framework. Subgroup analysis will be performed by domain of quality of care domain and by time scale.

326x170mm (300 x 300 DPI)

Review only

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 | Page |
|-----------------------------------|---------|---|----------------|
| ADMINISTRATIVE INFORMATION | | | |
| Title: | | | |
| Identification | 1a | Identify the report as a protocol of a systematic review | 1, 2, |
| Update | 1b | If the protocol is for an update of a previous systematic review, identify as such | Not applicable |
| Registration | 2 | If registered, provide the name of the registry (such as PROSPERO) and registration number | 2 |
| Authors: | | | |
| Contact | 3a | Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author | 1 |
| Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review | 12 |
| 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 | Not applicable |
| Support: | | | |
| Sources | 5a | Indicate sources of financial or other support for the review | 12 |
| Sponsor | 5b | Provide name for the review funder and/or sponsor | 12 |
| Role of sponsor or funder | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol | 12 |
| INTRODUCTION | | | |
| Rationale | 6 | Describe the rationale for the review in the context of what is already known | 4-6 |
| Objectives | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) | 7 |
| 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 | 6,7,17 |
| 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 | 6,7 |
| 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 | 6, 13-16 |

| | | | |
|------------------------------------|-----|--|-----|
| Study records: | | | |
| Data management | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review | 6-9 |
| 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) | 2,8 |
| 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 | 8 |
| 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 | 7 |
| Outcomes and prioritization | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale | 7 |
| 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 | 8-9 |
| Data synthesis | 15a | Describe criteria under which study data will be quantitatively synthesised | 8 |
| | 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) | 8 |
| | 15c | Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) | 8 |
| | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | 8 |
| Meta-bias(es) | 16 | Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) | 8 |
| Confidence in cumulative evidence | 17 | Describe how the strength of the body of evidence will be assessed (such as GRADE) | 8 |

*** 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.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

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Impact of sharing electronic health records with patients on the quality and safety of care: a systematic review and narrative synthesis protocol

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Manuscripts

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4 1 **Impact of sharing electronic health records with patients**
5 2 **on the quality and safety of care:**
6
7 3 **a systematic review and narrative synthesis protocol**
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9 4

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53 29 Quality of Health Care, Patient Safety
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3 **31 Abstract**
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6 **32**
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8 **33** Introduction: Providing patients with access to Electronic Health Records (EHR) has emerged as a
9 **34** promising solution to improve quality of care and safety. As the efforts to develop and implement EHR-
10 **35** based data sharing platforms mature and scale up worldwide, there is a need to evaluate the impact of
11 **36** these interventions and to weigh their relative risks and benefits, in order to inform evidence-based health
12 **37** policies. The aim of this work is to systematically characterise and appraise the demonstrated benefits and
13 **38** risks of sharing EHR with patients, by mapping them across the six domains of quality of care of the
14 **39** Institute of Medicine (IOM) analytical framework (*i.e.* patient-centredness, effectiveness, efficiency,
15 **40** timeliness, equity and safety).
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21 **41**
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23 **42** Methods and analysis: CINAHL, Cochrane, Embase, HMIC, Medline/PubMed and PsycINFO databases
24 **43** will be searched from January 1997 to August 2017. Primary outcomes will include measures related with
25 **44** the six domains of quality of care of the IOM analytical framework. The quality of the studies will be
26 **45** assessed using the Cochrane Risk of Bias Tool, the ROBINS-I Tool and the Drummond's checklist. A
27 **46** narrative synthesis will be conducted for all included studies. Subgroup analysis will be performed by
28 **47** domain of quality of care domain and by time scale (*i.e.* short-, medium- or long-term impact). The body
29 **48** of evidence will be summarised in a Summary of Findings table and its strength assessed according to the
30 **49** GRADE criteria. This protocol was registered in PROSPERO (CRD42017070092).
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39 **51** Ethics and dissemination: This review does not require ethical approval as it will summarise published
40 **52** studies with non-identifiable data. This protocol complies with the Preferred Reporting Items for
41 **53** Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines. Findings will be disseminated
42 **54** widely through peer-reviewed publication and conference presentations, and patient partners will be
43 **55** included in summarising the research findings into lay summaries and reports.
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Strengths and limitations of this study

- Comprehensive characterisation of interventions sharing EHR with patients
- Summary and appraisal of existing evidence on the potential benefits and risks of these interventions, grouped by domain of quality of care
- Map the contribution of these interventions in short-, medium- and long-term time frames, in order to customise informed decisions in health policies
- Expected limitations include the heterogenous nature of the outcomes assessed and the potentially reduced sample size in subgroup analyses, which may negatively impact the statistical power in data synthesis.

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45 91 **Introduction**

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7 92 Although, in England, patients have had the legal right to access their health records since 1998, access to
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9 93 paper-based health records is mediated by health professionals and data controllers, through a
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11 94 cumbersome procedural process [1]. Additionally, as health information is fragmented between different
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13 95 organisations and levels of care, data access requests are often unable to provide a comprehensive health
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15 96 history record [2, 3].

16 97 In the last decade, electronic health records (EHR), have emerged as a promising solution to enhance
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18 98 patients' access to centralised medical information [4]. The adoption of EHR by primary care practices,
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20 99 hospitals and other healthcare organizations has steadily increased in the last years. In England, the
21
22 100 percentage of General Practice surgeries that allowed patients to access their medical records online
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24 101 increased from 3% to 97% between April 2014 and February 2016 [5]. Patients' willingness and ability to
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26 102 access their health information through web portals is influenced by both individual (*i.e.* age, ethnicity,
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28 103 education level, health literacy and health status) and by health care delivery factors (*i.e.* provider
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30 104 endorsement and portal usability) [6, 7]. Various EHR-based platforms are currently used to share health
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32 105 information with patients, including direct online access, with or without patient-provider communication
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34 106 systems [8, 9] and health maintenance reminders [10, 11]. As these efforts mature and scale up
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36 107 worldwide, there is a need to evaluate the impact of interventions sharing EHR with patients, in order to
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38 108 weigh their relative risks and benefits and inform evidence-based health policies.

39 109 The Institute of Medicine (IOM) identified six domains of health care quality: patient-centredness,
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41 110 effectiveness, efficiency, timeliness, equity and safety [12]. Patient-centredness ensures that the care
42
43 111 provided respects and responds to individual patient preferences, needs and values, thus incorporating
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45 112 these in clinical decisions [12, 13]. Health care shall provide evidence-based services, which can be
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47 113 ultimately expressed as improvements in health outcomes (*i.e.* effectiveness) [14], while ensuring patient
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49 114 safety (*i.e.* prevention of errors and adverse effects associated with health care) [12]. Other aspects of
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51 115 quality of delivery of care include the minimisation of the waste of human, physical or economical
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53 116 resources (*i.e.* efficiency), the reduction of waits and harmful delays (*i.e.* timeliness) and the reduction of
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55 117 avoidable differences on the delivery of care between different groups of health care users (*i.e.* equity)
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57 118 [12, 15, 16].

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59 119 Providing patients with access to their health records has been linked to theorised benefits in four major
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61 120 domains of health care quality: patient-centredness, effectiveness, safety and efficiency [17-19].
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63 121 However, despite the growing body of evidence on the theorised benefits of sharing EHR with patients on

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3 122 these domains, there is still a considerable gap between the predicted and demonstrated benefits of these
4 123 interventions [20].

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7 124 In order to analyse the effect of providing patients access to their medical records on quality outcomes,
8 125 Davis-Giardina T. *et al* performed a systematic review including studies published between 1970 and
9 126 2012 [21]. According to this work, a limited amount of evidence suggests that access to medical records
11 127 improves patient satisfaction and enhances patient-provider communication [21]. Similarly, a systematic
13 128 review from de Lusignan *et al.* reported that providing patients online access to their EHR increased
14 129 convenience and satisfaction [22]. These findings are in line with the model proposed by Otte-Trojel T. *et*
15 130 *al*, according to which sharing EHR with patients can improve both patient-provider communication and
16 131 patient satisfaction, by increasing continuity of care and patient convenience, respectively [23].

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20 132 Conversely, no clear benefits were found on effectiveness [21]. Until 2012, only a few studies evaluated
21 133 the impact on effectiveness studies, most focusing on type 2 diabetes and with inconsistent results.
22 134 Tenforde *et al* showed that providing access to medical records was associated with lower glycated
23 135 haemoglobin A1c values [24]; however, no significant effect was found in three other studies assessing
24 136 diabetes-specific effectiveness measures [25, 26]. One of the limitations of this review consists in the
25 137 inclusion of studies evaluating the impact of sharing both electronic and paper-based health records - and
26 138 this heterogeneity might mask potential specific benefits and risks of sharing EHR with patients.
27 139 Furthermore, as pointed by the authors, the paucity of papers published up to that date resulted in a
28 140 tendency to include small and methodologically less robust studies, thus increasing the risk of selective
29 141 reporting and/or publication bias [21]. Mold F. *et al* also performed a systematic review assessing the
30 142 impact of providing patients with access to their EHR; based in studies published between 1999 and 2012,
31 143 this work found a positive influence in patient safety [27].

32
33 144 However, the authors were unable to find a consistent beneficial effect on efficiency measures (*i.e.*
34 145 number of face-to-face visits and telephone appointments) in both reviews [21, 27]. While some studies
35 146 reported an increase in the number of face-to-face consultations [8, 28], others document a decrease [11,
36 147 29, 30]. Similarly, inconsistent results were found regarding the impact on telephone consultations: only
37 148 one study reported a decline in the total number [31], whilst six other studies reported either no change or
38 149 an increase [9, 28-30, 32, 33]. It is important to note, however, that most of the included studies assessing
39 150 efficiency measures included in this review showed a high risk of bias, mostly related to either unclear or
40 151 absent blinding methods [27].

41
42 152 The landmark reviews of Mold F. *et al* [27], Davis-Giardina T. *et al* [21], Ammenwerth E. *et al* [34] and
43 153 Goldweig CL *et al* [7] provide a comprehensive characterisation of the literature published until 2013,
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3 154 highlighting the paucity and the scientific limitations of the evidence published until that date. Although
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5 155 these reviews were unable to demonstrate clear benefits on efficiency and effectiveness measures, the
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7 156 debates around patients' rights and data ownership in the digital era, and the need to improve patient-
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9 157 centredness of health care delivery have acted as strong drivers to allocate resources to interventions and
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11 158 platforms aiming to share EHR with patients. As consequence of these efforts, it is plausible that studies
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13 159 performed in the last 5 years can provide further clarification for this evidence gap.

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15 160 Furthermore, systematic reviews performed to the date do not address all domains of quality of care; in
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17 161 particular, the impact of sharing EHR with patients on timeliness or equity has not been addressed [7, 21,
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19 162 27, 34, 35]. This is a particularly relevant gap in knowledge, given that interventions aimed at improving
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21 163 the quality of care do not necessarily improve all specific domains, and may even have a deleterious
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23 164 effect in some of them.

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25 165 This review will expand on the above-mentioned work, in order to identify recent methodological and
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27 166 scientific progress until June 2017. Following the PRISMA-P checklist as guidance [36], we propose a
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29 167 systematic and reproducible strategy to query the literature on the demonstrated benefits and risks of
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31 168 sharing EHR with patients and map these results in a comprehensive framework of health care quality
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33 169 measures.

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36 37 171 **Research aims**

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39 172 The main objectives of this review are: 1) to systematically characterise interventions sharing EHR with
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41 173 patients; and 2) to assess the demonstrated risks and benefits of these interventions on patient-
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43 174 centredness, effectiveness, safety, efficiency, timeliness and equity, compared to usual care (no
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45 175 intervention). As secondary aim, we will map the contribution of these interventions in short-, medium-
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47 176 and long-term timeframes (Figure 1).

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50 51 178 **Methods and analysis**

52 53 179 *Search strategy*

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55 180 The search strategy will be performed using resources that enhance methodological transparency and
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57 181 improve the reproducibility of the results and evidence synthesis. A search of the literature from the last
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59 182 20 years (January 1997 – August 2017) will be performed on CINAHL, Cochrane, Embase, HMIC,
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183 Medline/PubMed and PsycINFO. Search strings (Table 1) will combine free terms and controlled

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3 184 vocabulary, whenever supported. We will also search grey literature sources, including registrations in the
4 185 International Prospective Register of Systematic Reviews (PROSPERO), reports of relevant stakeholder
5 186 organisations (NHS Digital, AMIA, eHealth at WHO, International Society for Telemedicine and
6 187 eHealth), and conference proceedings (last 5 years) of several related conferences (American Medical
7 188 Informatics Association [AMIA], MedInfo, Medicine 2.0, Medicine X), in order to identify possible
8 189 additional studies that meet the inclusion criteria. Language restrictions will be applied and only articles
9 190 in English will be included.
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17 192 *Study selection criteria*

19 193 A summary of the participants, interventions, comparators and outcomes (PICO) considered, as well as
20 194 the type of studies included, is provided in Table 2.

23 195 The systematic review will focus on studies on adult subjects, including both patients and carers (mean
24 196 age of study sample ≥ 16 years). The systematic review does not focus on a particular disease area or
25 197 health system setting as it intends to comprehensively characterise the scope of interventions sharing EHR
26 198 with patients.
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30 199 Studies assessing the impact of sharing EHR with patients, either isolated or as part of a multicomponent
31 200 intervention, will be included. Included interventions will comprise: 1) web-based patient access to EHR;
32 201 2) EHR-based health reminders / messaging or 3) online patient-provider communication systems (health
33 202 information exchange platforms). Studies focusing on health reminders only (not EHR-based) or
34 203 appointment reminders will not be considered. The comparator will be 'no intervention' (e.g. usual care).
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39 204 Primary outcomes will include any measure related to a) patient-centredness (e.g. patient-reported
40 205 experience measures (PREMs), b) effectiveness (e.g. health outcomes); c) patient safety (e.g.
41 206 identification of medication discrepancies); d) efficiency (e.g. economic evaluation measures and proxies;
42 207 including service costs, number of consultations/admissions, e) timeliness (e.g. waiting lists, time-to-
43 208 treatment) and f) equity (e.g. discrepancies in quality measures between different groups of patients)
44 209 (Figure 1). Studies that only report cognitive outcomes (e.g. intent), motivational outcomes or other
45 210 subjective psychological measures will be excluded. The types of study considered in this systematic
46 211 review will be a) randomised controlled trials; b) cluster randomised trials; c) quasi-experimental studies;
47 212 d) case-control studies, e) cohort studies and f) cost-effectiveness studies. The reference lists of
48 213 systematic reviews identified in this search will also be screened to ensure all eligible studies are
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3 215 *Screening and data extraction*
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5 216 Quantitative studies will be independently assessed by three reviewers and reported using the Preferred
6 217 Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-P) flow diagram [36]. Initial
7 218 screening of studies will be based on the information contained in their titles and abstracts and will be
8 219 conducted by two independent investigators. Full-paper screening will be conducted by the same
9 220 independent investigators. Cohen's kappa will be used to measure inter-coder agreement in each
10 221 screening phase. When there are doubts regarding inclusion or exclusion, a third investigator will be
11 222 involved in the decision. Two independent investigators will extract information from the included
12 223 studies into a standardized form. The data collected for each study will include: name of the first author,
13 224 year of publication, technology, intervention components and characteristics, study duration, participants'
14 225 and setting characteristics, outcomes and retention rates. Two investigators will review the abstraction
15 226 form for consistency. Disagreements will be resolved by a third investigator.
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26 228 *Quality assessment*
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28 229 The quality of randomised controlled trials and cluster randomized trials will be assessed using the
29 230 Cochrane Risk of Bias Tool [37], that assesses the following study-level aspects: a) randomisation
30 231 sequence allocation; b) allocation concealment; c) blinding; d) completeness of outcome data and e)
31 232 selective outcome reporting. The quality of non-randomised intervention studies (*i.e.* case control, cohort,
32 233 quasi-experimental) will be appraised using the ROBINS-I tool, which assesses bias due to a)
33 234 confounding, b) selection of participants, c) classification of interventions, d) deviations from intended
34 235 interventions, e) missing data, f) measurement of outcomes and g) selection of reported results [38]. For
35 236 cost-effectiveness studies, the Drummond's checklist for assessing economic evaluations will be used
36 237 [39]. Two independent reviewers will score the selected studies and disagreements will be resolved by a
37 238 third person.
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44 239 The risk of bias for each outcome across individual studies will be summarised as a narrative statement,
45 240 and supported by a risk of bias table. A review-level narrative summary of the risk of bias will also be
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3 245 *Descriptive analysis and meta-analysis*
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5 246 Planned subgroup analysis will be performed by domain of quality of care (IOM framework) and by time
6 247 scale (*i.e.* short-, medium- or long-term impact). For studies with a high or unclear risk of bias, defined as
7 248 high or unclear risk in 50% or more of the quality assessment outcomes, a narrative description of the risk
8 249 of bias will be provided. Risk of bias assessments will be incorporated into synthesis by performing
9 250 sensitivity analysis (*i.e.* limiting to studies at lowest risk of bias in a secondary analysis). Depending on
10 251 the amount of information retrieved, subgroup analysis will also be performed for specific diseases.

11 252 A narrative synthesis will be conducted for all the included studies. Parallel-group trials that are deemed
12 253 comparable in relevant ways will be pooled together for a summary effect. Whenever possible,
13 254 continuous and dichotomous outcomes will be pooled together for meta-analysis purposes. All effect sizes
14 255 will be transformed into a common metric, in order to make them comparable across studies — the bias-
15 256 corrected standardized difference in means (Hedges' g) — classified as positive when in favor of the
16 257 intervention and negative when in favor of the control. Heterogeneity will be assessed using I^2 . The
17 258 presence of publication bias will be evaluated by use of a funnel plot and the Duval and Tweedie's trim
18 259 and fill method [40].

19 260 The body of evidence will be summarised in a Summary of Findings table and the strength of the body of
20 261 evidence will be assessed according to GRADE criteria [41].
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23 263 *Patient and public involvement*
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29 264 Our research question emerged from the implementation evaluation of the Care Information Exchange
30 265 (CIE), a pilot web portal/patient-controlled EHR happening across a 2.4 million population in North West
31 266 London. CIE implementation evaluation was shaped by its steering group, which included lay partners,
32 267 and their perspectives reinforced that our research question was relevant and aligned with
33 268 patients' interest.

34 269 Patients were not directly involved in the design of this study. As this is a protocol for a systematic
35 270 review and no participant recruitment will take place, their involvement on the recruitment and
36 271 dissemination of findings to participants was not applicable.

37 272 However, patient partners will be included in the interpretation of our results, in the co-development of a
38 273 dissemination strategy, and in summarising the research findings into lay summaries and reports, in order
39 274 to raise awareness and stimulate public participation on this topic.
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3 276 *Amendments*
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5 277 Any amendments to this protocol will be documented with reference to saved searches and analysis
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7 278 methods, which will be recorded in bibliographic databases (Ovid), Endnote, and Excel templates for data
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9 279 collection and synthesis.
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281 Discussion

282 As the implementation of interventions to share EHR with patients scales up worldwide, the systematic
283 evaluation of their impact emerges as a priority research topic.

284 One of the strengths of the proposed study is to apply a reproducible and transparent procedure for
285 systematic review of the literature. In this protocol, we clearly describe the types of studies, participants,
286 interventions, and outcomes that will be included, as well as the data sources, search strategy, data
287 extraction methods (including quality assessment) and methods of combining data [42]. By publishing the
288 research protocol, we reinforce the clarity of the strategy and minimise the risk of bias, namely selective
289 outcome reporting [37]. Second, we will focus solely on the impact of EHR-based studies, increasing the
290 sensitivity to detect specific benefits of this type of intervention. Third, for the first time, we aim to
291 comprehensively evaluate both the benefits and risks of these interventions in a wide range of domains of
292 quality of care, as defined by the IOM, and in diverse time frames. This results shall provide high-level
293 information to inform, support and customise decisions in health policies.

294 Potential limitations of this study include the heterogeneity of measures and outcomes evaluated and the
295 potentially reduced number of studies in subgroup analyses, which may negatively influence the statistical
296 power in data synthesis.

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315 Centre for Health Policy at the Institute of Global Health Innovation) and Dr Joachim Marti (Senior
316 Lecturer in Health Economics at the Centre for Health Policy at the Institute of Global Health Innovation)
317 for their advices regarding the quality appraisal of cost-effectiveness studies, and Miss Anna Lawrence-
318 Jones (Patient and Public Involvement and Engagement Manager at Imperial National Institute for Health
319 Research (NIHR) Patient Safety Translation Research Centre) for the useful discussions around public
320 and patient involvement.

322 **Ethics and dissemination**

323 This review does not require ethical approval as it will summarise published studies with non-identifiable
324 data. This protocol complies with the PRISMA-P guidelines. Findings will be disseminated widely
325 through peer-reviewed publication and conference presentations. Patient partners will be included in the
326 co-development of our dissemination strategy, and in summarising the research findings into lay
327 summaries and reports.

329 **Authors' contributions**

330 ALN, AC and EKM conceptualised this research. ALN, AC and LL designed the protocol. ALN and LF
331 defined the concepts and search items. EKM and AD contributed to the conceptualisation and commented
332 on the multiple versions of the protocol. The manuscript was written by ALN with contributions from all
333 authors.

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337 (NIHR) Patient Safety Translation Research Centre. The views of the authors do not necessarily reflect
338 those of the NHS, NIHR or the Department of Health.

340 **Competing interests' statement**

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3 341 We declare no conflict(s) of interest associated with this research.
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8 343 **Data sharing statement**

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10 344 No additional data relevant to this protocol are available for distribution. All relevant data and search
11 345 terms are published in this manuscript.
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347 **Table 1. Concepts and search items**

| Database | Search items |
|---|--|
| CINAHL via EBSCO | <ol style="list-style-type: none"> 1. (((electronic* or online or on-line or digital*) N1 (health record* or medical record* or personal record* or patient record*)) or EHR# or EMR# or ephr#) 2. ((information or data) N4 (shar* or exchange*)) or HIE or HIEs or access*) 3. #1 and #2 4. (((experience or satisfaction) N4 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 5.(effectiveness or health outcome*) 6. (patient N1 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss* 7. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number N1 appointment*) or (number adj2 admission*) or (number N1 telephone visit*)) 8. waiting lists or timeliness or time-to-treatment 9. health equity 10. #4 or #5 or #6 or #7 or #8 or #9 13. 3 and 10 |
| Cochrane via url: http://onlinelibrary.wiley.com/cochranelibrary/search/advanced | <ol style="list-style-type: none"> 1. (((electronic* or online or on-line or digital*) near/1 (health record* or medical record* or personal record* or patient record*)) or EHR or EHRs or EMR or EMRs or ephr or ephrs) 2. Electronic Health Records [MesH] 3. #1 or #2 4. (((information or data) near/4 (shar* or exchange*)) or HIE or HIES or access*) 5. Information Dissemination [MesH] 6. #4 or #5 7. #3 and #6 8. (((experience or satisfaction) near/4 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 9. (effectiveness or health outcome*) 10. (patient near/1 safety) or (patient near/1 harm) or safety manag* or accident prevent* or error* or medication reconcil* 11. (efficiency or economic* or cost* or expenditure* or charge* or fee* or (number near/1 appointment*) or (number near/1 admission*) or (number near/1 telephone visit*)) 12. time-to-treatment or timeliness 13. waiting lists [MesH] 14. health equity [MesH] 15. #8 or #9 or #10 or #11 or #12 or #13 or #14 |

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|--|--|
| <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31</p> <p>Embase via Ovid</p> | <p>17. 7 and 15</p> <p>1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?)</p> <p>2. Electronic health record/</p> <p>3. 1 or 2</p> <p>4. (((information or data) adj5 (shar* or exchang*)) or HIE*2 or access*)</p> <p>5. Information dissemination/</p> <p>6. 4 or 5</p> <p>7. 3 and 6</p> <p>8. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*)</p> <p>9. (effectiveness or health outcome*) 10. (patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss*</p> <p>11. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or (number adj2 telephone visit*))</p> <p>12. waiting list* or time to treatment/ or timeliness</p> <p>13. health equity/</p> <p>14. 8 or 9 or 10 11 or 12 or 13</p> <p>15. 7 and 14</p> |
| <p>32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60</p> <p>HMIC via Ovid</p> | <p>1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?)</p> <p>2. Electronic patient records/</p> <p>3. 1 or 2</p> <p>4. (((information or data) adj5 (shar* or exchang*)) or HIE*2 or access*)</p> <p>5. Information exchange/</p> <p>6. 4 or 5</p> <p>7. 3 and 6</p> <p>8. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*)</p> <p>9. (effectiveness or health outcome*) 10. (patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss*</p> <p>11. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or (number adj2 telephone visit*))</p> <p>12. waiting lists/ or patient waiting time or timeliness</p> <p>13. health inequalities/ or equity</p> |

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| | 14. 8 or 9 or 10 or 11 or 12 or 13 15. 7 and 14 |
| Medline via Ovid | 1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?) 2. Electronic Health Records/ 3. 1 or 2 4. (((information or data) adj5 (shar* or exchang*)) or HIE*2 or access* 5. Information Dissemination/ 6. 4 or 5 7. 3 and 6 8. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 9. (effectiveness or health outcome*) 10. ((patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss*) 11. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or (number adj2 telephone visit*)) 12. Waiting Lists/ or Time-to-treatment/ or timeliness 13. Health Equity/ 14. 8 or 9 or 10 or 11 or 12 or 13 15. 7 and 14 |
| PsycINFO via Ovid | 1. (((electronic* or online or on-line or digital*) adj2 (health record* or medical record* or personal record* or patient record*)) or EHR? or EMR? or ephr?) 2. (((information or data) adj5 (shar* or exchang*)) or HIE*2 or access* 3. 1 and 2 4. (((experience or satisfaction) adj5 (patient* or consumer* or client* or survey or questionnaire*)) or PREM* or patient-reported experience measure*) 5. (effectiveness or health outcome*) 6. (patient adj2 (safety or harm)) or safety manag* or accident prevent* or error* or medication reconcil* or near miss* 7. (efficiency or economic* or cost* or expenditure* or charge* or fee*1 or (number adj2 appointment*) or (number adj2 admission*) or (number adj2 telephone visit*)) 8. waiting list* or time-to-treatment or timeliness 9. equity or health disparities/ 10. 4 or 5 or 6 or 7 or 8 or 9 11. 3 and 10 |

348 Search themes (facets) and terms derived for each theme relating to the use of EHR and predicted benefits
349 (patient experience, effectiveness and efficiency)

Table 2. Inclusion and exclusion criteria

| | Inclusion criteria | Exclusion criteria |
|---------------------|--|---|
| Population | Adult subjects (patients and carers) | Individuals 16 years of age and under (e.g. mean age of study sample <16) |
| Intervention | Electronic health record-based interventions, including: <ul style="list-style-type: none"> • Patient access to EHR • EHR-based reminders / messaging • Unidirectional or bidirectional online patient-provider communication systems (care information exchange platforms); | <ul style="list-style-type: none"> • Health reminders only |
| Comparison | No intervention (e.g. usual care) | |
| Outcome | Any measure related to a) patient-centredness (e.g. PREMs), b) effectiveness (e.g. health outcomes); c) patient safety (e.g. identification of medication discrepancies); d) efficiency (e.g. economic evaluation measures and proxies; including service costs, number of consultations/admissions, e) timeliness (e.g. waiting lists, time-to-treatment) or f) equity (e.g. discrepancies in quality measures between different groups of patients). | Studies that only report cognitive outcomes (e.g. intention to), motivational outcomes or other subjective psychological measures |
| Study type | Randomised controlled trials, cluster randomised trials, quasi-experimental, case-control, cohort studies, cost-effectiveness | |

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3 449 **Figure Legends**
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5 450 **Figure 1. Mapping the demonstrated benefits and risks of sharing EHR with patients across the six**
6 **domains of quality of care, as previously defined by the Institute of Medicine analytical framework**
7 **[12].** Subgroup analysis will be performed by domain of quality of care domain and by time scale.
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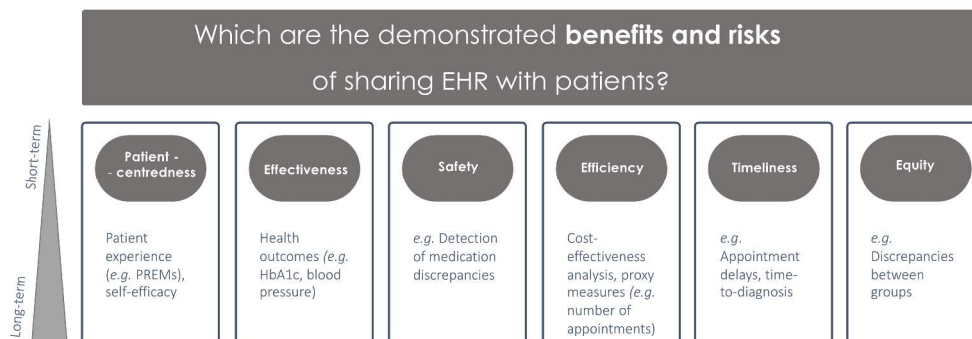


Figure 1. Mapping the demonstrated benefits and risks of sharing EHR with patients across the six domains of quality of care, as defined by the Institute of Medicine analytical framework. Subgroup analysis will be performed by domain of quality of care domain and by time scale.

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Review only

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 | Page |
|-----------------------------------|---------|---|----------------|
| ADMINISTRATIVE INFORMATION | | | |
| Title: | | | |
| Identification | 1a | Identify the report as a protocol of a systematic review | 1, 2, |
| Update | 1b | If the protocol is for an update of a previous systematic review, identify as such | Not applicable |
| Registration | 2 | If registered, provide the name of the registry (such as PROSPERO) and registration number | 2 |
| Authors: | | | |
| Contact | 3a | Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author | 1 |
| Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review | 12 |
| 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 | Not applicable |
| Support: | | | |
| Sources | 5a | Indicate sources of financial or other support for the review | 12 |
| Sponsor | 5b | Provide name for the review funder and/or sponsor | 12 |
| Role of sponsor or funder | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol | 12 |
| INTRODUCTION | | | |
| Rationale | 6 | Describe the rationale for the review in the context of what is already known | 4-6 |
| Objectives | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) | 7 |
| 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 | 6,7,17 |
| 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 | 6,7 |
| 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 | 6, 13-16 |

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|------------------------------------|-----|--|-----|
| Study records: | | | |
| Data management | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review | 6-9 |
| 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) | 2,8 |
| 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 | 8 |
| 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 | 7 |
| Outcomes and prioritization | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale | 7 |
| 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 | 8-9 |
| Data synthesis | 15a | Describe criteria under which study data will be quantitatively synthesised | 8 |
| | 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) | 8 |
| | 15c | Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) | 8 |
| | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | 8 |
| Meta-bias(es) | 16 | Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) | 8 |
| Confidence in cumulative evidence | 17 | Describe how the strength of the body of evidence will be assessed (such as GRADE) | 8 |

*** 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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