

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [info.bmjopen@bmj.com](mailto:info.bmjopen@bmj.com)

# BMJ Open

## Implementation of national hypertension in pregnancy guidelines: a multi-centre mixed methods study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-035762
Article Type:	Original research
Date Submitted by the Author:	19-Nov-2019
Complete List of Authors:	Whybrow, rebecca; King's College London, Women and Children's Health; Guy's and Saint Thomas' Hospitals NHS Trust, Division of Women and Children's Health Webster, Louise; King's College London, Women and Children's Health Girling, Joanna; Chelsea and Westminster Hospital NHS Foundation Trust Brown, Heather; Brighton and Sussex University Hospitals NHS Trust Wilson, Hannah; King's College London, Women and Children's Health Sandall, Jane; Kings College, London, Women and Children's Health Chappell, Dr Lucy; King's College London, Department of Women and Children's Health; Guy's and Saint Thomas' Hospitals NHS Trust, Division of Women and Children's Health
Keywords:	Maternal medicine < OBSTETRICS, OBSTETRICS, Hypertension < CARDIOLOGY

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3 1 **Title:** Implementation of national hypertension in pregnancy guidelines: a multi-centre mixed  
4 2 methods study

5  
6  
7 3 Rebecca Whybrow<sup>1</sup>, Louise Webster<sup>1</sup>, Joanna Girling<sup>2</sup>, Heather Brown<sup>3</sup>, Hannah Wilson<sup>1</sup>, Jane Sandall<sup>1</sup>,  
8 4 Lucy Chappell<sup>1</sup>

9  
10  
11 5 1 Department of Women and Children's Health, King's College London, St Thomas' Hospital, London,  
12 6 UK.

13  
14  
15 7 2 Chelsea and Westminster Hospital NHS Foundation Trust, London, UK.

16  
17  
18 8 3 Brighton and Sussex Universities Hospital Trust, East Sussex, UK.

19  
20 9 Corresponding author: Rebecca Whybrow, Department of Women and Children's Health, King's  
21 10 College London, St Thomas' Hospital, London, UK. [Rebecca.whybrow@kcl.ac.uk](mailto:Rebecca.whybrow@kcl.ac.uk) Tel: 07804690276

22  
23  
24 11 **Word Count:** 4225

25  
26 12 **Abstract:**

27  
28  
29 13 **Objective** To evaluate the implementation of NICE hypertension in pregnancy guidelines, to identify  
30 14 strategies to reduce incidences of severe hypertension and associated maternal and perinatal  
31 15 morbidity and mortality in pregnant women with chronic hypertension.

32  
33  
34 16 **Methods** We used a multi-method multi-site approach to establish implementation of guidelines and  
35 17 the associated barriers and facilitators. We used a national survey (n=97), case-notes review (n=55)  
36 18 and structured observations (n=42) to assess implementation. The barriers and facilitators to  
37 19 implementation were identified from semi-structured qualitative interviews with professionals (n=13)  
38 20 and pregnant women (n=18) using inductive thematic analysis. The findings were integrated and  
39 21 evaluated using the Consolidated Framework for Implementation Research (CFIR).

40  
41  
42 22 **Setting and participants** Pregnant women with chronic hypertension and their principle carers  
43 23 (obstetricians, midwives and physicians), at three NHS hospital trusts with different models of care.

44  
45  
46 24 **Results** We found severe hypertension to be prevalent (46% of case notes reviewed) and target blood  
47 25 pressure practices to be sub-optimal (56% of women had an antenatal blood pressure target  
48 26 documented). Women were infrequently given information (52%) or offered choice (19%) regarding  
49 27 antihypertensives. Women (14/18) reported conflict in taking antihypertensives and non-adherence  
50 28 was prevalent (8/18). Women who were concordant with treatment recommendations described  
51 29 having mutual trust with professionals mediated through appropriate information, side-effect  
52 30 management and involvement in decision-making. Professionals reported needing updates and tools

1  
2  
3 31 for target blood pressure setting and shared decision-making underpinned by antihypertensive safety  
4 32 and effectiveness research.

5  
6  
7 33 **Conclusions** Women's nonadherence to antihypertensives is higher than anticipated, which is likely  
8 34 to be contributing to adverse perinatal outcomes, as is sub-optimal target setting practices. Education  
9 35 and decision-making strategies are needed to address both clinician and women's behaviour. Further  
10 36 research into the effectiveness and long-term safety of common antihypertensives is also required.

11  
12  
13  
14  
15 37

16  
17 38 **Strengths and limitations of this study**

- 18  
19 39 – Multi-methodological approaches and an implementation framework improved the  
20 40 reliability, validity and generalisability of the study.  
21  
22 41 – Structured observations were carried out using a validated tool with high interrater  
23 42 reliability.  
24  
25 43 – Women's medication behaviours were explored in-depth using a novel qualitative interview  
26 44 approach and have identified antihypertensive side-effects to be a determinant of non-  
27 45 adherence in pregnant women.  
28  
29 46 – The study is limited by the population size (and hence statistical power) for each of the  
30 47 methods.  
31  
32 48 – Respondents to the survey were self-selecting and may represent a relatively interested  
33 49 group of healthcare professionals.  
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

## 51 BACKGROUND

52 Hypertension in pregnancy is one of the leading causes of maternal mortality worldwide<sup>1</sup> and although  
53 mortality is declining in the UK,<sup>2</sup> women can still experience substantial morbidity from complications  
54 such as eclampsia and stroke<sup>3</sup>. Additionally, perinatal mortality remains high, with the UK population-  
55 attributable risk of stillbirth from chronic hypertension at 14%<sup>4</sup> and around half of all neonates born  
56 to mothers who have had severe hypertension in pregnancy being admitted to the neonatal unit<sup>5</sup>. The  
57 morbidity and mortality attributable to hypertension, in many cases, may be modifiable through  
58 optimal use of antihypertensive agents during pregnancy.

59 The National Institute for Health and Care Excellence (NICE) hypertension in pregnancy guidelines  
60 (2010)<sup>6</sup> and linked quality statements (2013)<sup>7</sup> contain a quality statement regarding the provision of  
61 information on the use of safe antihypertensive medication in pregnancy and has related guidance  
62 that recommends discontinuation of teratogenic medications such as angiotensin-converting-enzyme  
63 inhibitors or angiotensin II receptor blockers with prescribing of safe alternatives. Any prescribing of  
64 alternative antihypertensive medication should be dependent on pre-pregnancy treatment, side-  
65 effect profiles and teratogenicity. A second quality statement advocates that women taking  
66 antihypertensive medication should have a blood pressure target (usually of less than 150/100mmHg)  
67 set in pregnancy. All NICE guidelines are underpinned by the recommendation of enabling patients to  
68 actively participate in their care which includes adopting a shared decision-making approach to  
69 treatment decisions<sup>8</sup>.

70 Despite publication of the guideline almost a decade ago, the implementation and evaluation of  
71 associated determinants of uptake have not been nationally evaluated. As a result, targeted strategies  
72 to reduce maternal and perinatal morbidity (and mortality) resulting from severe hypertension remain  
73 unidentified. The study draws on the Consolidated Framework for Implementation Research (CFIR) as  
74 a guide for analysing, interpreting, and reporting implementation-related findings. Without a  
75 theoretical framework to guide data collection, analysis, and interpretation, implementation  
76 researchers are less able to generalise the findings beyond the context in which the data were  
77 collected.<sup>9</sup> The aim of this study was to evaluate the variance in provision of, and the barriers and  
78 facilitators involved in, the delivery of the national guidelines for the management of hypertensive  
79 disorders of pregnancy, using this framework.

80

## 81 RESEARCH DESIGN AND METHODS

### 82 Study setting and overall methodology

83 The CHAMPION study (Chronic Hypertension in pregnAncy iMplementatiON study) is a multi-methods  
84 evaluation of the implementation of the NICE hypertension in pregnancy guidelines (2010 and  
85 updated in 2013).<sup>6,7</sup> Ethical approval for the CHAMPION study was provided by the National Research  
86 Ethics Service (17/LO/2041). The study aimed to evaluate the variance in implementation of  
87 hypertension management practices set out in the NICE hypertension in pregnancy guidelines (2010).<sup>6</sup>  
88 As all guidelines should be underpinned by the 'Patient experience in adult NHS services guideline'<sup>8</sup>  
89 which specifies 'actively involving patient in decisions about their care through 'information provision'  
90 and 'shared decision-making' the provision of information and women's involvement in decision-  
91 making was also evaluated. The involvement of women in decision-making was considered integral to  
92 the implementation study because successful hypertension management strategies involve the  
93 adherence to, alongside the prescribing of, antihypertensive medication.

94 Implementation was assessed through multiple methods: an online national survey of healthcare  
95 professionals, designed to describe general trends in guideline implementation; through case-notes  
96 review, a method that assessed the documentation of hypertension management occurrence in each  
97 woman's maternity record. Aspects of care that would not normally be documented or are more  
98 difficult to capture, such as in-consultation discussions and occurrence of shared decision-making  
99 were assessed through observations carried out by a midwife researcher (RW). The evaluation of the  
100 barriers and facilitators to implementation of NICE guidelines was assessed through qualitative  
101 interviews (with women and healthcare professionals) using the Consolidated Framework for  
102 Implementation Research (CFIR). The CFIR framework specifically evaluates five key domains that  
103 influence implementation; each domain has several subgroups to it, although only those relevant to  
104 this study have been identified. These include the intervention characteristics (the NICE guidelines),  
105 the outer context (the pregnant women), the inner context (NHS maternity services), individual  
106 context (the healthcare professionals) and the process of implementation (potential strategies).

107 Implementation of guidelines was assessed between November 2017 to December 2018 at three NHS  
108 Trusts with typical configurations of services for pregnant women with hypertension in the UK.  
109 Hospital Trust 1 was a tertiary city centre hospital with a newly formed specialist service that included  
110 consultant obstetricians, obstetric physicians and midwives who provided antenatal and intrapartum  
111 care to women with chronic hypertension within a specialist clinic; Hospital Trust 2 was a suburban  
112 district general hospital with a consultant-led antenatal clinic with antenatal midwives alongside  
113 providing care to women with a variety of pre-existing medical conditions; and Hospital Trust 3 had

1  
2  
3 114 both a tertiary and a semi-rural hospital with a joint obstetric and physician led clinic and usual  
4  
5 115 community-based midwifery care. The NICE hypertension in pregnancy guidelines (2010)<sup>6</sup> had been  
6  
7 116 adopted into local clinical guidelines at all three participating NHS Trusts for several years prior to the  
8  
9 117 assessment of implementation.

10  
11 118

### 12 13 119 **The National Survey**

14  
15 120 The implementation of evidence-based practices for the management of hypertension in pregnancy  
16  
17 121 was assessed through self-reporting using an online survey (surveygizmo/s3). We embedded  
18  
19 122 questions relating to the uptake of the NICE hypertension in pregnancy guidelines (2010)<sup>6</sup> using the  
20  
21 123 TIDieR framework.<sup>10</sup> The 12-item TIDieR checklist (brief name, why, what (materials), what  
22  
23 124 (procedure), who provided, how, where, when and how much, tailoring, modifications, how well  
24  
25 125 (planned), how well (actual)) is an extension of the CONSORT 2010 statement (item 5) and the SPIRIT  
26  
27 126 2013 statement (item 11). Although the emphasis of the checklist is on trials, the guidance was  
28  
29 127 adopted for this study as it is also intended to apply across all evaluative study designs.<sup>10</sup> National  
30  
31 128 organisations including British Maternal and Fetal Medicine Society (BMFMS), Macdonald UK  
32  
33 129 Obstetric Medicine Society (MOMS) and Royal College of Midwives (RCM) distributed the survey (April  
34  
35 130 to September 2018). A convenience sample of ninety-seven healthcare professionals from sixty-nine  
36  
37 131 NHS Trusts was obtained, including 53 consultant obstetricians (55%), 16 doctors in training (16%), 22  
38  
39 132 specialist midwives (23%) and six community midwives (6%) (full copy of survey questions shown in  
40  
41 133 supplementary material 1).

### 42 43 134 **Case-notes review**

44  
45 135 The implementation of NICE guidelines (2010)<sup>6</sup> was also assessed through review of 100 maternity  
46  
47 136 case-notes from the maternity electronic databases (32, 33, 35 per Trust). At Hospital Trust 1 this  
48  
49 137 consisted of all women who had given birth over the last three months of 2017, at the other two Trusts  
50  
51 138 this consisted of all women who had given birth in 2017 as they had approximately a quarter of the  
52  
53 139 number of women with chronic hypertension per annum compared to Hospital Trust 1. The inclusion  
54  
55 140 criteria consisted of women with chronic hypertension in pregnancy (defined as hypertension present  
56  
57 141 at the booking visit or before 20 weeks or already taking antihypertensive medication when referred  
58  
59 142 to maternity services)<sup>6</sup> who had been booked for care at one of the participating NHS Trusts. Women  
60  
143 who miscarried before the first obstetric appointment or who delivered at another hospital and or  
144 had incomplete health records were excluded from the study. A total of 55 sets of notes (29, 13, 13  
145 per Trust) met the inclusion and exclusion criteria. Data extraction based on the NICE hypertension in



1  
2  
3 146 pregnancy guidelines (2010)<sup>6</sup> was completed by two midwife researchers (RW, HW), and discrepancies  
4  
5 147 were resolved by discussion between the two researchers. Unclear or absent documentation was  
6  
7 148 recorded as missing data.

### 8 9 149 **Observations**

10  
11 150 Forty-two antenatal appointments involving 23 women with chronic hypertension and their respective  
12  
13 151 doctors (nine) and midwives (five) were observed by a midwife researcher (RW) at the three NHS  
14  
15 152 Trusts. Staff and women gave written informed consent. During observations, data about antenatal  
16  
17 153 care provision were recorded using the Calgary-Cambridge communication guide<sup>11</sup> chosen for its high  
18  
19 154 interrater reliability. For example, offering choice is a sub-section of shared decision-making and is  
20  
21 155 defined as “encourages patient to make choices and decisions to the level that they wish”. Attainment  
22  
23 156 of each section and sub-sections was established through the analysis of all 42 appointments using  
24  
25 157 descriptive statistics.

### 25 158 **Semi-structured interviews**

26  
27  
28 159 Views about barriers and facilitators to implementation of evidence-based guidelines were collected  
29  
30 160 from nine doctors and four midwives who were providing antenatal care for women with chronic  
31  
32 161 hypertension. The interviews were carried out by a midwife researcher (RW) following informed  
33  
34 162 consent and took place in privacy away from the clinical setting. The interviews were audio  
35  
36 163 transcribed, coded and thematically analysed using inductive reasoning. The codes generated formed  
37  
38 164 small themes which were organised into the CFIR evaluation guide<sup>12</sup>. As formal implementation  
39  
40 165 strategies had not been adopted beyond producing local guidance, interviewees were asked how they  
41  
42 166 thought they could improve the implementation in the future.

43  
44 167 Semi-structured interviews with 18 women recruited for antenatal observations were carried out in  
45  
46 168 the third trimester with informed consent. Women were asked about their antenatal care experiences  
47  
48 169 using an interview schedule which reflected the concepts from the International Consortium for  
49  
50 170 Health Outcome Measure (ICHOM) maternity standards sets<sup>13</sup> which include women’s overall  
51  
52 171 satisfaction with their care during pregnancy; satisfaction with information provision and their  
53  
54 172 relationships with their care providers. ICHOM standards are internationally recognised measures that  
55  
56 173 evaluate health outcomes that are important to patients (or pregnant women) and are used to  
57  
58 174 improve local healthcare and compare outcomes internationally. The closed survey questions were  
59  
60 175 turned into open ended questions to explore in-depth the quality of antenatal care provided. The  
176  
177 interviews were carried out by a midwife researcher (RW) and took place away from the clinical  
setting, with assurance that discussions would not be shared with healthcare professionals and that

1  
2  
3 178 participation or non-participation would not influence their care. The interviews were audio  
4  
5 179 transcribed, coded and thematically analysed using an inductive approach. Women's experiences  
6  
7 180 were analysed to improve understanding of their antenatal care needs, which included how their  
8  
9 181 hypertension was managed and the barriers and facilitators to the uptake of antihypertensives in  
10  
11 182 pregnancy.

### 12 183 **Data analysis**

14 184 The quantitative and qualitative data were initially analysed separately to generate independent  
15  
16 185 results. Descriptive analysis and summary statistics were used for the quantitative data. The semi-  
17  
18 186 structured interviews were thematically analysed using inductive techniques.<sup>14</sup> The mixed-methods  
19  
20 187 data were integrated and analysed using the CFIR evaluation framework.<sup>12</sup> The interpretation of the  
21  
22 188 intervention constructs (characteristics the inner and outer settings, the individual characteristics and  
23  
24 189 the implementation processes) was carried out initially by the midwife researcher (RW) who collected  
25  
26 190 the data, then with a second and third researcher (LC, JS) interpreting and agreeing final interpretation  
27  
28 191 of integrated data. Rigour was maintained through member reflection, attention to interview and  
29  
30 192 transcription quality and systematic analysis. Rigour was improved using multiple data sources and  
31  
32 193 analytic integration methods.

### 32 194 **Patient and Public Involvement**

34 195 A patient participant involvement (PPI) group consisting of women with experience of hypertension  
35  
36 196 in pregnancy and a maternity voices partnership group provided feedback on the design of the study,  
37  
38 197 research questions and outcome measures. Women in both groups wanted measures of information  
39  
40 198 provision and shared decision-making to be included in the evaluation of the national guidelines  
41  
42 199 implementation as both underpinned the prescribing practices being measured. The advisory groups  
43  
44 200 reviewed and approved the patient information leaflet and recommended women participants be  
45  
46 201 asked to provide their email addresses if they would like to receive a copy of the study results.

47 202

### 49 203 **RESULTS**

51 204 Antenatal care for women with chronic hypertension was provided by consultant obstetricians and  
52  
53 205 midwives at all three hospitals. In two of the hospitals, women with chronic hypertension had  
54  
55 206 designated midwives attached to the obstetric clinic. Approximately one-third of those recruited to  
56  
57 207 the study had a BMI over 30kg/m<sup>2</sup>, approximately one-third were over the age of 35 and  
58  
59 208 approximately one-third were of black minority ethnic backgrounds (shown in supplementary material  
60  
209 2). Hospital Trust 1 had four times the population of women with chronic hypertension compared to

210 the other two units, comprising a large black minority ethnic population (many with associated co-  
 211 morbidities). Perinatal outcomes from the fifty-five pregnancies showed that just under half of the  
 212 women (46%) developed severe hypertension and that one in six babies were admitted to the  
 213 neonatal unit (16%) (shown in supplementary material 3). At all three hospitals electronic coding of  
 214 women with chronic hypertension was inaccurate and episodes of severe hypertension were not  
 215 electronically recorded.

216

### 217 **Implementation of NICE hypertension in pregnancy 2010 guidelines and 2013 quality standards**

#### 218 **Setting a blood pressure target (quality statement 3)**

219 Both the survey and the case-notes review found the practice of setting an antenatal target blood  
 220 pressure to be variable (table 1). Just over half of women with chronic hypertension had a target blood  
 221 pressure documented in maternity notes (44% did not) yet substantial variation in practice between  
 222 hospitals existed. At Hospital Trust 1, 77% of women had a target blood pressure documented in  
 223 pregnancy compared to 23% and 38% at Hospital Trusts 2 and 3 respectively (supplementary material  
 224 4). The survey results support these findings as only a third of healthcare professional respondents  
 225 reported always setting a target. The practice of undocumented 'unshared' target setting was  
 226 identified through case-notes review, as for about three quarters of women whose blood pressure  
 227 rose above systolic 150mmHg and or diastolic 100mmHg action was taken by professionals to lower it  
 228 (24% did not) (table 1).

229 Table 1. Variation in implementation of evidence-based care evaluated through a national survey of  
 230 obstetricians and midwives and women's case-notes review at three representative NHS Trusts.

Care quality indicators	National Survey n=97 (%)	Case-notes review n=55 (%)
<b>Blood pressure target setting (QS3)</b>		
Target blood pressure 'always' set	36 (37.1)	
Target blood pressure 'almost always' set	36 (37.1)	
Target blood pressure 'never' set/ not documented	1 (1.0)	26 (43.6)
Target blood pressure set at first opportunity (whichever first: booking or commencement of AHT)	-	9 (18.0)
<b>Systolic target blood pressure</b>		
<160mmHg	8 (8.2)	
<150mmHg	89 (91.8)	2 (7.4)

≤140mmHg		27 (49.0)
<b>Diastolic target blood pressure</b>		
<100mmHg	94 (96.9)	2 (7.4)
≤90mmHg		27 (49.0)
Action taken to reduce blood pressure if above 150/100mmHg		13/17 (76.5)
<b>Safe antihypertensive prescribing (linked to QS1)</b>		
<b>ACEi and ARBs cessation</b>		
On ACEis or ARBs at antenatal booking appointment		4 (7.3)
Stopping ACEi or ARBs at first app if woman on either		
Always	57/86 (66.3)	-
Almost always	27/86 (31.4)	-
ACEis or ARBs stopped at 1 <sup>st</sup> obstetric appointment		4/4 (100.0)
<b>1<sup>st</sup> line AHT prescribing (non-exclusive)</b>		
Labetalol	85 (87.6)	28 (50.9)
Nifedipine	32 (33.0)	9 (16.4)
Methyldopa	29 (29.9)	8 (14.5)
Other e.g. amlodipine	2 (2.1)	4 (7.3)
None	-	6 (10.9)
<b>2<sup>nd</sup> line AHT prescribing (non-exclusive)</b>		
Nifedipine	79 (81.4)	9 (16.4)
Methyldopa	60 (61.9)	4 (7.3)
Labetalol	38 (39.2)	3 (5.4)
Amlodipine	37 (38.1)	2 (3.6)
Doxazosin	23 (23.7)	0 (0.0)
Other	5 (5.2)	0 (0.0)
None	-	37 (67.3)

231

232 Antihypertensive information provision, decision-making and prescribing (quality statement 1 and  
233 associated guidance)

234 Variation in practice regarding first- and second-line prescribing was identified through both the notes  
235 review and survey (table 1). In both, labetalol was the most commonly prescribed first line and  
236 nifedipine the most commonly used second line antihypertensive agent; nevertheless, in about half

237 of the cases reviewed labetalol was not the first line antihypertensive prescribed. Variation in  
238 prescribing practice existed when comparing the different Hospital Trusts, possibly reflecting women's  
239 ethnicity (supplementary material 4), clinician preference or women indicating their medication  
240 preferences through shared decision-making.

241 Information provision about antihypertensive prescribing

242 Across all three Trusts, 52% (41/79) of the time the correct type and amount of information was  
243 provided during the consultation (measured using the Calgary-Cambridge Guide). Visual techniques  
244 such as drawing or using charts to provide information occurred during consultation in 14% (3/21) of  
245 cases.

246 Achieving a shared understanding: incorporating the patient's perspective

247 Of the survey respondents 96.9% strongly agreed or agreed that involving women with chronic  
248 hypertension in management plans during pregnancy was important. However, when asked to give  
249 examples of how they involve women, only 4.3% identified discussing risks and benefits of treatment  
250 choice and 10% of respondents identified that women could be involved in plans about  
251 antihypertensive prescribing. The observations in the three hospital trusts found that 43% of the time  
252 (41/96) shared decision-making occurred and 19% of women (3/16) were offered a choice regarding  
253 their hypertensive plans (including choice of antihypertensive).

254

## 255 **Barriers and Facilitators to implementation (CFIR)**

256 Intervention characteristics (evidence and guideline)

257 All professionals interviewed, except one, saw value in having national guidance and understood that  
258 the local guidelines had been adapted from the 2010 national guideline<sup>6</sup>. Midwives relied more on  
259 local guidelines compared to obstetricians who referred more commonly to NICE guidelines. Some of  
260 the medical professionals had been involved in the development of a NICE guideline and were aware  
261 of the strengths and limitations of producing evidence-based recommendations. Professionals  
262 described difficulties in creating guidelines where there is a paucity of robust data as is sometimes the  
263 case in maternity care. Weak, out of date or absent evidence influenced doctors' decisions to  
264 implement guidelines. Those working in hospital Trust 1 described the weaknesses in the evidence  
265 underpinning the hypertension guidelines and described relying more on recent research compared  
266 to older national guidelines (table 2). The professionals identified that further research is necessary to  
267 support evidenced-based national guidelines (figure 1).

268 Table 2. Barriers to healthcare professional's implementation of hypertension in pregnancy guidelines

Barriers	Frequency	Items	Representative answer
<b>Intervention characteristics</b>			
Evidence strength, quality, source and adaptability	17	AHT prescribing; target setting;	<ul style="list-style-type: none"> <li>- "I think the fact that it says use labetalol first line is not what we do, I don't believe the evidence for labetalol being better than methyldopa is there."<sup>H</sup></li> <li>- "we can't get away from the fact that there aren't the source data there to make evidence-based guidelines."<sup>B</sup></li> <li>- So, I kept a close track of what was happening with the CHIPS study...I got a lot of information and knowledge from it."<sup>A</sup></li> </ul>
<b>Inner setting</b>			
Structural characteristics	43	Information provision; pathways and models; training and education; time	<ul style="list-style-type: none"> <li>- "I don't think we have a hand-out for, to give to hypertensive women about hypertension in pregnancy"<sup>L</sup></li> <li>- "we don't have a dedicated hypertension clinic here. So, most of these women will get seen in general antenatal clinic"<sup>I</sup></li> <li>- "you have people coming in three times weekly or something for their blood pressure, really? And other people who perhaps aren't being seen enough"<sup>I</sup></li> </ul>
Relative priority	26	Guidelines; self-study; beliefs; experience;	<ul style="list-style-type: none"> <li>- "Well actually I don't even know what the NICE guidelines are for hypertension, I'm not a... as my colleagues will tell you, not a huge fan of NICE, in many ways."<sup>L</sup></li> <li>- "I'm not just interested in guidelines; I'm interested in people's clinical experience...and that feel."<sup>C</sup></li> </ul>
Culture of decision-making	19	Patriarchy; shared decision-making; type of decision:	<ul style="list-style-type: none"> <li>- "Doctors... see it as patients not doing what they're told"<sup>A</sup></li> <li>- "I think that there's a balance to be had between involving women in the decisions, versus, them coming for expert recommendations"<sup>F</sup></li> </ul>

		emergency, urgent and non-urgent	- "If I have a clinical situation where I want to start antihypertensives because she's got a dangerously high blood pressure, then that discussion is inevitably truncated." <sup>B</sup>
<b>Individual characteristic</b>			
Beliefs about the intervention	35	AHT medication; AHT safety and side-effects; target setting	- "National guidelines do not sanction any particular antihypertensive, or that the, the drug licenses do not sanction any particular antihypertensive" <sup>B</sup> - "I think that might be something we're not quite as good at as we should be about defining a target for women....I suspect it's something we don't really document and clarify" <sup>H</sup>
Self-efficacy	17	Women's concordance/ desire for involvement/ first language	- "I think sometimes women don't necessarily want to make the decision" <sup>D</sup> - "There's a lot of 'mumsnet'....and I would say they take a, that advice just as seriously as they do the advice that we give them here." <sup>C</sup>
<b>Process of implementation</b>			
Engaging people and process of implementation	16	Using guidelines; updates, toolkits and information; shared decision-making	- "Awareness for people, if you're a busy jobbing healthcare practitioner, keeping up to date with each new area" <sup>H</sup> - "Practical toolkits to help with that consultation" <sup>B</sup> - Evidenced based information having it more readily available for patient" <sup>D</sup>
Opinion leaders; Champions;	5	Utilisation of opinion leaders/ champions in implementation	- "I find as a midwife sometimes you're a bit powerless, you know what the guidelines are, but depending on the doctor you're working with, tends to be the influencing factor on the decisions that are made... so it seems to be clinician-based guidelines sometimes, rather than the trust or national guidelines" <sup>D1</sup>

---

<sup>1</sup> Letters <sup>A-M</sup> represent the healthcare professionals interviewed

1  
2  
3 270 Inner setting (organisation structure and culture)  
4

5 271 The most frequently cited barriers to implementing high quality care for women with chronic  
6 272 hypertension were linked to the structure and organisation of antenatal care. Interviewees reported  
7 273 that a lack of consensus and guidance exists relating to models of care (such as whether specialist  
8 274 services would improve outcomes through better implementation) and pathways of care (such as  
9 275 frequency of blood pressure and medication reviews) (table 2). Evidence-based recommendations on  
10 276 models, and pathways of care, were identified as future facilitators to providing optimal antenatal  
11 277 care (figure 1). Whilst most healthcare professionals initially described the uptake of the guidelines as  
12 278 a clinical priority during the interviews, clinicians identified difficulty with keeping up with  
13 279 recommendations and using them alongside clinical judgement as barriers to implementation (table  
14 280 2).

15 281 Healthcare professionals considered the absence of written information a barrier to the uptake of  
16 282 antihypertensives in women with hypertension (table 2). A degree of paternalism exists in relation to  
17 283 involving women in decisions about their care. In principle, clinicians would like to involve women in  
18 284 decision-making, yet they gave many examples of situations where they would exercise restraint in  
19 285 doing so (table 2). Education and tools to support shared decision-making were identified as  
20 286 facilitators to optimizing antenatal care for women with hypertension (figure 1).

21  
22  
23 287

24 288 Characteristics of individuals (beliefs, knowledge and self-efficacy)  
25

26 289 Interview analysis identified doctors' and midwives' knowledge and beliefs as the second most  
27 290 frequently cited barrier and facilitator to the implementation of hypertension management guidelines  
28 291 (table 2). There existed confusion about whether the guidelines sanction one antihypertensive  
29 292 medication over another for the management of chronic hypertension and if so, what evidence was  
30 293 used to support this. Likewise, confusion about blood pressure targets was described frequently as  
31 294 outcomes from a recent randomised controlled trial superseded the pre-dated national guidelines  
32 295 (table 2). Whilst midwives experienced less self-efficacy than the doctors, doctors still experienced  
33 296 difficulties in this area. They occasionally described the women's beliefs and views as a barrier to  
34 297 implementing the recommendations (table 2).

35 298

36 299 Outer setting (women's views and experiences)  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



1  
2  
3 300 The quality of antenatal care experience was affected by women's internal conflict. There was also a  
4  
5 301 high degree of variance in medication adherence and concordance. Analysis identified that women  
6  
7 302 require quality information about antihypertensives and their side-effects, blood pressure ranges in  
8  
9 303 pregnancy, as well as support to actively participate in decision-making.

10  
11 304

12  
13 305 *Conflict*

14  
15 306 The majority (14 of 18) of women experienced internal conflict relating to the management of their  
16  
17 307 hypertension during pregnancy, defined as a state of uncertainty about the course of action to take  
18  
19 308 often in relation to making choices involving risk or uncertainty of outcomes (8) (figure 2a). The causes  
20  
21 309 of conflict were identified as a lack of information provision, poorly managed side-effects, women's  
22  
23 310 personal beliefs and factors relating to the healthcare professional (table 3).

24  
25 311  
26  
27  
28  
29  
30  
31  
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

312 Table 3. Barriers to women's uptake of hypertension in pregnancy guidelines

Women's sources of conflict	Frequency	Items	Representative answer
Information	30	Medication (choices, dose, effectiveness, safety, interactions); severity of HTN; effect of HTN on pregnancy	<ul style="list-style-type: none"> <li>- "[I wanted to know] how safe it is, about the dosage, about the, taking the med-, this medication, about the side-effects and so and so and so, if they think any other option for me, or if this medication is not working, what will be the other option for me"<sup>J</sup></li> <li>- "He was, you still need to carry on with your ramipril. I know I can't take it. It says in the leaflet not to take once you've hit 6 weeks, you need to stop. So, he was like oh, and then he phoned here, and he said oh well just take what you took before"<sup>H</sup></li> </ul>
Side-effects	21	Maternal side-effects; fetal side-effects; Interactions; allergies; choices	<ul style="list-style-type: none"> <li>- "They gave me first three, twice a day, then I was so giddy where I couldn't, if I take, I had to sleep all day for two days...Then I complained, but they still say to still take tablet."<sup>I</sup></li> <li>- "I'm on 18 pills a day, I do worry a bit about how they kind of potentially interact with each other and affect the baby"<sup>F</sup></li> </ul>
Beliefs	17	Hypertension status; understanding HTN; effectiveness AHT; safety AHT	<ul style="list-style-type: none"> <li>- "I felt like I had to justify why I wasn't taking my tablet, which to me didn't seem right, 'cause if it, if my blood pressure was normal, and I took a tablet, surely my blood pressure then would be low?"<sup>Q</sup></li> <li>- "cause everything I take my baby takes. So, it's like, what happens if my child comes out and then they're addicted to something, or they're high-strung because of something, or they're really moody and they're crying all the time because of the medicine I've had to take for the past 4 months"<sup>L</sup></li> </ul>

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  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

HCP factors	17	Continuity; listening to women; explaining regimes, mutual trust; communication	- "My issue has been where I've seen somebody who doesn't know the history, and typically they are a more junior doctor, and typically they are ticking a box and following a flow chart....the doctor said, you know, we're going to come to an agreement together but there was absolutely no discussion, she had no interest in what I had to say." <sup>K</sup>
External factors	7	Family and friends; internet; access to services	- "My dad had been on beta blockers, which is what labetalol is, when he was younger, and he found, he was very ill on them, so he gave me a really negative impression of them" <sup>P2</sup>

313

<sup>2</sup> Letters <sup>A-R</sup> represent the pregnant women interviewed

1  
2  
3 314 *Concordance*  
4

5 315 All women identified as concordant with healthcare professional management plans described being  
6  
7 316 adherent to their antihypertensives. Facilitators to concordance included trust in the healthcare  
8  
9 317 professional, mediated through information about safety of antihypertensives in pregnancy,  
10  
11 318 knowledge about target blood pressure in pregnancy hypertension, acknowledgement of medication  
12  
13 319 side-effects and a positive interaction with the healthcare professional (including communication and  
14  
15 320 approach to decision-making) (figure 2b).

16 321 *Adherence*  
17

18 322 Internal conflict was an important determinant of non-adherence (figure 2a) as only the women who  
19  
20 323 expressed conflict reported non-adherence to antihypertensive medication. Around half (8 of 18) the  
21  
22 324 women interviewed described non-adherence to prescribed antihypertensives at some point during  
23  
24 325 pregnancy with three women non-adherent at the time of interview (third trimester). However, nine  
25  
26 326 of 14 women describing internal conflict were adherent at the time of interview which was mediated  
27  
28 327 by the 'responsibility of motherhood' rather than concordance with the hypertension management  
29  
30 328 plan (figure 2b).

31 329

32  
33 330 Process of implementation (implementation strategies)  
34

35  
36 331 All three Trusts had a consultant obstetrician who led the care of women with chronic hypertension  
37  
38 332 and could be considered the opinion leader. Two of three Trusts had a named midwife or team of  
39  
40 333 midwives who specialised in the care of these women and were potential champions. However,  
41  
42 334 influencers and champions were not always utilised to support guideline implementation. Further, as  
43  
44 335 implementation of the guidelines had not been audited in any of the Trusts, although some outcome  
45  
46 336 data was routinely collected and analysed, opportunities to address unwanted variance were being  
47  
48 337 missed. These findings are supported by the national survey which found only a quarter of the Trusts  
49  
50 338 collected and analysed the outcomes of women with chronic hypertension in pregnancy.

51 339  
52  
53  
54  
55  
56  
57  
58  
59  
60

## 340 DISCUSSION

341 Women in this study (14/18) reported conflict relating to the uptake of prescribed antihypertensives  
342 in pregnancy and in many cases (8/14) internal conflict resulted in non-adherence. The most  
343 commonly cited reasons for conflict were lack of information provision, the side-effects experienced  
344 from the medication, beliefs about safety of medication and uncertainty about normal blood pressure  
345 ranges in pregnancy. Adherence to antihypertensives in conflicted pregnant women was mediated  
346 through a responsibility to motherhood rather than through a trusting partnership with healthcare  
347 professionals (supported by information provision, management of side-effects and relational factors)  
348 as found in concordant adherent women. Despite this, our findings demonstrated that optimal  
349 information provision about antihypertensives and shared decision-making occurred infrequently  
350 during antenatal consultations. Our findings also illustrated that the implementation of blood pressure  
351 target setting was sub-optimal as a result of 'unshared' or undocumented target setting and in some  
352 cases an absence of target setting.

353 A major strength of the study is the use of multi-methodological approaches and an implementation  
354 framework in order to improve reliability, validity and generalisability. However, the study is limited  
355 by the population size for each of the methods and the limited statistical power for further analysis of  
356 the quantitative results. Results from the national survey may overstate compliance with national  
357 guidance. The survey was sent out to healthcare professionals from professional organisations;  
358 respondents were therefore self-selecting and may represent a relatively interested group of  
359 healthcare professionals. The non-response rate is also unknown. The structured observations were  
360 carried out using a validated tool with high interrater reliability.<sup>11</sup> However, the observations were  
361 carried out by one midwife researcher which may affect the validity of the findings. Finally, the  
362 purposive sampling of healthcare professionals providing routine antenatal care for women with  
363 chronic hypertension resulted in a focus on lead carers (consultant obstetricians, obstetric medicine  
364 specialists and named midwives) being interviewed, rather than doctors in training and midwives in  
365 acute areas such as the maternity assessment unit.

366 The emergence of implementation science in recent years has identified that a gap between research  
367 findings and clinical practice exists, and that clinical guideline production does not ensure evidence-  
368 based practices are routinely adopted.<sup>15</sup> A recent study in British Columbia evaluated the  
369 implementation of recently published pregnancy hypertension guidelines and its associated effect on  
370 maternal and perinatal outcomes.<sup>16</sup> Following guideline dissemination the study reported a fall of  
371 about a third in combined adverse maternal health outcomes (3.1% to 1.9%) but did not report a  
372 significant reduction in adverse perinatal outcomes.<sup>16</sup> However, the wanted and unwanted variance

1  
2  
3 373 in guidance uptake was not reported and the underlying mechanisms that influenced outcomes is not  
4  
5 374 described. Our study uses an implementation framework by which variance in the implementation of  
6  
7 375 existing guidelines could be described and mechanisms that support and hinder their uptake can be  
8  
9 376 analysed, uniquely identifying strategies to improve the uptake of guidance and reduce maternal and  
10  
11 377 fetal morbidity. Critically, although the NICE hypertension in pregnancy guidelines<sup>6</sup> have been recently  
12  
13 378 updated, the core hypertension management recommendations remain unchanged, as do the quality  
14  
15 379 statements. Therefore, the findings of this study remain important and relevant to those wanting to  
16  
17 380 improve implementation.

17 381 The study also adds to the small body of antihypertensive adherence in pregnancy research that has  
18  
19 382 found antihypertensive side-effects are a determinant of non-adherence. One recent randomised  
20  
21 383 controlled trial identified 11% of those included in randomisation discontinued the antihypertensive  
22  
23 384 due to side-effects.<sup>17</sup> Our study found about 40% of all women did not adhere to their prescribed  
24  
25 385 antihypertensives at some point during pregnancy. This number compared more similarly to an  
26  
27 386 internet-based study of 210 pregnant women undertaken in Europe, America and Australia which  
28  
29 387 identified a 32.9% non-adherence rate in women taking cardiovascular medications in pregnancy.<sup>18</sup>  
30  
31 388 These findings are supported by similar smaller questionnaire-based studies of pregnant women's  
32  
33 389 medication adherence.<sup>19 20</sup> Our study may have identified higher rates of non-adherence due to the  
34  
35 390 nature of qualitative interviewing that explore in-depth women's experiences and therefore unpick  
36  
37 391 medication behaviours in a way that quantitative studies cannot.

36 392 Women's adherence to antihypertensives in pregnancy was found to be sub-optimal, and strategies  
37  
38 393 to improve adherence are likely to reduce incidences of severe hypertension and prevent associated  
39  
40 394 morbidity (and mortality).<sup>21</sup> These include improved information provision about anti-hypertensives  
41  
42 395 and blood pressure targets as well as embedding shared decision-making into practice. Improvements  
43  
44 396 in target blood pressure setting practices overall are also likely to reduce incidences of severe  
45  
46 397 hypertension and prevent associated morbidity (and mortality).<sup>3 5</sup>

47 398 This study adds to the body of research that already exists outside of pregnancy which demonstrates  
48  
49 399 that implementation of guidelines is not optimally achieved through the process of diffusion.<sup>15</sup>  
50  
51 400 Although there was some evidence that some aspects of implementation were improved by having a  
52  
53 401 specialist service for hypertension, this is likely to be most easily justified in areas where there is a  
54  
55 402 high prevalence of chronic hypertension. Therefore, strategies to improve implementation in wider  
56  
57 403 settings are required. Professionals require guideline updates, implementation toolkits (to improve  
58  
59 404 target blood pressure setting practices, standardised information about antihypertensives and in  
60  
405 consultation aids to support decision-making) but also need to buy into the evidence that underpins

1  
2  
3 406 the guidance. Maternal and perinatal outcomes, which includes episodes of severe hypertension,  
4 407 should be collected annually and used to support informed discussions about optimising antenatal  
5 408 care for this group of women.

8  
9 409 Further research into the effectiveness and long-term safety of common antihypertensives in  
10 410 pregnancy to support evidenced-based guidelines is required. Future research may also wish to  
11 411 evaluate strategies to reduce women's conflict regarding their antihypertensive use in pregnancy and  
12 412 establish the effect of interventions on maternal concordance and health outcomes. However,  
13 413 without further evidence relating to the safety and effectiveness of common antihypertensives it is  
14 414 unclear if further reductions in maternal and fetal morbidity can be achieved through prescribing  
15 415 practices. Future research should also focus on active implementation of blood pressure target setting  
16 416 and pathways for those with outside of target blood pressure readings. This is likely to reduce  
17 417 morbidity as target blood pressure setting in pregnancy has been shown to reduce incidences of  
18 418 severe hypertension.<sup>3 5</sup> Policymakers may also wish to consider further studies that identify effective  
19 419 models and pathways of care for reducing adverse perinatal outcomes within the context of pregnancy  
20 420 hypertension.

21 421

## 22 422 **CONCLUSION**

23 423 Maternal and neonatal morbidity resulting from severe hypertension in pregnancy is prevalent.<sup>1 4 5</sup>  
24 424 This evaluation of the implementation of the NICE hypertension in pregnancy guidelines (2010)<sup>6</sup>  
25 425 addresses strategies to reduce the number of episodes of severe hypertension and has identified sub-  
26 426 optimal target setting practices, poor information provision for pregnant women and variance in  
27 427 prescribing practices. Women's non-adherence to antihypertensives is higher than previously  
28 428 reported and this is likely to be contributing to adverse perinatal outcomes. Analysis of the domains  
29 429 that influence implementation of the guidelines have identified that education and decision-making  
30 430 strategies are needed to address both clinician and women's behaviour. Further research into the  
31 431 effectiveness and long-term safety of common antihypertensives is also required.

32 432

- 1  
2  
3 433 a. Contributorship statement – RW, LC and JS conceived of the study, the manuscript and analyses,  
4 434 with contributions from LW, JG, HB and HW. RW was responsible for data management and data  
5 435 analysis. All authors reviewed, critically revised and approved the manuscript.  
6  
7  
8  
9 436 b. Competing interests – None declared  
10  
11 437 c. Funding – This work was supported National Institute for Health Research (Research Professorship  
12 438 RP-2014-05-019) and by the National Institute for Health Research (NIHR) Collaboration for Leadership  
13 439 in Applied Health Research and Care South London (NIHR CLAHRC South London) at King’s College  
14 440 Hospital NHS Foundation Trust.  
15  
16  
17  
18 441 d. Data sharing statement - All data relevant to the study are included in the article.  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
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



## 442 References

- 443 1. Bramham K, Parnell B, Nelson-Piercy C, et al. Chronic hypertension and pregnancy outcomes:  
444 systematic review and meta-analysis. *BMJ : British Medical Journal* 2014;348:g2301. doi:  
445 10.1136/bmj.g2301
- 446 2. Knight M NM, Tuffnell D, Kenyon S, Shakespeare J, Brocklehurst P, Kurinczuk JJ (Eds.) on behalf of  
447 MBRRACE-UK. . Saving Lives, Improving Mothers' Care – Surveillance of maternal deaths in  
448 the UK 2012–14 and lessons learned to inform maternity care from the UK and Ireland  
449 Confidential Enquiries into Maternal Deaths and Morbidity 2009-14, 2016.
- 450 3. Magee LA, von Dadelszen P, Rey E, et al. Less-tight versus tight control of hypertension in  
451 pregnancy. *N Engl J Med* 2015;372(5):407-17. doi: 10.1056/NEJMoa1404595 [published  
452 Online First: 2015/01/30]
- 453 4. Flenady V, Koopmans L, Middleton P, et al. Major risk factors for stillbirth in high-income  
454 countries: a systematic review and meta-analysis. *Lancet* 2011;377(9774):1331-40. doi:  
455 10.1016/S0140-6736(10)62233-7 [published Online First: 2011/04/19]
- 456 5. Magee LA, von Dadelszen P, Singer J, et al. The CHIPS Randomized Controlled Trial (Control of  
457 Hypertension in Pregnancy Study): Is Severe Hypertension Just an Elevated Blood Pressure?  
458 *Hypertension* 2016;68(5):1153-59. doi: 10.1161/HYPERTENSIONAHA.116.07862 [published  
459 Online First: 2016/09/14]
- 460 6. (NICE) NIfHCE. Hypertension in pregnancy CG107 2010 [Available from:  
461 <https://www.nice.org.uk/guidance/cg107>
- 462 7. (NICE) NIfHCE. Hypertension in pregnancy. Quality Standard (QS35), 2013.
- 463 8. (NICE) NIfHCE. Patient Experience in Adult NHS Services: Improving the Experience of Care for  
464 People Using Adult NHS Services: Patient Experience in Generic Terms. London 2012.
- 465 9. Kirk MA, Kelley C, Yankey N, et al. A systematic review of the use of the Consolidated Framework  
466 for Implementation Research. *Implementation Science* 2016;11(1):72. doi: 10.1186/s13012-  
467 016-0437-z
- 468 10. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for  
469 intervention description and replication (TIDieR) checklist and guide. *BMJ : British Medical  
470 Journal* 2014;348:g1687. doi: 10.1136/bmj.g1687
- 471 11. Burt J, Abel G, Elmore N, et al. Assessing communication quality of consultations in primary care:  
472 initial reliability of the Global Consultation Rating Scale, based on the Calgary-Cambridge  
473 Guide to the Medical Interview. *BMJ Open* 2014;4(3):e004339. doi: 10.1136/bmjopen-2013-  
474 004339

- 1  
2  
3 475 12. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research  
4  
5 476 findings into practice: a consolidated framework for advancing implementation science.  
6  
7 477 *Implementation science : IS* 2009;4:50. doi: 10.1186/1748-5908-4-50 [published Online First:  
8  
9 478 2009/08/12]
- 10 479 13. International consortium for health outcome measurements i. Pregnancy and childbirth standard  
11  
12 480 set. 2016
- 13 481 14. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *BMJ*  
14  
15 482 2000;320(7227):114-16. doi: 10.1136/bmj.320.7227.114
- 16 483 15. Rangachari P, Rissing P, Rethemeyer K. Awareness of evidence-based practices alone does not  
17  
18 484 translate to implementation: insights from implementation research. *Quality management*  
19  
20 485 *in health care* 2013;22(2):117-25. doi: 10.1097/QMH.0b013e31828bc21d [published Online  
21  
22 486 First: 2013/04/02]
- 23 487 16. von Dadelszen P, Sawchuck D, McMaster R, et al. The Active Implementation of Pregnancy  
24  
25 488 Hypertension Guidelines in British Columbia. *Obstetrics & Gynecology* 2010;116(3):659-66.  
26  
27 489 doi: 10.1097/AOG.0b013e3181eb669d
- 28 490 17. Webster Louise M, Myers Jenny E, Nelson-Piercy C, et al. Labetalol Versus Nifedipine as  
29  
30 491 Antihypertensive Treatment for Chronic Hypertension in Pregnancy. *Hypertension*  
31  
32 492 2017;70(5):915-22. doi: 10.1161/HYPERTENSIONAHA.117.09972
- 33 493 18. Lupattelli A, Spigset O, Nordeng H. Adherence to medication for chronic disorders during  
34  
35 494 pregnancy: results from a multinational study. *International Journal of Clinical Pharmacy*  
36  
37 495 2014;36(1):145-53. doi: 10.1007/s11096-013-9864-y
- 38 496 19. Matsui D. Adherence with Drug Therapy in Pregnancy. *Obstetrics and Gynecology International*  
39  
40 497 2012;2012:5. doi: 10.1155/2012/796590
- 41  
42 498 20. Abheiden CNH, van Reuler AVR, Fuijkschot WW, et al. Aspirin adherence during high-risk  
43  
44 499 pregnancies, a questionnaire study. *Pregnancy Hypertension: An International Journal of*  
45  
46 500 *Women's Cardiovascular Health* 2016;6(4):350-55. doi:  
47 501 <https://doi.org/10.1016/j.preghy.2016.08.232>
- 48 502 21. Abalos E, Duley L, Steyn DW, et al. Antihypertensive drug therapy for mild to moderate  
49  
50 503 hypertension during pregnancy. *Cochrane Database Syst Rev* 2018;10:CD002252. doi:  
51  
52 504 10.1002/14651858.CD002252.pub4 [published Online First: 2018/10/03]
- 53  
54  
55  
56  
57  
58  
59  
60

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  
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

505 Figure 1. Interpretation of integrated analysis: a strategy for improved implementation of evidence-  
506 based hypertension in pregnancy management  
507 Figure 2a. Women’s adherence and concordance with prescribed antihypertensives. 2b. Facilitators of  
508 women’s adherence and of concordance.

For peer review only

Individual setting

Information and education (doctors and midwives)

Offering women informed choices about AHTs based on evidence, side effects and medicine history

Shared decision-making

Share target blood pressure (and above target pathways) with all HCPs and women

Sub-optimal antenatal hypertension management

Optimised antenatal hypertension management



Access to early pregnancy care

Multi-disciplined care

Specialist midwives

Inner setting

Defined pathways and schedule of care

Evidence-based guidelines for CHT in pregnancy

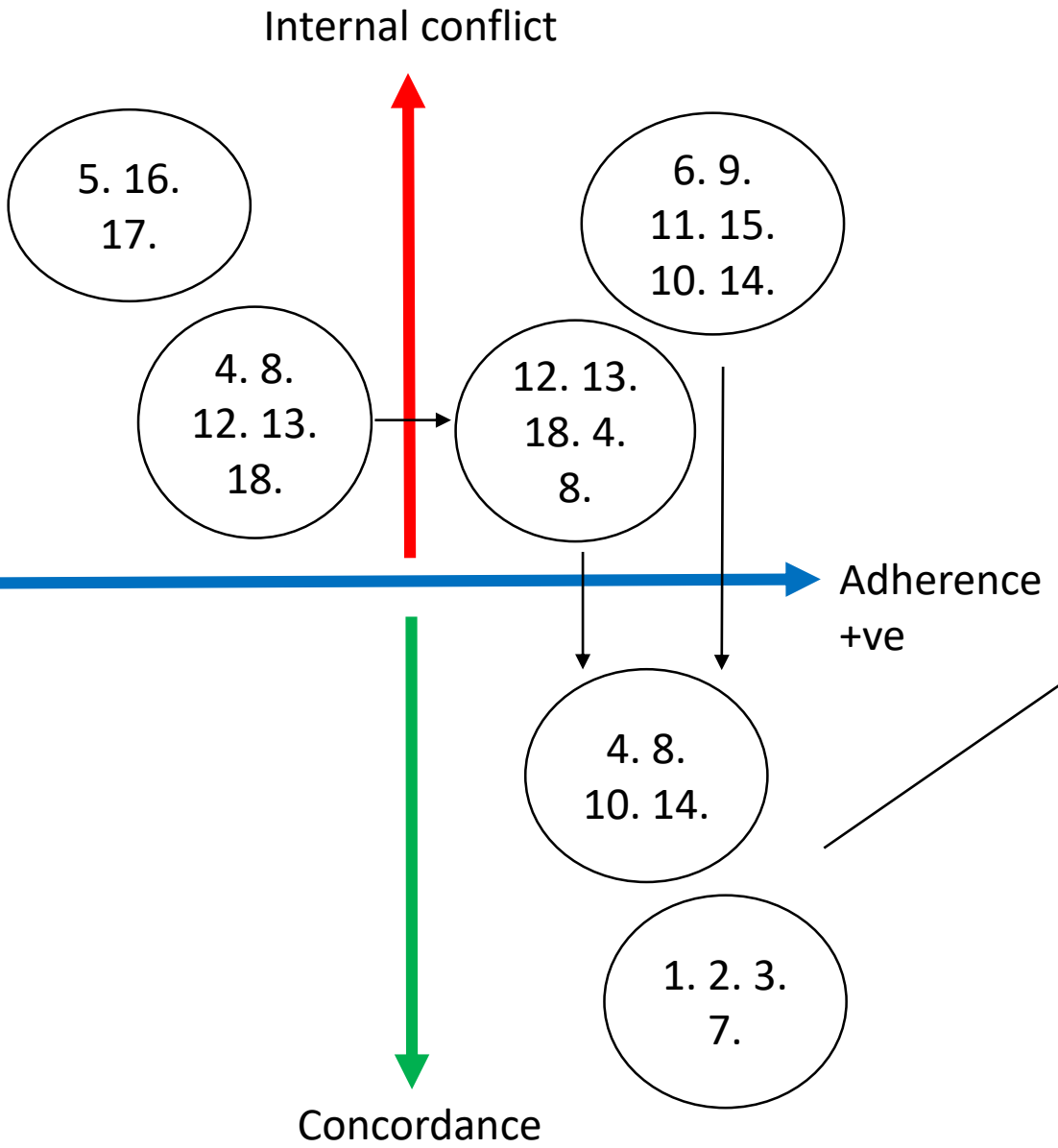
Outer setting

Research in the management of CHT in pregnancy

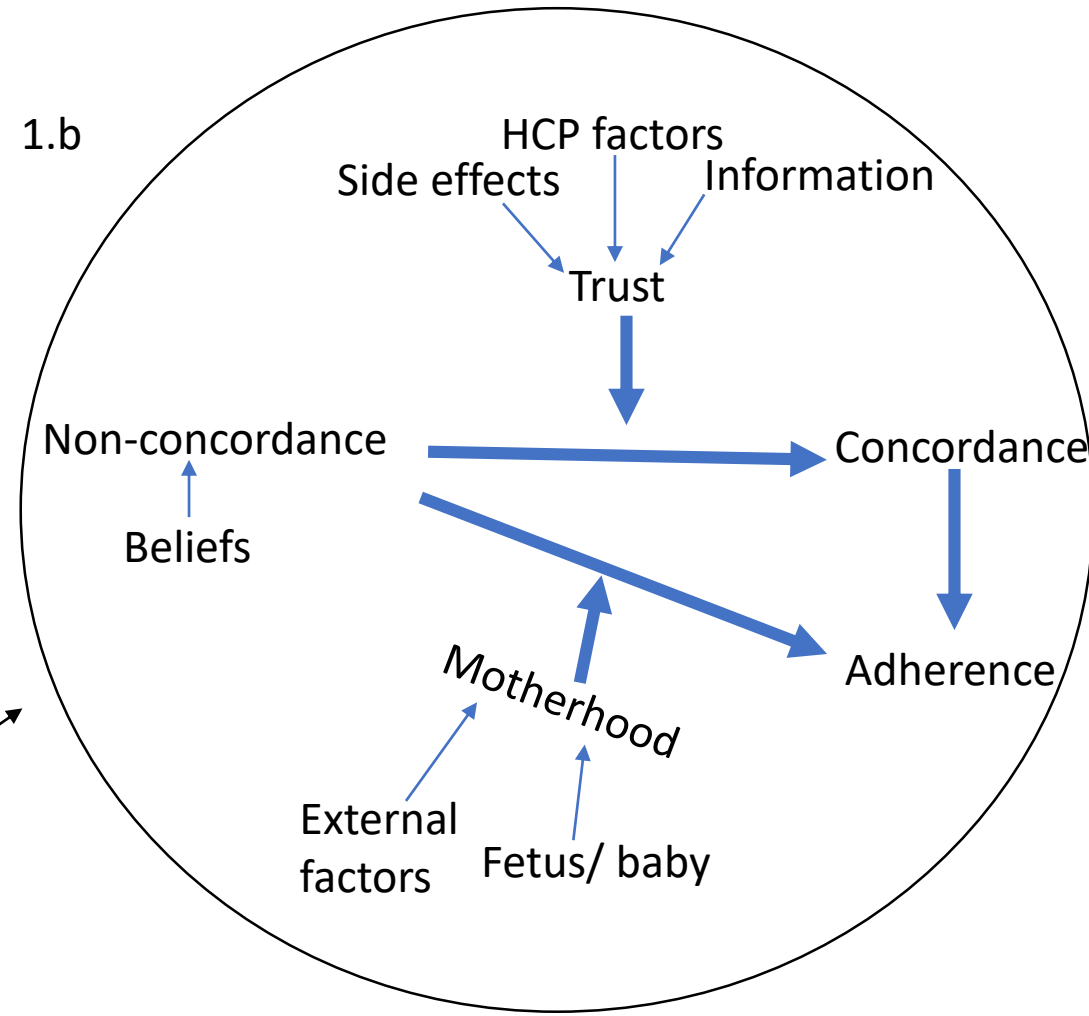
1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41

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  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41

1.a



1.b



## Supplementary file 1

## Chronic hypertension in pregnancy – healthcare professional survey

Respondents	Number (97)	Percentage %
Obstetrician	69	71.1
Of which are consultants	53	55
Midwife	28	28.9
Of which are specialist/ senior midwife	22	22.7
NHS hospital trusts represented (including England, Ireland, Scotland and Wales)	69	-

Question 1: If you see a pregnant woman with chronic hypertension who is currently taking either ACEIs or ARBs (e.g. at the beginning of pregnancy), how often would you ask her to stop taking them?

Response	Number (97)	Percentage (%)
Always	57	57.8
Almost always	27	27.8
About two thirds of the time	1	1
About half of the time	4	4.1
About a third of the time	0	0
Very rarely	1	1
Never	3	3.1
Missing	4	4.1

Question 2: What do you usually use as your first line anti-hypertensive treatment(s) for women with chronic hypertension in pregnancy?

Anti-hypertensive	Number (97)	Percentage (%)
Labetalol	85	87.6
Methyldopa	29	29.9
Nifedipine	32	33.0
Amlodipine	2	2.1

Question 3: What additional anti-hypertensive medication do you use for treating women with chronic hypertension in pregnancy?

Anti-hypertensive	Number (97)	Percentage (%)
Amlodipine	37	38.1
Atenolol	2	2.1
Doxazosin	23	23.7
Enalapril	1	1.0
Hydralazine (oral)	2	2.1
Labetalol	38	39.2
Methyldopa	60	61.9
Metoprolol	1	1.0
Nifedipine	79	81.4

Question 4: How frequently do you set a blood pressure target for women with chronic hypertension in pregnancy who need anti-hypertensive treatment (assuming no other co-morbidity) (mmHg)?

Answer	Number (97)	Percentage %
Always	36	37.1
Almost always	36	37.1
About two thirds of the time	8	8.2
About half of the time	3	3.1
About a third of the time	4	4.1
Very rarely	3	3.1
Never	1	1.0
Other	6	6.2
In the guidelines but compliance unknown	2	
Frequency not described	4	

Question 5: What blood pressure target do you usually set for pregnant women with chronic hypertension (assuming no other co-morbidity) (mmHg)?

Systolic	Number (97)	Percentage %	Median (IQR1-IQR3)
120	2	2.1	
125	0	0.0	
130	6	6.2	
135	2	2.1	
140	33	34.0	
145	0	0.0	
150	40	41.2	
155	1	1.0	
160	8	8.2	
Missing	4	4.1	
Median			150 (140-150)

Diastolic	Number (97)	Percentage %	Median (IQR1-IQR3)
80	9	9.3	
85	7	7.2	
90	37	38.1	
95	8	8.2	
100	27	27.8	
110	3	3.1	
Missing	5	5.2	
Median			90 (90-100)

Question 6: How often do you prescribe Aspirin for women with chronic hypertension in pregnancy?

Answer	Number (97)	Percentage %
Always	53	54.6
Almost always	36	37.1
About two thirds of the time	5	5.2
About half of the time	2	2.1
Very rarely	1	1.0

Question 7: At what gestation do these women usually receive their first Aspirin prescription?

Answer	Number (97)	Percentage %
Before 12 weeks	41	42.3
12-15+6 weeks	52	53.6
16-19+6 weeks	1	1.0
Missing answer	3	3.1

Question 8: For a woman with uncomplicated chronic hypertension in pregnancy (i.e. no additional risk factors), how many routine fetal growth do they receive (excluding nuchal and anomaly scans)?

Additional scans	Number (97)	Percentage %	Median (IQR1-IQR3)
None	4	4.1	
1	12	12.4	
2	23	23.7	
3	37	38.1	
4	21	21.6	
>4	1	1.0	
			3 (2-3)

Question 9: When do you usually plan birth for women with chronic hypertension whose blood pressure is controlled below 160/110?

Gestation	Number (97)	Percentage (%)	Median (IQR1-IQR3)
Before 34 weeks	3	3.1	
34-34+6 weeks	2	2.1	
35-35+6 weeks	2	2.1	
36-36+6 weeks	4	4.1	
37-37+6 weeks	27	27.8	
38-38+6 weeks	36	37.1	
39-39+6 weeks	41	42.3	
40-41 weeks	28	28.9	
Await spontaneous labour	5	5.2	
Other – individualised	4	4.2	
			38.5 (37-39)



Question 10: Involving pregnant women who have chronic hypertension in their pregnancy and birth planning is an important part of the consultation?

Sentiment	Number (97)	Percentage (%)
Agree Strongly	79	81.4
Agree	15	15.5
Slightly Agree	2	2.1
Slightly disagree	0	0.0
Disagree	0	0.0
Disagree Strongly	1	1.0

Question 11: If you wish, can you give an example of how you enable women to be actively involved in their care?

Themes	Number (47)	Percentage %
Total responses	47	
SDM in the following areas		
• Home BP	10	21
• Monitoring BP	6	12.8
• Anti-hypertensives	5	10.6
• Planning birth (IOL)	17	36
• Organisation of care	4	8.5
Discussing risks and benefits	2	4.3
How to identify pre-eclampsia	2	4.3

Question 12: In your maternity unit what term/s best describes the antenatal care provided to most women with chronic hypertension?

Care provision	Number (97)	Percentage %
Named consultant-led general antenatal clinic (maternal medicine clinic)	63 (7)	64.9 (7.2)
Consultant-led specialist hypertension in pregnancy clinic	25	25.8
Multi-disciplinary clinic with additional medical professional	20	20.6
Consultant obstetrician and midwife antenatal clinic	15	15.5
Shared-care GP/ obstetrician/ midwife	7	7.2
Specialist midwifery care (e.g. medical conditions team)	6	6.2
Hospital midwifery care	1	1.0
Community based midwifery care	4	4.1
Day assessment unit	2	2.1

1  
2  
3 Question 13: In your maternity unit when do the pregnant women with chronic hypertension usually  
4 first get seen by an obstetrician?  
5

<b>Gestation</b>	<b>Number (97)</b>	<b>Percentage %</b>
Before 12 weeks	24	24.7
12-15+6 weeks	63	64.9
16-27+6 weeks	9	9.3
Missing data	1	1.0

17  
18 Question 14: Do you or someone in your unit specifically collect and analyse the outcomes of  
19 women with chronic hypertension in pregnancy annually?  
20

<b>Response</b>	<b>Number (97)</b>	<b>Percentage (%)</b>
Yes	24	24.7
No	67	69.0
Unsure	4	4.1
Some aspects	2	2.0

## Supplementary file 2

## Demographics of women

Women demographics	Observed n=28 (%)	Interviewed n=18 (%)	Case notes n=55 (%)
<b>Ethnicity</b>			
White British	9 (32.0)	7 (39.0)	15 (27.3)
White Other	6 (21.0)	4 (22.0)	8 (14.5)
Black	9 (32.0)	5 (28.0)	18 (32.7)
Asian	2 (7.0)	1 (5.5)	8 (14.5)
Any other	2 (7.0)	1 (5.5)	6 (10.9)
<b>Parity at booking</b>			
0	9 (32.0)	7 (39.0)	15 (27.3)
1	11 (39.0)	7 (39.0)	21 (38.2)
2	7 (25.0)	4 (22.0)	10 (18.2)
3	0 (0.0)	0 (0.0)	6 (10.9)
4	0 (0.0)	0 (0.0)	2 (3.6)
5	1 (4.0)	0 (0.0)	1 (1.8)
<b>Age</b>			
<20	0 (0.0)	0 (0.0)	0 (0.0)
20-34	17 (61.0)	11 (61.0)	23 (41.8)
35-39	7 (25.0)	5 (28.0)	21 (38.9)
40-44	4 (14.0)	2 (11.0)	11 (20.4)
45-49	0 (0.0)	0 (0.0)	0 (0.0)
<b>BMI</b>			
<18.5	0 (0.0)	0 (0.0)	1/52 (1.9)
18.5-24.9	7 (25)	6 (33.3)	13/52 (25.0)
25-29.9	10 (36)	6 (33.3)	13/52 (25.0)
30-34.9	9 (32)	5 (28.0)	11/52 (21.2)
35-39.0	2 (7)	1 (5.5)	6/52 (11.5)
>40.0	0 (0)	0 (0.0)	8/52 (7.7)

## Supplementary file 3

## Pregnancy and birth outcomes – Case notes review

<b>Outcomes</b>	<b>Case notes review Nominator/denominator (%)</b>
Women with episode of severe hypertension	25/55 (45.5)
1 <sup>st</sup> trimester episode	2/40 (5.0)
2 <sup>nd</sup> trimester episode	13/40 (32.5)
3 <sup>rd</sup> trimester episode	25/40 (62.5)
Birth weight - median (IQR1 – IQR3)	2927.5 (2592.5 - 3200)
Admission to NNU	9/55 (16.4)

## Supplementary file 4

## Target blood pressure setting and prescribing practices per Trust

	<b>Hospital Trust 1 n=29 (%)</b>	<b>Hospital Trust 2 n=13 (%)</b>	<b>Hospital Trust 3 n=13 (%)</b>
<b>Target BP documented &lt;150/100mmHg</b>	20/26 (77.0)	3/13 (23.0)	5 (38.0)
<b>Labetalol</b>	12/26 (46.0)	7/12 (58.3)	9/11 (82.0)
<b>Nifedipine</b>	9/26 (34.5)	0/12 (0.0)	0/11 (0.0)
<b>Methyldopa</b>	3/26 (11.5)	4/12 (33.3)	1/11 (9.0)
<b>Other</b>	2/26 (8.0)	1/12 (8.3)	1/11 (9.0)

For peer review only

# The quality of mixed methods studies in health services research

Alicia O’Cathain, Elizabeth Murphy<sup>1</sup>, Jon Nicholl

Medical Care Research Unit, School of Health and Related Research, University of Sheffield, Sheffield; <sup>1</sup>School of Sociology and Social Policy, University of Nottingham, Nottingham, UK

**Objectives:** To assess the quality of mixed methods studies in health services research (HSR).

**Methods:** We identified 118 mixed methods studies funded by the Department of Health in England between 1994 and 2004, and obtained proposals and/or final reports for 75. We applied a set of quality questions to both the proposal and report of each study, addressing the success of the study, the mixed methods design, the individual qualitative and quantitative components, the integration between methods and the inferences drawn from completed studies.

**Results:** Most studies were completed successfully. Researchers mainly ignored the mixed methods design and described only the separate components of a study. There was a lack of justification for, and transparency of, the mixed methods design in both proposals and reports, and this had implications for making judgements about the quality of individual components in the context of the design used. There was also a lack of transparency of the individual methods in terms of clear exposition of data collection and analysis, and this was more a problem for the qualitative than the quantitative component: 42% (19/45) versus 18% (8/45) of proposals ( $p = 0.011$ ). Judgements about integration could rarely be made due to the absence of an attempt at integration of data and findings from different components within a study.

**Conclusions:** The HSR community could improve mixed methods studies by giving more consideration to describing and justifying the design, being transparent about the qualitative component, and attempting to integrate data and findings from the individual components.

*Journal of Health Services Research & Policy* Vol 13 No 2, 2008: 92–98

© The Royal Society of Medicine Press Ltd 2008

## Introduction

Mixed methods studies are common in health services research (HSR).<sup>1</sup> They consist of two separate components of data collection and analysis within a single study: at least one quantitative method with structured data collection and statistical analysis, and at least one qualitative method with less structured data collection and thematic analysis.<sup>2</sup> Commissioners and consumers of research, as well as researchers themselves, need to judge whether a mixed methods study has been undertaken well or poorly, assessing whether it is good mixed methods research as well as good research. The quality of mixed methods research has been considered explicitly in health, educational and social research,<sup>3–8</sup> and implicitly when researchers have discussed the challenges of designing and implementing these studies.<sup>9,10</sup> However, the issue has received little

consideration overall, with a recent search for quality criteria for mixed methods research concluding that there were none available,<sup>7</sup> even though attempts have been made to develop them.<sup>3</sup> Given that there are no agreed criteria for assessing the quality of these studies,<sup>8</sup> and that researchers are still debating the meaning of quality for mixed methods research,<sup>6</sup> it is premature to attempt to develop definitive criteria. Instead, it seems sensible to follow an approach taken by researchers considering quality in the context of synthesizing qualitative and quantitative evidence<sup>11</sup> and devise a set of questions which could be applied to mixed methods primary research to facilitate judgements about quality. We devised a set of ‘quality questions’ and applied them to proposals and reports of mixed methods studies to assess the quality of mixed methods studies in HSR.

Alicia O’Cathain PhD, MRC Fellow, Jon Nicholl MSc, Professor, Medical Care Research Unit, School of Health and Related Research, University of Sheffield, Regent Street, Sheffield S1 4DA, UK; Elizabeth Murphy PhD, Professor, School of Sociology and Social Policy, University of Nottingham, Nottingham, UK.

Correspondence to: a.ocathain@sheffield.ac.uk

## Methods

This research was part of a wider study exploring the use of mixed methods research in HSR. The wider study consisted of a quantitative documentary analysis of 75 mixed methods studies to determine the type

1 and quality of mixed methods research undertaken, and  
2 qualitative interviews with 20 researchers to explore  
3 facilitators and barriers to exploiting the potential of  
4 this approach.<sup>1,12</sup>

### 7 Devising questions about quality

9 We devised a framework for the quality assessment  
10 based on detailed consideration of the literature on  
11 mixed methods research in the fields of health, social  
12 and educational research. We searched the health data-  
13 bases MEDLINE and CINAHL. We then sought expert  
14 opinion encapsulated in key textbooks.<sup>10,13-20</sup> Finally  
15 we searched the Social Science Citations Index,  
16 PsycINFO, ERIC and the British Education Index to  
17 identify social, behavioural and educational research.  
18 The search for literature took place in 2003 and was  
19 updated in 2006. Quality was one of 11 issues identified  
20 in this review.

21 Within the literature, one suggested assessment cri-  
22 terion for mixed methods studies was whether they  
23 had been completed successfully in terms of adequately  
24 addressing the research questions with allocated  
25 resources.<sup>5</sup> Other researchers focused on the quality of  
26 methods. There was no suggestion of using a tool devel-  
27 oped for generic use across all designs. Rather, research-  
28 ers attempted to develop quality criteria by devising  
29 separate lists of criteria for the quantitative and the  
30 qualitative research.<sup>7</sup> Their assumption was that  
31 methods are linked to paradigms and therefore the  
32 criteria used to assess different methods should also be  
33 linked to paradigms.<sup>7</sup> However, not everyone agrees  
34 that methods are paradigm-specific<sup>18</sup> or that different  
35 criteria are needed for qualitative and quantitative  
36 research.<sup>21</sup> The same criteria have been proposed for  
37 both<sup>21</sup> although the appropriate means for judging  
38 against these criteria may differ because of the research  
39 practices employed in different methodological  
40 approaches. The mixed methods design<sup>10</sup> and the inte-  
41 gration between methods<sup>3</sup> can be assessed as well as the  
42 individual methods. A good mixed methods study  
43 clearly justifies why a mixed methods approach is  
44 necessary or superior to another, offers transparency  
45 of the mixed methods design, and offers appropriate  
46 sampling, data collection and analysis of individual com-  
47 ponents relating to that design.<sup>3,4,10</sup> Thus the design  
48 may determine the criteria used to make judgements  
49 about the individual components of the study. In-  
50 tegration of data or findings from each component  
51 is a key part of mixed methods research,<sup>10</sup> distinguish-  
52 ing it from qualitative and quantitative studies under-  
53 taken independently. When integration occurs, it is  
54 important that data transformations are defensible,  
55 that contradictory findings are explained and conver-  
56 gent findings are not related to shared bias between  
57 methods.<sup>3</sup> Expertise may be needed within a research  
58 team to integrate at the analysis stage.<sup>22</sup> Finally,  
59 researchers have discussed the importance of inferences  
60 from mixed methods studies being trustworthy<sup>6</sup> and  
appropriate in the light of the design used.<sup>3</sup> As yet

there are no criteria for assessing the quality of infer-  
ences from mixed methods research, although research-  
ers are considering the complexity of this issue.<sup>23</sup>

When developing the framework for our quality ques-  
tions we chose not to use a generic tool because they  
have variable applicability across different research  
designs.<sup>24</sup> We chose to assess the qualitative and quanti-  
tative components separately because they each contri-  
bute to the study as a whole and because the quality of  
one or both components may suffer as a consequence  
of being part of a mixed methods study.<sup>25-27</sup> In  
addition to the individual components, we included  
an assessment of the success of the study, the design,  
the integration and the inferences. Within this frame-  
work we constructed questions based on the literature  
review and reading the proposals and reports from  
four mixed methods studies in HSR.

### Identifying mixed methods studies

In 2004, mixed methods studies were identified  
through a systematic search of summaries of studies  
funded by the Department of Health, a key commis-  
sioner of health services research in England at that  
time. The methods have been described elsewhere<sup>1,12</sup>  
and are summarized here. Summaries of single studies  
funded between 1994 and 2004 through 10 pro-  
grammes were read. The programmes were: Health  
Technology Assessment; Service Delivery and  
Organization; New and Emerging Applications of  
Technology; Policy Research Programme; and the  
NHS Research & Development programmes of  
maternal and child health, primary and secondary  
care interface, cardiovascular disease and stroke, foren-  
sic mental health, primary dental care, and promoting  
implementation of research findings. A total of 118  
mixed methods studies were identified. The lead  
researcher of each study was written to with a request  
for the research proposal, the final report for completed  
studies and a list of any emerging publications.

### Application of quality questions

A data extraction form was devised which consisted of  
the quality questions with the tick box options of 'yes',  
'yes, but improvements are possible', 'no', 'not enough  
information (NEI)' and 'not applicable (N/A)'. Space  
for open comments was available alongside each ques-  
tion, where the assessor (AOC) could record details of  
good and poor practice. The data extraction form was  
applied to each study by one researcher, first to the pro-  
posal and then to the report. Finally, any differences  
between the proposal and report were noted.

### Analysis

The structured data were entered into SPSS. The main  
analysis was descriptive, displaying the proportions of  
proposals and reports falling into each category of  
each question. The chi-squared test was used when



comparing results for the individual qualitative and quantitative components. Open comments were quantized<sup>28</sup> by transcribing them into Word, grouping them into themes, and counting the number of studies in which a theme occurred.<sup>29</sup>

## Results

Documentation was received for 75 mixed methods studies. Full proposals were obtained for 60% (45/75) of the studies. Final reports were only available for the 52 studies completed by the time of data collection, and were obtained for 92% (48), although one was a summary report that was too brief for inclusion in the assessment of quality, leaving 47 reports. Both a proposal and report was available for 20 studies.

### Success

The potential to produce a successfully completed study was assessed using the research proposals. In most proposals, the quantitative methods appeared to be feasible within the time and money allocated (Table 1). However, even recognizing that some aspects of qualitative research cannot be fixed at the design stage (e.g. sample size for theoretical sampling), there was not enough detail to determine the feasibility of the qualitative methods in one-third of studies – for example, no indication of numbers of interviews to be undertaken or no indication of when the qualitative research would be conducted in the study timetable. We had concerns about the feasibility of the qualitative component in another one-third of proposals. From the open comments we identified 14 proposals where a large number of qualitative interviews were planned in a short time scale – for example, 40 interviews in four months without specifying the depth of interview and analysis. In nine of these studies the report was available and in four cases considerably fewer interviews were undertaken than planned. However, concerns highlighted about the feasibility of the qualitative research did not necessarily translate into shortfalls in the final study.

We defined a successful study as one that produced everything that had been planned at the proposal stage. A direct comparison of the final study report with the proposal was only possible on the subset of 20

studies for which both were available. In other cases the assessment relied on researchers detailing the planned and implemented study within their final report. Non-completion of a whole component of a study was rare (Table 1). However, in one-fifth of reports, one of the methods within a component was not executed as planned. This tended to be due to a range of problems in the field.

### Mixed methods design

A justification for using mixed methods research was only given in one-third of proposals and reports (Table 2). A minority of studies explicitly articulated the design in terms of the priority of methods, the purpose of combining methods, the sequence of methods and the stage at which integration would or did occur. It was particularly helpful for the subsequent quality assessment of individual components if researchers were explicit about the priority of methods and the role of any less dominant method. For example, it seemed inappropriate to have 40 in-depth interviews as a preliminary aid to develop a questionnaire, but appropriate if these interviews were also to be used as a primary means of investigating the issue under study. A lack of transparency of the overall design could occur in the context of excellent description of individual components.

When the design was not discussed explicitly it was usually possible to work out the key elements from reading the documentation. In most cases the design was assessed as appropriate for addressing the research question. However, researchers rarely discussed issues of rigour in relation to the design employed. An example of addressing rigour for the design was where researchers proposed that qualitative findings would not be shared with quantitative colleagues undertaking a randomized controlled trial to minimize the possibility of contamination of that trial; in another two studies, the qualitative research was undertaken with people not participating in the trial in order to avoid contaminating the trial. While the extent to which this attention to contamination avoidance was necessary may be debatable, it constitutes some evidence that researchers had given serious consideration to design issues related to mixed methods research.

**Table 1** Assessment of the success of mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the quantitative component feasible?	82%	2%	4%	11%				
2 Is the qualitative component feasible?	38%	20%	13%	29%				
3 Is the mixed methods design feasible?	51%	0%	7%	42%				
4 Have both qualitative and quantitative components been completed?					87%	6%	2%	4%
5 Were some quantitative methods planned but not executed?					19%	0%	45%	36%
6 Were some qualitative methods planned but not executed?					21%	2%	38%	38%
7 Did the mixed methods design work in practice?					85%	0%	2%	13%

NEI, not enough information; N/A, not applicable



**Table 2** Assessment of the mixed methods design of studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the use of mixed methods research justified?	31%	3%	60%	4%	30%	2%	66%	2%
2 Is the design for mixing methods described?								
Priority	16%	2%	78%	4%	15%	0	83%	2%
Purpose	42%	0	53%	4%	34%	4%	60%	2%
Sequence	56%	0	40%	4%	49%	0	49%	2%
Stage of integration	24%	0	71%	4%	21%	0	77%	2%
3 Is the design clearly communicated?	80%	0	16%	4%	81%	4%	9%	6%
4 Is the design appropriate for addressing the research questions?	87%	2%	2%	9%	87%	0%	2%	11%
5 Has rigour of the design been considered (proposal) or adhered to (report)?	7%	0	93%	0%	21%	0%	0%	79%

NEI, not enough information; N/A, not applicable

### Quantitative component

The roles of the quantitative methods were usually communicated well within proposals and reports (Table 3). However, sufficient details were sometimes not given about these methods. In eight proposals the quantitative methods were only sketchily described and in a further 13 proposals some aspects of the quantitative methods were not described, in particular, the analysis (8) and the numbers involved (5). This was less of an issue for reports but nonetheless there were still problems with sketchy description overall (4) or little or no description of the analysis (5). This lack of transparency made it difficult to assess other aspects of quality.

Validity of the methods within the quantitative components was assessed by considering the attention researchers gave to issues such as confounding and bias. Validity was explicitly discussed in two-thirds of proposals, with little evidence that the rigour of any method was compromised (Table 3). There were few examples of an individual method being compromised by the mixed methods approach. One example was a Delphi exercise which was restricted in order to fit the timetable of the qualitative fieldwork.

It was difficult to determine the sophistication of proposed analyses due to the lack of detail about analysis in the research proposals. There was more information about analyses available in research reports and here

concerns were identified about the sophistication of one-quarter of quantitative analyses. We identified 12 studies where the reported quantitative results seemed simplistic, sometimes only presenting descriptive statistics with no statistical tests and in two cases using an experimental design which was then ignored in the analysis.

### Qualitative component

The roles of the qualitative methods were usually communicated well within proposals and reports (Table 4). However, qualitative methods were often not described in sufficient detail and this occurred more frequently than for the quantitative components, both within proposals ( $p = 0.011$ ) and reports ( $p = 0.08$ ). First, there was sketchy description of the qualitative methods overall (15 proposals and 11 reports). In three of these reports there was no description of the qualitative methods at all, only the findings. Second, there were no details about an important aspect of the qualitative research, particularly the analysis (six proposals and nine reports). Third, one method was described in detail, usually interviews with a particular group, but a further qualitative method such as observation or focus groups appeared to be 'tagged on' with no description (six proposals). Fourth, the overall size of the qualitative component was not clear, with a few

**Table 3** Assessment of the quantitative component of mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the role of each method clear?	98%	0%	2%	0%	96%	2%	0%	2%
2 Is each method described in sufficient detail?	53%	29%	18%	0%	68%	13%	15%	4%
3 Is each method appropriate for addressing the research question?	93%	0	2%	4%	98%	0%	0%	2%
4 Is the approach to sampling and analysis appropriate for its purpose?	67%	4%	4%	24%	70%	9%	6%	15%
5 Is there expertise among applicants/authors?	67%	2%	7%	24%	30%	0%	0%	70%
6 Is there expertise on the team to undertake each method?	60%	0%	2%	24%				
7 Have issues of validity been addressed for each method?	64%	0%	30%	7%	49%	4%	40%	6%
8 Has the rigour of any method been compromised?	7%	0%	91%	2%	9%	4%	83%	4%
9 Is each method sufficiently developed for its purpose?	84%	0%	7%	9%	83%	0%	4%	13%
10 Is the (intended) analysis sufficiently sophisticated?	56%	4%	2%	38%	51%	15%	25%	9%

NEI, not enough information; N/A, not applicable

**Table 4** Assessment of the qualitative component of mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the role of each method clear?	87%	0%	9%	4%	92%	4%	4%	0%
2 Is each method described in sufficient detail?	24%	29%	42%	4%	38%	28%	30%	4%
3 Is each method appropriate for addressing the research question?	87%	7%	2%	4%	91%	2%	2%	4%
4 Is the approach to sampling and analysis appropriate for its purpose?	42%	4%	9%	40%	53%	9%	4%	34%
5 Is there expertise among the applicants/authors?	56%	2%	11%	31%	32%	4%	0%	64%
6 Is there expertise on the team to undertake each method?	44%	9%	7%	40%				
7 Have issues of validity been addressed for each method?	24%	0%	64%	11%	30%	2%	57%	11%
8 Has the rigour of any method been compromised?	2%	0%	91%	7%	6%	2%	81%	11%
9 Is each method sufficiently developed for its purpose?	64%	0%	9%	27%	77%	2%	9%	13%
10 Is the (intended) analysis sufficiently sophisticated?	40%	4%	7%	49%	51%	13%	19%	17%

NEI, not enough information; N/A, not applicable

interviews here and there throughout the study adding up to a sizeable qualitative component of over 100 interviews (10 proposals).

Validity of the methods within the qualitative components was assessed by considering the attention researchers gave to issues such as reflexivity and negative cases. Validity was not addressed within proposals for more qualitative than quantitative components ( $p = 0.001$ ), although any apparent difference in reports was not statistically significantly different ( $p = 0.100$ ) (Table 4). Researchers did take the validity of qualitative methods seriously in some proposals, for example, paying attention to deviant cases and peer review of transcripts.

Concerns were identified with the sophistication of one-fifth of qualitative analyses. In nine studies the reported qualitative findings remained at a descriptive level, or reported findings in a quantitative manner only, or failed to distinguish between data collected using different methods such as focus groups and interviews.

## Integration

Integration of data or findings from the different methods received little attention in either proposals or

reports, with researchers rarely discussing the type of integration, how it occurred in the context of team working and who was involved in it (Table 5). Because of the lack of integration, questions about the appropriateness of integration and the effect of integration on the rigour of individual methods were irrelevant.

## Inferences

In the reports, researchers were clear about which results had emerged from which methods, and inferences seemed appropriate (Table 6). For one-fifth of studies there was a concern that the inferences were based disproportionately on one method rather than the findings of all the methods. The imbalance was likely to be towards qualitative findings as it was towards quantitative findings.

## Discussion

### The quality of studies in HSR

Mixed methods studies tend to be successful in HSR insofar that the qualitative and quantitative components are usually completed as planned. The main quality issue identified was a lack of transparency of the

**Table 5** Assessment of integration in mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the type of integration stated?	11%	0%	84%	4%	2%	2%	94%	2%
2 Is the type of integration appropriate to the design?	16%	0%	0%	84%	34%	0%	2%	64%
3 Has enough time been allocated for integration?	2%	0%	13%	85%				
4 Is the approach to integration detailed in terms of working together as a team?	7%	0%	80%	13%				
5 Does the dissemination strategy detail how the mixed methods will be reported in final reports and peer-reviewed publications?	0%	0%	84%	16%				
6 Are the personnel who participate in the integration clearly identified?	9%	0%	80%	11%	6%	0%	70%	23%
7 Did appropriate members of the team participate in integration?					0%	0%	2%	98%
8 Is there evidence of communication within the team?					19%	0%	6%	75%
9 Has rigour been compromised by the process of integration?					4%	0%	0%	96%

NEI, not enough information; N/A, not applicable

**Table 6** Assessment of the inferences made in completed reports of mixed methods studies in HSR

	Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A
1 Is there clarity about which results have emerged from which methods?	87%	2%	6%	4%
2 Are inferences appropriate?	83%	4%	9%	4%
3 Are the results of all the methods considered sufficiently in the interpretation?	66%	6%	19%	9%

NEI, not enough information; N/A, not applicable

mixed methods aspects of the studies and the individual components. The qualitative components were more likely to be poorly described than the quantitative ones. To some extent the poor description of qualitative methods is not a surprising finding given the historical dominance of quantitative methods in HSR. However, it raises concerns that the HSR community may be failing on occasions to exploit the potential of qualitative methods within mixed methods studies. Where a qualitative component is in a supporting role to a more dominant method, and does not have stand-alone status in terms of independently addressing an aspect of the research question, then limited description is acceptable. However, because researchers were often not explicit about the status of methods within the study design, it was difficult to make judgements about the individual components in the context of the design used. Integration of data and findings is a key part of mixed methods research. There was no evidence that inappropriate integration was undertaken because there was a tendency for researchers to keep the qualitative and quantitative components separate rather than attempt to integrate data or findings in reports or publications.<sup>12</sup>

### Developing quality criteria for mixed methods studies in HSR

There was a lack of transparency in the reporting of mixed methods studies in HSR which made it difficult to assess other aspects of the quality of these studies. This has been identified as a problem facing the quality assessment of other types of studies<sup>11</sup> and has led to the development of guidelines for reporting studies. Creswell has suggested a list of issues to consider when designing a mixed methods study<sup>10</sup> and we have considered this in conjunction with the literature on the quality of mixed methods studies to suggest some guidelines for Good Reporting of A Mixed Methods Study (GRAMMS) (Box 1). We present this as guidance for researchers rather than as a formal checklist.

### Box 1 Good Reporting of A Mixed Methods Study (GRAMMS)

- (1) Describe the justification for using a mixed methods approach to the research question
- (2) Describe the design in terms of the purpose, priority and sequence of methods
- (3) Describe each method in terms of sampling, data collection and analysis
- (4) Describe where integration has occurred, how it has occurred and who has participated in it
- (5) Describe any limitation of one method associated with the present of the other method
- (6) Describe any insights gained from mixing or integrating methods

### Limitations

The study is based on mixed methods research funded by one commissioner in one country. The response rate to requests for documentation for mixed methods studies was good but non-responders may have been more likely to be problematic studies, biasing the findings towards higher quality studies. The questions were devised and applied by one researcher (AOC) in the context of team discussions which meant that the data extraction process was unchallenged by an external source. A coding protocol was devised to accompany the data extraction form to aid transparency and reduce intra-rater variability. However the studies could have been rated differently by another researcher. Finally, the studies included were funded between 1994 and 2004 and improvements may have occurred since then.

We have taken a technical stance in our discussions of quality in mixed methods research. However, the philosophical stance adopted by researchers may affect the quality criteria they use, and wish to see applied to their studies. Subtle realism<sup>30</sup> has been proposed as a philosophical position appropriate for qualitative and quantitative research in health technology assessment.<sup>21</sup> An implication of this stance is that researchers would need to consider whether reflexivity has been applied to the whole of a mixed methods study rather than simply the qualitative component.

### Conclusions

This is the first attempt to consider the quality of mixed methods studies in HSR. We are not offering this as a definitive approach to be used by others, but to start the debate about how to assess and improve quality. We recommend that if we use mixed methods studies in HSR then we need to be more transparent about the design and the individual components in the context of the design, and attempt to integrate data and findings from the qualitative and quantitative methods.

### Acknowledgements

Many thanks to the researchers who kindly sent copies of their study documents. The Medical Research Council funded the study through their Fellowship scheme.

## References

- 1 O’Cathain A, Murphy E, Nicholl J. Why, and how, mixed methods research is undertaken in health services research: a mixed methods study. *BMC Health Serv Res* 2007;**7**:85
- 2 Bryman A. Quantitative and qualitative research: further reflections on their integration. In: Brannen J, ed. *Mixing Methods: Qualitative and Quantitative Research*. Aldershot: Ashgate, 1992:57–78
- 3 Caracelli VJ, Riggan LJC. Mixed-method evaluation: developing quality criteria through concept mapping. *Eval Pract* 1994;**15**:139–52
- 4 Creswell JW, Fetters MD, Ivankova NV. Designing a mixed methods study in primary care. *Ann Fam Med* 2004;**2**:7–12
- 5 Datta L. A pragmatic basis for mixed-method designs. In: Greene JC, Caracelli VJ, eds. *Advances in Mixed-method Evaluation: The Challenges and Benefits of Integrating Diverse Paradigms*. San Francisco, CA: Jossey-Bass, 1997:33–46
- 6 Teddlie C, Tashakkori A. Major issues and controversies in the use of mixed methods in the social and behavioural sciences. In: Tashakkori A, Teddlie C, eds. *Handbook of Mixed Methods in Social and Behavioural Research*. London: Sage Publications, 2003:3–50
- 7 Sale JEM, Brazil K. A strategy to identify critical appraisal criteria for primary mixed method studies. *Quality and Quantity* 2004;**38**:351–65
- 8 Creswell JW, Plano-Clark V. *Designing and Conducting Mixed Methods Research*. Thousand Oaks, CA: Sage Publications, 2007
- 9 Brannen J. Combining qualitative and quantitative approaches: an overview. In: Brannen J, ed. *Mixing Methods: Qualitative and Quantitative Research*. Aldershot: Ashgate, 1992:3–38
- 10 Creswell JW. *Research Design. Qualitative, Quantitative, and Mixed Methods Approaches*. 2nd edn. London: Sage Publications, 2003
- 11 Mays N, Pope C, Popay J. Systematically reviewing qualitative and quantitative evidence to inform management and policy-making in the health field. *J Health Serv Res Policy* 2005;**10** (Suppl. 1):6–20
- 12 O’Cathain A, Murphy E, Nicholl J. Integration and publications as indicators of ‘yield’ from mixed methods studies. *Journal of Mixed Methods Research* 2007;**1**:147–63
- 13 Brewer J, Hunter A. *Multimethod Research*. London: Sage Publications, 1989
- 14 Tashakkori A, Teddlie C, eds. *Handbook of Mixed Methods in Social and Behavioural Research*. London: Sage, 2003
- 15 Tashakkori A, Teddlie C. *Mixed Methodology: Combining Qualitative and Quantitative Approaches*. London: Sage, 1998
- 16 Gorard S, Taylor C. *Combining Methods in Educational and Social Research*. Maidenhead: Open University Press, 2004
- 17 Brannen J, ed. *Mixing Methods: Qualitative and Quantitative Research*. Aldershot: Ashgate, 1992
- 18 Bryman A. *Quantity and Quality in Social Research*. London: Routledge, 1988
- 19 Greene JC, Caracelli VJ, eds. *Advances in Mixed-method Evaluation: The Challenges and Benefits of Integrating Diverse Paradigms*. San Francisco, CA: Jossey-Bass, 1997
- 20 Fielding NG, Fielding JL. *Linking Data*. Sage Publications, 1986
- 21 Murphy E, Dingwall R, Greatbatch D, Parker S, Watson P. Qualitative research methods in health technology assessment: a review of the literature. *Health Tech Assess* 1998;**2**:16
- 22 Mason J. Linking qualitative and quantitative data analysis. In: Bryman A, Burgess RG, eds. *Analysing Qualitative Data*. London: Routledge, 1994:89–110
- 23 Miller S. Impact of mixed methods and design on inference quality. In: Tashakkori A, Teddlie C, eds. *Handbook of Mixed Methods in Social and Behavioural Research*. London: Sage Publications, 2003:423–55
- 24 Katrak P, Bialocerkowski AE, Massy-Westropp N, Kumar VS, Grimmer KA. A systematic review of the content of critical appraisal tools. *BMC Med Res Meth* 2004;**4**:22
- 25 Silverman D. *Doing Qualitative Research. A Practical Handbook*. London: Sage Publications, 2000
- 26 Steckler A, Mcleroy KR, Goodman RM, Bird ST, McCormick L. Toward integrating qualitative and quantitative methods: an introduction. *Health Educ Q* 1992;**19**:1–8
- 27 Chen H. Applying mixed methods: a dominant methodology for the future? In: Greene JC, Caracelli VJ, eds. *Advances in Mixed-method Evaluation: The Challenges and Benefits of Integrating Diverse Paradigms*. San Francisco, CA: Jossey-Bass, 1997:61–72
- 28 Sandelowski M. Combining qualitative and quantitative sampling, data collection, and analysis techniques in mixed-method studies. *Res Nurs Health* 2000;**23**:246–55
- 29 O’Cathain A, Thomas KJ. “Any other comments?” Open questions on questionnaires – a bane or a bonus to research? *BMC Med Res Meth* 2004;**4**:25
- 30 Hammersley M. *What’s Wrong with Ethnography?* London: Routledge, 1992



# BMJ Open

## Implementation of national antenatal hypertension guidelines: a multi-centre mixed methods study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-035762.R1
Article Type:	Original research
Date Submitted by the Author:	30-Jun-2020
Complete List of Authors:	Whybrow, rebecca; King's College London, Women and Children's Health; Guy's and Saint Thomas' Hospitals NHS Trust, Division of Women and Children's Health Webster, Louise; King's College London, Women and Children's Health Girling, Joanna; Chelsea and Westminster Hospital NHS Foundation Trust Brown, Heather; Brighton and Sussex University Hospitals NHS Trust Wilson, Hannah; King's College London, Women and Children's Health Sandall, Jane; Kings College, London, Women and Children's Health Chappell, Dr Lucy; King's College London, Department of Women and Children's Health; Guy's and Saint Thomas' Hospitals NHS Trust, Division of Women and Children's Health
<b>Primary Subject Heading</b>:	Obstetrics and gynaecology
Secondary Subject Heading:	Cardiovascular medicine
Keywords:	Maternal medicine < OBSTETRICS, OBSTETRICS, Hypertension < CARDIOLOGY

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3 1 **Title:** Implementation of national antenatal hypertension guidelines: a multi-centre mixed methods  
4  
5 2 study

6  
7 3 Rebecca Whybrow<sup>1</sup>, Louise Webster<sup>1</sup>, Joanna Girling<sup>2</sup>, Heather Brown<sup>3</sup>, Hannah Wilson<sup>1</sup>, Jane Sandall<sup>1</sup>,  
8  
9 4 Lucy Chappell<sup>1</sup>

10  
11 5 1 Department of Women and Children's Health, King's College London, St Thomas' Hospital, London,  
12 6 UK.

13  
14 7 2 Chelsea and Westminster Hospital NHS Foundation Trust, London, UK.

15  
16 8 3 Brighton and Sussex Universities Hospital Trust, East Sussex, UK.

17  
18 9 Corresponding author: Rebecca Whybrow, Department of Women and Children's Health, King's  
19  
20 10 College London, St Thomas' Hospital, London, UK. [Rebecca.whybrow@kcl.ac.uk](mailto:Rebecca.whybrow@kcl.ac.uk) Tel: 07804690276

21  
22 11 **Word Count:** 4796

23  
24 12 **Abstract:**

25  
26 13 **Objective** To evaluate the implementation of NICE antenatal hypertension in pregnancy guidelines, to  
27  
28 14 identify strategies to reduce incidences of severe hypertension and associated maternal and perinatal  
29  
30 15 morbidity and mortality in pregnant women with chronic hypertension.

31  
32 16 **Methods** We used a multi-method multi-site approach to establish implementation of guidelines and  
33  
34 17 the associated barriers and facilitators. We used a national survey of healthcare professionals (n=97),  
35  
36 18 case-notes review (n=55) and structured observations (n=42) to assess implementation. The barriers  
37  
38 19 and facilitators to implementation were identified from semi-structured qualitative interviews with  
39  
40 20 healthcare professionals (n=13) and pregnant women (n=18) using inductive thematic analysis. The  
41  
42 21 findings were integrated and evaluated using the Consolidated Framework for Implementation  
43  
44 22 Research (CFIR).

45  
46 23 **Setting and participants** Pregnant women with chronic hypertension and their principle carers  
47  
48 24 (obstetricians, midwives, and physicians), at three NHS hospital trusts with different models of care.

49  
50 25 **Results** We found severe hypertension to be prevalent (46% of case-notes reviewed) and target blood  
51  
52 26 pressure practices to be sub-optimal (56% of women had an antenatal blood pressure target  
53  
54 27 documented). Women were infrequently given information (52%) or offered choice (19%) regarding  
55  
56 28 antihypertensives. Women (14/18) reported internal conflict in taking antihypertensives and non-  
57  
58 29 adherence was prevalent (8/18). Women who were concordant with treatment recommendations  
59  
60 30 described having mutual trust with professionals mediated through appropriate information, side-  
31 effect management and involvement in decision-making. Professionals reported needing updates and

32 tools for target blood pressure setting and shared decision-making underpinned by antihypertensive  
33 safety and effectiveness research.

34 **Conclusions** Women's nonadherence to antihypertensives is higher than anticipated. Sub-optimal  
35 information provision around treatment, choice of antihypertensives and target setting practices by  
36 healthcare professionals may be contributory. Understanding the reasons for non-adherence will  
37 inform education and decision-making strategies needed to address both clinician and women's  
38 behaviour. Further research into the effectiveness and long-term safety of common antihypertensives  
39 is also required.

40

#### 41 **Strengths and limitations of this study**

- 42 – Multi-methodological approaches and an implementation framework improved the reliability,  
43 validity, and generalisability of the study.
- 44 – Structured observations were carried out using a validated tool with high interrater reliability.
- 45 – Women's medication behaviours were explored in-depth using a qualitative interview  
46 approach and have identified antihypertensive side-effects to be a factor of non-adherence in  
47 pregnant women.
- 48 – About two-fifths of women who participated in this study were from Black, Asian and minority  
49 ethnic groups, providing a diverse range of voices.
- 50 – Respondents to the survey were self-selecting and may represent a relatively interested group  
51 of healthcare professionals.

52



## 53 BACKGROUND

54 Hypertension in pregnancy is one of the leading causes of maternal mortality worldwide<sup>1</sup> and although  
55 mortality is declining in the UK,<sup>2</sup> women can still experience substantial morbidity from complications  
56 such as eclampsia and stroke.<sup>3</sup> Additionally, perinatal mortality remains high, with the UK population-  
57 attributable risk of stillbirth from chronic hypertension at 14%<sup>4</sup> and around half of all neonates born  
58 to mothers who have had severe hypertension in pregnancy being admitted to the neonatal unit.<sup>5</sup> The  
59 morbidity and mortality attributable to hypertension, in many cases, may be modifiable through  
60 optimal use of antihypertensive agents during pregnancy.

61 The National Institute for Health and Care Excellence (NICE) hypertension in pregnancy guidelines  
62 (2010)<sup>6</sup> and linked quality statements (2013)<sup>7</sup> contain a quality statement regarding the provision of  
63 information on the use of safe antihypertensive medication in pregnancy and has related guidance  
64 that recommends discontinuation of teratogenic medications such as angiotensin-converting-enzyme  
65 inhibitors or angiotensin II receptor blockers with prescribing of safe alternatives. Any prescribing of  
66 alternative antihypertensive medication should be dependent on pre-pregnancy treatment, side-  
67 effect profiles and teratogenicity. A second quality statement advocates that women taking  
68 antihypertensive medication should have a blood pressure target (usually of less than 150/100mmHg)  
69 set in pregnancy. All NICE guidelines are underpinned by the recommendation of enabling patients to  
70 actively participate in their care which includes adopting a shared decision-making approach to  
71 treatment decisions.<sup>8</sup>

72 Despite publication of the guideline almost a decade ago, the implementation and evaluation of  
73 associated determinants of uptake have not been nationally evaluated. As a result, targeted strategies  
74 to reduce maternal and perinatal morbidity (and mortality) resulting from severe hypertension remain  
75 unidentified. Using the Consolidated Framework for Implementation Research (CFIR),<sup>9</sup> the aim of the  
76 study was to evaluate the implementation of NICE hypertension in pregnancy guidelines, to identify  
77 strategies to reduce incidence of severe hypertension and associated maternal and perinatal  
78 morbidity and mortality in pregnant women with chronic hypertension. In many countries, there is a  
79 movement toward establishing consensus-driven standardised clinical guidelines with the aim of  
80 improving patient safety and clinical outcomes. Whilst new research continually emerges, guidelines  
81 are periodically updated and therefore remain an appropriate standard for evaluating routine clinical  
82 practice.<sup>10</sup>

83

## 84 RESEARCH DESIGN AND METHODS

### 85 Study setting and overall methodology

86 The CHAMPION study (Chronic Hypertension in pregnAncy iMPLementatiON study) is a multi-methods  
87 evaluation of the implementation of the NICE hypertension in pregnancy guidelines (2010 and  
88 updated in 2013) in women with chronic hypertension diagnosed before 20 weeks.<sup>6,7</sup> Ethical approval  
89 for the CHAMPION study was provided by the National Research Ethics Service (17/LO/2041). The  
90 study aimed to evaluate the variability in implementation of hypertension management practices set  
91 out in the NICE hypertension in pregnancy guidelines (2010).<sup>6</sup> As all guidelines should be underpinned  
92 by the 'Patient experience in adult NHS services guideline'<sup>8</sup> which specifies 'actively involving patient  
93 in decisions about their care through 'information provision' and 'shared decision-making' the  
94 provision of information and women's involvement in decision-making was also evaluated. The  
95 involvement of women in decision-making was considered integral to the implementation study  
96 because successful hypertension management strategies involve the adherence to, alongside the  
97 prescribing of, antihypertensive medication.

98 Implementation was assessed through multiple methods: an online national survey of healthcare  
99 professionals, designed to describe general trends in guideline implementation; through review of the  
100 maternity case-notes of women who had already given birth, a method that assessed the  
101 documentation of hypertension management occurrence in each woman's maternity record. Aspects  
102 of care that would not normally be documented or are more difficult to capture, such as in-  
103 consultation discussions and occurrence of shared decision-making were assessed through  
104 observations carried out by a midwife researcher (RW). The evaluation of the barriers and facilitators  
105 to implementation of NICE guidelines was assessed through qualitative interviews (with the same  
106 women and healthcare professionals who participated in the observation phase) using the  
107 Consolidated Framework for Implementation Research (CFIR). The study draws on CFIR as a  
108 theoretical framework to guide data collection, analysis, and interpretation. The CFIR framework  
109 specifically evaluates five key domains that influence implementation; each domain has several  
110 subgroups to it, although only those relevant to this study have been identified. These include the  
111 intervention characteristics (the NICE guidelines), the outer context (the pregnant women), the inner  
112 context (NHS maternity services), individual context (the healthcare professionals) and the process of  
113 implementation (potential strategies).

114 Implementation of guidelines was assessed between November 2017 to December 2018 at three NHS  
115 Trusts with typical configurations of services for pregnant women with hypertension in the UK.  
116 Hospital Trust 1 was a tertiary city centre hospital with a newly formed specialist service that included

1  
2  
3 117 consultant obstetricians, obstetric physicians and midwives who provided antenatal and intrapartum  
4 118 care to women with chronic hypertension within a specialist clinic; Hospital Trust 2 was a suburban  
5 119 district general hospital with a consultant-led antenatal clinic with antenatal midwives alongside  
6 120 providing care to women with a variety of pre-existing medical conditions; and Hospital Trust 3 had  
7 121 both a tertiary and a semi-rural hospital with a joint obstetric and physician led clinic and usual  
8 122 community-based midwifery care. No adjustment for clustering was required as no statistical  
9 123 comparison between sites was made. The NICE hypertension in pregnancy guidelines (2010)<sup>6</sup> had been  
10 124 adopted into local clinical guidelines at all three participating NHS Trusts for several years prior to the  
11 125 assessment of implementation.

126

### 127 **The National Survey**

128 The implementation of evidence-based practices for the management of hypertension in pregnancy  
129 was assessed through self-reporting using an online survey (surveygizmo/s3). We embedded  
130 questions relating to the uptake of the NICE hypertension in pregnancy guidelines (2010)<sup>6</sup> using the  
131 TIDieR framework.<sup>11</sup> The 12-item TIDieR checklist (brief name, why, what (materials), what  
132 (procedure), who provided, how, where, when and how much, tailoring, modifications, how well  
133 (planned), how well (actual) is an extension of the CONSORT 2010 statement (item 5) and the SPIRIT  
134 2013 statement (item 11). Although the emphasis of the TIDieR checklist is on reporting interventions  
135 for trials, the checklist was used as a basis for this survey (but not as a reporting guideline) as it is also  
136 intended to apply across all evaluative study designs.<sup>11</sup> There is no single database of healthcare  
137 professionals' email addresses so national organisations including British Maternal and Fetal Medicine  
138 Society (BMFMS), Macdonald UK Obstetric Medicine Society (MOMS) and Royal College of Midwives  
139 (RCM) were asked to email the survey (April to September 2018) to their members. No fee was  
140 charged as members' contact details were not shared with us and as a result the response rate could  
141 not be calculated. Ninety-seven healthcare professionals from sixty-nine NHS Trusts was obtained,  
142 including 53 consultant obstetricians (55%), 16 doctors in training (16%), 22 specialist midwives (23%)  
143 and six community midwives (6%) (full copy of survey questions shown in supplementary material 1).

### 144 **Case-notes review**

145 The implementation of NICE guidelines (2010)<sup>6</sup> was also assessed through review of 100 maternity  
146 case-notes of women with chronic hypertension identified from the electronic maternity records (32,  
147 33, 35 women per Trust). At two of the Trusts all women who had given birth in 2017 were included,  
148 whereas at the other Trust all women who had given birth over the final three months of 2017 were

1  
2  
3 149 included as this third Trust had approximately four times the number of women with chronic  
4  
5 150 hypertension per annum. In the UK, many women have abridged electronic maternity records and  
6  
7 151 extensive handheld paper notes that are carried throughout pregnancy but are stored thereafter in  
8  
9 152 the hospital. Both the electronic system and paper notes were obtained in the case-notes review of  
10  
11 153 care. Due to use of varying terms for hypertension on the electronic system, some women identified  
12  
13 154 for case-note review were excluded as they did not have chronic hypertension when the full case-  
14  
15 155 notes were examined. Other reasons for exclusion included early miscarriage and transfer of care to  
16  
17 156 another maternity unit. Data extraction based on the NICE hypertension in pregnancy guidelines  
18  
19 157 (2010)<sup>6</sup> was completed by two midwife researchers (RW, HW), and minor discrepancies were resolved  
20  
21 158 by discussion between the two researchers. It was not necessary to include a third reviewer as no  
22  
23 159 major discrepancies were identified. Unclear or absent documentation including height, weight and  
24  
25 160 body mass index or antenatal blood pressure recordings was recorded as missing data. Severe  
26  
27 161 hypertension was defined as systolic blood pressure greater than or equal to 160 mmHg systolic or  
28  
29 162 diastolic blood pressure greater than or equal to 110 mmHg. For the assessment of BP targets, the  
30  
31 163 quality statement related to documentation of a target (or not), not to the specific numerical  
32  
33 164 thresholds chosen.

### 31 165 **Observations**

32  
33 166 Forty-two antenatal appointments involving 23 women with chronic hypertension and their respective  
34  
35 167 doctors (nine) and midwives (five) were observed by a midwife researcher (RW) at the three NHS  
36  
37 168 Trusts. Women with chronic hypertension were purposively sampled at their first obstetric antenatal  
38  
39 169 appointment and based on the availability of the midwife researcher, were approached consecutively  
40  
41 170 along with their respective healthcare professionals until data saturation occurred. Staff and women  
42  
43 171 gave written informed consent. Two women declined recruitment to the study. During observations,  
44  
45 172 data about antenatal care provision were recorded using the Calgary-Cambridge communication  
46  
47 173 guide<sup>12</sup> chosen for validity in relation to the research question, and its high interrater reliability. For  
48  
49 174 example, offering choice is a sub-section of shared decision-making and is defined as “encourages  
50  
51 175 patient to make choices and decisions to the level that they wish”. Attainment of each section and  
52  
53 176 sub-sections was established through the analysis of all 42 appointments using descriptive statistics.

### 52 177 **Semi-structured interviews**

54  
55 178 Views about barriers and facilitators to implementation of evidence-based guidelines were collected  
56  
57 179 from nine doctors and four midwives who were providing antenatal care for women with chronic  
58  
59 180 hypertension. The interviews were carried out by a midwife researcher (RW) following informed  
60  
181 consent and took place in privacy away from the clinical setting. The interviews were audio

1  
2  
3 182 transcribed, coded and thematically analysed using inductive reasoning.<sup>13</sup> The codes generated  
4  
5 183 formed small themes which were organised into the CFIR evaluation guide.<sup>14</sup> As formal  
6  
7 184 implementation strategies had not been adopted beyond producing local guidance, interviewees were  
8  
9 185 asked how they thought they could improve the implementation in the future.

10  
11 186 Semi-structured interviews with 18 women recruited for antenatal observations were carried out in  
12  
13 187 the third trimester with informed consent. Women were asked about their antenatal care experiences  
14  
15 188 using an interview schedule which reflected the concepts from the International Consortium for  
16  
17 189 Health Outcome Measure (ICHOM) maternity standards sets<sup>15</sup> which include women's overall  
18  
19 190 satisfaction with their care during pregnancy; satisfaction with information provision and their  
20  
21 191 relationships with their care providers (see supplementary material 2). ICHOM standards are  
22  
23 192 internationally recognised measures that evaluate health outcomes that are important to patients (or  
24  
25 193 pregnant women) and are used to improve local healthcare and compare outcomes internationally.  
26  
27 194 The closed survey questions were turned into open ended questions to explore in-depth the quality  
28  
29 195 of antenatal care provided. The interviews were carried out by a midwife researcher (RW) and took  
30  
31 196 place away from the clinical setting, with assurance that discussions would not be shared with  
32  
33 197 healthcare professionals and that participation or non-participation would not influence their care.  
34  
35 198 The interviews were audio transcribed, coded, and thematically analysed using an inductive approach.  
36  
37 199 Women's experiences were analysed to improve understanding of their antenatal care needs, which  
38  
39 200 included how their hypertension was managed and the barriers and facilitators to the uptake of  
40  
41 201 antihypertensives in pregnancy.

## 202 **Data analysis**

42  
43 203 The quantitative and qualitative data were analysed separately before being integrated. Descriptive  
44  
45 204 analysis and summary statistics were used for the quantitative data. The semi-structured interviews  
46  
47 205 were thematically analysed by researchers (RW, JS and LC) using inductive techniques and typically  
48  
49 206 lasted between 30 and 60 minutes.<sup>16</sup> The mixed-methods data were integrated and analysed using  
50  
51 207 the CFIR evaluation framework.<sup>14</sup> This included probing the inductively generated qualitative themes  
52  
53 208 that related to implementation. The interpretation of the intervention constructs (characteristics, the  
54  
55 209 inner and outer settings, the individual characteristics and the implementation processes) was carried  
56  
57 210 out initially by the midwife researcher (RW) who collected the data, then with a second and third  
58  
59 211 researcher (LC, JS) interpreting and discussing final interpretation of integrated data. Rigour was  
60  
212 maintained through member reflection, attention to interview and transcription quality and  
213 systematic analysis. Rigour was improved using multiple data sources, a comprehensive integration  
214 framework (CFIR) and a mixed methods integration checklist.<sup>17</sup> Researchers were aware of, and

1  
2  
3 215 sensitive to, the way in which their roles as midwives and doctor may have shaped the generation and  
4  
5 216 analysis of the qualitative data.

### 7 217 **Patient and Public Involvement**

8  
9 218 A patient participant involvement (PPI) group consisting of women with experience of hypertension  
10 219 in pregnancy (n=7) and a maternity voices partnership group (n=15) provided feedback on the design  
11 220 of the study, research questions and outcome measures. The views of Black, Asian and minority ethnic  
12 221 women were purposively sought as they are disproportionately represented in the chronic  
13 222 hypertension in pregnancy population. PPI focus groups discussed what aspects of care were  
14 223 important to evaluate, this included the information women were given during pregnancy and  
15 224 whether women were involved in decision about their care. They also provided constructively critical  
16 225 feedback on the patient information leaflets and consent forms.

### 23 226 **RESULTS**

24  
25 227 Antenatal care for women with chronic hypertension was provided by consultant obstetricians and  
26 228 midwives at all three hospitals. In two of the hospitals, women with chronic hypertension had  
27 229 designated midwives attached to the obstetric clinic. Approximately one-third of those recruited to  
28 230 the study had a BMI over 30kg/m<sup>2</sup>, approximately one-third were over the age of 35 and  
29 231 approximately two-fifths were of Black, Asian and minority ethnic backgrounds (shown in  
30 232 supplementary material 3). Hospital Trust 1 had four times the population of women with chronic  
31 233 hypertension compared to the other two units, comprising a large black minority ethnic population  
32 234 (many with associated co-morbidities). Perinatal outcomes from the fifty-five pregnancies identified  
33 235 for case-notes review showed that just under half of the women (46%) developed severe hypertension  
34 236 and that one in six babies were admitted to the neonatal unit (16%) (shown in supplementary material  
35 237 4). At all three hospitals medical history of women with chronic hypertension was inaccurate in the  
36 238 maternity records system and episodes of severe hypertension were recorded only in hand-written  
37 239 notes.

38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49 240

50  
51 241

### 52 242 **Implementation of NICE hypertension in pregnancy 2010 guidelines and 2013 quality standards**

53 243 Setting a blood pressure target (quality statement 3)

54  
55 244 Both the survey and the case-notes review found the practice of setting an antenatal target blood  
56 245 pressure to be variable (table 1). Just over half of women with chronic hypertension had a target blood

246 pressure documented in maternity notes (44% did not) yet substantial variation in practice between  
 247 hospitals existed. At Hospital Trust 1, 77% of women had a target blood pressure documented in  
 248 pregnancy compared to 23% and 38% at Hospital Trusts 2 and 3 respectively (supplementary material  
 249 5). Whilst it is possible that undocumented discussions occurred during consultations, which could not  
 250 be extracted from case-note review, such discussions would not be accessible on a longer term basis  
 251 to the woman or to other healthcare professionals involved in her care. The survey results support the  
 252 case-notes review findings as only a third of healthcare professional respondents reported always  
 253 setting a target. The practice of undocumented 'unshared' target setting was identified through case-  
 254 notes review. Evidence of blood pressure targets being used by healthcare professionals but not  
 255 shared with the woman and other professionals ('unshared') was found in about three quarters of  
 256 women whose blood pressure rose above systolic 150mmHg and or diastolic 100mmHg action was  
 257 taken by professionals to lower it. Action was defined as making changes to blood pressure treatment,  
 258 changing frequency of blood pressure monitoring or frequency of appointments (table 1).

259 Table 1. Variation in implementation of evidence-based care evaluated through a national survey of  
 260 obstetricians and midwives and women's case-notes review at three representative NHS Trusts.

Care quality indicators	National Survey n=97 (%)	Case-notes review n=55 (%)
<b>Blood pressure target setting (QS3)</b>		
Target blood pressure 'always' set	36 (37.1)	
Target blood pressure 'almost always' set	36 (37.1)	
Target blood pressure 'never' set	1 (1.0)	
Target blood pressure not applicable (midwife)	24 (23.3)	
Target blood pressure set at first opportunity (whichever first: booking or commencement of AHT)	-	9 (18.0)
Target blood pressure not documented		26 (43.6)
<b>Systolic target blood pressure</b>		
<160mmHg	8 (8.2)	
<150mmHg	89 (91.8)	2 (7.4)
≤140mmHg		27 (49.0)
<b>Diastolic target blood pressure</b>		
<100mmHg	94 (96.9)	2 (7.4)
≤90mmHg		27 (49.0)



Action taken to reduce blood pressure if above 150/100mmHg		13/17 (76.5)
<b>Safe antihypertensive prescribing (linked to QS1)</b>		
<b>ACEi and ARBs cessation</b>		
On ACEis or ARBs at antenatal booking appointment		4 (7.3)
Stopping ACEi or ARBs at first app if woman on either		
Always	57/86 (66.3)	-
Almost always	27/86 (31.4)	-
ACEis or ARBs stopped at 1 <sup>st</sup> obstetric appointment		4/4 (100.0)
<b>1<sup>st</sup> line AHT prescribing (non-exclusive)</b>		
Labetalol	85 (87.6)	28 (50.9)
Nifedipine	32 (33.0)	9 (16.4)
Methyldopa	29 (29.9)	8 (14.5)
Other e.g. amlodipine	2 (2.1)	4 (7.3)
None	-	6 (10.9)
<b>2<sup>nd</sup> line AHT prescribing (non-exclusive)</b>		
Nifedipine	79 (81.4)	9 (16.4)
Methyldopa	60 (61.9)	4 (7.3)
Labetalol	38 (39.2)	3 (5.4)
Amlodipine	37 (38.1)	2 (3.6)
Doxazosin	23 (23.7)	0 (0.0)
Other	5 (5.2)	0 (0.0)
None	-	37 (67.3)

261

262 Antihypertensive information provision, decision-making and prescribing (quality statement 1 and  
263 associated guidance)

264 Variation in practice regarding first- and second-line prescribing was identified through both the notes  
265 review and survey (table 1). In both, labetalol was the most commonly prescribed first line and  
266 nifedipine the most commonly used second line antihypertensive agent; nevertheless, in about half  
267 of the case-notes reviewed labetalol was not the first line antihypertensive prescribed. First line  
268 prescribing is not always exclusive as it may vary by ethnicity (e.g. some doctors use labetalol as first  
269 line for many women, but nifedipine for Black women, in line with national guidelines for prescribing  
270 outside of pregnancy)<sup>18</sup> which may explain the variation in prescribing practice that existed



1  
2  
3 271 (supplementary material 5). Variation may also be explained by clinician preference or medication  
4 preference identified through shared decision-making.  
5 272

6  
7 273 Information provision about antihypertensive prescribing  
8

9 274 Across all three Trusts, 52% (41/79) of the time the correct type and amount of information was  
10 provided during the consultation (measured using the Calgary-Cambridge Guide). Visual techniques  
11 275 such as drawing or using charts to provide information occurred during consultation in 14% (3/21) of  
12 276 cases.  
13 277

14  
15  
16 278 Achieving a shared understanding: incorporating the woman's perspective  
17

18  
19 279 Of the survey respondents 96.9% strongly agreed or agreed that involving women with chronic  
20 hypertension in management plans during pregnancy was important. However, when asked to give  
21 280 examples of how they involve women, only 4.3% identified discussing risks and benefits of treatment  
22 281 choice and 10% of respondents identified that women could be involved in plans about  
23 282 antihypertensive prescribing. The observations in the three hospital trusts found that 43% of the time  
24 283 (41/96) shared decision-making occurred and 19% of women (3/16) were offered a choice regarding  
25 284 their hypertensive plans (including choice of antihypertensive).  
26 285  
27  
28  
29  
30  
31

32 286

### 33 287 **Barriers and Facilitators to implementation (CFIR)**

34 288 Intervention characteristics (evidence and guideline)  
35

36 289 All professionals interviewed, except one, saw value in having national guidance and understood that  
37 290 the local guidelines had been adapted from the 2010 national guideline.<sup>6</sup> Midwives relied more on  
38 291 local guidelines compared to obstetricians who referred more commonly to NICE guidelines. Some of  
39 292 the medical professionals had been involved in the development of a NICE guideline and were aware  
40 293 of the strengths and limitations of producing evidence-based guidelines in terms of the need for timely  
41 294 updating. Professionals described difficulties in creating guidelines where there is a paucity of robust  
42 295 data as is sometimes the case in maternity care. Weak, out of date or absent evidence influenced  
43 296 doctors' decisions not to implement guidelines. Some doctors described the weaknesses in the  
44 297 evidence underpinning the hypertension guidelines and described relying more on recent research  
45 298 compared to older national guidelines (table 2). The professionals identified that further research is  
46 299 necessary to support evidenced-based national guidelines (figure 1).  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57

58 300  
59  
60

301 Table 2. Barriers to healthcare professional's implementation of hypertension in pregnancy guidelines, based on Consolidated Framework for Implementation  
 302 Research (CFIR) implementation themes.

CFIR implementation themes	Frequency	Codes	Representative answer
<b>Intervention characteristics</b>			
Evidence strength, quality, source, and adaptability	17	AHT prescribing; target setting;	<ul style="list-style-type: none"> <li>- "I think the fact that it says use labetalol first line is not what we do, I don't believe the evidence for labetalol being better than methyldopa is there."<sup>H</sup></li> <li>- "we can't get away from the fact that there aren't the source data there to make evidence-based guidelines."<sup>B</sup></li> <li>- So, I kept a close track of what was happening with the CHIPS study...I got a lot of information and knowledge from it."<sup>A</sup></li> </ul>
<b>Inner setting</b>			
Structural characteristics	43	Information provision; pathways and models; training and education; time	<ul style="list-style-type: none"> <li>- "I don't think we have a hand-out for, to give to hypertensive women about hypertension in pregnancy"<sup>L</sup></li> <li>- "we don't have a dedicated hypertension clinic here. So, most of these women will get seen in general antenatal clinic"<sup>I</sup></li> <li>- "you have people coming in three times weekly or something for their blood pressure, really? And other people who perhaps aren't being seen enough"<sup>I</sup></li> </ul>
Relative priority	26	Guidelines; self-study; beliefs; experience;	<ul style="list-style-type: none"> <li>- "Well actually I don't even know what the NICE guidelines are for hypertension, I'm not a... as my colleagues will tell you, not a huge fan of NICE, in many ways."<sup>L</sup></li> <li>- "I'm not just interested in guidelines; I'm interested in people's clinical experience...and that feel."<sup>C</sup></li> </ul>

Culture of decision-making	19	Patriarchy; shared decision-making; type of decision: emergency, urgent and non-urgent	<ul style="list-style-type: none"> <li>- “Doctors... see it as patients not doing what they’re told”<sup>A</sup></li> <li>- “I think that there’s a balance to be had between involving women in the decisions, versus, them coming for expert recommendations”<sup>F</sup></li> <li>- “If I have a clinical situation where I want to start antihypertensives because she’s got a dangerously high blood pressure, then that discussion is inevitably truncated.”<sup>B</sup></li> </ul>
<b>Individual characteristic</b>			
Beliefs about the intervention	35	AHT medication; AHT safety and side-effects; target setting	<ul style="list-style-type: none"> <li>- “National guidelines do not sanction any particular antihypertensive, or that the, the drug licenses do not sanction any particular antihypertensive”<sup>B</sup></li> <li>- “I think that might be something we’re not quite as good at as we should be about defining a target for women....I suspect it’s something we don’t really document and clarify”<sup>H</sup></li> </ul>
Self-efficacy	17	Women’s concordance/ desire for involvement/ first language	<ul style="list-style-type: none"> <li>- “I think sometimes women don’t necessarily want to make the decision”<sup>D</sup></li> <li>- “There’s a lot of ‘mumsnet’....and I would say they take a, that advice just as seriously as they do the advice that we give them here.”<sup>C</sup></li> </ul>
<b>Process of implementation</b>			
Engaging people and process of implementation	16	Using guidelines; updates, toolkits, and information; shared decision-making	<ul style="list-style-type: none"> <li>- “Awareness for people, if you’re a busy jobbing healthcare practitioner, keeping up to date with each new area”<sup>H</sup></li> <li>- “Practical toolkits to help with that consultation”<sup>B</sup></li> <li>- Evidenced based information having it more readily available for patient”<sup>D</sup></li> </ul>

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  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

Opinion leaders; Champions;	5	Utilisation of opinion leaders/ champions in implementation	- "I find as a midwife sometimes you're a bit powerless, you know what the guidelines are, but depending on the doctor you're working with, tends to be the influencing factor on the decisions that are made... so it seems to be clinician-based guidelines sometimes, rather than the trust or national guidelines" <sup>D1</sup>
--------------------------------	---	---	--

For peer review only

<sup>1</sup> Letters <sup>A-M</sup> represent the healthcare professionals interviewed

1  
2  
3 304 Inner setting (organisation structure and culture)  
4

5 305 The most frequently cited barriers to implementing high quality care for women with chronic  
6  
7 306 hypertension were linked to the structure and organisation of antenatal care. Interviewees reported  
8  
9 307 that a lack of consensus and guidance exists relating to models of care (such as whether specialist  
10  
11 308 services would improve outcomes through better implementation) and pathways of care (such as  
12  
13 309 frequency of blood pressure and medication reviews) (table 2). Evidence-based recommendations on  
14  
15 310 models, and pathways of care, were identified as future facilitators to providing optimal antenatal  
16  
17 311 care (figure 1). Whilst most healthcare professionals initially described the uptake of the guidelines as  
18  
19 312 a clinical priority during the interviews, clinicians identified difficulty with keeping up with  
20  
21 313 recommendations and using them alongside clinical judgement as barriers to implementation (table  
22  
23 314 2).

24 315 Healthcare professionals considered the absence of written information a barrier to the uptake of  
25  
26 316 antihypertensives in women with hypertension (table 2). A degree of paternalism exists in relation to  
27  
28 317 involving women in decisions about their care. In principle, clinicians would like to involve women in  
29  
30 318 decision-making, yet they gave many examples of situations where they would exercise restraint in  
31  
32 319 doing so (table 2). Education and tools to support shared decision-making were identified as  
33  
34 320 facilitators to optimizing antenatal care for women with hypertension (figure 1).

35 321

36 322 Characteristics of individuals (beliefs, knowledge, and self-efficacy)

37  
38 323 Interview analysis identified doctors' and midwives' knowledge and beliefs as the second most  
39  
40 324 frequently cited barrier and facilitator to the implementation of hypertension management guidelines  
41  
42 325 (table 2). There existed confusion about whether the guidelines sanction one antihypertensive  
43  
44 326 medication over another for the management of chronic hypertension and if so, what evidence was  
45  
46 327 used to support this. Likewise, confusion about blood pressure targets was described frequently as  
47  
48 328 outcomes from a recent randomised controlled trial superseded the pre-dated national guidelines  
49  
50 329 (table 2). Whilst midwives experienced less self-efficacy than the doctors, doctors still experienced  
51  
52 330 difficulties in this area. They occasionally described the women's beliefs and views as a barrier to  
53  
54 331 implementing the recommendations (table 2).

55 332

56 333

57 334

1  
2  
3 335 Outer setting (women's views and experiences)  
4

5 336 The quality of antenatal care experience was affected by women's internal conflict. There was also a  
6  
7 337 high degree of variability in medication adherence (defined as, a blanket term factoring the extent to  
8  
9 338 which patients' drug dosing histories conform, or not, to their corresponding prescribed drug dosing  
10  
11 339 regimen).<sup>19</sup> and concordance (defined as, an agreement after negotiation between a woman and a  
12  
13 340 healthcare professional that respects the beliefs and wishes of the woman in determining whether,  
14  
15 341 when, and how medicines are to be taken).<sup>20</sup> Analysis identified that women require quality  
16  
17 342 information about antihypertensives and their side-effects, blood pressure ranges in pregnancy, as  
18  
19 343 well as support to actively participate in decision-making.  
20

21 344

22 345 *Internal Conflict*

23  
24 346 The majority (14 of 18) of women experienced internal conflict relating to the management of their  
25  
26 347 hypertension during pregnancy, defined as a state of uncertainty about the course of action to take  
27  
28 348 often in relation to making choices involving risk or uncertainty of outcomes (8) (figure 2a). The causes  
29  
30 349 of internal conflict were identified as a lack of information provision, poorly managed side-effects,  
31  
32 350 women's personal beliefs and factors relating to the healthcare professional (table 3).  
33

34 351  
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

352 Table 3. Barriers to women's uptake of hypertension in pregnancy guidelines

CFIR outer context themes Women's internal conflict	Frequency	Codes	Representative answer
Information	30	Medication (choices, dose, effectiveness, safety, interactions); severity of HTN; effect of HTN on pregnancy	<ul style="list-style-type: none"> <li>- "[I wanted to know] how safe it is, about the dosage, about the, taking the med-, this medication, about the side-effects and so and so and so, if they think any other option for me, or if this medication is not working, what will be the other option for me"<sup>J</sup></li> <li>- "He was, you still need to carry on with your ramipril. I know I can't take it. It says in the leaflet not to take once you've hit 6 weeks, you need to stop. So, he was like oh, and then he phoned here, and he said oh well just take what you took before"<sup>H</sup></li> </ul>
Side-effects	21	Maternal side-effects; fetal side-effects; Interactions ; allergies; choices	<ul style="list-style-type: none"> <li>- "They gave me first three, twice a day, then I was so giddy where I couldn't, if I take, I had to sleep all day for two days...Then I complained, but they still say to still take tablet."<sup>I</sup></li> <li>- "I'm on 18 pills a day, I do worry a bit about how they kind of potentially interact with each other and affect the baby"<sup>F</sup></li> </ul>

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  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

Beliefs	17	Hypertension status; understanding HTN; effectiveness AHT; safety AHT	<ul style="list-style-type: none"> <li>- "I felt like I had to justify why I wasn't taking my tablet, which to me didn't seem right, 'cause if it, if my blood pressure was normal, and I took a tablet, surely my blood pressure then would be low?"<sup>Q</sup></li> <li>- "cause everything I take my baby takes. So, it's like, what happens if my child comes out and then they're addicted to something, or they're high-strung because of something, or they're really moody and they're crying all the time because of the medicine I've had to take for the past 4 months"<sup>L</sup></li> </ul>
HCP factors	17	Continuity; listening to women; explaining regimes, mutual trust; communication	<ul style="list-style-type: none"> <li>- "My issue has been where I've seen somebody who doesn't know the history, and typically they are a more junior doctor, and typically they are ticking a box and following a flow chart....the doctor said, you know, we're going to come to an agreement together but there was absolutely no discussion, she had no interest in what I had to say."<sup>K</sup></li> </ul>
External factors	7	Family and friends; internet; access to services	<ul style="list-style-type: none"> <li>- "My dad had been on beta blockers, which is what labetalol is, when he was younger, and he found, he was very ill on them, so he gave me a really negative impression of them"<sup>P2</sup></li> </ul>

353

<sup>2</sup> Letters <sup>A-R</sup> represent the pregnant women interviewed



1  
2  
3 354 *Concordance*  
4

5 355 All women identified as concordant with healthcare professional management plans described being  
6  
7 356 adherent to their antihypertensives. Facilitators to concordance included trust in the healthcare  
8  
9 357 professional, mediated through information about safety of antihypertensives in pregnancy,  
10  
11 358 knowledge about target blood pressure in pregnancy hypertension, acknowledgement of medication  
12  
13 359 side-effects and a positive interaction with the healthcare professional (including communication and  
14  
15 360 approach to decision-making) (figure 2b).

16 361 *Adherence*  
17

18 362 Internal conflict was an important determinant of non-adherence (figure 2a) as only the women who  
19  
20 363 expressed internal conflict reported non-adherence to antihypertensive medication. Around half (8 of  
21  
22 364 18) the women interviewed described non-adherence to prescribed antihypertensives at some point  
23  
24 365 during pregnancy with three women non-adherent at the time of interview (third trimester). However,  
25  
26 366 nine of 14 women describing internal conflict were adherent at the time of interview which was  
27  
28 367 mediated by the 'responsibility of motherhood' rather than concordance with the hypertension  
29  
30 368 management plan (figure 2b).

31 369

32  
33 370 Process of implementation (implementation strategies)  
34

35  
36 371 All three Trusts had a consultant obstetrician who led the care of women with chronic hypertension  
37  
38 372 and could be considered the opinion leader. Two of three Trusts had a named midwife or team of  
39  
40 373 midwives who specialised in the care of these women and were potential champions. However,  
41  
42 374 influencers and champions were not always utilised to support guideline implementation. Further, as  
43  
44 375 implementation of the guidelines had not been audited in any of the Trusts, although some outcome  
45  
46 376 data was routinely collected and analysed, opportunities to address unwanted variability were being  
47  
48 377 missed. These findings are supported by the national survey which found only a quarter of the Trusts  
49  
50 378 collected and analysed the outcomes of women with chronic hypertension in pregnancy.

51 379  
52  
53  
54  
55  
56  
57  
58  
59  
60

380

381 **DISCUSSION**

382 Women in this study (14/18) reported conflict relating to the uptake of prescribed antihypertensives  
383 in pregnancy and in many cases (8/14) internal conflict resulted in non-adherence. The most  
384 commonly cited reasons for conflict were lack of information provision, the side-effects experienced  
385 from the medication, beliefs about safety of medication and uncertainty about normal blood pressure  
386 ranges in pregnancy. Adherence to antihypertensives in conflicted pregnant women was mediated  
387 through a responsibility to motherhood rather than through a trusting partnership with healthcare  
388 professionals (supported by information provision, management of side-effects and relational factors)  
389 as found in concordant adherent women. Despite this, our findings demonstrated that optimal  
390 information provision about antihypertensives and shared decision-making occurred infrequently  
391 during antenatal consultations. Our findings also illustrated that the implementation of blood pressure  
392 target setting was sub-optimal as a result of 'unshared' or undocumented target setting and in some  
393 cases an absence of target setting.

394 A major strength of the study is the recruitment of Black, Asian and minority ethnic women to both  
395 the research (40%) and in the PPI planning stage as these women are disproportionately represented  
396 in the chronic hypertension in pregnancy population. A further strength is the use of multi-  
397 methodological approaches and an implementation framework in order to improve reliability, validity  
398 and generalisability. However, results from the national survey may overstate compliance with  
399 national guidance. The survey was sent out to healthcare professionals from professional  
400 organisations; respondents were therefore self-selecting and may represent a relatively interested  
401 group of healthcare professionals. The non-response rate is also unknown. The structured  
402 observations were carried out using a validated tool with high interrater reliability.<sup>12</sup> However, the  
403 observations were carried out by one midwife researcher which may affect the validity of the findings.  
404 Finally, the purposive sampling of healthcare professionals providing routine antenatal care for  
405 women with chronic hypertension resulted in a focus on lead carers (consultant obstetricians,  
406 obstetric medicine specialists and named midwives) being interviewed, rather than doctors in training  
407 and midwives in acute areas such as the maternity assessment unit.

408 The emergence of implementation science in recent years has identified that a gap between research  
409 findings and clinical practice exists, and that clinical guideline production does not ensure evidence-  
410 based practices are routinely adopted.<sup>21</sup> A recent study in British Columbia evaluated the  
411 implementation of recently published pregnancy hypertension guidelines and its associated effect on  
412 maternal and perinatal outcomes.<sup>22</sup> Following guideline dissemination the study reported a fall of

1  
2  
3 413 about a third in combined adverse maternal health outcomes (3.1% to 1.9%) but did not report a  
4  
5 414 significant reduction in adverse perinatal outcomes.<sup>22</sup> However, the wanted and unwanted variability  
6  
7 415 in guidance uptake was not reported and the underlying mechanisms that influenced outcomes is not  
8  
9 416 described. Our study uses an implementation framework by which variability in the implementation  
10  
11 417 of existing guidelines could be described and mechanisms that support and hinder their uptake can  
12  
13 418 be analysed, uniquely identifying strategies to improve the uptake of guidance and reduce maternal  
14  
15 419 and fetal morbidity. Critically, although the NICE hypertension in pregnancy guidelines<sup>6</sup> have been  
16  
17 420 recently updated, the core hypertension management recommendations remain unchanged, as do  
18  
19 421 the quality statements. Therefore, the findings of this study remain important and relevant to those  
20  
21 422 wanting to improve implementation.

22  
23 423 The study also adds to the small body of antihypertensive adherence in pregnancy research that has  
24  
25 424 found antihypertensive side-effects are a determinant of non-adherence. One recent randomised  
26  
27 425 controlled trial identified 11% of those included in randomisation discontinued the antihypertensive  
28  
29 426 due to side-effects.<sup>23</sup> Through the qualitative interview approach that enabled in depth exploration of  
30  
31 427 women's medication behaviours, our study found about 40% of all women did not adhere to their  
32  
33 428 prescribed antihypertensives at some point during pregnancy. This number compared more similarly  
34  
35 429 to an internet-based study of 210 pregnant women undertaken in Europe, America and Australia  
36  
37 430 which identified a 32.9% non-adherence rate in women taking cardiovascular medications in  
38  
39 431 pregnancy.<sup>24</sup> These findings are supported by similar smaller questionnaire-based studies of pregnant  
40  
41 432 women's medication adherence.<sup>25 26</sup> Our study may have identified higher rates of non-adherence  
42  
43 433 due to the nature of qualitative interviewing that explore in-depth women's experiences and  
44  
45 434 therefore unpick medication behaviours in a way that quantitative studies cannot.

46  
47 435 Women's adherence to antihypertensives in pregnancy was found to be sub-optimal, and strategies  
48  
49 436 to improve adherence are likely to reduce incidences of severe hypertension and prevent associated  
50  
51 437 morbidity (and mortality).<sup>27</sup> These include improved information provision about anti-hypertensives  
52  
53 438 and blood pressure targets as well as embedding shared decision-making into practice. Improvements  
54  
55 439 in target blood pressure setting practices overall are also likely to reduce incidences of severe  
56  
57 440 hypertension and prevent associated morbidity (and mortality).<sup>35</sup>

58  
59 441 This study adds to the body of research that already exists outside of pregnancy which demonstrates  
60  
442 that implementation of guidelines is not optimally achieved through the process of diffusion.<sup>21</sup>  
443 Although there was some evidence that some aspects of implementation were improved by having a  
444 specialist service for hypertension, this is likely to be most easily justified in areas where there is a  
445 high prevalence of chronic hypertension. Therefore, strategies to improve implementation in wider

1  
2  
3 446 settings are required. Professionals require guideline updates, implementation toolkits (to improve  
4 447 target blood pressure setting practices, standardised information about antihypertensives and in  
5 448 consultation aids) as well as support to have better conversations with their patients about medication  
6 449 choices and to improve the involvement of the women in the decision-making. Professionals also  
7 450 need to buy into the evidence that underpins the guidance. Maternal and perinatal outcomes, which  
8 451 includes episodes of severe hypertension, should be collected annually, and used to support informed  
9 452 discussions about optimising antenatal care for this group of women.

10 453 Further research into the effectiveness and long-term safety of common antihypertensives in  
11 454 pregnancy and breastfeeding to support evidenced-based guidelines is required.<sup>28</sup> Future research  
12 455 may also wish to evaluate strategies to reduce women's conflict regarding their antihypertensive use  
13 456 in pregnancy and establish the effect of interventions on maternal concordance and health outcomes.  
14 457 However, without further evidence relating to the safety and effectiveness of common  
15 458 antihypertensives it is unclear if further reductions in maternal and fetal morbidity can be achieved  
16 459 through prescribing practices. Future research should also focus on active implementation of blood  
17 460 pressure target setting and pathways for those with outside of target blood pressure readings. This is  
18 461 likely to reduce morbidity as target blood pressure setting in pregnancy has been shown to reduce  
19 462 incidences of severe hypertension.<sup>3 5</sup> Policymakers may also wish to consider further studies that  
20 463 identify effective models and pathways of care for reducing adverse perinatal outcomes within the  
21 464 context of pregnancy hypertension.

## 22 465 **CONCLUSION**

23 466 Maternal and neonatal morbidity resulting from severe hypertension in pregnancy is prevalent.<sup>1 4 5</sup>  
24 467 This evaluation of the implementation of the NICE hypertension in pregnancy guidelines (2010)<sup>6</sup>  
25 468 addresses strategies to reduce the number of episodes of severe hypertension and has identified sub-  
26 469 optimal target setting practices, poor information provision for pregnant women and variability in  
27 470 prescribing practices. Women's non-adherence to antihypertensives is higher than previously  
28 471 reported and this is likely to be contributing to adverse perinatal outcomes. Analysis of the domains  
29 472 that influence implementation of the guidelines have identified that education and decision-making  
30 473 strategies are needed to address both clinician and women's behaviour. Further research into the  
31 474 effectiveness and long-term safety of common antihypertensives is also required.

32 475 a. Contributor statement – RW, LC and JS conceived of the study, the manuscript, and analyses, with  
33 476 contributions from LW, JG, HB and HW. RW was responsible for data management and data analysis.  
34 477 All authors reviewed, critically revised, and approved the manuscript.

1  
2  
3 478 b. Competing interests – None declared  
4

5 479 c. Funding – This work was supported by the National Institute for Health Research (Research  
6  
7 480 Professorship RP-2014-05-019) and by the National Institute for Health Research (NIHR) Collaboration  
8  
9 481 for Leadership in Applied Health Research and Care South London (NIHR CLAHRC South London) at  
10  
11 482 King’s College Hospital NHS Foundation Trust. Jane Sandall is an NIHR Senior Investigator and is  
12  
13 483 supported by the National Institute for Health Research (NIHR) Applied Research Collaboration South  
14  
15 484 London (NIHR ARC South London) at King’s College Hospital NHS Foundation Trust. The views  
16  
17 485 expressed are those of the author[s] and not necessarily those of the NIHR or the Department of  
18  
19 486 Health and Social Care.

20 487 d. Data sharing statement - All data relevant to the study are included in the article.  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
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

## 488 References

- 489 1. Bramham K, Parnell B, Nelson-Piercy C, et al. Chronic hypertension and pregnancy outcomes:  
490 systematic review and meta-analysis. *BMJ : British Medical Journal* 2014;348:g2301. doi:  
491 10.1136/bmj.g2301
- 492 2. Knight M NM, Tuffnell D, Kenyon S, Shakespeare J, Brocklehurst P, Kurinczuk JJ (Eds.) on behalf of  
493 MBRRACE-UK. . Saving Lives, Improving Mothers' Care – Surveillance of maternal deaths in  
494 the UK 2012–14 and lessons learned to inform maternity care from the UK and Ireland  
495 Confidential Enquiries into Maternal Deaths and Morbidity 2009-14, 2016.
- 496 3. Magee LA, von Dadelszen P, Rey E, et al. Less-tight versus tight control of hypertension in  
497 pregnancy. *N Engl J Med* 2015;372(5):407-17. doi: 10.1056/NEJMoa1404595 [published  
498 Online First: 2015/01/30]
- 499 4. Flenady V, Koopmans L, Middleton P, et al. Major risk factors for stillbirth in high-income  
500 countries: a systematic review and meta-analysis. *Lancet* 2011;377(9774):1331-40. doi:  
501 10.1016/S0140-6736(10)62233-7 [published Online First: 2011/04/19]
- 502 5. Magee LA, von Dadelszen P, Singer J, et al. The CHIPS Randomized Controlled Trial (Control of  
503 Hypertension in Pregnancy Study): Is Severe Hypertension Just an Elevated Blood Pressure?  
504 *Hypertension* 2016;68(5):1153-59. doi: 10.1161/HYPERTENSIONAHA.116.07862 [published  
505 Online First: 2016/09/14]
- 506 6. (NICE) NifHCE. Hypertension in pregnancy CG107 2010 [Available from:  
507 <https://www.nice.org.uk/guidance/cg107>
- 508
- 509 7. (NICE) NifHCE. Hypertension in pregnancy. Quality Standard (QS35), 2013.
- 510 8. (NICE) NifHCE. Patient Experience in Adult NHS Services: Improving the Experience of Care for  
511 People Using Adult NHS Services: Patient Experience in Generic Terms. London 2012.
- 512 9. Kirk MA, Kelley C, Yankey N, et al. A systematic review of the use of the Consolidated Framework  
513 for Implementation Research. *Implementation Science* 2016;11(1):72. doi: 10.1186/s13012-  
514 016-0437-z
- 515 10. Kirkpatrick DH, Burkman RT. Does Standardization of Care Through Clinical Guidelines Improve  
516 Outcomes and Reduce Medical Liability? *Obstetrics & Gynecology* 2010;116(5):1022-26. doi:  
517 10.1097/AOG.0b013e3181f97c62
- 518 11. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for  
519 intervention description and replication (TIDieR) checklist and guide. *BMJ : British Medical  
520 Journal* 2014;348:g1687. doi: 10.1136/bmj.g1687
- 521 12. Burt J, Abel G, Elmore N, et al. Assessing communication quality of consultations in primary care:  
522 initial reliability of the Global Consultation Rating Scale, based on the Calgary-Cambridge  
523 Guide to the Medical Interview. *BMJ Open* 2014;4(3):e004339. doi: 10.1136/bmjopen-2013-  
524 004339
- 525 13. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology*  
526 2006;3(2):77-101. doi: 10.1191/1478088706qp063oa
- 527 14. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research  
528 findings into practice: a consolidated framework for advancing implementation science.  
529 *Implementation science : IS* 2009;4:50. doi: 10.1186/1748-5908-4-50 [published Online First:  
530 2009/08/12]
- 531 15. International consortium for health outcome measurements i. Pregnancy and childbirth standard  
532 set. 2016
- 533 16. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *BMJ*  
534 2000;320(7227):114-16. doi: 10.1136/bmj.320.7227.114
- 535 17. O'Cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health services  
536 research. *Journal of health services research & policy* 2008;13(2):92-8. doi:  
537 10.1258/jhsrp.2007.007074 [published Online First: 2008/04/18]



- 1  
2  
3 538 18. excellence Nifhac. Hypertension in adults: diagnosis and management (NG136). 2019  
4 539 19. Vrijens B, Vincze G, Kristanto P, et al. Adherence to prescribed antihypertensive drug treatments:  
5 540 longitudinal study of electronically compiled dosing histories. *BMJ* 2008;336(7653):1114-17.  
6 541 doi: 10.1136/bmj.39553.670231.25  
7 542 20. Dickinson D, Wilkie P, Harris M. Taking medicines: concordance is not compliance. *BMJ*  
8 543 1999;319(7212):787. doi: 10.1136/bmj.319.7212.787  
9 544 21. Rangachari P, Rissing P, Rethemeyer K. Awareness of evidence-based practices alone does not  
10 545 translate to implementation: insights from implementation research. *Quality management*  
11 546 *in health care* 2013;22(2):117-25. doi: 10.1097/QMH.0b013e31828bc21d [published Online  
12 547 First: 2013/04/02]  
13 548 22. von Dadelszen P, Sawchuck D, McMaster R, et al. The Active Implementation of Pregnancy  
14 549 Hypertension Guidelines in British Columbia. *Obstetrics & Gynecology* 2010;116(3):659-66.  
15 550 doi: 10.1097/AOG.0b013e3181eb669d  
16 551 23. Webster Louise M, Myers Jenny E, Nelson-Piercy C, et al. Labetalol Versus Nifedipine as  
17 552 Antihypertensive Treatment for Chronic Hypertension in Pregnancy. *Hypertension*  
18 553 2017;70(5):915-22. doi: 10.1161/HYPERTENSIONAHA.117.09972  
19 554 24. Lupattelli A, Spigset O, Nordeng H. Adherence to medication for chronic disorders during  
20 555 pregnancy: results from a multinational study. *International Journal of Clinical Pharmacy*  
21 556 2014;36(1):145-53. doi: 10.1007/s11096-013-9864-y  
22 557 25. Matsui D. Adherence with Drug Therapy in Pregnancy. *Obstetrics and Gynecology International*  
23 558 2012;2012:5. doi: 10.1155/2012/796590  
24 559 26. Abheiden CNH, van Reuler AVR, Fuijkschot WW, et al. Aspirin adherence during high-risk  
25 560 pregnancies, a questionnaire study. *Pregnancy Hypertension: An International Journal of*  
26 561 *Women's Cardiovascular Health* 2016;6(4):350-55. doi:  
27 562 <https://doi.org/10.1016/j.preghy.2016.08.232>  
28 563 27. Abalos E, Duley L, Steyn DW, et al. Antihypertensive drug therapy for mild to moderate  
29 564 hypertension during pregnancy. *Cochrane Database Syst Rev* 2018;10:CD002252. doi:  
30 565 10.1002/14651858.CD002252.pub4 [published Online First: 2018/10/03]  
31 566 28. Excellence NifHaC. Hypertension in pregnancy: diagnosis and management  
32 567 NICE guideline [NG133]. 2019  
33 568  
34 569  
35 570  
36 571  
37 572  
38 573  
39 574  
40 575  
41 576  
42 577

43 570 Figure 1. Interpretation of integrated analysis: a strategy for improved implementation of evidence-  
44 571 based hypertension in pregnancy management

45 572 Figure 2a. Women's adherence and concordance with prescribed antihypertensives. Numbers 1-18  
46 573 represent interviewed women and their experiences of anti-hypertensive prescribing during  
47 574 pregnancy. Women who experienced a change in their adherence or in the reporting of internal  
48 575 conflict are plotted more than once in different bubbles. 2b. Facilitators of women's adherence and  
49 576 of concordance.

Individual setting

Information and education (doctors and midwives)

Offering women informed choices about AHTs based on evidence, side effects and medicine history

Shared decision-making

Share target blood pressure (and above target pathways) with all HCPs and women

Sub-optimal antenatal hypertension management



Optimised antenatal hypertension management

Access to early pregnancy care    Multi-disciplined care    Specialist midwives

Inner setting

Defined pathways and schedule of care

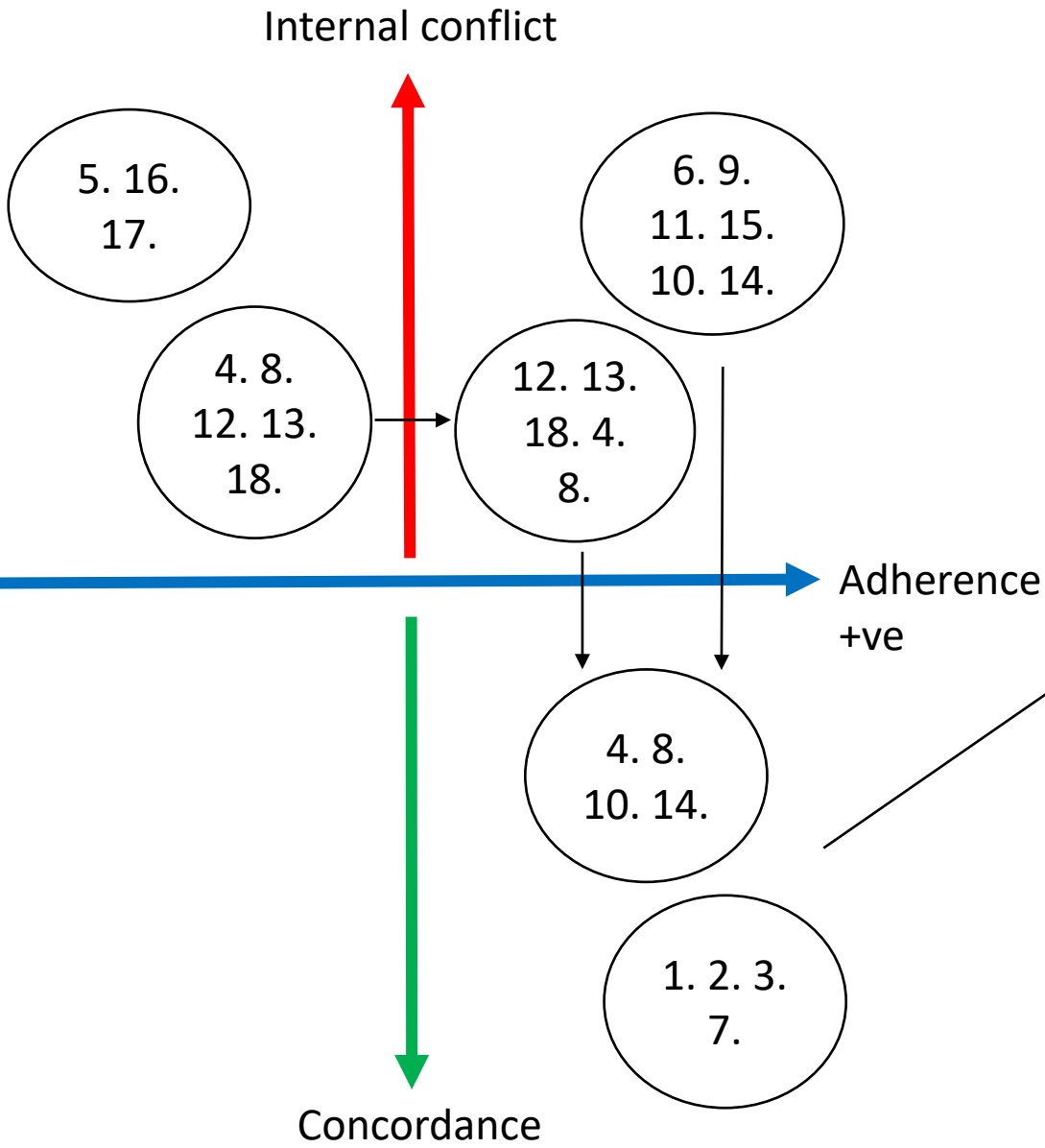
Evidence-based guidelines for CHT in pregnancy

Outer setting

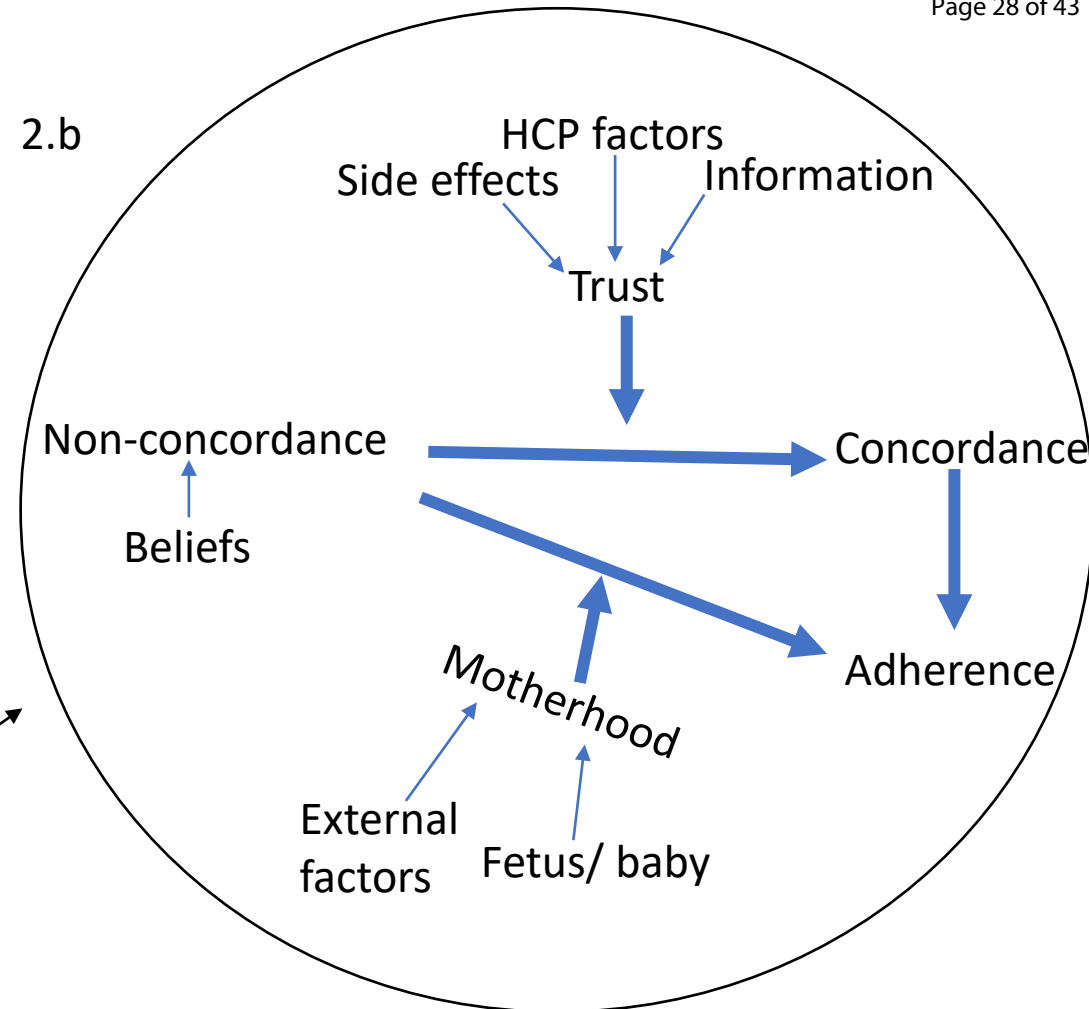
Research in the management of CHT in pregnancy



2.a



2.b



## Supplementary file 1

## Chronic hypertension in pregnancy – healthcare professional survey

Respondents	Number (97)	Percentage %
Obstetrician	69	71.1
Of which are consultants	53	55
Midwife	28	28.9
Of which are specialist/ senior midwife	22	22.7
NHS hospital trusts represented (including England, Northern Ireland, Scotland and Wales)	69	-

Question 1: If you see a pregnant woman with chronic hypertension who is currently taking either ACEIs or ARBs (e.g. at the beginning of pregnancy), how often would you ask her to stop taking them?

Response	Number (97)	Percentage (%)
Always	57	57.8
Almost always	27	27.8
About two thirds of the time	1	1
About half of the time	4	4.1
About a third of the time	0	0
Very rarely	1	1
Never	3	3.1
Missing	4	4.1

Question 2: What do you usually use as your first line anti-hypertensive treatment(s) for women with chronic hypertension in pregnancy?

Anti-hypertensive (non-exclusive)	Number (97)	Percentage (%)
Labetalol	85	87.6
Methyldopa	29	29.9
Nifedipine	32	33.0
Amlodipine	2	2.1

Question 3: What additional anti-hypertensive medication do you use for treating women with chronic hypertension in pregnancy?

Anti-hypertensive (non-exclusive)	Number (97)	Percentage (%)
Amlodipine	37	38.1
Atenolol	2	2.1
Doxazosin	23	23.7
Enalapril	1	1.0
Hydralazine (oral)	2	2.1
Labetalol	38	39.2
Methyldopa	60	61.9
Metoprolol	1	1.0
Nifedipine	79	81.4

Question 4: How frequently do you set a blood pressure target for women with chronic hypertension in pregnancy who need anti-hypertensive treatment (assuming no other co-morbidity) (mmHg)?

Answer	Number (97)	Percentage %
Always	36	37.1
Almost always	36	37.1
About two thirds of the time	8	8.2
About half of the time	3	3.1
About a third of the time	4	4.1
Very rarely	3	3.1
Never	1	1.0
Other	6	6.2
In the guidelines but compliance unknown	2	
Frequency not described	4	

Question 5: What blood pressure target do you usually set for pregnant women with chronic hypertension (assuming no other co-morbidity) (mmHg)?

Systolic	Number (97)	Percentage %	Median (IQR1-IQR3)
120	2	2.1	
125	0	0.0	
130	6	6.2	
135	2	2.1	
140	33	34.0	
145	0	0.0	
150	40	41.2	
155	1	1.0	
160	8	8.2	
Missing	4	4.1	
Median			150 (140-150)

Diastolic	Number (97)	Percentage %	Median (IQR1-IQR3)
80	9	9.3	
85	7	7.2	
90	37	38.1	
95	8	8.2	
100	27	27.8	
110	3	3.1	
Missing	5	5.2	
Median			90 (90-100)

Question 6: How often do you prescribe Aspirin for women with chronic hypertension in pregnancy?

Answer	Number (97)	Percentage %
Always	53	54.6
Almost always	36	37.1
About two thirds of the time	5	5.2
About half of the time	2	2.1
Very rarely	1	1.0

Question 7: At what gestation do these women usually receive their first Aspirin prescription?

Answer	Number (97)	Percentage %
Before 12 weeks	41	42.3
12-15+6 weeks	52	53.6
16-19+6 weeks	1	1.0
Missing answer	3	3.1

Question 8: For a woman with uncomplicated chronic hypertension in pregnancy (i.e. no additional risk factors), how many routine fetal growth scans do they receive (excluding nuchal and anomaly scans)?

Additional scans	Number (97)	Percentage %	Median (IQR1-IQR3)
None	4	4.1	
1	12	12.4	
2	23	23.7	
3	37	38.1	
4	21	21.6	
>4	1	1.0	
			3 (2-3)

Question 9: When do you usually plan birth for women with chronic hypertension whose blood pressure is controlled below 160/110?

Gestation	Number (97)	Percentage (%)	Median (IQR1-IQR3)
Before 34 weeks	3	3.1	
34-34+6 weeks	2	2.1	
35-35+6 weeks	2	2.1	
36-36+6 weeks	4	4.1	
37-37+6 weeks	27	27.8	
38-38+6 weeks	36	37.1	
39-39+6 weeks	41	42.3	
40-41 weeks	28	28.9	
Await spontaneous labour	5	5.2	
Other – individualised	4	4.2	
			38.5 (37-39)

Question 10: Involving pregnant women who have chronic hypertension in their pregnancy and birth planning is an important part of the consultation?

Sentiment	Number (97)	Percentage (%)
Agree Strongly	79	81.4
Agree	15	15.5
Slightly Agree	2	2.1
Slightly disagree	0	0.0
Disagree	0	0.0
Disagree Strongly	1	1.0

Question 11: If you wish, can you give an example of how you enable women to be actively involved in their care?

Themes	Number (47)	Percentage %
Total responses	47	
SDM in the following areas		
• Home BP	10	21
• Monitoring BP	6	12.8
• Anti-hypertensives	5	10.6
• Planning birth (induction of labour)	17	36
• Organisation of care	4	8.5
Discussing risks and benefits	2	4.3
How to identify pre-eclampsia	2	4.3

Question 12: In your maternity unit what term/s best describes the antenatal care provided to most women with chronic hypertension?

Care provision	Number (97)	Percentage %
Named consultant-led general antenatal clinic (maternal medicine clinic)	63 (7)	64.9 (7.2)
Consultant-led specialist hypertension in pregnancy clinic	25	25.8
Multi-disciplinary clinic with additional medical professional	20	20.6
Consultant obstetrician and midwife antenatal clinic	15	15.5
Shared-care GP/ obstetrician/ midwife	7	7.2
Specialist midwifery care (e.g. medical conditions team)	6	6.2
Hospital midwifery care	1	1.0
Community based midwifery care	4	4.1
Day assessment unit	2	2.1

1  
2  
3 Question 13: In your maternity unit when do the pregnant women with chronic hypertension usually  
4 first get seen by an obstetrician?  
5

Gestation	Number (97)	Percentage %
Before 12 weeks	24	24.7
12-15+6 weeks	63	64.9
16-27+6 weeks	9	9.3
Missing data	1	1.0

6  
7  
8  
9  
10  
11  
12  
13  
14 Question 14: Do you or someone in your unit specifically collect and analyse the outcomes of  
15 women with chronic hypertension in pregnancy annually?  
16

Response	Number (97)	Percentage (%)
Yes	24	24.7
No	67	69.0
Unsure	4	4.1
Some aspects	2	2.0

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  
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

Supplementary file 2

**Interview topic guide for clinicians:**

- Descriptions of the general approach to practice and how clinicians approach treatment decisions
- Discussion about the sources of evidence and knowledge that influence practice in general
- Participants' beliefs and experiences of using or having contact with clinical guidance (NICE in particular),
- Participants' views regarding how EBM and clinical guidelines could be better mobilised into practice

Interview schedule:

- Introductions
- Confidentiality
- I am interviewing you today for the CHAMPION study about chronic hypertension, you provide antenatal care for women with CHP is that right?
- Can you tell me a about your CHP clinic and your clinical practice in relation to chronic hypertension in pregnancy?
- How do you approach decision-making, for example commencing or changing hypertensive medication or delivery the baby early?
- What are you views and experiences of involving women in decision about their care or treatment plan?
- How do you source evidence and develop knowledge around hypertension in pregnancy?
- What are you experiences of clinical guidance e.g. NICE/ RCOG?
- How do you think we could better implement evidence-based medicine into clinical practice?

Reference: Grove, A., Clarke, A. and Currie, G. (2015) 'The barriers and facilitators to the implementation of clinical guidance in elective orthopaedic surgery: a qualitative study protocol', *Implementation Science*, 10(1), 81.

**Women's experience of their care**

- Introductions
- Confidentiality
- During this pregnancy you have been treated for chronic hypertension is that right?
- Can you tell me a bit about your high blood pressure and your pregnancy?
- How satisfied are you with the results of your care during your pregnancy?
- Thinking about your care during your pregnancy...Were you given information about your choices for maternity care?
- Were you given enough information to help you decide about your care?
- Were you given information at the right time to help you decide about your care?
- Did you have confidence and trust in the staff caring for you?

Reference: International Consortium for Health Outcomes Measurement. Pregnancy and Childbirth Standard Set and Reference Guide. 2016. <http://www.ichom.org/medical-conditions/pregnancy-and-childbirth/>.

## Supplementary file 3

Maternal demographics of women observed, interviewed and included for case-note review. Women interviewed are a subset of those observed. Case-notes identified for review are a different cohort of women.

Women demographics	Observed n=28 (%)	Interviewed n=18 (%)	Case-notes n=55 (%)
<b>Ethnicity</b>			
White British	9 (32.0)	7 (39.0)	15 (27.3)
White Other	6 (21.0)	4 (22.0)	8 (14.5)
Black	9 (32.0)	5 (28.0)	18 (32.7)
Asian	2 (7.0)	1 (5.5)	8 (14.5)
Any other	2 (7.0)	1 (5.5)	6 (10.9)
<b>Parity at booking</b>			
0	9 (32.0)	7 (39.0)	15 (27.3)
1	11 (39.0)	7 (39.0)	21 (38.2)
2	7 (25.0)	4 (22.0)	10 (18.2)
3	0 (0.0)	0 (0.0)	6 (10.9)
4	0 (0.0)	0 (0.0)	2 (3.6)
5	1 (4.0)	0 (0.0)	1 (1.8)
<b>Age</b>			
20-34	17 (61.0)	11 (61.0)	23 (41.8)
35-39	7 (25.0)	5 (28.0)	21 (38.9)
40-44	4 (14.0)	2 (11.0)	11 (20.4)
<b>BMI</b>			
<18.5	0 (0.0)	0 (0.0)	1/52 (1.9)
18.5-24.9	7 (25)	6 (33.3)	13/52 (25.0)
25-29.9	10 (36)	6 (33.3)	13/52 (25.0)
30-34.9	9 (32)	5 (28.0)	11/52 (21.2)
35-39.0	2 (7)	1 (5.5)	6/52 (11.5)
>40.0	0 (0)	0 (0.0)	8/52 (7.7)



## Supplementary file 4

## Pregnancy and birth outcomes – Case notes review

<b>Outcomes</b>	<b>Case notes review Nominator/denominator (%)</b>
Women with episode of severe hypertension	25/55 (45.5)
1 <sup>st</sup> trimester episode	2/40 (5.0)
2 <sup>nd</sup> trimester episode	13/40 (32.5)
3 <sup>rd</sup> trimester episode	25/40 (62.5)
Birth weight - median (IQR1 – IQR3)	2927.5 (2592.5 - 3200)
Admission to NNU	9/55 (16.4)

## Supplementary file 5

Target blood pressure setting and prescribing practices per Trust – as derived from case-note review

	<b>Hospital Trust 1 n=29 (%)</b>	<b>Hospital Trust 2 n=13 (%)</b>	<b>Hospital Trust 3 n=13 (%)</b>
<b>Target BP documented &lt;150/100mmHg</b>	20/26 (77.0)	3/13 (23.0)	5 (38.0)
<b>Labetalol</b>	12/26 (46.0)	7/12 (58.3)	9/11 (82.0)
<b>Nifedipine</b>	9/26 (34.5)	0/12 (0.0)	0/11 (0.0)
<b>Methyldopa</b>	3/26 (11.5)	4/12 (33.3)	1/11 (9.0)
<b>Other</b>	2/26 (8.0)	1/12 (8.3)	1/11 (9.0)

For peer review only

# The quality of mixed methods studies in health services research

Alicia O’Cathain, Elizabeth Murphy<sup>1</sup>, Jon Nicholl

Medical Care Research Unit, School of Health and Related Research, University of Sheffield, Sheffield; <sup>1</sup>School of Sociology and Social Policy, University of Nottingham, Nottingham, UK

**Objectives:** To assess the quality of mixed methods studies in health services research (HSR).

**Methods:** We identified 118 mixed methods studies funded by the Department of Health in England between 1994 and 2004, and obtained proposals and/or final reports for 75. We applied a set of quality questions to both the proposal and report of each study, addressing the success of the study, the mixed methods design, the individual qualitative and quantitative components, the integration between methods and the inferences drawn from completed studies.

**Results:** Most studies were completed successfully. Researchers mainly ignored the mixed methods design and described only the separate components of a study. There was a lack of justification for, and transparency of, the mixed methods design in both proposals and reports, and this had implications for making judgements about the quality of individual components in the context of the design used. There was also a lack of transparency of the individual methods in terms of clear exposition of data collection and analysis, and this was more a problem for the qualitative than the quantitative component: 42% (19/45) versus 18% (8/45) of proposals ( $p = 0.011$ ). Judgements about integration could rarely be made due to the absence of an attempt at integration of data and findings from different components within a study.

**Conclusions:** The HSR community could improve mixed methods studies by giving more consideration to describing and justifying the design, being transparent about the qualitative component, and attempting to integrate data and findings from the individual components.

*Journal of Health Services Research & Policy* Vol 13 No 2, 2008: 92–98

© The Royal Society of Medicine Press Ltd 2008

## Introduction

Mixed methods studies are common in health services research (HSR).<sup>1</sup> They consist of two separate components of data collection and analysis within a single study: at least one quantitative method with structured data collection and statistical analysis, and at least one qualitative method with less structured data collection and thematic analysis.<sup>2</sup> Commissioners and consumers of research, as well as researchers themselves, need to judge whether a mixed methods study has been undertaken well or poorly, assessing whether it is good mixed methods research as well as good research. The quality of mixed methods research has been considered explicitly in health, educational and social research,<sup>3–8</sup> and implicitly when researchers have discussed the challenges of designing and implementing these studies.<sup>9,10</sup> However, the issue has received little

consideration overall, with a recent search for quality criteria for mixed methods research concluding that there were none available,<sup>7</sup> even though attempts have been made to develop them.<sup>3</sup> Given that there are no agreed criteria for assessing the quality of these studies,<sup>8</sup> and that researchers are still debating the meaning of quality for mixed methods research,<sup>6</sup> it is premature to attempt to develop definitive criteria. Instead, it seems sensible to follow an approach taken by researchers considering quality in the context of synthesizing qualitative and quantitative evidence<sup>11</sup> and devise a set of questions which could be applied to mixed methods primary research to facilitate judgements about quality. We devised a set of ‘quality questions’ and applied them to proposals and reports of mixed methods studies to assess the quality of mixed methods studies in HSR.

Alicia O’Cathain PhD, MRC Fellow, Jon Nicholl MSc, Professor, Medical Care Research Unit, School of Health and Related Research, University of Sheffield, Regent Street, Sheffield S1 4DA, UK; Elizabeth Murphy PhD, Professor, School of Sociology and Social Policy, University of Nottingham, Nottingham, UK.

Correspondence to: a.ocathain@sheffield.ac.uk

## Methods

This research was part of a wider study exploring the use of mixed methods research in HSR. The wider study consisted of a quantitative documentary analysis of 75 mixed methods studies to determine the type

1 and quality of mixed methods research undertaken, and  
2 qualitative interviews with 20 researchers to explore  
3 facilitators and barriers to exploiting the potential of  
4 this approach.<sup>1,12</sup>

### 7 Devising questions about quality

9 We devised a framework for the quality assessment  
10 based on detailed consideration of the literature on  
11 mixed methods research in the fields of health, social  
12 and educational research. We searched the health data-  
13 bases MEDLINE and CINAHL. We then sought expert  
14 opinion encapsulated in key textbooks.<sup>10,13-20</sup> Finally  
15 we searched the Social Science Citations Index,  
16 PsycINFO, ERIC and the British Education Index to  
17 identify social, behavioural and educational research.  
18 The search for literature took place in 2003 and was  
19 updated in 2006. Quality was one of 11 issues identified  
20 in this review.

21 Within the literature, one suggested assessment cri-  
22 terion for mixed methods studies was whether they  
23 had been completed successfully in terms of adequately  
24 addressing the research questions with allocated  
25 resources.<sup>5</sup> Other researchers focused on the quality of  
26 methods. There was no suggestion of using a tool devel-  
27 oped for generic use across all designs. Rather, research-  
28 ers attempted to develop quality criteria by devising  
29 separate lists of criteria for the quantitative and the  
30 qualitative research.<sup>7</sup> Their assumption was that  
31 methods are linked to paradigms and therefore the  
32 criteria used to assess different methods should also be  
33 linked to paradigms.<sup>7</sup> However, not everyone agrees  
34 that methods are paradigm-specific<sup>18</sup> or that different  
35 criteria are needed for qualitative and quantitative  
36 research.<sup>21</sup> The same criteria have been proposed for  
37 both<sup>21</sup> although the appropriate means for judging  
38 against these criteria may differ because of the research  
39 practices employed in different methodological  
40 approaches. The mixed methods design<sup>10</sup> and the inte-  
41 gration between methods<sup>3</sup> can be assessed as well as the  
42 individual methods. A good mixed methods study  
43 clearly justifies why a mixed methods approach is  
44 necessary or superior to another, offers transparency  
45 of the mixed methods design, and offers appropriate  
46 sampling, data collection and analysis of individual com-  
47 ponents relating to that design.<sup>3,4,10</sup> Thus the design  
48 may determine the criteria used to make judgements  
49 about the individual components of the study. In-  
50 tegration of data or findings from each component  
51 is a key part of mixed methods research,<sup>10</sup> distinguish-  
52 ing it from qualitative and quantitative studies under-  
53 taken independently. When integration occurs, it is  
54 important that data transformations are defensible,  
55 that contradictory findings are explained and conver-  
56 gent findings are not related to shared bias between  
57 methods.<sup>3</sup> Expertise may be needed within a research  
58 team to integrate at the analysis stage.<sup>22</sup> Finally,  
59 researchers have discussed the importance of inferences  
60 from mixed methods studies being trustworthy<sup>6</sup> and  
appropriate in the light of the design used.<sup>3</sup> As yet

there are no criteria for assessing the quality of infer-  
ences from mixed methods research, although research-  
ers are considering the complexity of this issue.<sup>23</sup>

When developing the framework for our quality ques-  
tions we chose not to use a generic tool because they  
have variable applicability across different research  
designs.<sup>24</sup> We chose to assess the qualitative and quanti-  
tative components separately because they each contri-  
bute to the study as a whole and because the quality of  
one or both components may suffer as a consequence  
of being part of a mixed methods study.<sup>25-27</sup> In  
addition to the individual components, we included  
an assessment of the success of the study, the design,  
the integration and the inferences. Within this frame-  
work we constructed questions based on the literature  
review and reading the proposals and reports from  
four mixed methods studies in HSR.

### Identifying mixed methods studies

In 2004, mixed methods studies were identified  
through a systematic search of summaries of studies  
funded by the Department of Health, a key commis-  
sioner of health services research in England at that  
time. The methods have been described elsewhere<sup>1,12</sup>  
and are summarized here. Summaries of single studies  
funded between 1994 and 2004 through 10 pro-  
grammes were read. The programmes were: Health  
Technology Assessment; Service Delivery and  
Organization; New and Emerging Applications of  
Technology; Policy Research Programme; and the  
NHS Research & Development programmes of  
maternal and child health, primary and secondary  
care interface, cardiovascular disease and stroke, foren-  
sic mental health, primary dental care, and promoting  
implementation of research findings. A total of 118  
mixed methods studies were identified. The lead  
researcher of each study was written to with a request  
for the research proposal, the final report for completed  
studies and a list of any emerging publications.

### Application of quality questions

A data extraction form was devised which consisted of  
the quality questions with the tick box options of 'yes',  
'yes, but improvements are possible', 'no', 'not enough  
information (NEI)' and 'not applicable (N/A)'. Space  
for open comments was available alongside each ques-  
tion, where the assessor (AOC) could record details of  
good and poor practice. The data extraction form was  
applied to each study by one researcher, first to the pro-  
posal and then to the report. Finally, any differences  
between the proposal and report were noted.

### Analysis

The structured data were entered into SPSS. The main  
analysis was descriptive, displaying the proportions of  
proposals and reports falling into each category of  
each question. The chi-squared test was used when

1 comparing results for the individual qualitative and  
2 quantitative components. Open comments were quanti-  
3 tized<sup>28</sup> by transcribing them into Word, grouping them  
4 into themes, and counting the number of studies in  
5 which a theme occurred.<sup>29</sup>

## 8 Results

9 Documentation was received for 75 mixed methods  
10 studies. Full proposals were obtained for 60% (45/75)  
11 of the studies. Final reports were only available for the  
12 52 studies completed by the time of data collection,  
13 and were obtained for 92% (48), although one was a  
14 summary report that was too brief for inclusion in the  
15 assessment of quality, leaving 47 reports. Both a propo-  
16 sal and report was available for 20 studies.

### 19 Success

20 The potential to produce a successfully completed study  
21 was assessed using the research proposals. In most pro-  
22 posals, the quantitative methods appeared to be feasible  
23 within the time and money allocated (Table 1).  
24 However, even recognizing that some aspects of quali-  
25 tative research cannot be fixed at the design stage (e.g.  
26 sample size for theoretical sampling), there was not  
27 enough detail to determine the feasibility of the qualitat-  
28 ive methods in one-third of studies – for example, no  
29 indication of numbers of interviews to be undertaken  
30 or no indication of when the qualitative research  
31 would be conducted in the study timetable. We had con-  
32 cerns about the feasibility of the qualitative component  
33 in another one-third of proposals. From the open com-  
34 ments we identified 14 proposals where a large number  
35 of qualitative interviews were planned in a short time  
36 scale – for example, 40 interviews in four months  
37 without specifying the depth of interview and analysis.  
38 In nine of these studies the report was available and in  
39 four cases considerably fewer interviews were under-  
40 taken than planned. However, concerns highlighted  
41 about the feasibility of the qualitative research did not  
42 necessarily translate into shortfalls in the final study.

43 We defined a successful study as one that produced  
44 everything that had been planned at the proposal  
45 stage. A direct comparison of the final study report  
46 with the proposal was only possible on the subset of 20  
47

studies for which both were available. In other cases  
the assessment relied on researchers detailing the  
planned and implemented study within their final  
report. Non-completion of a whole component of a  
study was rare (Table 1). However, in one-fifth of  
reports, one of the methods within a component was  
not executed as planned. This tended to be due to a  
range of problems in the field.

### Mixed methods design

A justification for using mixed methods research was  
only given in one-third of proposals and reports  
(Table 2). A minority of studies explicitly articulated  
the design in terms of the priority of methods, the  
purpose of combining methods, the sequence of  
methods and the stage at which integration would or  
did occur. It was particularly helpful for the subsequent  
quality assessment of individual components if research-  
ers were explicit about the priority of methods and the  
role of any less dominant method. For example, it  
seemed inappropriate to have 40 in-depth interviews  
as a preliminary aid to develop a questionnaire, but  
appropriate if these interviews were also to be used as  
a primary means of investigating the issue under  
study. A lack of transparency of the overall design  
could occur in the context of excellent description of  
individual components.

When the design was not discussed explicitly it was  
usually possible to work out the key elements from  
reading the documentation. In most cases the design  
was assessed as appropriate for addressing the research  
question. However, researchers rarely discussed issues  
of rigour in relation to the design employed. An  
example of addressing rigour for the design was  
where researchers proposed that qualitative findings  
would not be shared with quantitative colleagues under-  
taking a randomized controlled trial to minimize the  
possibility of contamination of that trial; in another  
two studies, the qualitative research was undertaken  
with people not participating in the trial in order to  
avoid contaminating the trial. While the extent to  
which this attention to contamination avoidance was  
necessary may be debatable, it constitutes some evidence  
that researchers had given serious consideration to  
design issues related to mixed methods research.

51 **Table 1** Assessment of the success of mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
54 1 Is the quantitative component feasible?	82%	2%	4%	11%				
55 2 Is the qualitative component feasible?	38%	20%	13%	29%				
56 3 Is the mixed methods design feasible?	51%	0%	7%	42%				
57 4 Have both qualitative and quantitative components been completed?					87%	6%	2%	4%
58 5 Were some quantitative methods planned but not executed?					19%	0%	45%	36%
59 6 Were some qualitative methods planned but not executed?					21%	2%	38%	38%
60 7 Did the mixed methods design work in practice?					85%	0%	2%	13%

NEI, not enough information; N/A, not applicable



**Table 2** Assessment of the mixed methods design of studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the use of mixed methods research justified?	31%	3%	60%	4%	30%	2%	66%	2%
2 Is the design for mixing methods described?								
Priority	16%	2%	78%	4%	15%	0	83%	2%
Purpose	42%	0	53%	4%	34%	4%	60%	2%
Sequence	56%	0	40%	4%	49%	0	49%	2%
Stage of integration	24%	0	71%	4%	21%	0	77%	2%
3 Is the design clearly communicated?	80%	0	16%	4%	81%	4%	9%	6%
4 Is the design appropriate for addressing the research questions?	87%	2%	2%	9%	87%	0%	2%	11%
5 Has rigour of the design been considered (proposal) or adhered to (report)?	7%	0	93%	0%	21%	0%	0%	79%

NEI, not enough information; N/A, not applicable

### Quantitative component

The roles of the quantitative methods were usually communicated well within proposals and reports (Table 3). However, sufficient details were sometimes not given about these methods. In eight proposals the quantitative methods were only sketchily described and in a further 13 proposals some aspects of the quantitative methods were not described, in particular, the analysis (8) and the numbers involved (5). This was less of an issue for reports but nonetheless there were still problems with sketchy description overall (4) or little or no description of the analysis (5). This lack of transparency made it difficult to assess other aspects of quality.

Validity of the methods within the quantitative components was assessed by considering the attention researchers gave to issues such as confounding and bias. Validity was explicitly discussed in two-thirds of proposals, with little evidence that the rigour of any method was compromised (Table 3). There were few examples of an individual method being compromised by the mixed methods approach. One example was a Delphi exercise which was restricted in order to fit the timetable of the qualitative fieldwork.

It was difficult to determine the sophistication of proposed analyses due to the lack of detail about analysis in the research proposals. There was more information about analyses available in research reports and here

concerns were identified about the sophistication of one-quarter of quantitative analyses. We identified 12 studies where the reported quantitative results seemed simplistic, sometimes only presenting descriptive statistics with no statistical tests and in two cases using an experimental design which was then ignored in the analysis.

### Qualitative component

The roles of the qualitative methods were usually communicated well within proposals and reports (Table 4). However, qualitative methods were often not described in sufficient detail and this occurred more frequently than for the quantitative components, both within proposals ( $p = 0.011$ ) and reports ( $p = 0.08$ ). First, there was sketchy description of the qualitative methods overall (15 proposals and 11 reports). In three of these reports there was no description of the qualitative methods at all, only the findings. Second, there were no details about an important aspect of the qualitative research, particularly the analysis (six proposals and nine reports). Third, one method was described in detail, usually interviews with a particular group, but a further qualitative method such as observation or focus groups appeared to be 'tagged on' with no description (six proposals). Fourth, the overall size of the qualitative component was not clear, with a few

**Table 3** Assessment of the quantitative component of mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the role of each method clear?	98%	0%	2%	0%	96%	2%	0%	2%
2 Is each method described in sufficient detail?	53%	29%	18%	0%	68%	13%	15%	4%
3 Is each method appropriate for addressing the research question?	93%	0	2%	4%	98%	0%	0%	2%
4 Is the approach to sampling and analysis appropriate for its purpose?	67%	4%	4%	24%	70%	9%	6%	15%
5 Is there expertise among applicants/authors?	67%	2%	7%	24%	30%	0%	0%	70%
6 Is there expertise on the team to undertake each method?	60%	0%	2%	24%				
7 Have issues of validity been addressed for each method?	64%	0%	30%	7%	49%	4%	40%	6%
8 Has the rigour of any method been compromised?	7%	0%	91%	2%	9%	4%	83%	4%
9 Is each method sufficiently developed for its purpose?	84%	0%	7%	9%	83%	0%	4%	13%
10 Is the (intended) analysis sufficiently sophisticated?	56%	4%	2%	38%	51%	15%	25%	9%

NEI, not enough information; N/A, not applicable

**Table 4** Assessment of the qualitative component of mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the role of each method clear?	87%	0%	9%	4%	92%	4%	4%	0%
2 Is each method described in sufficient detail?	24%	29%	42%	4%	38%	28%	30%	4%
3 Is each method appropriate for addressing the research question?	87%	7%	2%	4%	91%	2%	2%	4%
4 Is the approach to sampling and analysis appropriate for its purpose?	42%	4%	9%	40%	53%	9%	4%	34%
5 Is there expertise among the applicants/authors?	56%	2%	11%	31%	32%	4%	0%	64%
6 Is there expertise on the team to undertake each method?	44%	9%	7%	40%				
7 Have issues of validity been addressed for each method?	24%	0%	64%	11%	30%	2%	57%	11%
8 Has the rigour of any method been compromised?	2%	0%	91%	7%	6%	2%	81%	11%
9 Is each method sufficiently developed for its purpose?	64%	0%	9%	27%	77%	2%	9%	13%
10 Is the (intended) analysis sufficiently sophisticated?	40%	4%	7%	49%	51%	13%	19%	17%

NEI, not enough information; N/A, not applicable

interviews here and there throughout the study adding up to a sizeable qualitative component of over 100 interviews (10 proposals).

Validity of the methods within the qualitative components was assessed by considering the attention researchers gave to issues such as reflexivity and negative cases. Validity was not addressed within proposals for more qualitative than quantitative components ( $p = 0.001$ ), although any apparent difference in reports was not statistically significantly different ( $p = 0.100$ ) (Table 4). Researchers did take the validity of qualitative methods seriously in some proposals, for example, paying attention to deviant cases and peer review of transcripts.

Concerns were identified with the sophistication of one-fifth of qualitative analyses. In nine studies the reported qualitative findings remained at a descriptive level, or reported findings in a quantitative manner only, or failed to distinguish between data collected using different methods such as focus groups and interviews.

## Integration

Integration of data or findings from the different methods received little attention in either proposals or

reports, with researchers rarely discussing the type of integration, how it occurred in the context of team working and who was involved in it (Table 5). Because of the lack of integration, questions about the appropriateness of integration and the effect of integration on the rigour of individual methods were irrelevant.

## Inferences

In the reports, researchers were clear about which results had emerged from which methods, and inferences seemed appropriate (Table 6). For one-fifth of studies there was a concern that the inferences were based disproportionately on one method rather than the findings of all the methods. The imbalance was likely to be towards qualitative findings as it was towards quantitative findings.

## Discussion

### The quality of studies in HSR

Mixed methods studies tend to be successful in HSR insofar that the qualitative and quantitative components are usually completed as planned. The main quality issue identified was a lack of transparency of the

**Table 5** Assessment of integration in mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the type of integration stated?	11%	0%	84%	4%	2%	2%	94%	2%
2 Is the type of integration appropriate to the design?	16%	0%	0%	84%	34%	0%	2%	64%
3 Has enough time been allocated for integration?	2%	0%	13%	85%				
4 Is the approach to integration detailed in terms of working together as a team?	7%	0%	80%	13%				
5 Does the dissemination strategy detail how the mixed methods will be reported in final reports and peer-reviewed publications?	0%	0%	84%	16%				
6 Are the personnel who participate in the integration clearly identified?	9%	0%	80%	11%	6%	0%	70%	23%
7 Did appropriate members of the team participate in integration?					0%	0%	2%	98%
8 Is there evidence of communication within the team?					19%	0%	6%	75%
9 Has rigour been compromised by the process of integration?					4%	0%	0%	96%

NEI, not enough information; N/A, not applicable

**Table 6** Assessment of the inferences made in completed reports of mixed methods studies in HSR

	Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A
1 Is there clarity about which results have emerged from which methods?	87%	2%	6%	4%
2 Are inferences appropriate?	83%	4%	9%	4%
3 Are the results of all the methods considered sufficiently in the interpretation?	66%	6%	19%	9%

NEI, not enough information; N/A, not applicable

mixed methods aspects of the studies and the individual components. The qualitative components were more likely to be poorly described than the quantitative ones. To some extent the poor description of qualitative methods is not a surprising finding given the historical dominance of quantitative methods in HSR. However, it raises concerns that the HSR community may be failing on occasions to exploit the potential of qualitative methods within mixed methods studies. Where a qualitative component is in a supporting role to a more dominant method, and does not have stand-alone status in terms of independently addressing an aspect of the research question, then limited description is acceptable. However, because researchers were often not explicit about the status of methods within the study design, it was difficult to make judgements about the individual components in the context of the design used. Integration of data and findings is a key part of mixed methods research. There was no evidence that inappropriate integration was undertaken because there was a tendency for researchers to keep the qualitative and quantitative components separate rather than attempt to integrate data or findings in reports or publications.<sup>12</sup>

### Developing quality criteria for mixed methods studies in HSR

There was a lack of transparency in the reporting of mixed methods studies in HSR which made it difficult to assess other aspects of the quality of these studies. This has been identified as a problem facing the quality assessment of other types of studies<sup>11</sup> and has led to the development of guidelines for reporting studies. Creswell has suggested a list of issues to consider when designing a mixed methods study<sup>10</sup> and we have considered this in conjunction with the literature on the quality of mixed methods studies to suggest some guidelines for Good Reporting of A Mixed Methods Study (GRAMMS) (Box 1). We present this as guidance for researchers rather than as a formal checklist.

### Box 1 Good Reporting of A Mixed Methods Study (GRAMMS)

- (1) Describe the justification for using a mixed methods approach to the research question
- (2) Describe the design in terms of the purpose, priority and sequence of methods
- (3) Describe each method in terms of sampling, data collection and analysis
- (4) Describe where integration has occurred, how it has occurred and who has participated in it
- (5) Describe any limitation of one method associated with the present of the other method
- (6) Describe any insights gained from mixing or integrating methods

### Limitations

The study is based on mixed methods research funded by one commissioner in one country. The response rate to requests for documentation for mixed methods studies was good but non-responders may have been more likely to be problematic studies, biasing the findings towards higher quality studies. The questions were devised and applied by one researcher (AOC) in the context of team discussions which meant that the data extraction process was unchallenged by an external source. A coding protocol was devised to accompany the data extraction form to aid transparency and reduce intra-rater variability. However the studies could have been rated differently by another researcher. Finally, the studies included were funded between 1994 and 2004 and improvements may have occurred since then.

We have taken a technical stance in our discussions of quality in mixed methods research. However, the philosophical stance adopted by researchers may affect the quality criteria they use, and wish to see applied to their studies. Subtle realism<sup>30</sup> has been proposed as a philosophical position appropriate for qualitative and quantitative research in health technology assessment.<sup>21</sup> An implication of this stance is that researchers would need to consider whether reflexivity has been applied to the whole of a mixed methods study rather than simply the qualitative component.

### Conclusions

This is the first attempt to consider the quality of mixed methods studies in HSR. We are not offering this as a definitive approach to be used by others, but to start the debate about how to assess and improve quality. We recommend that if we use mixed methods studies in HSR then we need to be more transparent about the design and the individual components in the context of the design, and attempt to integrate data and findings from the qualitative and quantitative methods.

### Acknowledgements

Many thanks to the researchers who kindly sent copies of their study documents. The Medical Research Council funded the study through their Fellowship scheme.



## References

- 1 O’Cathain A, Murphy E, Nicholl J. Why, and how, mixed methods research is undertaken in health services research: a mixed methods study. *BMC Health Serv Res* 2007;**7**:85
- 2 Bryman A. Quantitative and qualitative research: further reflections on their integration. In: Brannen J, ed. *Mixing Methods: Qualitative and Quantitative Research*. Aldershot: Ashgate, 1992:57–78
- 3 Caracelli VJ, Riggan LJC. Mixed-method evaluation: developing quality criteria through concept mapping. *Eval Pract* 1994;**15**:139–52
- 4 Creswell JW, Fetters MD, Ivankova NV. Designing a mixed methods study in primary care. *Ann Fam Med* 2004;**2**:7–12
- 5 Datta L. A pragmatic basis for mixed-method designs. In: Greene JC, Caracelli VJ, eds. *Advances in Mixed-method Evaluation: The Challenges and Benefits of Integrating Diverse Paradigms*. San Francisco, CA: Jossey-Bass, 1997:33–46
- 6 Teddlie C, Tashakkori A. Major issues and controversies in the use of mixed methods in the social and behavioural sciences. In: Tashakkori A, Teddlie C, eds. *Handbook of Mixed Methods in Social and Behavioural Research*. London: Sage Publications, 2003:3–50
- 7 Sale JEM, Brazil K. A strategy to identify critical appraisal criteria for primary mixed method studies. *Quality and Quantity* 2004;**38**:351–65
- 8 Creswell JW, Plano-Clark V. *Designing and Conducting Mixed Methods Research*. Thousand Oaks, CA: Sage Publications, 2007
- 9 Brannen J. Combining qualitative and quantitative approaches: an overview. In: Brannen J, ed. *Mixing Methods: Qualitative and Quantitative Research*. Aldershot: Ashgate, 1992:3–38
- 10 Creswell JW. *Research Design. Qualitative, Quantitative, and Mixed Methods Approaches*. 2nd edn. London: Sage Publications, 2003
- 11 Mays N, Pope C, Popay J. Systematically reviewing qualitative and quantitative evidence to inform management and policy-making in the health field. *J Health Serv Res Policy* 2005;**10** (Suppl. 1):6–20
- 12 O’Cathain A, Murphy E, Nicholl J. Integration and publications as indicators of ‘yield’ from mixed methods studies. *Journal of Mixed Methods Research* 2007;**1**:147–63
- 13 Brewer J, Hunter A. *Multimethod Research*. London: Sage Publications, 1989
- 14 Tashakkori A, Teddlie C, eds. *Handbook of Mixed Methods in Social and Behavioural Research*. London: Sage, 2003
- 15 Tashakkori A, Teddlie C. *Mixed Methodology: Combining Qualitative and Quantitative Approaches*. London: Sage, 1998
- 16 Gorard S, Taylor C. *Combining Methods in Educational and Social Research*. Maidenhead: Open University Press, 2004
- 17 Brannen J, ed. *Mixing Methods: Qualitative and Quantitative Research*. Aldershot: Ashgate, 1992
- 18 Bryman A. *Quantity and Quality in Social Research*. London: Routledge, 1988
- 19 Greene JC, Caracelli VJ, eds. *Advances in Mixed-method Evaluation: The Challenges and Benefits of Integrating Diverse Paradigms*. San Francisco, CA: Jossey-Bass, 1997
- 20 Fielding NG, Fielding JL. *Linking Data*. Sage Publications, 1986
- 21 Murphy E, Dingwall R, Greatbatch D, Parker S, Watson P. Qualitative research methods in health technology assessment: a review of the literature. *Health Tech Assess* 1998;**2**:16
- 22 Mason J. Linking qualitative and quantitative data analysis. In: Bryman A, Burgess RG, eds. *Analysing Qualitative Data*. London: Routledge, 1994:89–110
- 23 Miller S. Impact of mixed methods and design on inference quality. In: Tashakkori A, Teddlie C, eds. *Handbook of Mixed Methods in Social and Behavioural Research*. London: Sage Publications, 2003:423–55
- 24 Katrak P, Bialocerkowski AE, Massy-Westropp N, Kumar VS, Grimmer KA. A systematic review of the content of critical appraisal tools. *BMC Med Res Meth* 2004;**4**:22
- 25 Silverman D. *Doing Qualitative Research. A Practical Handbook*. London: Sage Publications, 2000
- 26 Steckler A, Mcleroy KR, Goodman RM, Bird ST, McCormick L. Toward integrating qualitative and quantitative methods: an introduction. *Health Educ Q* 1992;**19**:1–8
- 27 Chen H. Applying mixed methods: a dominant methodology for the future? In: Greene JC, Caracelli VJ, eds. *Advances in Mixed-method Evaluation: The Challenges and Benefits of Integrating Diverse Paradigms*. San Francisco, CA: Jossey-Bass, 1997:61–72
- 28 Sandelowski M. Combining qualitative and quantitative sampling, data collection, and analysis techniques in mixed-method studies. *Res Nurs Health* 2000;**23**:246–55
- 29 O’Cathain A, Thomas KJ. “Any other comments?” Open questions on questionnaires – a bane or a bonus to research? *BMC Med Res Meth* 2004;**4**:25
- 30 Hammersley M. *What’s Wrong with Ethnography?* London: Routledge, 1992

# BMJ Open

## Implementation of national antenatal hypertension guidelines: a multi-centre multiple methods study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-035762.R2
Article Type:	Original research
Date Submitted by the Author:	03-Sep-2020
Complete List of Authors:	Whybrow, rebecca; King's College London, Women and Children's Health; Guy's and Saint Thomas' Hospitals NHS Trust, Division of Women and Children's Health Webster, Louise; King's College London, Women and Children's Health Girling, Joanna; Chelsea and Westminster Hospital NHS Foundation Trust Brown, Heather; Brighton and Sussex University Hospitals NHS Trust Wilson, Hannah; King's College London, Women and Children's Health Sandall, Jane; Kings College, London, Women and Children's Health Chappell, Dr Lucy; King's College London, Department of Women and Children's Health; Guy's and Saint Thomas' Hospitals NHS Trust, Division of Women and Children's Health
<b>Primary Subject Heading</b>:	Obstetrics and gynaecology
Secondary Subject Heading:	Cardiovascular medicine
Keywords:	Maternal medicine < OBSTETRICS, OBSTETRICS, Hypertension < CARDIOLOGY

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3 1 **Title:** Implementation of national antenatal hypertension guidelines: a multi-centre multiple methods  
4  
5 2 study

6  
7 3 Rebecca Whybrow<sup>1</sup>, Louise Webster<sup>1</sup>, Joanna Girling<sup>2</sup>, Heather Brown<sup>3</sup>, Hannah Wilson<sup>1</sup>, Jane Sandall<sup>1</sup>,  
8  
9 4 Lucy Chappell<sup>1</sup>

10  
11 5 1 Department of Women and Children's Health, King's College London, St Thomas' Hospital, London,  
12 6 UK.

13  
14 7 2 Chelsea and Westminster Hospital NHS Foundation Trust, London, UK.

15  
16 8 3 Brighton and Sussex Universities Hospital Trust, East Sussex, UK.

17  
18 9 Corresponding author: Rebecca Whybrow, Department of Women and Children's Health, King's  
19  
20 10 College London, St Thomas' Hospital, London, UK. [Rebecca.whybrow@kcl.ac.uk](mailto:Rebecca.whybrow@kcl.ac.uk) Tel: 07804690276

21  
22 11 **Word Count:** 4796

23  
24 12 **Abstract:**

25  
26 13 **Objective** To evaluate the implementation of NICE antenatal hypertension guidelines, to identify  
27 14 strategies to reduce incidences of severe hypertension and associated maternal and perinatal  
28 15 morbidity and mortality in pregnant women with chronic hypertension.

29  
30 16 **Methods** We used a multiple-method multi-site approach to establish implementation of guidelines  
31 17 and the associated barriers and facilitators. We used a national survey of healthcare professionals  
32 18 (n=97), case-notes review (n=55) and structured observations (n=42) to assess implementation. The  
33 19 barriers and facilitators to implementation were identified from semi-structured qualitative  
34 20 interviews with healthcare professionals (n=13) and pregnant women (n=18) using inductive thematic  
35 21 analysis. The findings were integrated and evaluated using the Consolidated Framework for  
36 22 Implementation Research (CFIR).

37  
38 23 **Setting and participants** Pregnant women with chronic hypertension and their principal carers  
39 24 (obstetricians, midwives, and physicians), at three NHS hospital trusts with different models of care.

40  
41 25 **Results** We found severe hypertension to be prevalent (46% of case-notes reviewed) and target blood  
42 26 pressure practices to be sub-optimal (56% of women had an antenatal blood pressure target  
43 27 documented). Women were infrequently given information (52%) or offered choice (19%) regarding  
44 28 antihypertensives. Women (14/18) reported internal conflict in taking antihypertensives and non-  
45 29 adherence was prevalent (8/18). Women who were concordant with treatment recommendations  
46 30 described having mutual trust with professionals mediated through appropriate information, side-  
47 31 effect management and involvement in decision-making. Professionals reported needing updates and  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

32 tools for target blood pressure setting and shared decision-making underpinned by antihypertensive  
33 safety and effectiveness research.

34 **Conclusions** Women's nonadherence to antihypertensives is higher than anticipated. Sub-optimal  
35 information provision around treatment, choice of antihypertensives and target setting practices by  
36 healthcare professionals may be contributory. Understanding the reasons for non-adherence will  
37 inform education and decision-making strategies needed to address both clinician and women's  
38 behaviour. Further research into the effectiveness and long-term safety of common antihypertensives  
39 is also required.

40

#### 41 **Strengths and limitations of this study**

- 42 – Multiple methodological approaches and an implementation framework improved the  
43 reliability, validity, and generalisability of the study.
- 44 – Structured observations were carried out using a validated tool with high interrater reliability.
- 45 – Women's medication behaviours were explored in-depth using a qualitative interview  
46 approach and have identified antihypertensive side-effects to be a factor of non-adherence in  
47 pregnant women.
- 48 – About two-fifths of women who participated in this study were from Black, Asian and minority  
49 ethnic groups, providing a diverse range of voices.
- 50 – Respondents to the survey were self-selecting and may represent a relatively interested group  
51 of healthcare professionals.

52

## 53 BACKGROUND

54 Hypertension in pregnancy is one of the leading causes of maternal mortality worldwide<sup>1</sup> and although  
55 mortality is declining in the UK,<sup>2</sup> women can still experience substantial morbidity from complications  
56 such as eclampsia and stroke.<sup>3</sup> Additionally, perinatal mortality remains high, with the UK population-  
57 attributable risk of stillbirth from chronic hypertension at 14%<sup>4</sup> and around half of all neonates born  
58 to mothers who have had severe hypertension in pregnancy being admitted to the neonatal unit.<sup>5</sup> The  
59 morbidity and mortality attributable to hypertension, in many cases, may be modifiable through  
60 optimal use of antihypertensive agents during pregnancy.

61 The National Institute for Health and Care Excellence (NICE) hypertension in pregnancy guidelines  
62 (2010)<sup>6</sup> and linked quality statements (2013)<sup>7</sup> contain a quality statement regarding the provision of  
63 information on the use of safe antihypertensive medication in pregnancy and has related guidance  
64 that recommends discontinuation of teratogenic medications such as angiotensin-converting-enzyme  
65 inhibitors or angiotensin II receptor blockers with prescribing of safe alternatives. Any prescribing of  
66 alternative antihypertensive medication should be dependent on pre-pregnancy treatment, side-  
67 effect profiles and teratogenicity. A second quality statement advocates that women taking  
68 antihypertensive medication should have a blood pressure target (usually of less than 150/100mmHg)  
69 set in pregnancy. All NICE guidelines are underpinned by the recommendation of enabling patients to  
70 actively participate in their care which includes adopting a shared decision-making approach to  
71 treatment decisions.<sup>8</sup>

72 Despite publication of the guideline almost a decade ago, the implementation and evaluation of  
73 associated determinants of uptake have not been nationally evaluated. As a result, targeted strategies  
74 to reduce maternal and perinatal morbidity (and mortality) resulting from severe hypertension remain  
75 unidentified. Using the Consolidated Framework for Implementation Research (CFIR),<sup>9</sup> the aim of the  
76 study was to evaluate the implementation of NICE hypertension in pregnancy guidelines, to identify  
77 strategies to reduce incidence of severe hypertension and associated maternal and perinatal  
78 morbidity and mortality in pregnant women with chronic hypertension. In many countries, there is a  
79 movement toward establishing consensus-driven standardised clinical guidelines with the aim of  
80 improving patient safety and clinical outcomes. Whilst new research continually emerges, guidelines  
81 are periodically updated and therefore remain an appropriate standard for evaluating routine clinical  
82 practice.<sup>10</sup>

83

## 84 RESEARCH DESIGN AND METHODS

### 85 Study setting and overall methodology

86 The CHAMPION study (Chronic Hypertension in pregnAncy iMPLementatIOn study) is a multiple  
87 methods evaluation of the implementation of the NICE hypertension in pregnancy guidelines (2010  
88 and updated in 2013) in women with chronic hypertension diagnosed before 20 weeks.<sup>6 7</sup> Ethical  
89 approval for the CHAMPION study was provided by the National Research Ethics Service (17/LO/2041).  
90 The study aimed to evaluate the variability in implementation of hypertension management practices  
91 set out in the NICE hypertension in pregnancy guidelines (2010).<sup>6</sup> As all guidelines should be  
92 underpinned by the 'Patient experience in adult NHS services guideline'<sup>8</sup> which includes, actively  
93 involving patient in decisions about their care through information provision and shared decision-  
94 making, the provision of information and women's involvement in decision-making was also  
95 evaluated. The involvement of women in decision-making was considered integral to the  
96 implementation study because successful hypertension management strategies involve the  
97 adherence to, alongside the prescribing of, antihypertensive medication.

98 Implementation was assessed through multiple methods: an online national survey of healthcare  
99 professionals, designed to describe general trends in guideline implementation; through review of the  
100 maternity case-notes of women who had already given birth, a method that assessed the  
101 documentation of hypertension management occurrence in each woman's maternity record. Aspects  
102 of care that would not normally be documented or are more difficult to capture, such as in-  
103 consultation discussions and occurrence of shared decision-making were assessed through  
104 observations carried out by a midwife researcher (RW). The evaluation of the barriers and facilitators  
105 to implementation of NICE guidelines was assessed through qualitative interviews (with the same  
106 women and healthcare professionals who participated in the observation phase) using the  
107 Consolidated Framework for Implementation Research (CFIR). The study draws on CFIR as a  
108 theoretical framework to guide data collection, analysis, and interpretation. The CFIR framework  
109 specifically evaluates five key domains that influence implementation; each domain has several  
110 subgroups to it, although only those relevant to this study have been identified. These include the  
111 intervention characteristics (the NICE guidelines), the outer context (the pregnant women), the inner  
112 context (NHS maternity services), individual context (the healthcare professionals) and the process of  
113 implementation (potential strategies).

114 Implementation of guidelines was assessed between November 2017 to December 2018 at three NHS  
115 Trusts with typical configurations of services for pregnant women with hypertension in the UK.  
116 Hospital Trust 1 was a tertiary city centre hospital with a newly formed specialist service that included



1  
2  
3 117 consultant obstetricians, obstetric physicians and midwives who provided antenatal and intrapartum  
4 118 care to women with chronic hypertension within a specialist clinic; Hospital Trust 2 was a suburban  
5 119 district general hospital with a consultant-led antenatal clinic with antenatal midwives alongside  
6 120 providing care to women with a variety of pre-existing medical conditions; and Hospital Trust 3 had  
7 121 both a tertiary and a semi-rural hospital with a joint obstetric and physician led clinic and usual  
8 122 community-based midwifery care. No adjustment for clustering was required as no statistical  
9 123 comparison between sites was made. The NICE hypertension in pregnancy guidelines (2010)<sup>6</sup> had been  
10 124 adopted into local clinical guidelines at all three participating NHS Trusts for several years prior to the  
11 125 assessment of implementation.  
12  
13  
14  
15  
16  
17  
18

19 126

### 20 21 127 **The National Survey**

22  
23 128 The implementation of evidence-based practices for the management of hypertension in pregnancy  
24 129 was assessed through self-reporting using an online survey (surveygizmo/s3). We embedded  
25 130 questions relating to the uptake of the NICE hypertension in pregnancy guidelines (2010)<sup>6</sup> using the  
26 131 TIDieR framework.<sup>11</sup> The 12-item TIDieR checklist (brief name, why, what (materials), what  
27 132 (procedure), who provided, how, where, when and how much, tailoring, modifications, how well  
28 133 (planned), how well (actual) is an extension of the CONSORT 2010 statement (item 5) and the SPIRIT  
29 134 2013 statement (item 11). Although the emphasis of the TIDieR checklist is on reporting interventions  
30 135 for trials, the checklist was used as a basis for this survey (but not as a reporting guideline) as it is also  
31 136 intended to apply across all evaluative study designs.<sup>11</sup> There is no single database of healthcare  
32 137 professionals' email addresses so national organisations including British Maternal and Fetal Medicine  
33 138 Society (BMFMS), Macdonald UK Obstetric Medicine Society (MOMS) and Royal College of Midwives  
34 139 (RCM) were asked to email the survey (April to September 2018) to their members. No fee was  
35 140 charged as members' contact details were not shared with us and as a result the response rate could  
36 141 not be calculated. Ninety-seven healthcare professionals from sixty-nine NHS Trusts responded,  
37 142 including 53 consultant obstetricians (55%), 16 doctors in training (16%), 22 specialist midwives (23%)  
38 143 and six community midwives (6%) (full copy of survey questions shown in supplementary material 1).  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49

### 50 51 144 **Case-notes review**

52  
53 145 The implementation of NICE guidelines (2010)<sup>6</sup> was also assessed through review of 100 maternity  
54 146 case-notes of women with chronic hypertension identified from the electronic maternity records (32,  
55 147 33, 35 women per Trust). At two of the Trusts all women who had given birth in 2017 were included,  
56 148 whereas at the other Trust all women who had given birth over the final three months of 2017 were  
57  
58  
59  
60



1  
2  
3 149 included as this third Trust had approximately four times the number of women with chronic  
4  
5 150 hypertension per annum. In the UK, many women have abridged electronic maternity records and  
6  
7 151 extensive handheld paper notes that are carried throughout pregnancy but are stored thereafter in  
8  
9 152 the hospital. Both the electronic system and paper notes were obtained in the case-notes review of  
10  
11 153 care. Due to use of varying terms for hypertension on the electronic system, some women identified  
12  
13 154 for case-note review were excluded as they did not have chronic hypertension when the full case-  
14  
15 155 notes were examined. Other reasons for exclusion included early miscarriage and transfer of care to  
16  
17 156 another maternity unit. Data extraction based on the NICE hypertension in pregnancy guidelines  
18  
19 157 (2010)<sup>6</sup> was completed by two midwife researchers (RW, HW), and minor discrepancies were resolved  
20  
21 158 by discussion between the two researchers. It was not necessary to include a third reviewer as no  
22  
23 159 major discrepancies were identified. Unclear or absent documentation including height, weight and  
24  
25 160 body mass index or antenatal blood pressure recordings was recorded as missing data. Severe  
26  
27 161 hypertension was defined as systolic blood pressure greater than or equal to 160 mmHg systolic or  
28  
29 162 diastolic blood pressure greater than or equal to 110 mmHg. For the assessment of BP targets, the  
30  
31 163 quality statement related to documentation of a target (or not), not to the specific numerical  
32  
33 164 thresholds chosen.

### 31 **Observations**

32  
33 166 Forty-two antenatal appointments involving 23 women with chronic hypertension and their respective  
34  
35 167 doctors (nine) and midwives (five) were observed by a midwife researcher (RW) at the three NHS  
36  
37 168 Trusts. Women with chronic hypertension were purposively sampled at their first obstetric antenatal  
38  
39 169 appointment and, based on the availability of the midwife researcher, were approached consecutively  
40  
41 170 along with their respective healthcare professionals until data saturation occurred. Staff and women  
42  
43 171 gave written informed consent. Two women declined recruitment to the study. During observations,  
44  
45 172 data about antenatal care provision were recorded using the Calgary-Cambridge communication  
46  
47 173 guide<sup>12</sup> chosen for validity in relation to the research question, and its high interrater reliability. For  
48  
49 174 example, offering choice is a sub-section of shared decision-making and is defined as “encourages  
50  
51 175 patient to make choices and decisions to the level that they wish”. Attainment of each section and  
52  
53 176 sub-sections was established through the analysis of all 42 appointments using descriptive statistics.

### 52 **Semi-structured interviews**

54  
55 178 Views about barriers and facilitators to implementation of evidence-based guidelines were collected  
56  
57 179 from nine doctors and four midwives who were providing antenatal care for women with chronic  
58  
59 180 hypertension. The interviews were carried out by a midwife researcher (RW) following informed  
60  
181 consent and took place in privacy away from the clinical setting. The interviews were audio

1  
2  
3 182 transcribed, coded and thematically analysed using inductive reasoning.<sup>13</sup> The codes generated  
4  
5 183 formed small themes which were organised into the CFIR evaluation guide.<sup>14</sup> As formal  
6  
7 184 implementation strategies had not been adopted beyond producing local guidance, interviewees were  
8  
9 185 asked how they thought they could improve the implementation in the future.

10  
11 186 Semi-structured interviews with 18 women recruited for antenatal observations were carried out in  
12  
13 187 the third trimester with informed consent. Women were asked about their antenatal care experiences  
14  
15 188 using an interview schedule which reflected the concepts from the International Consortium for  
16  
17 189 Health Outcome Measure (ICHOM) maternity standards sets<sup>15</sup> which include women's overall  
18  
19 190 satisfaction with their care during pregnancy; satisfaction with information provision and their  
20  
21 191 relationships with their care providers (see supplementary material 2). ICHOM standards are  
22  
23 192 internationally recognised measures that evaluate health outcomes that are important to patients (or  
24  
25 193 pregnant women) and are used to improve local healthcare and compare outcomes internationally.  
26  
27 194 The closed survey questions were turned into open ended questions to explore in-depth the quality  
28  
29 195 of antenatal care provided. The interviews were carried out by a midwife researcher (RW) and took  
30  
31 196 place away from the clinical setting, with assurance that discussions would not be shared with  
32  
33 197 healthcare professionals and that participation or non-participation would not influence their care.  
34  
35 198 The interviews were audio transcribed, coded, and thematically analysed using an inductive approach.  
36  
37 199 Women's experiences were analysed to improve understanding of their antenatal care needs, which  
38  
39 200 included how their hypertension was managed and the barriers and facilitators to the uptake of  
40  
41 201 antihypertensives in pregnancy.

## 202 **Data analysis**

42  
43 203 The quantitative and qualitative data were analysed separately before being integrated. Descriptive  
44  
45 204 analysis and summary statistics were used for the quantitative data. The semi-structured interviews  
46  
47 205 were thematically analysed by researchers (RW, JS and LC) using inductive techniques and typically  
48  
49 206 lasted between 30 and 60 minutes.<sup>16</sup> The multiple methods data were integrated and analysed using  
50  
51 207 the CFIR evaluation framework.<sup>14</sup> This included probing the inductively generated qualitative themes  
52  
53 208 that related to implementation. The interpretation of the intervention constructs (characteristics, the  
54  
55 209 inner and outer settings, the individual characteristics and the implementation processes) was carried  
56  
57 210 out initially by the midwife researcher (RW) who collected the data, then with a second and third  
58  
59 211 researcher (LC, JS) interpreting and discussing final interpretation of integrated data. Rigour was  
60  
212 maintained through member reflection, attention to interview and transcription quality and  
213 systematic analysis. Rigour was improved using multiple data sources, a comprehensive integration  
214 framework (CFIR) and a multiple methods integration checklist.<sup>17</sup> Researchers were aware of, and

1  
2  
3 215 sensitive to, the way in which their roles as midwives and doctor may have shaped the generation and  
4  
5 216 analysis of the qualitative data.

### 7 217 **Patient and Public Involvement**

8  
9 218 A patient participant involvement (PPI) group consisting of women with experience of hypertension  
10 219 in pregnancy (n=7) and a maternity voices partnership group (n=15) provided feedback on the design  
11 220 of the study, research questions and outcome measures. The views of Black, Asian and minority ethnic  
12 221 women were purposively sought as they are disproportionately represented in the chronic  
13 222 hypertension in pregnancy population. PPI focus groups discussed what aspects of care were  
14 223 important to evaluate, this included the information women were given during pregnancy and  
15 224 whether women were involved in decisions about their care. They also provided constructively critical  
16 225 feedback on the patient information leaflets and consent forms.

### 23 226 **RESULTS**

24  
25 227 Antenatal care for women with chronic hypertension was provided by consultant obstetricians and  
26 228 midwives at all three hospitals. In two of the hospitals, women with chronic hypertension had  
27 229 designated midwives attached to the obstetric clinic. Approximately one-third of those recruited to  
28 230 the study had a BMI over 30kg/m<sup>2</sup>, approximately one-third were over the age of 35 and  
29 231 approximately two-fifths were of Black, Asian and minority ethnic backgrounds (shown in  
30 232 supplementary material 3). Hospital Trust 1 had four times the population of women with chronic  
31 233 hypertension compared to the other two units, comprising a large black minority ethnic population  
32 234 (many with associated co-morbidities). Perinatal outcomes from the fifty-five pregnancies identified  
33 235 for case-notes review showed that just under half of the women (46%) developed severe hypertension  
34 236 and that one in six babies were admitted to the neonatal unit (16%) (shown in supplementary material  
35 237 4). At all three hospitals medical history of women with chronic hypertension was inaccurate in the  
36 238 maternity records system and episodes of severe hypertension were recorded only in hand-written  
37 239 notes.

38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49 240

50  
51 241

### 52 242 **Implementation of NICE hypertension in pregnancy 2010 guidelines and 2013 quality standards**

53 243 Setting a blood pressure target (quality statement 3)

54  
55 244 Both the survey and the case-notes review found the practice of setting an antenatal target blood  
56 245 pressure to be variable (table 1). Just over half of women with chronic hypertension had a target blood

246 pressure documented in maternity notes (44% did not) yet substantial variation in practice between  
 247 hospitals existed. At Hospital Trust 1, 77% of women had a target blood pressure documented in  
 248 pregnancy compared to 23% and 38% at Hospital Trusts 2 and 3 respectively (supplementary material  
 249 5). Whilst it is possible that undocumented discussions occurred during consultations, which could not  
 250 be extracted from case-note review, such discussions would not be accessible on a longer term basis  
 251 to the woman or to other healthcare professionals involved in her care. The survey results support the  
 252 case-notes review findings as only a third of healthcare professional respondents reported always  
 253 setting a target. The practice of undocumented 'unshared' target setting was identified through case-  
 254 notes review. Evidence of blood pressure targets being used by healthcare professionals but not  
 255 shared with the woman and other professionals ('unshared') was frequently found. In about three  
 256 quarters of cases where the target blood pressure was unshared, and the blood pressure rose above  
 257 systolic 150mmHg and or diastolic 100mmHg action was taken by professionals to lower it. Action  
 258 was defined as making changes to blood pressure treatment, changing frequency of blood pressure  
 259 monitoring or frequency of appointments (table 1).

260 Table 1. Variation in implementation of evidence-based care evaluated through a national survey of  
 261 obstetricians and midwives and women's case-notes review at three representative NHS Trusts.

Care quality indicators	National Survey n=97 (%)	Case-notes review n=55 (%)
<b>Blood pressure target setting (QS3)</b>		
Target blood pressure 'always' set	36 (37.1)	
Target blood pressure 'almost always' set	36 (37.1)	
Target blood pressure 'never' set	1 (1.0)	
Target blood pressure not applicable (midwife)	24 (23.3)	
Target blood pressure set at first opportunity (whichever first: booking or commencement of AHT)	-	9 (18.0)
Target blood pressure not documented		26 (43.6)
<b>Systolic target blood pressure</b>		
<160mmHg	8 (8.2)	
<150mmHg	89 (91.8)	2 (7.4)
≤140mmHg		27 (49.0)
<b>Diastolic target blood pressure</b>		
<100mmHg	94 (96.9)	2 (7.4)
≤90mmHg		27 (49.0)

Action taken to reduce blood pressure if above 150/100mmHg		13/17 (76.5)
<b>Safe antihypertensive prescribing (linked to QS1)</b>		
<b>ACEi and ARBs cessation</b>		
On ACEis or ARBs at antenatal booking appointment		4 (7.3)
Stopping ACEi or ARBs at first app if woman on either		
Always	57/86 (66.3)	-
Almost always	27/86 (31.4)	-
ACEis or ARBs stopped at 1 <sup>st</sup> obstetric appointment		4/4 (100.0)
<b>1<sup>st</sup> line AHT prescribing (non-exclusive)</b>		
Labetalol	85 (87.6)	28 (50.9)
Nifedipine	32 (33.0)	9 (16.4)
Methyldopa	29 (29.9)	8 (14.5)
Other e.g. amlodipine	2 (2.1)	4 (7.3)
None	-	6 (10.9)
<b>2<sup>nd</sup> line AHT prescribing (non-exclusive)</b>		
Nifedipine	79 (81.4)	9 (16.4)
Methyldopa	60 (61.9)	4 (7.3)
Labetalol	38 (39.2)	3 (5.4)
Amlodipine	37 (38.1)	2 (3.6)
Doxazosin	23 (23.7)	0 (0.0)
Other	5 (5.2)	0 (0.0)
None	-	37 (67.3)

262

263 Antihypertensive information provision, decision-making and prescribing (quality statement 1 and  
 264 associated guidance)

265 Variation in practice regarding first- and second-line prescribing was identified through both the notes  
 266 review and survey (table 1). In both, labetalol was the most commonly prescribed first line and  
 267 nifedipine the most commonly used second line antihypertensive agent; nevertheless, in about half  
 268 of the case-notes reviewed labetalol was not the first line antihypertensive prescribed. First line  
 269 prescribing is not always exclusive as it may vary by ethnicity (e.g. some doctors use labetalol as first  
 270 line for many women, but nifedipine for Black women, in line with national guidelines for prescribing  
 271 outside of pregnancy)<sup>18</sup> which may explain the variation in prescribing practice that existed

1  
2  
3 272 (supplementary material 5). Variation may also be explained by clinician preference or medication  
4 preference identified through shared decision-making.  
5 273

6  
7 274 Information provision about antihypertensive prescribing  
8

9 275 Across all three Trusts, 52% (41/79) of the time the correct type and amount of information was  
10 provided during the consultation (measured using the Calgary-Cambridge Guide). Visual techniques  
11 276 such as drawing or using charts to provide information occurred during consultation in 14% (3/21) of  
12 cases.  
13 277  
14 278

15  
16  
17 279 Achieving a shared understanding: incorporating the woman's perspective  
18

19 280 Of the survey respondents 96.9% strongly agreed or agreed that involving women with chronic  
20 hypertension in management plans during pregnancy was important. However, when asked to give  
21 281 examples of how they involve women, only 4.3% identified discussing risks and benefits of treatment  
22 choice and 10% of respondents identified that women could be involved in plans about  
23 282 antihypertensive prescribing. The observations in the three hospital trusts found that 43% of the time  
24 283 (41/96) shared decision-making occurred and 19% of women (3/16) were offered a choice regarding  
25 their hypertensive plans (including choice of antihypertensive).  
26 284  
27 285  
28 286  
29  
30  
31

32 287

### 33 34 288 **Barriers and Facilitators to implementation (CFIR)**

35  
36 289 Intervention characteristics (evidence and guideline)  
37

38  
39 290 All professionals interviewed, except one, saw value in having national guidance and understood that  
40 the local guidelines had been adapted from the 2010 national guideline.<sup>6</sup> Midwives relied more on  
41 291 local guidelines compared to obstetricians who referred more commonly to NICE guidelines. Some of  
42 292 the medical professionals had been involved in the development of a NICE guideline and were aware  
43 of the strengths and limitations of producing evidence-based guidelines in terms of the need for timely  
44 293 updating. Professionals described difficulties in creating guidelines where there is a paucity of robust  
45 294 data as is sometimes the case in maternity care. Weak, out of date or absent evidence influenced  
46 295 doctors' decisions not to implement guidelines. Some doctors described the weaknesses in the  
47 296 evidence underpinning the hypertension guidelines and described relying more on recent research  
48 compared to older national guidelines (table 2). The professionals identified that further research is  
49 297 necessary to support evidenced-based national guidelines (figure 1).  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

302 Table 2. Barriers to healthcare professional's implementation of hypertension in pregnancy guidelines, based on Consolidated Framework for Implementation  
 303 Research (CFIR) implementation themes.

CFIR implementation themes	Frequency	Codes	Representative answer
<b>Intervention characteristics</b>			
Evidence strength, quality, source, and adaptability	17	AHT prescribing; target setting;	<ul style="list-style-type: none"> <li>- "I think the fact that it says use labetalol first line is not what we do, I don't believe the evidence for labetalol being better than methyldopa is there."<sup>H</sup></li> <li>- "we can't get away from the fact that there aren't the source data there to make evidence-based guidelines."<sup>B</sup></li> <li>- So, I kept a close track of what was happening with the CHIPS study...I got a lot of information and knowledge from it."<sup>A</sup></li> </ul>
<b>Inner setting</b>			
Structural characteristics	43	Information provision; pathways and models; training and education; time	<ul style="list-style-type: none"> <li>- "I don't think we have a hand-out for, to give to hypertensive women about hypertension in pregnancy"<sup>L</sup></li> <li>- "we don't have a dedicated hypertension clinic here. So, most of these women will get seen in general antenatal clinic"<sup>I</sup></li> <li>- "you have people coming in three times weekly or something for their blood pressure, really? And other people who perhaps aren't being seen enough"<sup>I</sup></li> </ul>
Relative priority	26	Guidelines; self-study; beliefs; experience;	<ul style="list-style-type: none"> <li>- "Well actually I don't even know what the NICE guidelines are for hypertension, I'm not a... as my colleagues will tell you, not a huge fan of NICE, in many ways."<sup>L</sup></li> <li>- "I'm not just interested in guidelines; I'm interested in people's clinical experience...and that feel."<sup>C</sup></li> </ul>

Culture of decision-making	19	Patriarchy; shared decision-making; type of decision: emergency, urgent and non-urgent	<ul style="list-style-type: none"> <li>- “Doctors... see it as patients not doing what they’re told”<sup>A</sup></li> <li>- “I think that there’s a balance to be had between involving women in the decisions, versus, them coming for expert recommendations”<sup>F</sup></li> <li>- “If I have a clinical situation where I want to start antihypertensives because she’s got a dangerously high blood pressure, then that discussion is inevitably truncated.”<sup>B</sup></li> </ul>
<b>Individual characteristic</b>			
Beliefs about the intervention	35	AHT medication; AHT safety and side-effects; target setting	<ul style="list-style-type: none"> <li>- “National guidelines do not sanction any particular antihypertensive, or that the, the drug licenses do not sanction any particular antihypertensive”<sup>B</sup></li> <li>- “I think that might be something we’re not quite as good at as we should be about defining a target for women....I suspect it’s something we don’t really document and clarify”<sup>H</sup></li> </ul>
Self-efficacy	17	Women’s concordance/ desire for involvement/ first language	<ul style="list-style-type: none"> <li>- “I think sometimes women don’t necessarily want to make the decision”<sup>D</sup></li> <li>- “There’s a lot of ‘mumsnet’....and I would say they take a, that advice just as seriously as they do the advice that we give them here.”<sup>C</sup></li> </ul>
<b>Process of implementation</b>			
Engaging people and process of implementation	16	Using guidelines; updates, toolkits, and information; shared decision-making	<ul style="list-style-type: none"> <li>- “Awareness for people, if you’re a busy jobbing healthcare practitioner, keeping up to date with each new area”<sup>H</sup></li> <li>- “Practical toolkits to help with that consultation”<sup>B</sup></li> <li>- Evidenced based information having it more readily available for patient”<sup>D</sup></li> </ul>



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  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

Opinion leaders; Champions;	5	Utilisation of opinion leaders/ champions in implementation	- "I find as a midwife sometimes you're a bit powerless, you know what the guidelines are, but depending on the doctor you're working with, tends to be the influencing factor on the decisions that are made... so it seems to be clinician-based guidelines sometimes, rather than the trust or national guidelines" <sup>D1</sup>
--------------------------------	---	---	--

For peer review only

<sup>1</sup> Letters <sup>A-M</sup> represent the healthcare professionals interviewed

1  
2  
3 305 Inner setting (organisation structure and culture)  
4

5 306 The most frequently cited barriers to implementing high quality care for women with chronic  
6  
7 307 hypertension were linked to the structure and organisation of antenatal care. Interviewees reported  
8  
9 308 that a lack of consensus and guidance exists relating to models of care (such as whether specialist  
10  
11 309 services would improve outcomes through better implementation) and pathways of care (such as  
12  
13 310 frequency of blood pressure and medication reviews) (table 2). Evidence-based recommendations on  
14  
15 311 models, and pathways of care, were identified as future facilitators to providing optimal antenatal  
16  
17 312 care (figure 1). Whilst most healthcare professionals initially described the uptake of the guidelines as  
18  
19 313 a clinical priority during the interviews, clinicians identified difficulty with keeping up with  
20  
21 314 recommendations and using them alongside clinical judgement as barriers to implementation (table  
22  
23 315 2).

24 316 Healthcare professionals considered the absence of written information a barrier to the uptake of  
25  
26 317 antihypertensives in women with hypertension (table 2). A degree of paternalism exists in relation to  
27  
28 318 involving women in decisions about their care. In principle, clinicians would like to involve women in  
29  
30 319 decision-making, yet they gave many examples of situations where they would exercise restraint in  
31  
32 320 doing so (table 2). Education and tools to support shared decision-making were identified as  
33  
34 321 facilitators to optimizing antenatal care for women with hypertension (figure 1).  
35

36 322  
37 323 Characteristics of individuals (beliefs, knowledge, and self-efficacy)

38 324 Interview analysis identified doctors' and midwives' knowledge and beliefs as the second most  
39  
40 325 frequently cited barrier and facilitator to the implementation of hypertension management guidelines  
41  
42 326 (table 2). There existed confusion about whether the guidelines sanction one antihypertensive  
43  
44 327 medication over another for the management of chronic hypertension and if so, what evidence was  
45  
46 328 used to support this. Likewise, confusion about blood pressure targets was described frequently as  
47  
48 329 outcomes from a recent randomised controlled trial superseded the pre-dated national guidelines  
49  
50 330 (table 2). Whilst midwives experienced less self-efficacy than the doctors, doctors still experienced  
51  
52 331 difficulties in this area. They occasionally described the women's beliefs and views as a barrier to  
53  
54 332 implementing the recommendations (table 2).  
55

56 333

57 334

58 335

1  
2  
3 336 Outer setting (women's views and experiences)  
4

5 337 The quality of antenatal care experience was affected by women's internal conflict. There was also a  
6  
7 338 high degree of variability in medication adherence (defined as, a blanket term factoring the extent to  
8  
9 339 which patients' drug dosing histories conform, or not, to their corresponding prescribed drug dosing  
10  
11 340 regimen).<sup>19</sup> and concordance (defined as, an agreement after negotiation between a woman and a  
12  
13 341 healthcare professional that respects the beliefs and wishes of the woman in determining whether,  
14  
15 342 when, and how medicines are to be taken).<sup>20</sup> Analysis identified that women require quality  
16  
17 343 information about antihypertensives and their side-effects, blood pressure ranges in pregnancy, as  
18  
19 344 well as support to actively participate in decision-making.  
20

21 345

22 346 *Internal Conflict*

23  
24 347 The majority (14 of 18) of women experienced internal conflict relating to the management of their  
25  
26 348 hypertension during pregnancy, defined as a state of uncertainty about the course of action to take  
27  
28 349 often in relation to making choices involving risk or uncertainty of outcomes (8) (figure 2a). The causes  
29  
30 350 of internal conflict were identified as a lack of information provision, poorly managed side-effects,  
31  
32 351 women's personal beliefs and factors relating to the healthcare professional (table 3).  
33

34 352  
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

353 Table 3. Barriers to women's uptake of hypertension in pregnancy guidelines

CFIR outer context themes Women's internal conflict	Frequency	Codes	Representative answer
Information	30	Medication (choices, dose, effectiveness, safety, interactions); severity of HTN; effect of HTN on pregnancy	<ul style="list-style-type: none"> <li>- "[I wanted to know] how safe it is, about the dosage, about the, taking the med-, this medication, about the side-effects and so and so and so, if they think any other option for me, or if this medication is not working, what will be the other option for me"<sup>J</sup></li> <li>- "He was, you still need to carry on with your ramipril. I know I can't take it. It says in the leaflet not to take once you've hit 6 weeks, you need to stop. So, he was like oh, and then he phoned here, and he said oh well just take what you took before"<sup>H</sup></li> </ul>
Side-effects	21	Maternal side-effects; fetal side-effects; Interactions ; allergies; choices	<ul style="list-style-type: none"> <li>- "They gave me first three, twice a day, then I was so giddy where I couldn't, if I take, I had to sleep all day for two days...Then I complained, but they still say to still take tablet."<sup>I</sup></li> <li>- "I'm on 18 pills a day, I do worry a bit about how they kind of potentially interact with each other and affect the baby"<sup>F</sup></li> </ul>

Beliefs	17	Hypertension status; understanding HTN; effectiveness AHT; safety AHT	<ul style="list-style-type: none"> <li>- "I felt like I had to justify why I wasn't taking my tablet, which to me didn't seem right, 'cause if it, if my blood pressure was normal, and I took a tablet, surely my blood pressure then would be low?"<sup>Q</sup></li> <li>- "cause everything I take my baby takes. So, it's like, what happens if my child comes out and then they're addicted to something, or they're high-strung because of something, or they're really moody and they're crying all the time because of the medicine I've had to take for the past 4 months"<sup>L</sup></li> </ul>
HCP factors	17	Continuity; listening to women; explaining regimes, mutual trust; communication	<ul style="list-style-type: none"> <li>- "My issue has been where I've seen somebody who doesn't know the history, and typically they are a more junior doctor, and typically they are ticking a box and following a flow chart....the doctor said, you know, we're going to come to an agreement together but there was absolutely no discussion, she had no interest in what I had to say."<sup>K</sup></li> </ul>
External factors	7	Family and friends; internet; access to services	<ul style="list-style-type: none"> <li>- "My dad had been on beta blockers, which is what labetalol is, when he was younger, and he found, he was very ill on them, so he gave me a really negative impression of them"<sup>P2</sup></li> </ul>

354

---

<sup>2</sup> Letters <sup>A-R</sup> represent the pregnant women interviewed

1  
2  
3 355 *Concordance*  
4

5 356 All women identified as concordant with healthcare professional management plans described being  
6  
7 357 adherent to their antihypertensives. Facilitators to concordance included trust in the healthcare  
8  
9 358 professional, mediated through information about safety of antihypertensives in pregnancy,  
10  
11 359 knowledge about target blood pressure in pregnancy hypertension, acknowledgement of medication  
12  
13 360 side-effects and a positive interaction with the healthcare professional (including communication and  
14  
15 361 approach to decision-making) (figure 2b).

16 362 *Adherence*  
17

18 363 Internal conflict was an important determinant of non-adherence (figure 2a) as only the women who  
19  
20 364 expressed internal conflict reported non-adherence to antihypertensive medication. Around half (8 of  
21  
22 365 18) the women interviewed described non-adherence to prescribed antihypertensives at some point  
23  
24 366 during pregnancy with three women non-adherent at the time of interview (third trimester). However,  
25  
26 367 nine of 14 women describing internal conflict were adherent at the time of interview which was  
27  
28 368 mediated by the 'responsibility of motherhood' rather than concordance with the hypertension  
29  
30 369 management plan (figure 2b).

31 370

32  
33 371 *Process of implementation (implementation strategies)*  
34

35 372 All three Trusts had a consultant obstetrician who led the care of women with chronic hypertension  
36  
37 373 and could be considered the opinion leader. Two of three Trusts had a named midwife or team of  
38  
39 374 midwives who specialised in the care of these women and were potential champions. However,  
40  
41 375 influencers and champions were not always utilised to support guideline implementation. Further, as  
42  
43 376 implementation of the guidelines had not been audited in any of the Trusts, although some outcome  
44  
45 377 data was routinely collected and analysed, opportunities to address unwanted variability were being  
46  
47 378 missed. These findings are supported by the national survey which found only a quarter of the Trusts  
48  
49 379 collected and analysed the outcomes of women with chronic hypertension in pregnancy.

50 380  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

381

382 **DISCUSSION**

383 Women in this study (14/18) reported conflict relating to the uptake of prescribed antihypertensives  
384 in pregnancy and in many cases (8/14) internal conflict resulted in non-adherence. The most  
385 commonly cited reasons for conflict were lack of information provision, the side-effects experienced  
386 from the medication, beliefs about safety of medication and uncertainty about normal blood pressure  
387 ranges in pregnancy. Adherence to antihypertensives in conflicted pregnant women was mediated  
388 through a responsibility to motherhood rather than through a trusting partnership with healthcare  
389 professionals (supported by information provision, management of side-effects and relational factors)  
390 as found in concordant adherent women. Despite this, our findings demonstrated that optimal  
391 information provision about antihypertensives and shared decision-making occurred infrequently  
392 during antenatal consultations. Our findings also illustrated that the implementation of blood pressure  
393 target setting was sub-optimal as a result of 'unshared' or undocumented target setting and in some  
394 cases an absence of target setting.

395 A major strength of the study is the recruitment of Black, Asian and minority ethnic women to both  
396 the research (40%) and in the PPI planning stage as these women are disproportionately represented  
397 in the chronic hypertension in pregnancy population. A further strength is the use of multiple  
398 methodological approaches and an implementation framework in order to improve reliability, validity  
399 and generalisability. However, results from the national survey may overstate compliance with  
400 national guidance. The survey was sent out to healthcare professionals from professional  
401 organisations; respondents were therefore self-selecting and may represent a relatively interested  
402 group of healthcare professionals. The non-response rate is also unknown. The structured  
403 observations were carried out using a validated tool with high interrater reliability.<sup>12</sup> However, the  
404 observations were carried out by one midwife researcher which may affect the validity of the findings.  
405 Finally, the purposive sampling of healthcare professionals providing routine antenatal care for  
406 women with chronic hypertension resulted in a focus on lead carers (consultant obstetricians,  
407 obstetric medicine specialists and named midwives) being interviewed, rather than doctors in training  
408 and midwives in acute areas such as the maternity assessment unit.

409 The emergence of implementation science in recent years has identified that a gap between research  
410 findings and clinical practice exists, and that clinical guideline production does not ensure evidence-  
411 based practices are routinely adopted.<sup>21</sup> A recent study in British Columbia evaluated the  
412 implementation of recently published pregnancy hypertension guidelines and its associated effect on  
413 maternal and perinatal outcomes.<sup>22</sup> Following guideline dissemination the study reported a fall of

1  
2  
3 414 about a third in combined adverse maternal health outcomes (3.1% to 1.9%) but did not report a  
4  
5 415 significant reduction in adverse perinatal outcomes.<sup>22</sup> However, the wanted and unwanted variability  
6  
7 416 in guidance uptake was not reported and the underlying mechanisms that influenced outcomes is not  
8  
9 417 described. Our study uses an implementation framework by which variability in the implementation  
10  
11 418 of existing guidelines could be described and mechanisms that support and hinder their uptake can  
12  
13 419 be analysed, uniquely identifying strategies to improve the uptake of guidance and reduce maternal  
14  
15 420 and fetal morbidity. Critically, although the NICE hypertension in pregnancy guidelines<sup>6</sup> have been  
16  
17 421 recently updated, the core hypertension management recommendations remain unchanged, as do  
18  
19 422 the quality statements. Therefore, the findings of this study remain important and relevant to those  
20  
21 423 wanting to improve implementation.

22  
23 424 The study also adds to the small body of antihypertensive adherence in pregnancy research that has  
24  
25 425 found antihypertensive side-effects are a determinant of non-adherence. One recent randomised  
26  
27 426 controlled trial identified 11% of those included in randomisation discontinued the antihypertensive  
28  
29 427 due to side-effects.<sup>23</sup> Through the qualitative interview approach that enabled in depth exploration of  
30  
31 428 women's medication behaviours, our study found about 40% of all women did not adhere to their  
32  
33 429 prescribed antihypertensives at some point during pregnancy. This number compared more similarly  
34  
35 430 to an internet-based study of 210 pregnant women undertaken in Europe, America and Australia  
36  
37 431 which identified a 32.9% non-adherence rate in women taking cardiovascular medications in  
38  
39 432 pregnancy.<sup>24</sup> These findings are supported by similar smaller questionnaire-based studies of pregnant  
40  
41 433 women's medication adherence.<sup>25 26</sup> Our study may have identified higher rates of non-adherence  
42  
43 434 due to the nature of qualitative interviewing that explore in-depth women's experiences and  
44  
45 435 therefore unpick medication behaviours in a way that quantitative studies cannot.

46  
47 436 Women's adherence to antihypertensives in pregnancy was found to be sub-optimal, and strategies  
48  
49 437 to improve adherence are likely to reduce incidences of severe hypertension and prevent associated  
50  
51 438 morbidity (and mortality).<sup>27</sup> These include improved information provision about anti-hypertensives  
52  
53 439 and blood pressure targets as well as embedding shared decision-making into practice. Improvements  
54  
55 440 in target blood pressure setting practices overall are also likely to reduce incidences of severe  
56  
57 441 hypertension and prevent associated morbidity (and mortality).<sup>35</sup>

58  
59 442 This study adds to the body of research that already exists outside of pregnancy which demonstrates  
60  
443 that implementation of guidelines is not optimally achieved through the process of diffusion.<sup>21</sup>  
444 Although there was some evidence that some aspects of implementation were improved by having a  
445 specialist service for hypertension, this is likely to be most easily justified in areas where there is a  
446 high prevalence of chronic hypertension. Therefore, strategies to improve implementation in wider



1  
2  
3 447 settings are required. Professionals require guideline updates, implementation toolkits (to improve  
4  
5 448 target blood pressure setting practices, standardised information about antihypertensives and in  
6  
7 449 consultation aids) as well as support to have better conversations with their patients about medication  
8  
9 450 choices and to improve the involvement of the women in the decision-making. Professionals also  
10  
11 451 need to buy into the evidence that underpins the guidance. Maternal and perinatal outcomes, which  
12  
13 452 includes episodes of severe hypertension, should be collected annually, and used to support informed  
14  
15 453 discussions about optimising antenatal care for this group of women.

16 454 Further research into the effectiveness and long-term safety of common antihypertensives in  
17  
18 455 pregnancy and breastfeeding to support evidenced-based guidelines is required.<sup>28</sup> Future research  
19  
20 456 may also wish to evaluate strategies to reduce women's conflict regarding their antihypertensive use  
21  
22 457 in pregnancy and establish the effect of interventions on maternal concordance and health outcomes.  
23  
24 458 However, without further evidence relating to the safety and effectiveness of common  
25  
26 459 antihypertensives it is unclear if further reductions in maternal and fetal morbidity can be achieved  
27  
28 460 through prescribing practices. Future research should also focus on active implementation of blood  
29  
30 461 pressure target setting and pathways for those with outside of target blood pressure readings. This is  
31  
32 462 likely to reduce morbidity as target blood pressure setting in pregnancy has been shown to reduce  
33  
34 463 incidences of severe hypertension.<sup>3 5</sup> Policymakers may also wish to consider further studies that  
35  
36 464 identify effective models and pathways of care for reducing adverse perinatal outcomes within the  
37  
38 465 context of pregnancy hypertension.

## 36 466 **CONCLUSION**

39 467 Maternal and neonatal morbidity resulting from severe hypertension in pregnancy is prevalent.<sup>1 4 5</sup>  
40  
41 468 This evaluation of the implementation of the NICE hypertension in pregnancy guidelines (2010)<sup>6</sup>  
42  
43 469 addresses strategies to reduce the number of episodes of severe hypertension and has identified sub-  
44  
45 470 optimal target setting practices, poor information provision for pregnant women and variability in  
46  
47 471 prescribing practices. Women's non-adherence to antihypertensives is higher than previously  
48  
49 472 reported and this is likely to be contributing to adverse perinatal outcomes. Analysis of the domains  
50  
51 473 that influence implementation of the guidelines have identified that education and decision-making  
52  
53 474 strategies are needed to address both clinician and women's behaviour. Further research into the  
54  
55 475 effectiveness and long-term safety of common antihypertensives is also required.

56 476 a. Contributor statement – RW, LC and JS conceived of the study, the manuscript, and analyses, with  
57  
58 477 contributions from LW, JG, HB and HW. RW was responsible for data management and data analysis.  
59  
60 478 All authors reviewed, critically revised, and approved the manuscript.

1  
2  
3 479 b. Competing interests – None declared  
4

5 480 c. Funding – This work was supported by the National Institute for Health Research (Research  
6  
7 481 Professorship RP-2014-05-019) and by the National Institute for Health Research (NIHR) Collaboration  
8  
9 482 for Leadership in Applied Health Research and Care South London (NIHR CLAHRC South London) at  
10  
11 483 King’s College Hospital NHS Foundation Trust. Jane Sandall is an NIHR Senior Investigator and is  
12  
13 484 supported by the National Institute for Health Research (NIHR) Applied Research Collaboration South  
14  
15 485 London (NIHR ARC South London) at King’s College Hospital NHS Foundation Trust. The views  
16  
17 486 expressed are those of the author[s] and not necessarily those of the NIHR or the Department of  
18  
19 487 Health and Social Care.

20 488 d. Data sharing statement - All data relevant to the study are included in the article.  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
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

## 489 References

- 490 1. Bramham K, Parnell B, Nelson-Piercy C, et al. Chronic hypertension and pregnancy outcomes:  
491 systematic review and meta-analysis. *BMJ : British Medical Journal* 2014;348:g2301. doi:  
492 10.1136/bmj.g2301
- 493 2. Knight M NM, Tuffnell D, Kenyon S, Shakespeare J, Brocklehurst P, Kurinczuk JJ (Eds.) on behalf of  
494 MBRRACE-UK. . Saving Lives, Improving Mothers' Care – Surveillance of maternal deaths in  
495 the UK 2012–14 and lessons learned to inform maternity care from the UK and Ireland  
496 Confidential Enquiries into Maternal Deaths and Morbidity 2009-14, 2016.
- 497 3. Magee LA, von Dadelszen P, Rey E, et al. Less-tight versus tight control of hypertension in  
498 pregnancy. *N Engl J Med* 2015;372(5):407-17. doi: 10.1056/NEJMoa1404595 [published  
499 Online First: 2015/01/30]
- 500 4. Flenady V, Koopmans L, Middleton P, et al. Major risk factors for stillbirth in high-income  
501 countries: a systematic review and meta-analysis. *Lancet* 2011;377(9774):1331-40. doi:  
502 10.1016/S0140-6736(10)62233-7 [published Online First: 2011/04/19]
- 503 5. Magee LA, von Dadelszen P, Singer J, et al. The CHIPS Randomized Controlled Trial (Control of  
504 Hypertension in Pregnancy Study): Is Severe Hypertension Just an Elevated Blood Pressure?  
505 *Hypertension* 2016;68(5):1153-59. doi: 10.1161/HYPERTENSIONAHA.116.07862 [published  
506 Online First: 2016/09/14]
- 507 6. (NICE) NifHCE. Hypertension in pregnancy CG107 2010 [Available from:  
508 <https://www.nice.org.uk/guidance/cg107>
- 509
- 510 7. (NICE) NifHCE. Hypertension in pregnancy. Quality Standard (QS35), 2013.
- 511 8. (NICE) NifHCE. Patient Experience in Adult NHS Services: Improving the Experience of Care for  
512 People Using Adult NHS Services: Patient Experience in Generic Terms. London 2012.
- 513 9. Kirk MA, Kelley C, Yankey N, et al. A systematic review of the use of the Consolidated Framework  
514 for Implementation Research. *Implementation Science* 2016;11(1):72. doi: 10.1186/s13012-  
515 016-0437-z
- 516 10. Kirkpatrick DH, Burkman RT. Does Standardization of Care Through Clinical Guidelines Improve  
517 Outcomes and Reduce Medical Liability? *Obstetrics & Gynecology* 2010;116(5):1022-26. doi:  
518 10.1097/AOG.0b013e3181f97c62
- 519 11. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for  
520 intervention description and replication (TIDieR) checklist and guide. *BMJ : British Medical  
521 Journal* 2014;348:g1687. doi: 10.1136/bmj.g1687
- 522 12. Burt J, Abel G, Elmore N, et al. Assessing communication quality of consultations in primary care:  
523 initial reliability of the Global Consultation Rating Scale, based on the Calgary-Cambridge  
524 Guide to the Medical Interview. *BMJ Open* 2014;4(3):e004339. doi: 10.1136/bmjopen-2013-  
525 004339
- 526 13. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology*  
527 2006;3(2):77-101. doi: 10.1191/1478088706qp063oa
- 528 14. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research  
529 findings into practice: a consolidated framework for advancing implementation science.  
530 *Implementation science : IS* 2009;4:50. doi: 10.1186/1748-5908-4-50 [published Online First:  
531 2009/08/12]
- 532 15. International consortium for health outcome measurements i. Pregnancy and childbirth standard  
533 set. 2016
- 534 16. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *BMJ*  
535 2000;320(7227):114-16. doi: 10.1136/bmj.320.7227.114
- 536 17. O'Cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health services  
537 research. *Journal of health services research & policy* 2008;13(2):92-8. doi:  
538 10.1258/jhsrp.2007.007074 [published Online First: 2008/04/18]

- 1  
2  
3 539 18. excellence Nifhac. Hypertension in adults: diagnosis and management (NG136). 2019  
4 540 19. Vrijens B, Vincze G, Kristanto P, et al. Adherence to prescribed antihypertensive drug treatments:  
5 541 longitudinal study of electronically compiled dosing histories. *BMJ* 2008;336(7653):1114-17.  
6 542 doi: 10.1136/bmj.39553.670231.25  
7 543 20. Dickinson D, Wilkie P, Harris M. Taking medicines: concordance is not compliance. *BMJ*  
8 544 1999;319(7212):787. doi: 10.1136/bmj.319.7212.787  
9 545 21. Rangachari P, Rissing P, Rethemeyer K. Awareness of evidence-based practices alone does not  
10 546 translate to implementation: insights from implementation research. *Quality management*  
11 547 *in health care* 2013;22(2):117-25. doi: 10.1097/QMH.0b013e31828bc21d [published Online  
12 548 First: 2013/04/02]  
13 549 22. von Dadelszen P, Sawchuck D, McMaster R, et al. The Active Implementation of Pregnancy  
14 550 Hypertension Guidelines in British Columbia. *Obstetrics & Gynecology* 2010;116(3):659-66.  
15 551 doi: 10.1097/AOG.0b013e3181eb669d  
16 552 23. Webster Louise M, Myers Jenny E, Nelson-Piercy C, et al. Labetalol Versus Nifedipine as  
17 553 Antihypertensive Treatment for Chronic Hypertension in Pregnancy. *Hypertension*  
18 554 2017;70(5):915-22. doi: 10.1161/HYPERTENSIONAHA.117.09972  
19 555 24. Lupattelli A, Spigset O, Nordeng H. Adherence to medication for chronic disorders during  
20 556 pregnancy: results from a multinational study. *International Journal of Clinical Pharmacy*  
21 557 2014;36(1):145-53. doi: 10.1007/s11096-013-9864-y  
22 558 25. Matsui D. Adherence with Drug Therapy in Pregnancy. *Obstetrics and Gynecology International*  
23 559 2012;2012:5. doi: 10.1155/2012/796590  
24 560 26. Abheiden CNH, van Reuler AVR, Fuijkschot WW, et al. Aspirin adherence during high-risk  
25 561 pregnancies, a questionnaire study. *Pregnancy Hypertension: An International Journal of*  
26 562 *Women's Cardiovascular Health* 2016;6(4):350-55. doi:  
27 563 <https://doi.org/10.1016/j.preghy.2016.08.232>  
28 564 27. Abalos E, Duley L, Steyn DW, et al. Antihypertensive drug therapy for mild to moderate  
29 565 hypertension during pregnancy. *Cochrane Database Syst Rev* 2018;10:CD002252. doi:  
30 566 10.1002/14651858.CD002252.pub4 [published Online First: 2018/10/03]  
31 567 28. Excellence NifHaC. Hypertension in pregnancy: diagnosis and management  
32 568 NICE guideline [NG133]. 2019  
33 569  
34 570  
35  
36  
37  
38  
39  
40  
41  
42

43 571 Figure 1. Interpretation of integrated analysis: a strategy for improved implementation of evidence-  
44 572 based hypertension in pregnancy management

45 573 Figure 2a. Women's adherence and concordance with prescribed antihypertensives. Numbers 1-18  
46 574 represent interviewed women and their experiences of anti-hypertensive prescribing during  
47 575 pregnancy. Women who experienced a change in their adherence or in the reporting of internal  
48 576 conflict are plotted more than once in different bubbles. 2b. Facilitators of women's adherence and  
49 577 of concordance.  
50  
51  
52  
53  
54  
55

56 578  
57  
58  
59  
60

Individual setting

Information and education (doctors and midwives)

Offering women informed choices about AHTs based on evidence, side effects and medicine history

Shared decision-making

Share target blood pressure (and above target pathways) with all HCPs and women

Sub-optimal antenatal hypertension management

Optimised antenatal hypertension management



Access to early pregnancy care

Multi-disciplined care

Specialist midwives

Inner setting

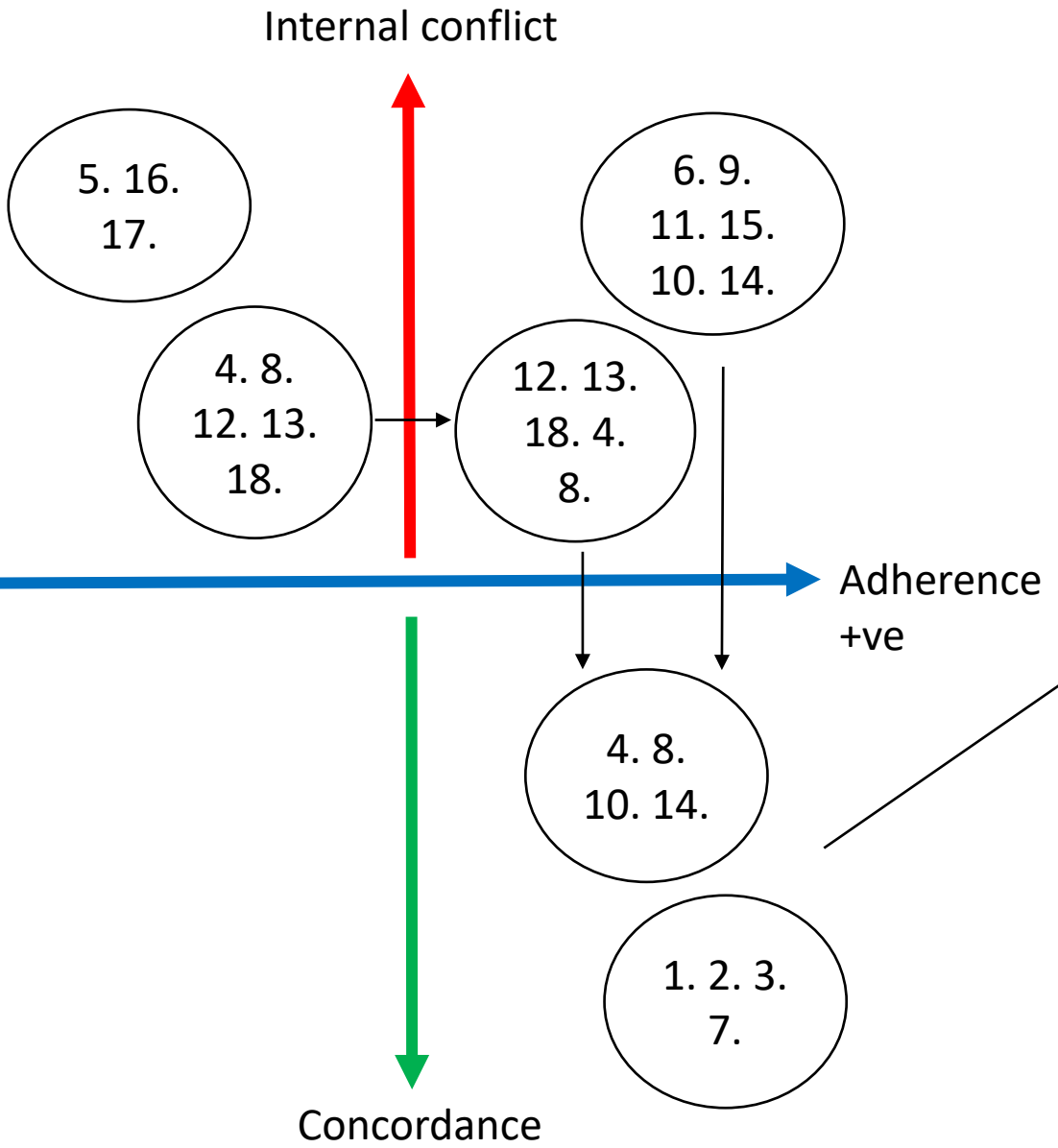
Defined pathways and schedule of care

Evidence-based guidelines for CHT in pregnancy

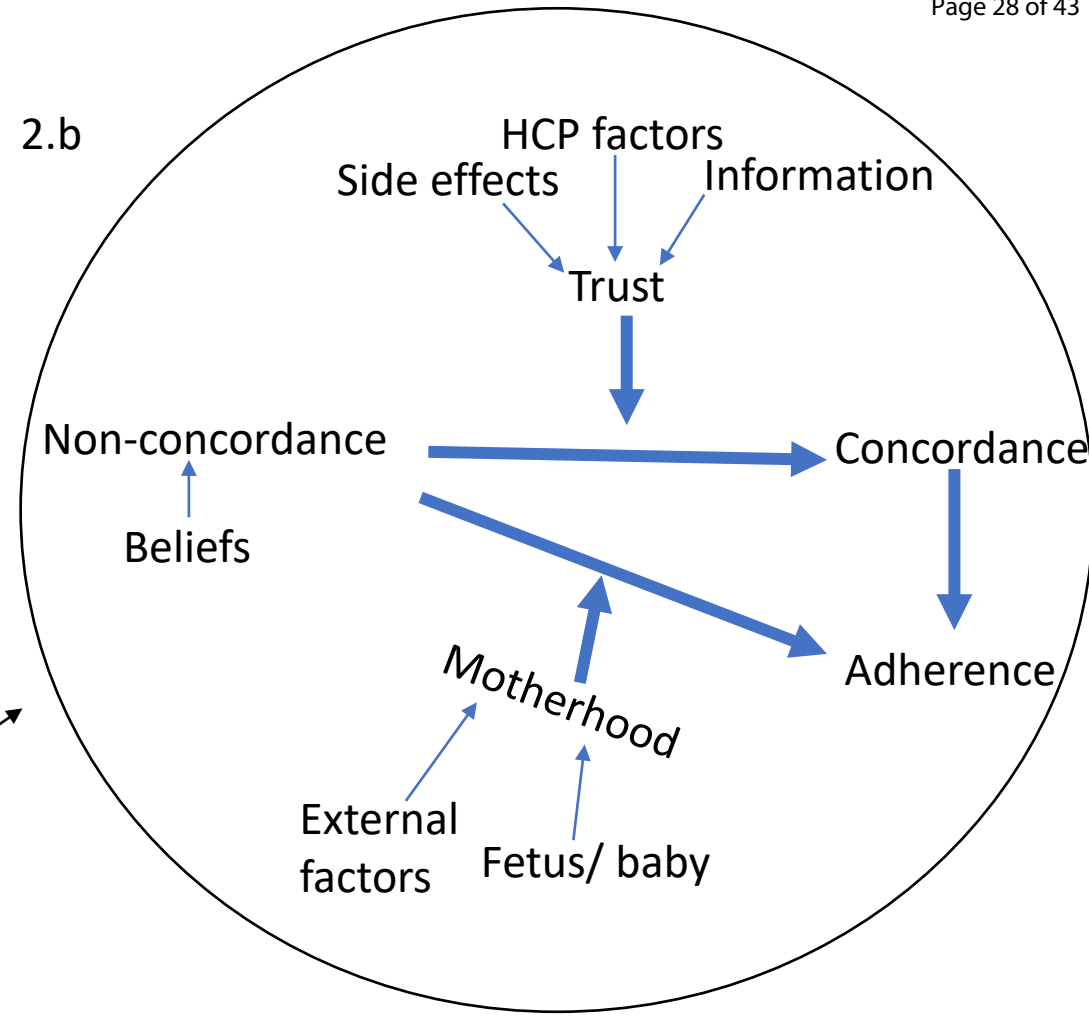
Outer setting

Research in the management of CHT in pregnancy

2.a



2.b



## Supplementary file 1

## Chronic hypertension in pregnancy – healthcare professional survey

Respondents	Number (97)	Percentage %
Obstetrician	69	71.1
Of which are consultants	53	55
Midwife	28	28.9
Of which are specialist/ senior midwife	22	22.7
NHS hospital trusts represented (including England, Northern Ireland, Scotland and Wales)	69	-

Question 1: If you see a pregnant woman with chronic hypertension who is currently taking either ACEIs or ARBs (e.g. at the beginning of pregnancy), how often would you ask her to stop taking them?

Response	Number (97)	Percentage (%)
Always	57	57.8
Almost always	27	27.8
About two thirds of the time	1	1
About half of the time	4	4.1
About a third of the time	0	0
Very rarely	1	1
Never	3	3.1
Missing	4	4.1

Question 2: What do you usually use as your first line anti-hypertensive treatment(s) for women with chronic hypertension in pregnancy?

Anti-hypertensive (non-exclusive)	Number (97)	Percentage (%)
Labetalol	85	87.6
Methyldopa	29	29.9
Nifedipine	32	33.0
Amlodipine	2	2.1

Question 3: What additional anti-hypertensive medication do you use for treating women with chronic hypertension in pregnancy?

Anti-hypertensive (non-exclusive)	Number (97)	Percentage (%)
Amlodipine	37	38.1
Atenolol	2	2.1
Doxazosin	23	23.7
Enalapril	1	1.0
Hydralazine (oral)	2	2.1
Labetalol	38	39.2
Methyldopa	60	61.9
Metoprolol	1	1.0
Nifedipine	79	81.4

Question 4: How frequently do you set a blood pressure target for women with chronic hypertension in pregnancy who need anti-hypertensive treatment (assuming no other co-morbidity) (mmHg)?

Answer	Number (97)	Percentage %
Always	36	37.1
Almost always	36	37.1
About two thirds of the time	8	8.2
About half of the time	3	3.1
About a third of the time	4	4.1
Very rarely	3	3.1
Never	1	1.0
Other	6	6.2
In the guidelines but compliance unknown	2	
Frequency not described	4	

Question 5: What blood pressure target do you usually set for pregnant women with chronic hypertension (assuming no other co-morbidity) (mmHg)?

Systolic	Number (97)	Percentage %	Median (IQR1-IQR3)
120	2	2.1	
125	0	0.0	
130	6	6.2	
135	2	2.1	
140	33	34.0	
145	0	0.0	
150	40	41.2	
155	1	1.0	
160	8	8.2	
Missing	4	4.1	
Median			150 (140-150)

Diastolic	Number (97)	Percentage %	Median (IQR1-IQR3)
80	9	9.3	
85	7	7.2	
90	37	38.1	
95	8	8.2	
100	27	27.8	
110	3	3.1	
Missing	5	5.2	
Median			90 (90-100)



Question 6: How often do you prescribe Aspirin for women with chronic hypertension in pregnancy?

Answer	Number (97)	Percentage %
Always	53	54.6
Almost always	36	37.1
About two thirds of the time	5	5.2
About half of the time	2	2.1
Very rarely	1	1.0

Question 7: At what gestation do these women usually receive their first Aspirin prescription?

Answer	Number (97)	Percentage %
Before 12 weeks	41	42.3
12-15+6 weeks	52	53.6
16-19+6 weeks	1	1.0
Missing answer	3	3.1

Question 8: For a woman with uncomplicated chronic hypertension in pregnancy (i.e. no additional risk factors), how many routine fetal growth scans do they receive (excluding nuchal and anomaly scans)?

Additional scans	Number (97)	Percentage %	Median (IQR1-IQR3)
None	4	4.1	
1	12	12.4	
2	23	23.7	
3	37	38.1	
4	21	21.6	
>4	1	1.0	
			3 (2-3)

Question 9: When do you usually plan birth for women with chronic hypertension whose blood pressure is controlled below 160/110?

Gestation	Number (97)	Percentage (%)	Median (IQR1-IQR3)
Before 34 weeks	3	3.1	
34-34+6 weeks	2	2.1	
35-35+6 weeks	2	2.1	
36-36+6 weeks	4	4.1	
37-37+6 weeks	27	27.8	
38-38+6 weeks	36	37.1	
39-39+6 weeks	41	42.3	
40-41 weeks	28	28.9	
Await spontaneous labour	5	5.2	
Other – individualised	4	4.2	
			38.5 (37-39)

Question 10: Involving pregnant women who have chronic hypertension in their pregnancy and birth planning is an important part of the consultation?

Sentiment	Number (97)	Percentage (%)
Agree Strongly	79	81.4
Agree	15	15.5
Slightly Agree	2	2.1
Slightly disagree	0	0.0
Disagree	0	0.0
Disagree Strongly	1	1.0

Question 11: If you wish, can you give an example of how you enable women to be actively involved in their care?

Themes	Number (47)	Percentage %
Total responses	47	
SDM in the following areas		
• Home BP	10	21
• Monitoring BP	6	12.8
• Anti-hypertensives	5	10.6
• Planning birth (induction of labour)	17	36
• Organisation of care	4	8.5
Discussing risks and benefits	2	4.3
How to identify pre-eclampsia	2	4.3

Question 12: In your maternity unit what term/s best describes the antenatal care provided to most women with chronic hypertension?

Care provision	Number (97)	Percentage %
Named consultant-led general antenatal clinic (maternal medicine clinic)	63 (7)	64.9 (7.2)
Consultant-led specialist hypertension in pregnancy clinic	25	25.8
Multi-disciplinary clinic with additional medical professional	20	20.6
Consultant obstetrician and midwife antenatal clinic	15	15.5
Shared-care GP/ obstetrician/ midwife	7	7.2
Specialist midwifery care (e.g. medical conditions team)	6	6.2
Hospital midwifery care	1	1.0
Community based midwifery care	4	4.1
Day assessment unit	2	2.1

1  
2  
3 Question 13: In your maternity unit when do the pregnant women with chronic hypertension usually  
4 first get seen by an obstetrician?  
5

Gestation	Number (97)	Percentage %
Before 12 weeks	24	24.7
12-15+6 weeks	63	64.9
16-27+6 weeks	9	9.3
Missing data	1	1.0

6  
7  
8  
9  
10  
11  
12  
13  
14 Question 14: Do you or someone in your unit specifically collect and analyse the outcomes of  
15 women with chronic hypertension in pregnancy annually?  
16

Response	Number (97)	Percentage (%)
Yes	24	24.7
No	67	69.0
Unsure	4	4.1
Some aspects	2	2.0

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  
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

Supplementary file 2

**Interview topic guide for clinicians:**

- Descriptions of the general approach to practice and how clinicians approach treatment decisions
- Discussion about the sources of evidence and knowledge that influence practice in general
- Participants' beliefs and experiences of using or having contact with clinical guidance (NICE in particular),
- Participants' views regarding how EBM and clinical guidelines could be better mobilised into practice

Interview schedule:

- Introductions
- Confidentiality
- I am interviewing you today for the CHAMPION study about chronic hypertension, you provide antenatal care for women with CHP is that right?
- Can you tell me a about your CHP clinic and your clinical practice in relation to chronic hypertension in pregnancy?
- How do you approach decision-making, for example commencing or changing hypertensive medication or delivery the baby early?
- What are you views and experiences of involving women in decision about their care or treatment plan?
- How do you source evidence and develop knowledge around hypertension in pregnancy?
- What are you experiences of clinical guidance e.g. NICE/ RCOG?
- How do you think we could better implement evidence-based medicine into clinical practice?

Reference: Grove, A., Clarke, A. and Currie, G. (2015) 'The barriers and facilitators to the implementation of clinical guidance in elective orthopaedic surgery: a qualitative study protocol', *Implementation Science*, 10(1), 81.

**Women's experience of their care**

- Introductions
- Confidentiality
- During this pregnancy you have been treated for chronic hypertension is that right?
- Can you tell me a bit about your high blood pressure and your pregnancy?
- How satisfied are you with the results of your care during your pregnancy?
- Thinking about your care during your pregnancy...Were you given information about your choices for maternity care?
- Were you given enough information to help you decide about your care?
- Were you given information at the right time to help you decide about your care?
- Did you have confidence and trust in the staff caring for you?

Reference: International Consortium for Health Outcomes Measurement. *Pregnancy and Childbirth Standard Set and Reference Guide*. 2016. <http://www.ichom.org/medical-conditions/pregnancy-and-childbirth/>.

## Supplementary file 3

Maternal demographics of women observed, interviewed and included for case-note review. Women interviewed are a subset of those observed. Case-notes identified for review are a different cohort of women.

Women demographics	Observed n=28 (%)	Interviewed n=18 (%)	Case-notes n=55 (%)
<b>Ethnicity</b>			
White British	9 (32.0)	7 (39.0)	15 (27.3)
White Other	6 (21.0)	4 (22.0)	8 (14.5)
Black	9 (32.0)	5 (28.0)	18 (32.7)
Asian	2 (7.0)	1 (5.5)	8 (14.5)
Any other	2 (7.0)	1 (5.5)	6 (10.9)
<b>Parity at booking</b>			
0	9 (32.0)	7 (39.0)	15 (27.3)
1	11 (39.0)	7 (39.0)	21 (38.2)
2	7 (25.0)	4 (22.0)	10 (18.2)
3	0 (0.0)	0 (0.0)	6 (10.9)
4	0 (0.0)	0 (0.0)	2 (3.6)
5	1 (4.0)	0 (0.0)	1 (1.8)
<b>Age</b>			
20-34	17 (61.0)	11 (61.0)	23 (41.8)
35-39	7 (25.0)	5 (28.0)	21 (38.9)
40-44	4 (14.0)	2 (11.0)	11 (20.4)
<b>BMI</b>			
<18.5	0 (0.0)	0 (0.0)	1/52 (1.9)
18.5-24.9	7 (25)	6 (33.3)	13/52 (25.0)
25-29.9	10 (36)	6 (33.3)	13/52 (25.0)
30-34.9	9 (32)	5 (28.0)	11/52 (21.2)
35-39.0	2 (7)	1 (5.5)	6/52 (11.5)
>40.0	0 (0)	0 (0.0)	8/52 (7.7)

## Supplementary file 4

## Pregnancy and birth outcomes – Case notes review

<b>Outcomes</b>	<b>Case notes review Nominator/denominator (%)</b>
Women with episode of severe hypertension	25/55 (45.5)
1 <sup>st</sup> trimester episode	2/40 (5.0)
2 <sup>nd</sup> trimester episode	13/40 (32.5)
3 <sup>rd</sup> trimester episode	25/40 (62.5)
Birth weight - median (IQR1 – IQR3)	2927.5 (2592.5 - 3200)
Admission to NNU	9/55 (16.4)

## Supplementary file 5

Target blood pressure setting and prescribing practices per Trust – as derived from case-note review

	<b>Hospital Trust 1 n=29 (%)</b>	<b>Hospital Trust 2 n=13 (%)</b>	<b>Hospital Trust 3 n=13 (%)</b>
<b>Target BP documented &lt;150/100mmHg</b>	20/26 (77.0)	3/13 (23.0)	5 (38.0)
<b>Labetalol</b>	12/26 (46.0)	7/12 (58.3)	9/11 (82.0)
<b>Nifedipine</b>	9/26 (34.5)	0/12 (0.0)	0/11 (0.0)
<b>Methyldopa</b>	3/26 (11.5)	4/12 (33.3)	1/11 (9.0)
<b>Other</b>	2/26 (8.0)	1/12 (8.3)	1/11 (9.0)

For peer review only

# The quality of mixed methods studies in health services research

Alicia O’Cathain, Elizabeth Murphy<sup>1</sup>, Jon Nicholl

Medical Care Research Unit, School of Health and Related Research, University of Sheffield, Sheffield; <sup>1</sup>School of Sociology and Social Policy, University of Nottingham, Nottingham, UK

**Objectives:** To assess the quality of mixed methods studies in health services research (HSR).

**Methods:** We identified 118 mixed methods studies funded by the Department of Health in England between 1994 and 2004, and obtained proposals and/or final reports for 75. We applied a set of quality questions to both the proposal and report of each study, addressing the success of the study, the mixed methods design, the individual qualitative and quantitative components, the integration between methods and the inferences drawn from completed studies.

**Results:** Most studies were completed successfully. Researchers mainly ignored the mixed methods design and described only the separate components of a study. There was a lack of justification for, and transparency of, the mixed methods design in both proposals and reports, and this had implications for making judgements about the quality of individual components in the context of the design used. There was also a lack of transparency of the individual methods in terms of clear exposition of data collection and analysis, and this was more a problem for the qualitative than the quantitative component: 42% (19/45) versus 18% (8/45) of proposals ( $p = 0.011$ ). Judgements about integration could rarely be made due to the absence of an attempt at integration of data and findings from different components within a study.

**Conclusions:** The HSR community could improve mixed methods studies by giving more consideration to describing and justifying the design, being transparent about the qualitative component, and attempting to integrate data and findings from the individual components.

*Journal of Health Services Research & Policy* Vol 13 No 2, 2008: 92–98

© The Royal Society of Medicine Press Ltd 2008

## Introduction

Mixed methods studies are common in health services research (HSR).<sup>1</sup> They consist of two separate components of data collection and analysis within a single study: at least one quantitative method with structured data collection and statistical analysis, and at least one qualitative method with less structured data collection and thematic analysis.<sup>2</sup> Commissioners and consumers of research, as well as researchers themselves, need to judge whether a mixed methods study has been undertaken well or poorly, assessing whether it is good mixed methods research as well as good research. The quality of mixed methods research has been considered explicitly in health, educational and social research,<sup>3–8</sup> and implicitly when researchers have discussed the challenges of designing and implementing these studies.<sup>9,10</sup> However, the issue has received little

consideration overall, with a recent search for quality criteria for mixed methods research concluding that there were none available,<sup>7</sup> even though attempts have been made to develop them.<sup>3</sup> Given that there are no agreed criteria for assessing the quality of these studies,<sup>8</sup> and that researchers are still debating the meaning of quality for mixed methods research,<sup>6</sup> it is premature to attempt to develop definitive criteria. Instead, it seems sensible to follow an approach taken by researchers considering quality in the context of synthesizing qualitative and quantitative evidence<sup>11</sup> and devise a set of questions which could be applied to mixed methods primary research to facilitate judgements about quality. We devised a set of ‘quality questions’ and applied them to proposals and reports of mixed methods studies to assess the quality of mixed methods studies in HSR.

Alicia O’Cathain PhD, MRC Fellow, Jon Nicholl MSc, Professor, Medical Care Research Unit, School of Health and Related Research, University of Sheffield, Regent Street, Sheffield S1 4DA, UK; Elizabeth Murphy PhD, Professor, School of Sociology and Social Policy, University of Nottingham, Nottingham, UK.

Correspondence to: a.ocathain@sheffield.ac.uk

## Methods

This research was part of a wider study exploring the use of mixed methods research in HSR. The wider study consisted of a quantitative documentary analysis of 75 mixed methods studies to determine the type



1 and quality of mixed methods research undertaken, and  
2 qualitative interviews with 20 researchers to explore  
3 facilitators and barriers to exploiting the potential of  
4 this approach.<sup>1,12</sup>

### 7 Devising questions about quality

9 We devised a framework for the quality assessment  
10 based on detailed consideration of the literature on  
11 mixed methods research in the fields of health, social  
12 and educational research. We searched the health data-  
13 bases MEDLINE and CINAHL. We then sought expert  
14 opinion encapsulated in key textbooks.<sup>10,13-20</sup> Finally  
15 we searched the Social Science Citations Index,  
16 PsycINFO, ERIC and the British Education Index to  
17 identify social, behavioural and educational research.  
18 The search for literature took place in 2003 and was  
19 updated in 2006. Quality was one of 11 issues identified  
20 in this review.

21 Within the literature, one suggested assessment cri-  
22 terion for mixed methods studies was whether they  
23 had been completed successfully in terms of adequately  
24 addressing the research questions with allocated  
25 resources.<sup>5</sup> Other researchers focused on the quality of  
26 methods. There was no suggestion of using a tool devel-  
27 oped for generic use across all designs. Rather, research-  
28 ers attempted to develop quality criteria by devising  
29 separate lists of criteria for the quantitative and the  
30 qualitative research.<sup>7</sup> Their assumption was that  
31 methods are linked to paradigms and therefore the  
32 criteria used to assess different methods should also be  
33 linked to paradigms.<sup>7</sup> However, not everyone agrees  
34 that methods are paradigm-specific<sup>18</sup> or that different  
35 criteria are needed for qualitative and quantitative  
36 research.<sup>21</sup> The same criteria have been proposed for  
37 both<sup>21</sup> although the appropriate means for judging  
38 against these criteria may differ because of the research  
39 practices employed in different methodological  
40 approaches. The mixed methods design<sup>10</sup> and the inte-  
41 gration between methods<sup>3</sup> can be assessed as well as the  
42 individual methods. A good mixed methods study  
43 clearly justifies why a mixed methods approach is  
44 necessary or superior to another, offers transparency  
45 of the mixed methods design, and offers appropriate  
46 sampling, data collection and analysis of individual com-  
47 ponents relating to that design.<sup>3,4,10</sup> Thus the design  
48 may determine the criteria used to make judgements  
49 about the individual components of the study.  
50 Integration of data or findings from each component  
51 is a key part of mixed methods research,<sup>10</sup> distinguish-  
52 ing it from qualitative and quantitative studies under-  
53 taken independently. When integration occurs, it is  
54 important that data transformations are defensible,  
55 that contradictory findings are explained and conver-  
56 gent findings are not related to shared bias between  
57 methods.<sup>3</sup> Expertise may be needed within a research  
58 team to integrate at the analysis stage.<sup>22</sup> Finally,  
59 researchers have discussed the importance of inferences  
60 from mixed methods studies being trustworthy<sup>6</sup> and  
appropriate in the light of the design used.<sup>3</sup> As yet

there are no criteria for assessing the quality of infer-  
ences from mixed methods research, although research-  
ers are considering the complexity of this issue.<sup>23</sup>

When developing the framework for our quality ques-  
tions we chose not to use a generic tool because they  
have variable applicability across different research  
designs.<sup>24</sup> We chose to assess the qualitative and quanti-  
tative components separately because they each contri-  
bute to the study as a whole and because the quality of  
one or both components may suffer as a consequence  
of being part of a mixed methods study.<sup>25-27</sup> In  
addition to the individual components, we included  
an assessment of the success of the study, the design,  
the integration and the inferences. Within this frame-  
work we constructed questions based on the literature  
review and reading the proposals and reports from  
four mixed methods studies in HSR.

### Identifying mixed methods studies

In 2004, mixed methods studies were identified  
through a systematic search of summaries of studies  
funded by the Department of Health, a key commis-  
sioner of health services research in England at that  
time. The methods have been described elsewhere<sup>1,12</sup>  
and are summarized here. Summaries of single studies  
funded between 1994 and 2004 through 10 pro-  
grammes were read. The programmes were: Health  
Technology Assessment; Service Delivery and  
Organization; New and Emerging Applications of  
Technology; Policy Research Programme; and the  
NHS Research & Development programmes of  
maternal and child health, primary and secondary  
care interface, cardiovascular disease and stroke, foren-  
sic mental health, primary dental care, and promoting  
implementation of research findings. A total of 118  
mixed methods studies were identified. The lead  
researcher of each study was written to with a request  
for the research proposal, the final report for completed  
studies and a list of any emerging publications.

### Application of quality questions

A data extraction form was devised which consisted of  
the quality questions with the tick box options of 'yes',  
'yes, but improvements are possible', 'no', 'not enough  
information (NEI)' and 'not applicable (N/A)'. Space  
for open comments was available alongside each ques-  
tion, where the assessor (AOC) could record details of  
good and poor practice. The data extraction form was  
applied to each study by one researcher, first to the pro-  
posal and then to the report. Finally, any differences  
between the proposal and report were noted.

### Analysis

The structured data were entered into SPSS. The main  
analysis was descriptive, displaying the proportions of  
proposals and reports falling into each category of  
each question. The chi-squared test was used when

comparing results for the individual qualitative and quantitative components. Open comments were quantized<sup>28</sup> by transcribing them into Word, grouping them into themes, and counting the number of studies in which a theme occurred.<sup>29</sup>

## Results

Documentation was received for 75 mixed methods studies. Full proposals were obtained for 60% (45/75) of the studies. Final reports were only available for the 52 studies completed by the time of data collection, and were obtained for 92% (48), although one was a summary report that was too brief for inclusion in the assessment of quality, leaving 47 reports. Both a proposal and report was available for 20 studies.

### Success

The potential to produce a successfully completed study was assessed using the research proposals. In most proposals, the quantitative methods appeared to be feasible within the time and money allocated (Table 1). However, even recognizing that some aspects of qualitative research cannot be fixed at the design stage (e.g. sample size for theoretical sampling), there was not enough detail to determine the feasibility of the qualitative methods in one-third of studies – for example, no indication of numbers of interviews to be undertaken or no indication of when the qualitative research would be conducted in the study timetable. We had concerns about the feasibility of the qualitative component in another one-third of proposals. From the open comments we identified 14 proposals where a large number of qualitative interviews were planned in a short time scale – for example, 40 interviews in four months without specifying the depth of interview and analysis. In nine of these studies the report was available and in four cases considerably fewer interviews were undertaken than planned. However, concerns highlighted about the feasibility of the qualitative research did not necessarily translate into shortfalls in the final study.

We defined a successful study as one that produced everything that had been planned at the proposal stage. A direct comparison of the final study report with the proposal was only possible on the subset of 20

studies for which both were available. In other cases the assessment relied on researchers detailing the planned and implemented study within their final report. Non-completion of a whole component of a study was rare (Table 1). However, in one-fifth of reports, one of the methods within a component was not executed as planned. This tended to be due to a range of problems in the field.

### Mixed methods design

A justification for using mixed methods research was only given in one-third of proposals and reports (Table 2). A minority of studies explicitly articulated the design in terms of the priority of methods, the purpose of combining methods, the sequence of methods and the stage at which integration would or did occur. It was particularly helpful for the subsequent quality assessment of individual components if researchers were explicit about the priority of methods and the role of any less dominant method. For example, it seemed inappropriate to have 40 in-depth interviews as a preliminary aid to develop a questionnaire, but appropriate if these interviews were also to be used as a primary means of investigating the issue under study. A lack of transparency of the overall design could occur in the context of excellent description of individual components.

When the design was not discussed explicitly it was usually possible to work out the key elements from reading the documentation. In most cases the design was assessed as appropriate for addressing the research question. However, researchers rarely discussed issues of rigour in relation to the design employed. An example of addressing rigour for the design was where researchers proposed that qualitative findings would not be shared with quantitative colleagues undertaking a randomized controlled trial to minimize the possibility of contamination of that trial; in another two studies, the qualitative research was undertaken with people not participating in the trial in order to avoid contaminating the trial. While the extent to which this attention to contamination avoidance was necessary may be debatable, it constitutes some evidence that researchers had given serious consideration to design issues related to mixed methods research.

**Table 1** Assessment of the success of mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the quantitative component feasible?	82%	2%	4%	11%				
2 Is the qualitative component feasible?	38%	20%	13%	29%				
3 Is the mixed methods design feasible?	51%	0%	7%	42%				
4 Have both qualitative and quantitative components been completed?					87%	6%	2%	4%
5 Were some quantitative methods planned but not executed?					19%	0%	45%	36%
6 Were some qualitative methods planned but not executed?					21%	2%	38%	38%
7 Did the mixed methods design work in practice?					85%	0%	2%	13%

NEI, not enough information; N/A, not applicable

**Table 2** Assessment of the mixed methods design of studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the use of mixed methods research justified?	31%	3%	60%	4%	30%	2%	66%	2%
2 Is the design for mixing methods described?								
Priority	16%	2%	78%	4%	15%	0	83%	2%
Purpose	42%	0	53%	4%	34%	4%	60%	2%
Sequence	56%	0	40%	4%	49%	0	49%	2%
Stage of integration	24%	0	71%	4%	21%	0	77%	2%
3 Is the design clearly communicated?	80%	0	16%	4%	81%	4%	9%	6%
4 Is the design appropriate for addressing the research questions?	87%	2%	2%	9%	87%	0%	2%	11%
5 Has rigour of the design been considered (proposal) or adhered to (report)?	7%	0	93%	0%	21%	0%	0%	79%

NEI, not enough information; N/A, not applicable

### Quantitative component

The roles of the quantitative methods were usually communicated well within proposals and reports (Table 3). However, sufficient details were sometimes not given about these methods. In eight proposals the quantitative methods were only sketchily described and in a further 13 proposals some aspects of the quantitative methods were not described, in particular, the analysis (8) and the numbers involved (5). This was less of an issue for reports but nonetheless there were still problems with sketchy description overall (4) or little or no description of the analysis (5). This lack of transparency made it difficult to assess other aspects of quality.

Validity of the methods within the quantitative components was assessed by considering the attention researchers gave to issues such as confounding and bias. Validity was explicitly discussed in two-thirds of proposals, with little evidence that the rigour of any method was compromised (Table 3). There were few examples of an individual method being compromised by the mixed methods approach. One example was a Delphi exercise which was restricted in order to fit the timetable of the qualitative fieldwork.

It was difficult to determine the sophistication of proposed analyses due to the lack of detail about analysis in the research proposals. There was more information about analyses available in research reports and here

concerns were identified about the sophistication of one-quarter of quantitative analyses. We identified 12 studies where the reported quantitative results seemed simplistic, sometimes only presenting descriptive statistics with no statistical tests and in two cases using an experimental design which was then ignored in the analysis.

### Qualitative component

The roles of the qualitative methods were usually communicated well within proposals and reports (Table 4). However, qualitative methods were often not described in sufficient detail and this occurred more frequently than for the quantitative components, both within proposals ( $p = 0.011$ ) and reports ( $p = 0.08$ ). First, there was sketchy description of the qualitative methods overall (15 proposals and 11 reports). In three of these reports there was no description of the qualitative methods at all, only the findings. Second, there were no details about an important aspect of the qualitative research, particularly the analysis (six proposals and nine reports). Third, one method was described in detail, usually interviews with a particular group, but a further qualitative method such as observation or focus groups appeared to be 'tagged on' with no description (six proposals). Fourth, the overall size of the qualitative component was not clear, with a few

**Table 3** Assessment of the quantitative component of mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the role of each method clear?	98%	0%	2%	0%	96%	2%	0%	2%
2 Is each method described in sufficient detail?	53%	29%	18%	0%	68%	13%	15%	4%
3 Is each method appropriate for addressing the research question?	93%	0	2%	4%	98%	0%	0%	2%
4 Is the approach to sampling and analysis appropriate for its purpose?	67%	4%	4%	24%	70%	9%	6%	15%
5 Is there expertise among applicants/authors?	67%	2%	7%	24%	30%	0%	0%	70%
6 Is there expertise on the team to undertake each method?	60%	0%	2%	24%				
7 Have issues of validity been addressed for each method?	64%	0%	30%	7%	49%	4%	40%	6%
8 Has the rigour of any method been compromised?	7%	0%	91%	2%	9%	4%	83%	4%
9 Is each method sufficiently developed for its purpose?	84%	0%	7%	9%	83%	0%	4%	13%
10 Is the (intended) analysis sufficiently sophisticated?	56%	4%	2%	38%	51%	15%	25%	9%

NEI, not enough information; N/A, not applicable

**Table 4** Assessment of the qualitative component of mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the role of each method clear?	87%	0%	9%	4%	92%	4%	4%	0%
2 Is each method described in sufficient detail?	24%	29%	42%	4%	38%	28%	30%	4%
3 Is each method appropriate for addressing the research question?	87%	7%	2%	4%	91%	2%	2%	4%
4 Is the approach to sampling and analysis appropriate for its purpose?	42%	4%	9%	40%	53%	9%	4%	34%
5 Is there expertise among the applicants/authors?	56%	2%	11%	31%	32%	4%	0%	64%
6 Is there expertise on the team to undertake each method?	44%	9%	7%	40%				
7 Have issues of validity been addressed for each method?	24%	0%	64%	11%	30%	2%	57%	11%
8 Has the rigour of any method been compromised?	2%	0%	91%	7%	6%	2%	81%	11%
9 Is each method sufficiently developed for its purpose?	64%	0%	9%	27%	77%	2%	9%	13%
10 Is the (intended) analysis sufficiently sophisticated?	40%	4%	7%	49%	51%	13%	19%	17%

NEI, not enough information; N/A, not applicable

interviews here and there throughout the study adding up to a sizeable qualitative component of over 100 interviews (10 proposals).

Validity of the methods within the qualitative components was assessed by considering the attention researchers gave to issues such as reflexivity and negative cases. Validity was not addressed within proposals for more qualitative than quantitative components ( $p = 0.001$ ), although any apparent difference in reports was not statistically significantly different ( $p = 0.100$ ) (Table 4). Researchers did take the validity of qualitative methods seriously in some proposals, for example, paying attention to deviant cases and peer review of transcripts.

Concerns were identified with the sophistication of one-fifth of qualitative analyses. In nine studies the reported qualitative findings remained at a descriptive level, or reported findings in a quantitative manner only, or failed to distinguish between data collected using different methods such as focus groups and interviews.

## Integration

Integration of data or findings from the different methods received little attention in either proposals or

reports, with researchers rarely discussing the type of integration, how it occurred in the context of team working and who was involved in it (Table 5). Because of the lack of integration, questions about the appropriateness of integration and the effect of integration on the rigour of individual methods were irrelevant.

## Inferences

In the reports, researchers were clear about which results had emerged from which methods, and inferences seemed appropriate (Table 6). For one-fifth of studies there was a concern that the inferences were based disproportionately on one method rather than the findings of all the methods. The imbalance was likely to be towards qualitative findings as it was towards quantitative findings.

## Discussion

### The quality of studies in HSR

Mixed methods studies tend to be successful in HSR insofar that the qualitative and quantitative components are usually completed as planned. The main quality issue identified was a lack of transparency of the

**Table 5** Assessment of integration in mixed methods studies in HSR

	Proposal (n = 45)				Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A	Yes	Yes, but	No	NEI or N/A
1 Is the type of integration stated?	11%	0%	84%	4%	2%	2%	94%	2%
2 Is the type of integration appropriate to the design?	16%	0%	0%	84%	34%	0%	2%	64%
3 Has enough time been allocated for integration?	2%	0%	13%	85%				
4 Is the approach to integration detailed in terms of working together as a team?	7%	0%	80%	13%				
5 Does the dissemination strategy detail how the mixed methods will be reported in final reports and peer-reviewed publications?	0%	0%	84%	16%				
6 Are the personnel who participate in the integration clearly identified?	9%	0%	80%	11%	6%	0%	70%	23%
7 Did appropriate members of the team participate in integration?					0%	0%	2%	98%
8 Is there evidence of communication within the team?					19%	0%	6%	75%
9 Has rigour been compromised by the process of integration?					4%	0%	0%	96%

NEI, not enough information; N/A, not applicable



**Table 6** Assessment of the inferences made in completed reports of mixed methods studies in HSR

	Report (n = 47)			
	Yes	Yes, but	No	NEI or N/A
1 Is there clarity about which results have emerged from which methods?	87%	2%	6%	4%
2 Are inferences appropriate?	83%	4%	9%	4%
3 Are the results of all the methods considered sufficiently in the interpretation?	66%	6%	19%	9%

NEI, not enough information; N/A, not applicable

mixed methods aspects of the studies and the individual components. The qualitative components were more likely to be poorly described than the quantitative ones. To some extent the poor description of qualitative methods is not a surprising finding given the historical dominance of quantitative methods in HSR. However, it raises concerns that the HSR community may be failing on occasions to exploit the potential of qualitative methods within mixed methods studies. Where a qualitative component is in a supporting role to a more dominant method, and does not have stand-alone status in terms of independently addressing an aspect of the research question, then limited description is acceptable. However, because researchers were often not explicit about the status of methods within the study design, it was difficult to make judgements about the individual components in the context of the design used. Integration of data and findings is a key part of mixed methods research. There was no evidence that inappropriate integration was undertaken because there was a tendency for researchers to keep the qualitative and quantitative components separate rather than attempt to integrate data or findings in reports or publications.<sup>12</sup>

### Developing quality criteria for mixed methods studies in HSR

There was a lack of transparency in the reporting of mixed methods studies in HSR which made it difficult to assess other aspects of the quality of these studies. This has been identified as a problem facing the quality assessment of other types of studies<sup>11</sup> and has led to the development of guidelines for reporting studies. Creswell has suggested a list of issues to consider when designing a mixed methods study<sup>10</sup> and we have considered this in conjunction with the literature on the quality of mixed methods studies to suggest some guidelines for Good Reporting of A Mixed Methods Study (GRAMMS) (Box 1). We present this as guidance for researchers rather than as a formal checklist.

### Box 1 Good Reporting of A Mixed Methods Study (GRAMMS)

- (1) Describe the justification for using a mixed methods approach to the research question
- (2) Describe the design in terms of the purpose, priority and sequence of methods
- (3) Describe each method in terms of sampling, data collection and analysis
- (4) Describe where integration has occurred, how it has occurred and who has participated in it
- (5) Describe any limitation of one method associated with the present of the other method
- (6) Describe any insights gained from mixing or integrating methods

### Limitations

The study is based on mixed methods research funded by one commissioner in one country. The response rate to requests for documentation for mixed methods studies was good but non-responders may have been more likely to be problematic studies, biasing the findings towards higher quality studies. The questions were devised and applied by one researcher (AOC) in the context of team discussions which meant that the data extraction process was unchallenged by an external source. A coding protocol was devised to accompany the data extraction form to aid transparency and reduce intra-rater variability. However the studies could have been rated differently by another researcher. Finally, the studies included were funded between 1994 and 2004 and improvements may have occurred since then.

We have taken a technical stance in our discussions of quality in mixed methods research. However, the philosophical stance adopted by researchers may affect the quality criteria they use, and wish to see applied to their studies. Subtle realism<sup>30</sup> has been proposed as a philosophical position appropriate for qualitative and quantitative research in health technology assessment.<sup>21</sup> An implication of this stance is that researchers would need to consider whether reflexivity has been applied to the whole of a mixed methods study rather than simply the qualitative component.

### Conclusions

This is the first attempt to consider the quality of mixed methods studies in HSR. We are not offering this as a definitive approach to be used by others, but to start the debate about how to assess and improve quality. We recommend that if we use mixed methods studies in HSR then we need to be more transparent about the design and the individual components in the context of the design, and attempt to integrate data and findings from the qualitative and quantitative methods.

### Acknowledgements

Many thanks to the researchers who kindly sent copies of their study documents. The Medical Research Council funded the study through their Fellowship scheme.

## References

- 1 O’Cathain A, Murphy E, Nicholl J. Why, and how, mixed methods research is undertaken in health services research: a mixed methods study. *BMC Health Serv Res* 2007;**7**:85
- 2 Bryman A. Quantitative and qualitative research: further reflections on their integration. In: Brannen J, ed. *Mixing Methods: Qualitative and Quantitative Research*. Aldershot: Ashgate, 1992:57–78
- 3 Caracelli VJ, Riggan LJC. Mixed-method evaluation: developing quality criteria through concept mapping. *Eval Pract* 1994;**15**:139–52
- 4 Creswell JW, Fetters MD, Ivankova NV. Designing a mixed methods study in primary care. *Ann Fam Med* 2004;**2**:7–12
- 5 Datta L. A pragmatic basis for mixed-method designs. In: Greene JC, Caracelli VJ, eds. *Advances in Mixed-method Evaluation: The Challenges and Benefits of Integrating Diverse Paradigms*. San Francisco, CA: Jossey-Bass, 1997:33–46
- 6 Teddlie C, Tashakkori A. Major issues and controversies in the use of mixed methods in the social and behavioural sciences. In: Tashakkori A, Teddlie C, eds. *Handbook of Mixed Methods in Social and Behavioural Research*. London: Sage Publications, 2003:3–50
- 7 Sale JEM, Brazil K. A strategy to identify critical appraisal criteria for primary mixed method studies. *Quality and Quantity* 2004;**38**:351–65
- 8 Creswell JW, Plano-Clark V. *Designing and Conducting Mixed Methods Research*. Thousand Oaks, CA: Sage Publications, 2007
- 9 Brannen J. Combining qualitative and quantitative approaches: an overview. In: Brannen J, ed. *Mixing Methods: Qualitative and Quantitative Research*. Aldershot: Ashgate, 1992:3–38
- 10 Creswell JW. *Research Design. Qualitative, Quantitative, and Mixed Methods Approaches*. 2nd edn. London: Sage Publications, 2003
- 11 Mays N, Pope C, Popay J. Systematically reviewing qualitative and quantitative evidence to inform management and policy-making in the health field. *J Health Serv Res Policy* 2005;**10** (Suppl. 1):6–20
- 12 O’Cathain A, Murphy E, Nicholl J. Integration and publications as indicators of ‘yield’ from mixed methods studies. *Journal of Mixed Methods Research* 2007;**1**:147–63
- 13 Brewer J, Hunter A. *Multimethod Research*. London: Sage Publications, 1989
- 14 Tashakkori A, Teddlie C, eds. *Handbook of Mixed Methods in Social and Behavioural Research*. London: Sage, 2003
- 15 Tashakkori A, Teddlie C. *Mixed Methodology: Combining Qualitative and Quantitative Approaches*. London: Sage, 1998
- 16 Gorard S, Taylor C. *Combining Methods in Educational and Social Research*. Maidenhead: Open University Press, 2004
- 17 Brannen J, ed. *Mixing Methods: Qualitative and Quantitative Research*. Aldershot: Ashgate, 1992
- 18 Bryman A. *Quantity and Quality in Social Research*. London: Routledge, 1988
- 19 Greene JC, Caracelli VJ, eds. *Advances in Mixed-method Evaluation: The Challenges and Benefits of Integrating Diverse Paradigms*. San Francisco, CA: Jossey-Bass, 1997
- 20 Fielding NG, Fielding JL. *Linking Data*. Sage Publications, 1986
- 21 Murphy E, Dingwall R, Greatbatch D, Parker S, Watson P. Qualitative research methods in health technology assessment: a review of the literature. *Health Tech Assess* 1998;**2**:16
- 22 Mason J. Linking qualitative and quantitative data analysis. In: Bryman A, Burgess RG, eds. *Analysing Qualitative Data*. London: Routledge, 1994:89–110
- 23 Miller S. Impact of mixed methods and design on inference quality. In: Tashakkori A, Teddlie C, eds. *Handbook of Mixed Methods in Social and Behavioural Research*. London: Sage Publications, 2003:423–55
- 24 Katrak P, Bialocerkowski AE, Massy-Westropp N, Kumar VS, Grimmer KA. A systematic review of the content of critical appraisal tools. *BMC Med Res Meth* 2004;**4**:22
- 25 Silverman D. *Doing Qualitative Research. A Practical Handbook*. London: Sage Publications, 2000
- 26 Steckler A, Mcleroy KR, Goodman RM, Bird ST, McCormick L. Toward integrating qualitative and quantitative methods: an introduction. *Health Educ Q* 1992;**19**:1–8
- 27 Chen H. Applying mixed methods: a dominant methodology for the future? In: Greene JC, Caracelli VJ, eds. *Advances in Mixed-method Evaluation: The Challenges and Benefits of Integrating Diverse Paradigms*. San Francisco, CA: Jossey-Bass, 1997:61–72
- 28 Sandelowski M. Combining qualitative and quantitative sampling, data collection, and analysis techniques in mixed-method studies. *Res Nurs Health* 2000;**23**:246–55
- 29 O’Cathain A, Thomas KJ. “Any other comments?” Open questions on questionnaires – a bane or a bonus to research? *BMC Med Res Meth* 2004;**4**:25
- 30 Hammersley M. *What’s Wrong with Ethnography?* London: Routledge, 1992