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Early Postnatal Discharge for Infants: A Meta-Analysis

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Abbreviations: United Kingdom (UK), United States (US); Effective Practice and Organisation of Care (EPOC); randomised controlled trials (RCT); non randomised controlled trials (NRCTs), controlled before-after studies (CBA); interrupted time series (ITS); risk ratio (RR); mean difference (MD).

Table of Contents summary (25 words max)

Postnatal length of hospital stay varies considerably internationally. This systematic review investigates the effects of early postnatal discharge policies on infant and maternal outcomes.

Contributors' Statement Page

Dr Jones designed the study, adapted data collection tools, collected data, carried out data analyses and interpretation, drafted the initial manuscript and revised the manuscript.

Dr Cummins conceptualised and designed the study, adapted data collection tools, collected data, carried out analyses and revised the manuscript critically for important intellectual content.

Dr Beck Taylor and Professor Christine MacArthur conceptualised and designed the study, interpreted data and critically reviewed and revised the manuscript for intellectual content.

Mrs Sally Bradshaw collected data, carried out analyses and interpretation of data and critically reviewed and revised the manuscript.

Dr Lucy Hope collected data and critically reviewed and revised the manuscript.

All authors agree to the final version of the manuscript and are accountable for all aspects of the work.

- 1 Abstract
- 2 Context: Postnatal length of hospital stay has reduced internationally but evidence based
- 3 policies to support earlier discharge are lacking.
- 4 Objective: To determine effects of early postnatal discharge on infant outcomes.

5 Data Sources: CENTRAL, Medline, EMBASE, CINAHL, SCi were searched through to 6 January 15, 2018.

- 7 Study Selection: Studies reporting infant outcomes with early postnatal discharge versus
- 8 standard discharge were included if they met Effective Practice and Organisation of Care
- 9 study design criteria.
- 10 Data extraction: Two authors independently assessed eligibility and extracted data, resolving
- 11 disagreements by consensus. Data from interrupted time series studies (ITSs) were extracted
- 12 and reanalysed in meta-analyses. Meta-analyses of RCTs used random effects models.
- 13 Results: Of 9298 studies identified, 15 studies satisfied the inclusion criteria. RCT meta-
- 14 analyses showed that infants discharged <48 hours following vaginal birth and <96 hours
- 15 following caesarean birth were more likely to be readmitted to hospital within 28 days
- 16 compared to standard discharge (RR 1.70, 95% CI 1.34-2.15). ITSs meta-analyses showed a
- 17 reduction in the proportion of infants readmitted within 28 days after minimum postnatal stay
- 18 policies and legislation were introduced (change in slope, -0.62 (95% CI-1.83, 0.60) with
- 19 increasing impact in the first and second years (effect estimate -4.27 (95% CI -7.91,-0.63)
- 20 and -6.23 (95% CI -10.15,-2.32).
- Limitations: Withdrawals and crossover limited the value of RCTs in this context but not ITSevidence.
- 23
- 24 Conclusions: Infants discharged early after birth were more likely to be admitted within 28
- 25 days. Introduction of postnatal minimum length of stay policies was associated with long
- 26 term reduction in neonatal hospital readmission rates.
- 27

1 Introduction

2 Internationally, there is considerable variation in postnatal length of stay (LoS). Despite an increase in medical intervention during childbirth and more complex maternities, over the last 3 4 40 years there has been a reduction in the postnatal LoS for women and babies. Several high 5 income counties including the United Kingdom, Australia and Canada have an average stay of 1.5 days, 2.8 days and 1.7 days respectively ^{1.} Whilst a reduction in LoS reduces hospital 6 costs¹, there is little data and some concern about whether earlier discharge from hospital is 7 safe and cost-effective. Although there is an existing Cochrane review² of RCTs on this 8 9 topic, it is limited by significant clinical and methodological heterogeneity and thus there is 10 insufficient evidence to inform policy. This systematic review and meta-analysis addressed the same objectives and outcome 11 measures as the Cochrane review 2 but broadened the study design to include both RCTs and 12

14 of studies are important and necessary to evaluate organisational change ³. To reduce

quasi-experimental studies because the intervention is often a policy change and other types

15 heterogeneity, unlike the Cochrane review which used trial authors' definitions, this

16 systematic review predefined early postnatal discharge as <48 hours following vaginal

17 delivery and <96 hours following caesarean section.

18 The aim of this review was to determine the effects of a policy of early postnatal discharge 19 for women and infants, specifically whether there is an association between early postnatal 20 discharge and infant readmission to hospital. It was hypothesised that early postnatal 21 discharge may increase infant utilisation of health services.

22 Methods

13

23 The full systematic review protocol has been published ⁴ and registered in PROSPERO

24 (registration CRD42015020545). This review conforms to the PRISMA statement 5 .

1 Data sources and search strategy

Electronic databases (CENTRAL, MEDLINE, EMBASE, CINAHL, SCi) were searched for
articles up to January 15, 2018 with the following search terms: postnatal care, postpartum
period, puerperium, postpartum, "length of stay", patient discharge, hospital stay*, patient
readmission. Searches used free text and indexed terms combined using boolean operators,
adjusted for each database (eTable 1). The search strategy was not limited by study design
and time, language or geographical restrictions. Where applicable, authors of primary studies
were contacted for further information.

9 Eligibility criteria

10 All studies were eligible to be included in the review if they met the following criteria: 11 women and infants considered 'fit for discharge' by their healthcare practitioners; all births 12 occurring in either obstetric-led (where obstetricians have primary professional responsibility 13 for women at high risk of complications during labour and birth and women are cared by a 14 team of midwives and doctors) or midwife-led care settings (where midwives take the 15 primary professional responsibility for the labour care for low risk women); studies had to 16 compare a policy of early discharge from hospital where 'early discharge' referred to a 17 hospital discharge that was <48 hours following birth (or <96 hours for caesarean delivery) and earlier than the standard care in the setting in which the intervention is implemented to be 18 included. The Cochrane review² identified that RCTs alone on this topic are limited by poor 19 20 compliance and clinical and methodological hetergeneity indicating that alternative study 21 designs may be more helpful for assessing the effect of policy change. Therefore, as guided by Cochrane Effective Practice and Organisation of Care (EPOC)³, in addition to randomised 22 23 controlled trials (RCTs), non randomised controlled trials (NRCTs), controlled before after 24 studies (CBAs) and interrupted time series (ITS) were also eligible for inclusion in the 25 review. ITSs can provide a method of measuring the effect of an intervention when

randomisation or identification of a control group are impractical ³. Multiple data points are
 collected before and after the intervention and the intervention effect is measured against the
 pre-intervention trend ³.

Infant and maternal outcome measures were guided by the Cochrane review². The primary 4 5 infant outcomes were the proportion of infants readmitted to hospital within 7 days and 6 within 28 days after birth. Maternal outcomes were: proportion of women readmitted for 7 complications related to childbirth (postpartum haemorrhage, retained products of 8 conception, infection, postpartum psychosis); proportion of women breastfeeding 9 (exclusively or partially) at 48 hours, 6 weeks and 6 months after birth; proportion of women with a score indicating probable depression on a validated standardized instrument for 10 11 measuring depression.

12 Data collection and extraction

Citations were screened for inclusion independently and in duplicate. Articles were assessed unblinded and differences in opinion resolved through discussion or a third researcher. Data extraction was performed independently and in duplicate. The EPOC data collection form ⁴ was adapted to answer review specific research questions. Data extraction forms were piloted on a sample of included studies. Methodological quality of included studies was assessed independently and in duplicate using EPOC criteria for risk of bias tool ⁵ and Cochrane RCT tool as appropriate ⁶.

20 Statistical Analysis

21 Meta-analyses of RCT studies were carried out in Revman (version 5.3)⁷ using a random 22 effects model and where significant heterogeneity was present, data were described in a 23 narrative synthesis. Where data from ITSs were presented graphically, data were extracted 24 from graphs using plot digitizer software ⁸ and reanalysed using autoregressive integrated

1 moving average (ARIMA analysis) using SPSS (version 22) 9 as described in EPOC guidance 2 10 .

3 The ARIMA analysis estimated the effect of a policy change whilst taking into account the 4 time trend and autocorrelation among the observations. Estimates for the regression 5 coefficients correspond to three standardised effect sizes: change in level at one year and two 6 years post-policy change and change in slope. The change in level was defined as the 7 difference between the observed level at the intervention time point and that predicted by the pre-intervention time trend ¹⁰. The change in slope was defined as the change in trend from 8 pre to post intervention reflecting the long term effect of the policy intervention ¹⁰. Data 9 10 were then standardised by dividing the level/slope and standard error by the standard 11 deviation of the pre intervention slope. The effect sizes for change in level at 1 year and 2 12 year and effect size for change in slope were entered into Revman5 and meta-analysed using 13 the generic inverse variance method with random effects. Statistical significance was set at 14 P<.05. When different studies used data from the same region and time period, only one 15 study was used for inclusion in the meta-analysis.

16 For RCTs, statistical heterogeneity was examined by inspection of confidence intervals and 17 the I² statistic. Heterogeneity was also explored through subgroup analysis. Sensitivity 18 analyses were planned to assess the effect of incomplete outcome data and fixed effects 19 versus random effects analysis. Based on the Cochrane review, subgroup analyses were 20 undertaken to compare trials with co-interventions (such as increased home visiting in the 21 early discharge group)/ no co-intervention). Further subgroup analysis were planned to 22 explore the effect of mode of birth, timing of discharge, type of hospital delivered at 23 (consultant led unit, midwife led unit), gestation at birth, and level of risk (high risk/low risk), however, these were not possible due to lack of participant level data and small number of 24 25 participants in most trials. For the ITSs, study methods to adjust for potential confounders

were taken into account in interpreting results. There were insufficient studies to assess
 publication bias through the use of funnel plots ¹¹.

3 Results

4 Study characteristics

5 9303 studies were found from electronic sources and hand searches. Following removal of 6 duplicates and eligibility screening, 15 studies were identified for inclusion (Figure 1). Ten 7 RCTs taking place between 1976 and 2015 in several countries including Canada, England, 8 Egypt, Malaysia, Spain, Sweden, Switzerland and the USA. All studies were conducted in obstetric-led hospital settings ¹²⁻²¹. The trials compared the effects of a policy of early 9 10 postnatal discharge with a standard length of postnatal stay for women and infants. In 11 contrast, four population-based cohort studies with ITS analyses assessed the effect of state 12 and federal legislation introduced in the US prohibiting insurance plans from limiting 13 coverage for postpartum hospital stay to <48 hours for normal vaginal deliveries and <96 hours for caesarean sections on various health related outcomes ²²⁻²⁵. Prior to the legislation 14 15 introduced in 1996-1997, there was no minimum length of postnatal stay in the United States 16 (US). The fifth ITS study examined the effect of a same day discharge policy in five Danish counties introduced over the period 1990-2003²⁶. All study characteristics are summarised in 17 18 Table 1 and Table 2 illustrates which studies reported on the outcomes described in the 19 review. Maternal outcomes are described in eFigure 1-5.

20 Infant readmission to hospital within 28 days of birth (RCTs)

21 The pooled result of the seven trials that reported on infant readmission to hospital within 28

22 days after birth showed that infants were significantly more likely to be readmitted to hospital

- 23 within 28 days after birth if they were discharged from hospital <48 hours compared to
- 24 infants discharged >48 hours (RR 1.70 95% CI 1.34-2.15) (Figure 2) ^{12-16 18 21}. A planned

subgroup analysis of RCTS with a co-intervention and of RCTs with no co-intervention was carried out. The two trials without a co-intervention happened to include only women who had caesarean section. These subgroups showed no change in the direction of the effect: no co-intervention RR 1.61 (95% CI 1.00-2.68, $I^2 = 14\%$) compared to co-intervention RR 1.74 (95% CI 0.82-6.68, $I^2=0\%$). There were insufficient data to provide a meta-analysis for readmissions within 7 days. Only one study reported on this outcome and reported a RR 3.24 (95% CI 0.13-77.63) in favour of the control group ¹⁶.

8 Infant readmission to hospital within 28 days of birth (ITSs)

9 Results from four primary ITS studies in the US, in contrast to the RCTs, looked at the reverse intervention: a policy of a minimum postnatal length of hospital stay. Datar and Sood 10 ²³ found that once a minimum legislation was introduced, there was a significant reduction in 11 12 the odds of neonatal readmission in California from (-9.3 per 1000 live births in the first year 13 post legislation, -11.8 per 1000 live births in second year post-legislation and -19.7 per 1000 14 live births in the third year post-legislation (P<0.01)). This trend was observed across all 15 subgroups including mother's education, mother's age at birth, race, parity, delivery type and antenatal complications (eTable 2). Evans, et al. ²² found that in California the legislation was 16 17 most beneficial for infants of caesarean delivery, complicated vaginal delivery or Medicaid recipient with complicated vaginal delivery, with little evidence that readmission rates 18 reduced for newborns from uncomplicated vaginal deliveries. Madden, et al.²⁷ and Meara, et 19 al.²⁴ found no significant change over the pre-legislative, legislative or post-legislative period 20 for neonatal readmission to hospital. The fifth ITS study was conducted in Denmark by 21 Sievertsen and Wust²⁶ found that the same day discharge policy resulted in a 3% increase in 22 infant readmission rates within 28 days of birth (0.031, SE 0.11, P<0.01) (etable 2). 23

The results of the meta-analysis of three digitised and then reanalysed ITSs show that when the pre-slope trend was taken into account, there was a decrease in the proportion of infants

1	readmitted within 28 days after the minimum postnatal stay policies and legislation were
2	introduced and this became statistically significant in the first and second year ((change in
3	slope, -0.62 (95% CI-1.83, 0.60) (change in level first year -4.27 (95% CI -7.91,-0.63)) and
4	(change in level second year -6.23 (95% CI -10.15,-2.32)) (figure 3).
5	The I ² statistic for assessment of heterogeneity was 19% for the change in level, and 0% for
6	the change in level at one year and change in level at two years: therefore, further
7	investigations for heterogeneity were deemed unnecessary.
8	Readmissions for Jaundice within 28 days after birth (ITSs)
9	Three ITSs reported on effect of postpartum legislation on readmissions for treatment of
10	jaundice ^{23 24 27} (Table 3). Meara, et al. ²⁴ found a significant decrease in readmissions for
11	jaundice following the minimum postnatal stay legislation whereas Datar and Sood ²³ found a
12	non-significant reduction in the readmissions for jaundice in the second and third years
13	following the legislation. Madden, et al. ²⁵ found no difference in jaundice related
14	readmissions following introduction of the minimum stay law (Table 3).
15	
16	Primary care utilisation (ITSs)
17	Two ITSs reported on primary care utilisation. Results from Madden, et al. ²⁷ suggest that
18	after adjustment for baseline trends, primary care utilisation increased after implementation
19	of the early discharge program which slowly decreased by 1% per quarter (P<0.01) after
20	minimum postnatal stay mandate (Table 3). Sievertsen and Wust ²⁸ found a significant
21	increase in GP contacts for infants who were discharged on the same day across all
22	propensity groups (Table 3).

- 1 Attendances at Emergency Department (ED) (ITSs)
- 2 Two ITS studies reported on this outcome and found that attendances at ED departments
- 3 decreased following introduction of the postnatal minimum stay mandate (Table 3).
- 4 Breastfeeding at 48 hours, 6 weeks and 6 months (RCTs)
- No significant differences in the proportion of women breastfeeding at 48 hours postpartum
 were found in the meta-analysis of three trials that reported this outcome (RR 1.05 (95% CI
 0.99, 1.11) (eFigure 2). No significant differences in the proportion of women breastfeeding
 between one-two months after birth were found in the eight trials that reported this outcome
 ^{16-21 29 31} (pooled estimate RR 1.01 95% CI 0.94, 1.09) or 6 months following birth (RR 1.18
 (95% CI 0.98-1.43) (eFigure 3 and 4). The conclusion remained unchanged when Tan, et al.
 ¹⁶ and Bayoumi, et al. ¹³ were removed in subgroup analysis (RR 1.05, 95% CI 0.98-1.12).
- 12 Breastfeeding at 48 hours, 6 weeks and 6 months (ITSs)

13 Two ITSs reported on the proportion of infants' breastfed before and after implementation of the law (Table 3). Madden, et al. ²⁵ found no evidence of an effect on breastfeeding rates at 14 three months. Sievertsen and Wust²⁶ assigned a propensity score (based on whether the 15 16 mother was married, unemployed, employed, in education, higher education degree and 17 maternal age) and found that women in the lowest propensity score sample were less likely to 18 breastfeed exclusively for at least four months if discharged on the day of birth (-0.311 19 P<0.05) but the breastfeeding rates of women in the middle and highest propensity score 20 groups were not affected (-0.213 (SE 0.146) and -0.015 (SE 0.244) respectively.

- 21 Infant feeding problems within 28 days after birth (RCTs)
- 22 Only one trial assessed the proportion of women reporting infant feeding problems in the first
- 23 four weeks after birth ¹⁴, showing significantly fewer (RR 0.65, 95% CI 0.48, 0.89) in the
- 24 first four weeks after birth in the standard length of stay group.

1 Risk of bias (RCTs)

The quality of individual studies was variable (efigure 6-9). Risk of bias was assessed using the EPOC criteria ⁵ which considers four domains: selection bias, performance bias, attrition bias and reporting bias for both RCTS and ITSs (eTable 6). The largest RCT with greatest weight in the meta-analyses for the primary outcome was of reasonable quality although attrition bias may have been an issue with >10% incomplete outcome data, and differential non-compliance: 132/1890 participants refused to be discharged early in intervention group compared to 188/1896 who refused to be discharged at 72 hours.

9 Sensitivity analyses allowing for loss to follow up in the RCTs was deemed inappropriate
10 given the large proportion of participants lost to follow up in many trials and considerable
11 variation in how protocol violations were managed.

12 Risk of bias (ITSs)

13 Overall, the quality of the five ITSs was good (efigure 8-9). All studies reported outcomes 14 that were described in the methods section, and had an intervention that did not affect data 15 collection. In all ITS analyses, the slope of the intervention was pre specified and authors 16 acknowledged the potential effect other factors that may have coincided with the passage of the law (including changes to service mix, breastfeeding rates, physician awareness and flu 17 outbreaks) ^{22-25 27}. Sievertsen and Wust ²⁶ also compared the trends in readmissions of 18 19 primiparous women and women who had a caesarean section (who were not eligible for same 20 day discharge) to determine whether additional policies (such as new medical routines at 21 birth) had an effect on the outcomes.

22 Discussion

This systematic review is, to our knowledge, the first to include evidence from both RCTs
and ITSs with a predefined description of early discharge (<48 hours following vaginal birth

1 and <96 hours following caesarean section) to assess the effect of a policy of early postnatal 2 discharge and minimum length of stay on health related outcomes. The pooled results of the 3 seven trials on infant readmission to hospital indicated that more infants who were discharged 4 early were readmitted compared to infants who had a >48 hours stay in hospital. The meta-5 analysis of ITSs, providing the next best available evidence on the subject, showed that the 6 US minimum stay law was an effective policy change, increasing postnatal length of stay in 7 hospital, and providing evidence of a long term reduction in infant readmission rates within 8 28 days of birth following this policy change. Due to lack of primary data, it was not possible 9 to examine the effect of length of stay on infant readmissions within 7 days. 10 This review included two additional RCTs not included in the existing Cochrane review last updated in 2008². It utilised evidence provided by study designs appropriate for policy 11 12 intervention, both RCTs and ITSs, including those evaluating the impact of US federal and 13 state legislation, and therefore provides a better understanding of the effect of postnatal LoS 14 in both an experimental trial and naturalistic setting. Use of EPOC criteria for study selection 15 enabled a wider range of evidence to be included without compromising the quality of the findings, taking advantage of the evidence provided by good quality, well designed ITSs. 16 17 This, in contrast to the RCTs, clearly demonstrated that interventions to institute a policy of 18 early discharge actually resulted in increased early discharge of women and infants, allowing 19 assessment of outcomes and therefore enhancing our knowledge of infant health outcomes in 20 relation to early postnatal discharge policy in a 'real life' setting.

This is the first study to carry out ITS meta-analysis on this topic and provided an insight into the effect of federal and state law across several different state populations in the US.

23 Inclusion of these studies has also provided an understanding of the health related outcomes

24 for all infants, regardless of medical status or gestation at birth. A sensitive and broad search

ensured that relevant evidence with any study design was included. Our review has also
 clearly defined early postnatal discharge allowing more meaningful comparison across trials.

3 Limitations of this review also reflect poor trial quality and poor reporting. Despite the status 4 of RCTs as gold standard design for intervention studies, in this area they have already been 5 described as problematic as they feature high rates of post-randomisation exclusions, cross 6 over and withdrawal. Many of the RCTs were low quality, lacking intention to treat analysis 7 with resultant systematic differences between participants in intervention and control group. 8 Many trials did not adhere to current trial reporting standards and therefore, the findings from 9 the RCT data should be treated with caution. We did not have any individual patient data 10 which may have provided more insight into subgroup analysis. Trials took place in several 11 different countries where postnatal provision in the community may have varied 12 considerably. The RCT analysis was insufficiently powered to explore early discharge 13 without the addition of additional post discharge support in the community. There was also 14 considerable clinical heterogeneity amongst the RCTs with regard to mode of delivery, with 15 the largest RCT trial (providing 88% of the weight in the meta-analysis) only including 16 women who had given birth via caesarean section. In light of the problematic participant 17 dropout and crossover in the RCTs, the evidence from the ITS studies is particularly useful. 18 Nevertheless findings from our review represent the best evidence to date and given problems 19 with undertaking trials and other high quality studies in this area may well remain so. 20 Differences found in meta-analysis of trial data for the neonatal readmission outcome, 21 resulted from one large study which only included women who had delivered via caesarean 22 section: the findings must be treated with caution. There were no differences in outcomes 23 related to maternal readmission, or maternal depression which might reflect insufficient 24 power to detect these differences given relatively low incidence sample attrition.

25 Breastfeeding rates were not measured in several studies. It was not possible to adequately

report effects of early postnatal discharge on primary care utilisation. Across the trials, it was
difficult to ascertain the proportion of mothers and infants who accessed primary care
services, outpatient services and accident and emergency care and there were inconsistent
definitions of primary care utilisation and wide-ranging measurement methods. The data from
ITSs were inconsistent, reporting both an increase and decrease in utilisation following the
postnatal mandate.

7 The definition of early discharge for this review (< 48 hours for vaginal delivery and < 968 hours for caesarean delivery) does not reflect the average length of postnatal stay for many high and middle income countries ²⁸. There was no evidence to support very early discharges 9 (less than 24 hours) from hospital, common practice internationally²⁹. Though there is an 10 11 assumption of reduced cost from earlier discharge, this may be off-set by increased costs 12 associated with readmission or greater alternative care usage and the cost effectiveness of 13 early discharge is unknown. Further research is needed to examine whether there are 14 particular subgroups of babies who are most at risk of readmission if they and their mothers 15 are discharged early, or subgroups for whom early discharge is safe. Research on the impact 16 of the very short postnatal stays experienced in some settings is also needed. Research 17 designs could build on the American Academy of Paediatrics' Policy (AAP) Statement on Hospital Stay for Healthy Term Newborn Infants³⁰ to evaluate standardising the discharge 18 19 process through the use of pre-discharge checklists.

State and Federal law appeared effective in increasing the postnatal length of stay for women and infants, and resulted in a long term reduction in the neonatal admission rate to hospital. Following the lead of the APP statement ³⁰, postnatal length of stay policies should incorporate the needs of mothers and infants and not be led health services capacity or third party payers, ensuring that standardised systems are in place to ensure that women and infants are discharged at a time more appropriate to their needs.

1 Conclusions

2 Taken together, evidence from this meta-analysis and review of RCTs and ITSs of legislation 3 mandating policies of a minimum stay postnatally and of minimum stay discharge policies 4 has shown that shorter postnatal stay in hospital (<48 hours following vaginal birth and <96 5 hours following caesarean section) is associated with increased infant readmissions to 6 hospital within 28 days of birth. 7 Acknowledgments 8 This research is funded by the National Institute for Health Research (NIHR) Applied 9 Research Centre (ARC) West Midlands. The views expressed are those of the author(s) and

10 not necessarily those of the NIHR or the Department of Health and Social Care.

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 Table 1 Characteristics of included studies
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