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Lessons learned from using linked administrative data to evaluate the Family Nurse Partnership in England and Scotland

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Abstract

Introduction
"Big data" – including linked administrative data – can be exploited to evaluate interventions for maternal and child health, providing time- and cost-effective alternatives to randomised controlled trials. However, using these data to evaluate population-level interventions can be challenging.

Objectives
We aimed to inform future evaluations of complex interventions by describing sources of bias, lessons learned, and suggestions for improvements, based on two observational studies using linked administrative data from health, education and social care sectors to evaluate the Family Nurse Partnership (FNP) in England and Scotland.

Methods
We first considered how different sources of potential bias within the administrative data could affect results of the evaluations. We explored how each study design addressed these sources of bias using maternal confounders captured in the data. We then determined what additional information could be captured at each step of the complex intervention to enable analysts to minimise bias and maximise comparability between intervention and usual care groups, so that any observed differences can be attributed to the intervention.

Results
Lessons learned include the need for i) detailed data on intervention activity (dates/geography) and usual care; ii) improved information on data linkage quality to accurately characterise control groups; iii) more efficient provision of linked data to ensure timeliness of results; iv) better measurement of confounding characteristics affecting who is eligible, approached and enrolled.

Conclusions
Linked administrative data are a valuable resource for evaluations of the FNP national programme and other complex population-level interventions. However, information on local programme delivery and usual care are required to account for biases that characterise those who receive the intervention, and to inform understanding of mechanisms of effect. National, ongoing, robust evaluations of complex public health evaluations would be more achievable if programme implementation was integrated with improved national and local data collection, and robust quasi-experimental designs.

Keywords
administrative data; cross-sectoral linkage; evaluation; early years; adolescent motherhood

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Introduction

"Big data" – including administrative data – offers promising avenues for evaluating child health interventions. Although randomised controlled trials (RCTs) are the gold standard for intervention evaluation, they are costly and time-consuming, and they include only a selected subset of service users who consent to enrolment. Observational studies using routinely collected administrative data offer potentially cost- and time-saving alternatives to RCTs, with the advantage of data being available for whole populations eligible for regional or national interventions. These studies offer exciting opportunities for ongoing evaluation of existing population health interventions to inform policy-making in a timely way, and large sample sizes enable detection of effects in subgroups or for rare outcomes. While administrative data can also be used to support long-term follow-up in RCTs, a growing number of observational evaluations in maternal and child health are designed using cohorts derived entirely from unconsented use of de-identified administrative data [1–4]. This includes two observational studies evaluating an intensive home-visiting programme for vulnerable younger mothers – the Family Nurse Partnership (FNP) – in England and Scotland [5, 6].

The main limitation of observational studies using administrative data to evaluate complex interventions is that researchers cannot randomly assign participants to 'intervention' and 'control' groups. Randomisation ensures those who do and do not receive an intervention are comparable at baseline, enabling observed differences to be attributed to the intervention. In contrast, when using observational data, important differences often exist between individuals who do and do not participate in an intervention, introducing the possibility of confounding (or indication bias). For example, if practitioners target enrolment to women with increased risks of adverse maternal and child health outcomes (e.g. with complex social needs), expectant mothers who are enrolled in the FNP will be more vulnerable than those not enrolled, leading to indication bias. Several quasi-experimental methods have been developed to help replicate randomisation in observational studies and minimise bias associated with confounding [7, 8]. These methods may adjust for unmeasured as well as measured confounders under the assumption that all characteristics affecting intervention assignment and outcome have been measured [9]. Replication studies have shown some RCT results can be reproduced using administrative health data using these methods [10, 11].

Linked administrative data from health, education and social care sectors have been used to support FNP evaluations in both England and Scotland (Table 1). The FNP aims to improve child health and development through intensive home-visiting from a dedicated Family Nurse [12]. It is usually offered to pregnant women aged $\leq$19, up to 28 weeks of pregnancy, although these conditions have been relaxed recently. The FNP has a comparatively strong evidence base, based on three US RCTs showing benefits for maternal and child health outcomes [13–17]. In England, a RCT showed no evidence for an effect on short- and medium-term primary outcomes (including birthweight and maltreatment outcomes by age six), but did provide evidence of benefit on secondary outcomes including child development outcomes [18, 19]. Our observational evaluations were conducted to capture the real-world effect of the FNP, including smaller effects and effects among particularly vulnerable young mothers.

The objective of this paper is to describe some sources of bias common in observational evaluations using administrative data, using an exemplar of the English and Scottish evaluations of FNP that used cross-sectoral, linked administrative data. We describe the lessons learned from these evaluations to inform future studies evaluating child health interventions.

Methods

Approach

We determined the sources of bias and challenges inherent in observational evaluations using administrative data, describing lessons learned from our joint experience in conducting evaluations of the FNP in England and Scotland. Our aim was to help inform other studies using administrative data to evaluate complex interventions in health. We first considered different sources of bias within the data, by systematically assessing potential biases at each stage of the recruitment, enrolment, and data collection stages chronologically, and how these could affect evaluation results. We explored how each study design addressed these sources of bias using maternal characteristics captured in the data. We then determined what additional information could be collected at each step of the complex intervention to enable researchers to minimise bias and maximise comparability between intervention and control groups, to enable better estimation of intervention effects. The next section describes the data sources and study design used in each evaluation.

Data sources and study design

Both studies used similar approaches to construct a retrospective cohort of adolescent mothers, using de-identified, linked administrative data (Table 1). We used Hospital Episode Statistics in England and Maternity Inpatient and Day Case (SMR02) in Scotland, to identify all births in NHS hospitals to mothers aged $\leq$19 in similar time periods. Our studies included over 110,000 mothers (c. 26,000 in FNP) in England and over 8,000 (c. 3,000 in FNP) in Scotland [20, 21]. Mothers were linked to their children in hospital data [21, 22]. In Scotland, all mothers and children were additionally linked to General/Acute Inpatient and Day Case (SMR01), Child Health Systems Programme Pre-School and School. Mothers and their children were linked to education and children's social care information (National Pupil Database in England, and Education Analytical Services in Scotland), including Children in Need and Children Looked After returns [5, 6]. Mothers and children enrolled in FNP were identified through linkage of hospital data to the FNP (Scottish) Information System.

We used two approaches to minimise biases due to differences between those enrolled or not in FNP (Table 2). In each study, we made use of information recorded in administrative data on characteristics likely to affect whether mothers were eligible, approached or enrolled in FNP (Figure 1). In England, we used propensity score matching of mothers enrolled in FNP to not enrolled controls in the same time period and area (Table 1) based on characteristics

Table 1: Description of observational studies evaluating the Family Nurse Partnership (FNP) using de-identified, linked administrative data in England and Scotland

	England evaluation	**Scotland evaluation**
Study design / Approach for dealing with confounding	Propensity score matched cohorts comparing outcomes for mothers (and their children) ever enrolled in FNP with similar mothers (based on characteristics at enrolment) who were eligible but not enrolled, within the same area and time.	Cohort study comparing outcomes for mothers (and their children) ever enrolled in FNP with mothers eligible for FNP who were pregnant in a time/area when FNP was not offered. Regression models adjusted for maternal and infant characteristics.
Definition of cases (FNP mothers)	Women • aged 13-19 years at last menstrual period • enrolled in the FNP up to 28 weeks gestation • first delivery with live birth in English NHS hospital (eligible if previous pregnancy ended in miscarriage or termination, but not if previous stillbirth)	Women • aged $\leq$19 years at last menstrual period • enrolled in the FNP up to 28 weeks gestation • first-time mother-to-be (eligible if previous pregnancy ended in miscarriage, stillbirth or termination) • living in an FNP-recruiting NHS Health board area
Definition of controls	Women • aged 13-19 years at last menstrual period • antenatal booking appointment up to 28 weeks gestation • living in an FNP catchment area at the time of booking appointment • first live birth in English NHS hospital (no previous deliveries)	Women • aged $\leq$19 years at last menstrual period • antenatal booking appointment up to 28 weeks gestation • living in an FNP catchment area when FNP recruitment was not offered: – in the 12 months prior to initiation of FNP recruitment or post FNP recruitment – between periods of FNP recruitment (temporary suspensions due to caseload capacity) • first live birth (no previous live births)
Study dates	Births between 1 April 2010 and 31 March 2017 (FNP mothers and controls)	FNP mothers with antenatal booking appointment between 1 January 2010 and 31 March 2016 Controls eligible for FNP with antenatal booking appointment between 1 January 2009 and 31 March 2016
Geographical coverage	136/152 local authorities in England with active FNP site	10/14 NHS Health boards in Scotland
Data approvals for unconsented use of data	Nottingham Research Ethics Committee, Department for Education, NHS Digital, and Confidentiality Advisory Group	Public Benefit and Privacy Panel (PBPP) NHS and the Scottish Government Education Analytical Services (EAS). Ethical review not required by South East Scotland Research Ethics Service
Data sources for mothers and children	• Hospital Episode Statistics (HES) • FNP Information System (IS) • National Pupil Database (NPD)	• NHS Scotland Health • FNP Scottish Information System (SIS) • Education Analytical Services (EAS)

Continued.

Table 1: Continued

	England evaluation	**Scotland evaluation**
Maternal characteristics adjusted for	Health characteristics • Age at last menstrual period • Ethnicity • Area-level deprivation • Gestation at antenatal booking appointment • History of unplanned mental health-, adversity- and chronic condition-related hospital admissions* • History of Accident & Emergency attendance* Social care characteristics • Ever had a child protection plan or been a child looked after Educational characteristics • Ever recorded as having Special Educational Needs • Ever received Free School Meals • Ever in IDACI bottom decile • Educational attainment at Key Stage 2 and 4 • Ever excluded, in pupil referral unit or alternative provision • Ever persistently absent in a term Geographic characteristic • FNP site area	Health characteristics • Age at last menstrual period • Ethnicity • Area-level deprivation • Gestational age at antenatal booking • Ever dispensed medication for asthma or depression • Diabetes at antenatal booking appointment • Body Mass Index at antenatal booking • Current smoker at booking appointment • Drug misuse during pregnancy • Ever injected illegal drugs prior to pregnancy • Alcohol consumed in a typical week (recorded at booking appointment) • Previous pregnancy Social care • Ever been on the child protection register • Looked after child before/at booking appointment Educational characteristics • Ever had additional student needs • Ever received Free School Meals • Left school by antenatal booking appointment • Ever excluded from school Geographic characteristic • Health board of residence
Child outcomes described	• Preterm birth • Low birthweight • Mode of delivery • Stillbirth • Discharge to social services at birth • Unplanned hospital admissions for injury or maltreatment** • Unplanned hospital admissions (any diagnosis)** • Accident & Emergency attendances** • Referral to outpatient services (uptake and non-attendance)** • Looked after status*** • Child in Need status*** • Death** • Good level of development in the early years assessment • Educational attainment at Key Stage 1 • Special Educational Needs status*** • School attendance***	• Breastfeeding (at birth and at 6-8 weeks) • Birthweight • Passive smoking in the home† • Safe home environment††† • Preterm birth • Body Mass Index††† • Gross/fine motor skills† • Registered with/attended dentist† • Hospital admission for dental procedure††† • Hospital admission for serious injuries††† • Accident & Emergency attendances††† • Accidental injuries††† • Child development concerns†, †† – Personal/social and behavioural difficulty – Speech, language and communication concern – Physical or motor impairment – Vision concern/impairment – Hearing concern/impairment

Continued.

Table 1: Continued

	England evaluation	Scotland evaluation
		• Student need concern††
		• Other student need††
		• More able pupil††
		• Child attainment at Primary 4 (5-6 years)
		• Child protection investigations†††
		• Investigations requiring a case conference†††
		• Type of concern identified at case conference†††
		• Length of time on child protection register†††
		• Child registered as result of conferences†††
		• Child de-registered†††
		• Looked after status†, †††
		• Placement†††
		• Placed for adoption†††
Maternal outcomes described	• Accident & Emergency attendances**	• Alcohol/substance misuse during pregnancy
	• Unplanned adversity-related hospital admissions after childbirth**	• Childcare use†
	• Unplanned hospital admissions (any diagnosis) after childbirth**	• Return to education within 24 months of child birth
	• Subsequent birth within 18 months of childbirth**	• Educational attainment
	• Death**	• Subsequent birth†††
	• Return to education	• Inter-pregnancy interval†††
	• Educational attainment at Key Stage 4 (where applicable)	

*in the 2 years prior to 20 weeks of pregnancy. Adversity-related admissions include diagnoses of self-harm, substance misuse, and violence.
**up to 2 years and 7 years after childbirth.
***between starting school and age 7.
† up to 27–30 month after childbirth.
†† 4–5 years after childbirth.
†††up to 2 years and 5–6 years of age after childbirth.

before enrolment or 20 weeks of pregnancy. This approach assumes that any observed differences in maternal and child outcomes are attributable to FNP enrolment, assuming there is no unmeasured confounding [9].

In Scotland, we used a different natural experiment study design to compare mothers enrolled in FNP with all mothers who met FNP eligibility criteria but who were pregnant at a time when the programme was not recruiting in their area (Table 1). Mothers enrolled in FNP and controls were not matched. This study used multivariable regression to adjust for characteristics measured at antenatal booking appointment that differed between mothers enrolled in FNP and controls, aiming to ensure comparability between groups.

Both methods have advantages and disadvantages. The unmatched comparison retained all mothers enrolled in FNP in the analysis, but excluded those who were eligible but not enrolled during a time in which FNP was offered. The controls were all eligible mothers at times when FNP was not enrolling mothers into the programme, some of whom would be more vulnerable mothers likely to be enrolled had the FNP been offered [20]. The propensity score analysis used more closely matched intervention and control mothers but may limit the generalisability of findings, by excluding some mothers enrolled in FNP.

Patient and public involvement

In England, we held several workshops with young mothers while designing our study, including mothers enrolled in the

Table 2: Potential sources of bias in evaluations of FNP in England and Scotland using linked administrative data and information needed to assess their likely extent

Bias	Description	Impact on effect estimates	Information needed to avoid or assess likely bias
Indication bias due to FNP nurses deciding which mothers to approach (unmeasured confounding)	Family nurses prioritise the more vulnerable mothers among those meeting eligibility criteria, and so those enrolled may have been more likely than those not enrolled to experience adverse outcomes.	Underestimation of the effect of the intervention.	Knowledge of which characteristics prioritised for enrolment in each site (including start and end dates of these prioritisation characteristics); availability of data on these characteristics and other important maternal characteristics for adjustment purposes
Misclassification bias of eligibility for FNP	In analyses, mothers may have been assigned to different groups than the ones they should be in, because eligibility is incorrectly defined.	Bias in either/both directions: random misclassification is likely to underestimate the intervention effect, but bias in misclassification may under- or over-estimate intervention effect.	Detailed recording of programme meta-data including site activity dates and geography, in order to correctly define eligible groups of mothers who were and were not enrolled or eligible for the intervention.
Consent bias for enrolment in FNP	Mothers who were offered the intervention but who declined may have been different to those who were not offered the intervention.	Bias in either/both directions. Those who were offered the intervention but who declined may be a mixture of the most vulnerable and the least vulnerable mothers.	Individual-level or aggregate data on characteristics of all mothers-to-be offered enrolment, and those who declined vs. who accepted enrolment.
Linkage bias	Linkage error (e.g. missed links or false links*) can mean that subgroups of the population were differentially excluded from the analysis cohort, or had missing data on variables obtained through linkage. Missed links can also lead to misclassification bias (see above).	Bias in either/both directions. It is difficult to ascertain the direction of effect, particularly when there are multiple complex linkages and when the impact of linkage errors work in opposite direction.	Detailed information about the characteristics of mothers more or less likely to link (subgroup-specific linkage rates), in order to identify groups that might be most affected by linkage error.
Measurement bias	Usual care for mothers not enrolled was not captured; some outcomes were measured by different professionals depending on whether the mother was enrolled in the intervention or not.	Bias in either direction. FNP nurses may have been more likely to record positive outcomes if they have built a stronger relationship with enrolled mothers, but might also have been more likely to pick up on areas of need (ascertainment/surveillance bias).	Improved, high-quality data on community health contacts are needed at the individual level (including e.g. public health or adolescent pregnancy midwife services, average number of health visitor contacts, number of children's centres).

*Missed links occur when a mother in the FNP Information System data is not linked to her health/education record and therefore appears twice in the data – once as an FNP mother with no linked health/education data, and once in the health data as being a mother who was not enrolled in the FNP; false links are likely to be less common, and occur when an FNP record is linked to the wrong health/education record, causing a mother not enrolled in the FNP to appear as though she was enrolled.

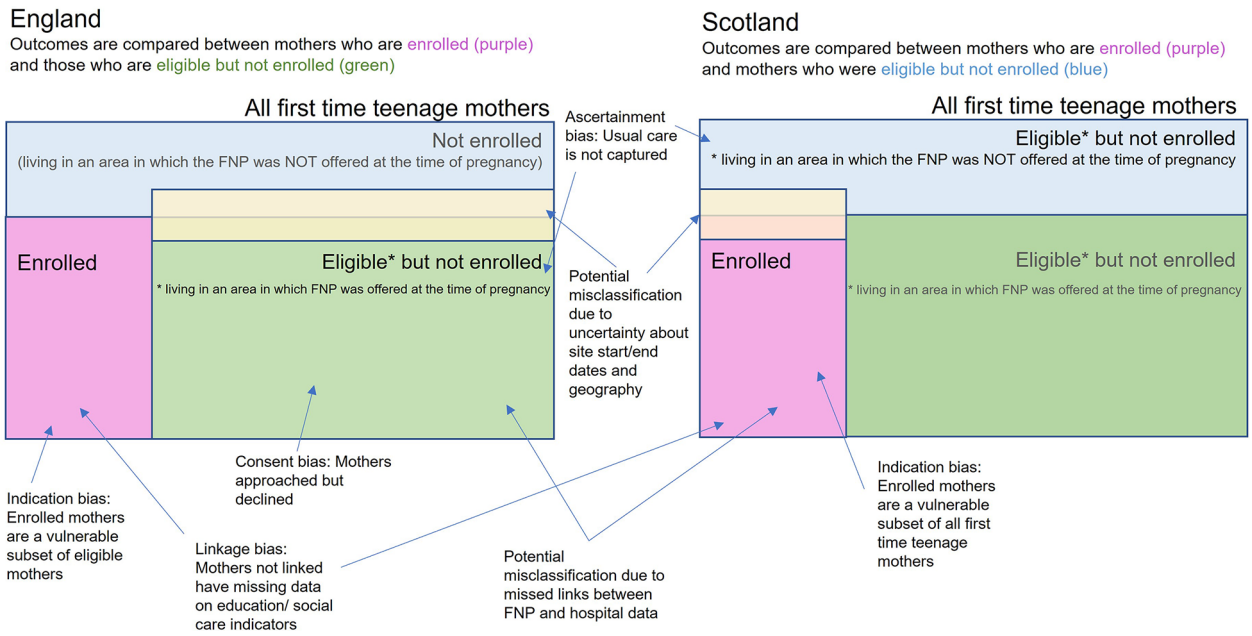
FNP and not. Both studies engaged a lay representative on the Study Steering Committees. In Scotland, patient and public engagement was carried out separately by the Scottish Government [23]. Much of the engagement work that the study team conducted as part of the RCT 2-6 year follow-up [19] (running in parallel) was transferable to the Scottish evaluation.

Results

Potential sources of bias in FNP evaluations

There were important differences in the characteristics of mothers enrolled in the FNP and those who were not, in England and Scotland (Appendix Tables 1 and 2) [20].

Figure 1: Study designs for the evaluation of the FNP in England and Scotland, with potential biases



Achieving comparability between these two groups was at the core of the study design for each evaluation. Table 2 summarises the potential sources of bias arising and the likely impact on effect estimates. Biases such as misclassification or consent bias are not intrinsic to administrative data, but in practice often concern evaluation studies using such data. In addition, there may be other biases operating that we did not identify. The following sections explore how each study design addressed these potential sources of bias.

Indication bias due to unmeasured confounders

Our different approaches – propensity score matching in England and unmatched adjustment for maternal characteristics in Scotland – both aimed to ensure comparability between mothers enrolled in FNP and controls, and therefore to minimise biases due to confounding in order to attribute observed differences to the intervention effect. However, assessing the extent to which indication bias was avoided was challenging: although the propensity score matching approach achieved balanced characteristics for measured variables, it was by definition not possible to evaluate the balance between groups in terms of unmeasured characteristics. We cannot know if groups were balanced on other important characteristics also associated with both enrolment and outcomes. For example, some important vulnerabilities (such as family violence) may not be disclosed until a trusting relationship has been built with providers, and may not be captured in administrative data at all [24–26].

In England, FNP eligibility criteria were broad (all first-time mothers aged $\leq$19 living in an FNP site catchment area and enrolling before 28 weeks of pregnancy were eligible). Since resources were insufficient to guarantee universal offer (only $\sim$25% of eligible mothers were enrolled), individual FNP sites were encouraged to develop their own local criteria for targeting, with many sites prioritising younger adolescent mothers. Knowledge of sites' targeting strategies over time would have helped us assess to what extent these strategies were successful in enrolling their target group and in improving outcomes.

Misclassification bias due to lack of programme delivery data

In both England and Scotland, we needed to define the population of teenage mothers who would have been eligible for the FNP, but who were not enrolled due to living in an area in which the FNP was not offered at the time of their pregnancy. If information on recruitment dates was inaccurate, misclassification bias could occur, where mothers were categorised as being eligible for the FNP when they were not, or vice versa (Figure 1). Site activity dates and geography were key to defining these populations, but this information was not readily available and is not typically captured in administrative datasets. In England, the FNP was rolled out in >130 local authorities, at different times. In Scotland, the FNP was rolled out in 10 health boards over a six-year period with different teams and cohorts occurring within sites and over time. Sites merged and split over time, site boundaries moved, and sites discontinued or joined the FNP at different times.

To address this challenge, in England, we drew a tentative list of site dates and catchment areas based on FNP Information System data, which was reviewed in detailed conversation with the FNP National Unit. In Scotland, distribution of enrolment in FNP across health board areas over time had been compiled during the assessment of the evaluation [27], but required further detail from the FNP Scottish Information System team and verification after the enrolment dates had been received. Dates when recruitment was temporarily suspended due to caseload capacity being reached were also ascertained.

Consent bias due to lack of information on mothers who declined the intervention

It was not possible to identify eligible mothers offered enrolment but who did not consent to participate in either country. In England, data on mothers who declined the programme were not collected. In Scotland, the Public Benefit and Privacy Panel did not permit the unconsented linkage of data on individuals who had declined the programme, even though data on these individuals were available. In England, these mothers were included in the control group as a result. This could lead to consent bias: if mothers who declined were more vulnerable than those who accepted, it might lead us to underestimate the intervention effect. English FNP sites had limited aggregate information on these mothers. Some sites reported that, although a small number were particularly vulnerable mothers (e.g. involved with social care services), the majority of mothers who declined were those with strong social support.

Missing data due to linkage bias

Linkages of health, education and social care data were performed by NHS Digital and the Department for Education in England, and Electronic Data Research and Innovation Service in Scotland. These organisations provided limited information on linkage quality, which limited our ability to assess the extent to which linkage error may have caused bias. In England, 83% of adolescent mothers in our cohort linked to the National Pupil Database. Some unlinked mothers would genuinely not have been captured in this database due to attending an independent school or a school in a different country. We were unable to evaluate the extent of missed links (mothers who were in the National Pupil Database, but who we could not link) among the 17% of unlinked mothers. For Scotland, match rates for linkage were not provided; as the cohort was created from the health records, we assumed all records were linked to the health datasets. However, 14% of mothers were potentially not linked to any Education Analytical Services dataset.

The extent to which these missed links lead to bias depends on how the unlinked records are dealt with in analysis [28]. Determining the potential direction of bias is complex, particularly when successive linkages are performed (such as FNP data linked to health data, then to educational data). In both countries, the control group was created by excluding those who had linked to FNP Information Systems (Figure 1). In England, hospital records for the 1.5% of FNP mothers who did not link to Hospital Episode Statistics would mistakenly have been treated as belonging to the control group. Similarly in Scotland, the 1.5% of FNP mothers who did not link to SMR02 would have been excluded from the FNP arm [21]. This lack of certainty around the "true" denominator means that linkage errors could contribute to misclassification bias (Table 2).

Bias may be introduced if the success of linkage depends on characteristics associated with outcomes. Individuals who should have, but did not, link (missed links) may have higher rates of adverse outcomes [29]. For example, children of Black or Asian ethnicity often have lower linkage rates and ethnic group is associated with risk of adverse outcomes [30]. Differential exclusion of some groups due to missed links may therefore underestimate the intervention effect.

Missing data – a problem that is well characterised in observational studies – may be introduced in linked administrative data studies when records fail to link. Moreover, certain characteristics were only available for a sub-sample of mothers or their children because different data sources covered different periods. In both countries, we used a complete case analysis whereby education and social care outcomes were evaluated for mothers/children linking to the relevant records (as well as multiple imputation to retain mothers with missing data as a secondary/sensitivity analysis).

In England, we attempted to identify groups of mothers who were more at risk of linkage bias or missing data by comparing the characteristics of FNP mothers who did and did not link with hospital and educational records (Appendix Table 3).

Outcome ascertainment bias and interpretation of outcomes reported in administrative data

Outcomes measured differently between the FNP and control groups may induce outcome ascertainment bias. For example, increased contact with families enrolled in FNP may lead to lower thresholds for referrals to social services, and any observed lack of effect or even increased risk of maltreatment in the FNP group complicates the interpretation of whether the true risk of maltreatment was lower, similar, or higher than in the control group. Moreover, child health outcomes measured at 10 days and 6–8 weeks postpartum were recorded by Family Nurses for enrolled mothers and health visitors for controls in Scotland, introducing further potential ascertainment bias if, for example, Family Nurses were more likely to record previously known issues not obvious during the checks, or less likely to record if these issues were being managed.

Outcomes captured in administrative data may also be proxies for the outcomes of real interest, making interpretation a challenge for several reasons. Firstly, determining whether an outcome is a positive or negative effect can be complex. For example, higher child A&E attendance rates may represent higher incidence of accidents, or more appropriate care-seeking behaviour by parents. This challenge is not specific to observational studies: indeed, the England RCT highlighted difficulties in interpreting maltreatment outcomes recorded in administrative data [19]. In Scotland, outcomes for which the study team were unable to pre-specify a hypothesised direction of effect were considered descriptive.

Some outcomes which are central to the FNP logic model – e.g. quality of parent-child relationships – were not captured in administrative data. Valid and reliable assessment of subjective and behavioural outcomes, often central to home-visiting programmes, is usually achieved through prospective measurement using specialist tools, and not usually recorded in routine datasets.

Lastly, ascertainment of usual care received by control mothers is important for interpreting results. Usual care for adolescent mothers differs substantially between local authorities (including varying numbers of health visitors contacts and additional services) [31, 32]. In England, although national data on health visiting is collected, this is not yet well completed nor disaggregated by maternal age [33, 34]. In

Scotland, community health data is underdeveloped compared to hospital data. Bespoke data collection was not feasible within the timeframe of our studies: we were therefore unable to include a quantitative measure of usual care in our models, limiting the precision of our intervention effect estimates. Understanding variations in usual care provision among both mothers enrolled in FNP and controls is necessary to better estimate the incremental effect of FNP and account for any unexpected variation in usual care during the evaluation period. Such information would allow more nuanced interpretation of results, including, for example, if the programme worked better in one local area than another.

Data approval and access delays

It took four years in England and five years Scotland, from data applications being submitted to the final linked dataset being available for analysis (Appendix Table 4 and Table 5). Although not inherently due to the nature of administrative data, delays are a widespread issue across countries with available large administrative datasets. Lengthy application processes, and delays in receiving administrative data have been widely documented [35–38]. Cross-sectoral data linkage adds other delays, including data providers sending identifier information to trusted third parties for linkage, and in migrating data to a single trusted research environment. In Scotland, requirements to create additional data sharing/processing agreements, memoranda of understanding for each of the 10 health boards, and a leaflet on data usage for new FNP clients [21], contributed to delays. Displacement of staff due to the pandemic and while waiting for data also caused delays. These delays impeded on analysis time: linked data were finally available one month before the initial grant endpoint in England, an insufficient period within which to deliver results based on extensive administrative data cleaning, assessment of linkage quality, construction of study cohorts, and optimisation of quasi-experimental approaches.

Discussion: suggested improvements for observational evaluations of complex interventions using linked administrative data

Lessons learned and suggestions for using administrative data to evaluate complex interventions are summarised in Table 3.

Assess the likelihood of unmeasured confounding

As well as careful comparisons between characteristics of cases and controls at baseline/enrolment, we suggest researchers reflect thoughtfully on what unavailable characteristics would have been important to control for, and use sensitivity analyses with different control cohorts, as well as – where possible – alternative approaches altogether to examine stability of results (e.g. sensitivity methods taking into consideration correlations of unmeasured confounders, calculating e-values or quantitative bias analyses [39]).

Document programme delivery information and usual care

Programme managers should document intervention delivery prospectively, including activity dates, catchment areas and eligibility. Usual care should also be documented by care leads in a complete, standardised way, by area and over time. A searchable, central repository for reporting programme activity would support knowledge of programme delivery and usual care, and help identify eligible populations in quasi-experimental methods. Such documentation would facilitate ongoing evaluations of what works, where, and for whom, for all interventions, contributing to a paradigm shift toward a culture of embedded, near real-time evaluation supporting evidence-based policy-making.

Document programme targeting

Guidelines for targeting interventions to the eligible population should be determined consistently within local areas, and explicitly documented by programme managers and care leads. This would enable researchers to understand which key characteristics need to be adjusted for, and support evaluation of which prioritisation strategies are most effective. Targeting information could be enhanced using linked primary care data and information on household members (e.g. fathers), filling important gaps in our understanding of how children and families interact with services [40].

Provide data on linkage quality

Detailed conversations with organisations performing linkages are crucial to understanding linkage approaches, and what decisions may lead to linkage errors. Linkage organisations should provide data on linkage quality (e.g. match strength/step stratified by important characteristics, criteria linked to each step [41]) to help researchers better understand linkage rates obtained. Identifying biases from linkage error can be complex and study-specific, however examining the percentage of missed links stratified according to important characteristics is one initial step researchers can take to help identify potential bias due to exclusion of some groups [29, 30]. We also encourage researchers to report linkage rates to enable comparisons between specific populations or datasets.

Conduct process evaluation and qualitative research alongside quantitative evaluation

Researchers should conduct process evaluations and qualitative research – funded by research funders – to provide a better understanding of the mechanisms of effect, and explanations of observed effects [42]. For example, in-depth interviews with parents, nurses and commissioners would contribute to an explanatory model of how data are collected and used on the ground, how programme criteria are developed, and the extent to which families are involved in developing new programmes that meet their needs. In addition, collecting more enriched quantitative data on short- and long-term outcomes thought to be impacted by early interventions (such as parent-child interaction, and child emotional and developmental outcomes) would help us understand programme effects on these important outcomes.

Table 3: Challenges, lessons learned, and suggestions for improvement for observational studies using administrative data to evaluate complex interventions

Challenges and lessons learned	Suggestions for improvement
• Evaluation of complex interventions requires **detailed national and local data on programme implementation about who is eligible, approached, enrolled in the intervention** with similar information for usual care. This information is crucial to minimise biases, enable fair and robust comparisons, and increase confidence that differences in outcomes can be attributed to the intervention, rather than to the characteristics of the people selected for intervention.	• Researchers should work in partnership with practitioners, commissioners and communities to ensure that **evaluations are integrated** into the design and implementation of interventions. • Programme managers and care leads should**document detailed information about programme delivery and usual care** (including activity dates and catchment area), across local areas and over time. • Programme managers should ensure detailed information are recorded on the **characteristics of those who are approached and offered an intervention**, and those who declined. • Programme managers should provide consistent guidelines about**programme targeting** and prioritisation, where resources are insufficient for universal offer. Targeting should be documented in detail, including where guidelines change over time or differ across local areas.
• Information on **linkage data quality** can be limited, making it challenging to define accurate denominators and comparator groups.	• Linkage organisations should provide **detailed data on linkage quality** (see GUILD reporting tool...[41]).
• Constructing a comparable control group is limited by measured characteristics, introducing the possibility of **unmeasured confounding.**	• Researchers should assess the likelihood of **unmeasured confounding.**
• **Interpreting outcomes** reported in administrative data – particularly regarding health or social services contact – is challenging without accurate and complete measures of need.	• Researchers should conduct and funders should fund **process evaluations and qualitative studies** alongside quantitative impact analyses.
• **Data approval and access delays** may impede substantially on data analysis time, even when applications are submitted several years before the planned grant start date.	• Data providers should streamline processes to **minimise data access delays** and enable timely information for evidence-based policy-making.

Streamline processes to minimise data access delays

Recommendations for improving timeliness of access to data for research in the public good have been outlined elsewhere, including streamlining applications across different data providers, consolidating trusted research environments to enable reuse of linked data, and increasing capacity among data providers [37, 43]. Reducing data access delays is crucial for more efficient use of research funds, and more timely research findings to support evidence-based policy-making (for observational studies and RCTs using administrative data).

Conclusion

Linkage of administrative data presents exciting opportunities for efficient evaluation of large-scale, complex public health interventions [44]. However, a lack of detailed data on how programmes are defined and how they are adapted locally, alongside other important challenges outlined here, limit the success of these approaches. This can lead to difficulties in interpreting results, contradictory or unintuitive findings, and continuing uncertainty about the effectiveness of interventions [45, 46].

Improved information on programme delivery, targeting, and important confounders, alongside careful design of observational evaluations, implementation of quasi-experimental methods and interpretation of results, could help facilitate ongoing evaluations that are integrated into the design and roll-out of large-scale interventions. Integration of research into system-wide practice is key: innovative approaches such as experimental birth cohorts that are designed to evaluate local interventions in real time may also help generate meaningful evidence on the effectiveness of programmes to improve maternal and child health [47, 48]. Reducing data delays would also help realise the efficiency of using administrative data rather than conducting RCTs. Findings of intervention evaluations should help stimulate exploration with practitioners about how programmes can be improved. These suggestions are particularly important for understanding the

effectiveness of large new investments such as the Start for Life offer in England.

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Statement on conflicts of interests

The authors declare no competing interests.

Ethics statement

In England, support was obtained from Nottingham Research Ethics Committee [ref 18/EM/0014], NHS Digital [ref NIC136916], the Department for Education [ref DR190430.02] and the Confidentiality Advisory Group [ref 18/CAG/0013]. In Scotland, NHS Ethical Review was not required by South-East Scotland Research Ethics Service as it was considered a service evaluation. Approval from the Public Benefit and Privacy Panel was granted [ref 1516-0040], and from the Education Analytical Services.

Data availability statement

We are unable to share the individual data used for this study. English Hospital Episode Statistics and FNP data can be requested through NHS Digital, National Pupil Database data can be requested through the Department for Education. Scottish health and education data can be requested through the electronic Data Research and Innovation Service, Public Health Scotland.

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Abbreviations

FNP: Family Nurse Partnership
NHS: National Health Service
RCT: Randomised Controlled Trial

Appendix Table 1: Comparison of characteristics of mothers enrolled in FNP, not enrolled in FNP but living in local authority with active FNP site at the time of pregnancy, and living in local authority where FNP never commissioned – England, births between April 2010–March 2017

	Mothers enrolled in FNP		Mothers not enrolled in FNP, living in LA with active FNP site (Controls)		Mothers in LAs where FNP never commissioned	
	N	%	N	%	N	%
Total	31,260	100.0	99,150	100.0	100,455	100.0
Maternal age (years)						
13-15	1,450	4.6	1,235	1.2	2,160	2.2
16-17	10,370	33.2	15,690	15.8	20,040	19.9
18-19	15,805	50.6	56,660	57.1	56,310	56.1
20-21	3,635	11.6	25,565	25.8	21,945	21.8
Ethnicity						
White	26,330	84.2	83,485	84.2	88,895	88.5
South Asian	670	2.1	3,030	3.1	2,325	2.3
Black	1,470	4.7	3,180	3.2	2,705	2.7
Mixed/other	1,685	5.4	5,155	5.2	3,905	3.9
Unknown	1,110	3.5	4,300	4.3	2,620	2.6
Area-level deprivation						
Least deprived	1,445	4.6	5,360	5.4	8,460	8.4
2	2,305	7.4	8,105	8.2	12,825	12.8
3	4,115	13.2	13,735	13.9	18,065	18.0
4	7,890	25.2	24,660	24.9	25,630	25.5
Most deprived	15,340	49.1	47,290	47.7	34,890	34.7
History of admissions with diagnoses within 2 years prior to 20 weeks gestation						
Mental health (any)	2,690	8.6	3,860	3.9	3,910	3.9
Chronic condition (any, exc. mental health)	4,125	13.2	7,805	7.9	8,105	8.1
A&E visits	21,985	70.3	60,335	60.8	61,255	61.0
Gestational age at antenatal booking appointment						
Before 10 weeks	8,390	26.8	26,890	27.1	25,840	25.7
10-20 weeks	11,530	36.9	36,455	36.8	36,325	36.2
20 weeks or more	1,925	6.2	5,395	5.4	10,180	10.1
Unknown	9,420	30.1	30,415	30.7	28,105	28.0
Exclusions and absences						
Ever excluded, in pupil referral unit or alternative provision	10,560	33.8	22,390	22.6	24,485	24.4
Ever recorded as persistently absent in a term	15,090	48.3	25,510	25.7	32,275	32.1
Social care characteristics before 20 weeks of pregnancy						
Ever in care	3,235	10.3	3,720	3.8	4,690	4.7
Ever had recorded child protection plan	1,990	6.4	1,895	1.9	14,970	14.9
Education variables						
Total	31,260	100.0	99,150	100.0	100,455	100.0
Ever recorded as having special educational needs	17,150	54.9	39,325	39.7	36,645	36.5
Ever recorded as having free school meals	18,525	59.3	42,795	43.2	36,820	36.7
Ever in bottom IDACI decile	11,565	37.0	27,525	27.8	19,280	19.2

*in those who were 20 weeks of gestation before Y11. FNP – Family Nurse Partnership; LA – local authority.

Appendix Table 2: Comparison of characteristics of mothers enrolled in FNP, controls (mothers pregnant at a time when FNP not enrolling mothers), and mothers offered FNP but declined or not offered FNP – Scotland, mothers-to-be eligible for FNP between 1 January 2009 and 31 March 2016

	Mothers enrolled in FNP		Mothers not enrolled in FNP, living in HB with outside period of recruitment (Controls)		Mothers offered but not enrolled in FNP, or not offered FNP within period of enrolment	
	N	%	N	%	N	%
Total	**3,205**	**100.0**	**5,016**	**100.0**	**2,214**	**100.0**
Maternal age at last menstrual period (years)						
Mean (SD)	18.30	1.41	18.22	1.23	18.4	2.20
Ethnicity						
White	2,724	87.6	3,573	78.7	1,733	82.8
Other	384	12.4	969	21.3	360	17.2
Scottish Index of Multiple Deprivation Quintile						
Most deprived	1,532	47.9	2,478	49.4	992	44.9
2	821	25.7	1,221	24.3	588	26.6
3	441	13.8	643	12.8	316	14.3
4	264	8.3	459	9.2	214	9.7
Least deprived	140	4.4	215	4.3	101	4.6
Body mass index (BMI) (kg/m2) at antenatal booking						
Mean (SD)	23.94	5.0	24.3	5.1	24.4	5.1
Smoking history at antenatal booking						
Never smoked	1,254	39.9	2,212	46.4	1,048	49.2
Former smoker	602	19.2	788	16.5	341	16.0
Current smoker	1,285	40.9	1,767	37.1	739	34.7
Drug misuse at any time during current pregnancy						
No	2,788	94.7	3,768	96.8	1,866	96.9
Yes	156	5.3	123	3.2	59	3.1
Previous pregnancy						
No	2,350	74.0	3,716	74.1	1,656	74.9
Yes	827	26.0	1,296	25.9	555	25.1

FNP – Family Nurse Partnership.

Appendix Table 3: Characteristics of mothers enrolled in FNP who did and did not link to HES in England

	Total FNP mothers		Linked mothers		Unlinked mothers	
	N	%	N	%	N	%
N (row %)	32,040	100.0	31,560	98.5	480	1.5
Year of birth of child						
2010	2,085	6.5	2,055	6.5	25	5.6
2011	1,925	6.0	1,870	5.9	55	11.0
2012	2,925	9.1	2,870	9.1	60	12.1
2013	4,130	12.9	4,075	12.9	50	10.8
2014	3,640	11.4	3,600	11.4	40	8.5
2015	5,180	16.2	5,115	16.2	65	13.5
2016	5,360	16.7	5,275	16.7	85	17.7
2017	3,275	10.2	3,225	10.2	50	10.8
2018	2,815	8.8	2,785	8.8	30	6.7
2019	710	2.2	695	2.2	15	3.1
Maternal age at birth						
13-15	265	0.8	260	0.8	<8	<1.7
16-17	11,705	36.5	11,525	36.5	180	37.1
18-19	15,960	49.8	15,735	49.9	225	46.9
20 and above	3,990	12.4	3,925	12.4	65	13.5
Missing	120	0.4	115	0.4	<8	<1.7
Ethnicity						
White	26,490	82.7	26,190	83.0	300	62.9
Asian	755	2.4	730	2.3	25	4.8
Black	1,640	5.1	1,585	5.0	55	11.7
Mixed/other	2,195	6.9	2,145	6.8	50	10.4
Missing	960	3.0	910	2.9	50	10.2
Region						
East Midlands	2,880	9.0	2,825	9.0	55	11.0
East of England	2,595	8.1	2,575	8.2	20	4.4
London	5,030	15.7	4,870	15.4	160	32.9
North East	2,185	6.8	2,170	6.9	15	3.3
North West	5,130	16.0	5,060	16.0	70	15.0
South East	4,605	14.4	4,550	14.4	55	11.0
South West	1,860	5.8	1,840	5.8	20	4.4
West Midlands	3,960	12.4	3,915	12.4	50	10.0
Yorkshire and The Humber	3,800	11.9	3,760	11.9	40	7.9
Relationship status (enrolment)						
In a relationship with biological father	22,710	70.9	22,400	71.0	310	64.2
In a relationship with other partner	1,005	3.1	990	3.1	10	2.5
Single	7,370	23.0	7,255	23.0	110	23.1
Missing	960	3.0	910	2.9	50	10.2
Living arrangements (enrolment)						
Mother (with or without partner)	16,995	53.0	16,790	53.2	205	42.3
Partner (with or without others, not mother)	6,175	19.3	6,065	19.2	105	22.3
Relatives/other adults	3,130	9.8	3,095	9.8	35	7.7
Alone	1,860	5.8	1,830	5.8	30	6.5
Foster carers/group home/other	2,920	9.1	2,865	9.1	55	11.0
Missing	960	3.0	910	2.9	50	10.2
Has any GCSEs (enrolment)						
No	10,270	32.1	10,120	32.1	150	31.5
Yes	20,795	64.9	20,515	65.0	280	58.1
Missing	975	3.0	925	2.9	50	10.4
Care leaver (during pregnancy)						
No	30,140	94.1	29,720	94.2	420	87.3
Yes	1,185	3.7	1,170	3.7	15	2.9
Missing	715	2.2	670	2.1	45	9.8

Continued.

Appendix Table 3: Continued

	Total FNP mothers		Linked mothers		Unlinked mothers	
	N	%	N	%	N	%
CIN, CPP, or CLA (during pregnancy)						
No	26,510	82.7	26,145	82.8	365	76.0
Yes	4,815	15.0	4,745	15.0	70	14.2
Missing	715	2.2	670	2.1	45	9.8
Drug and alcohol use during pregnancy (14 days before enrolment)						
No	29,165	91.0	28,770	91.2	395	82.3
Yes	1,535	4.8	1,510	4.8	25	4.8
Missing	1,345	4.2	1,280	4.1	60	12.9
Timing of first antenatal appointment						
Before 10 weeks	19,255	60.1	19,000	60.2	250	52.3
10-20 weeks	10,955	34.2	10,770	34.1	180	37.9
20 weeks or more	1,045	3.3	1,030	3.3	15	2.7
Missing	790	2.5	755	2.4	35	7.1
Foetal death						
No	31,900	99.6	31,455	99.7	445	92.9
Yes	120	0.4	90	0.3	35	7.1
Infant death						
No	31,885	99.6	31,410	99.6	475	99.6
Yes	135	0.4	130	0.4	<8	<1.7
Mean number of FNP visits		34.9		35.0		25.8

CIN – Child in Need status; CLA – Child Looked After; CPP – Child Protection Plan; FNP – Family Nurse Partnership.

Appendix Table 4: Timeline for linked FNP data access in England

October 2017	Application submitted to DfE for NPD data
	Application submitted to NHS Digital for linkage between FNP, HES and NPD
December 2017	Application submitted to Confidentiality Advisory Group (CAG) / National Research Ethics
January 2018	Ethics approval confirmed
February 2018	CAG provisional approval
	Delays due to security assurances for DfE not being in place: NHS Digital could not release identifiers for linkage
November 2018	Amendment submitted to NHS Digital removing request for DfE data (due to delays in security assurances being confirmed).
	Amendment submitted to CAG to remove DfE data
January 2019	CAG amendment approved
	New DARS application submitted
June 2019	DfE assurances now in place
	Amendment submitted to CAG to allow linkage with education data (as per original CAG application)
July 2019	CAG approval for second amendment received
	We were advised by NHS Digital to wait until the first application (without education data) had been approved before we submitted an amendment (for the education data)
September 2019	**Grant started**
November 2019	NHS Digital approval for linkage of HES and FNP data
July 2020	Linked HES – FNP data received from NHS Digital
August 2020	Amendment submitted to allow linkage with education data
March 2021	NHS Digital approval of linkage with education data
September 2021	Linkage with education data completed
October 2021	Linked education and social care data available on the ONS SRS
December 2021	HES and FNP data imported into the ONS SRS

Appendix Table 5: Timeline for linked FNP data access in Scotland

June 2016	Project start
October 2016	Application submitted to Education Analytical Services (EAS)
November 2016	Application submitted to the Public Benefit and Privacy Panel (PBPP) EAS application approved
December 2016	PBPP application approved with conditions (to set up additional data sharing/processing agreements and memoranda of understanding for each of the 10 Health Boards, and to create a new leaflet on data usage for new FNP clients)
February 2017	Set up of data sharing/processing agreements and memoranda of understanding commenced
May 2017	All data sharing/processing agreements and memoranda of understanding in place
June 2017	PBPP approval (conditions met)
September 2017	FNP data sent from FNP Scottish Information System (SIS) to the Electronic Data Research and Innovation Service (eDRIS)
December 2017	Amended data available in safe haven
January 2018	Data query regarding cases flagging and SMR02 flow
February 2018	Amendments submitted to EAS and PBPP regarding fields required
May 2018	PBPP and EAS amendments approved
August 2018	Outcomes list finalised
December 2018	Final controls identified, ready for outcomes to be linked
January 2019- February 2020	Delays in data provision
March 2020	Partial outcome data made available
September 2020	Partial outcome data made available
March 2021	Final datasets received