



Public Health
Research Consortium

Approaches to evaluating Healthy Start – a scoping review

Final Report - Revised

L Dyson, MJ Renfrew, R Jenkins, J Thomas, F McCormick, A Pearce, C Law

Mother and Infant Research Unit, University of York, with
The UCL Institute of Child Health, University College London

On behalf of the Public Health Research Consortium

3 September 2007

Contact:
Mother and Infant Research Unit
Dept of Health Sciences
Area 4, Seebohm Rowntree Building
University of York
Heslington
York
YO10 5DD

01904 321832
mjr505@york.ac.uk

Final Report

The work was undertaken by the Mother and Infant Research Unit as part of the Public Health Research Consortium. The Public Health Research Consortium is funded by the Department of Health Policy Research Programme. The views expressed in the publication are those of the authors and not necessarily those of the DH. Information about the wider programme of the PHRC is available from www.york.ac.uk/phrc <<http://www.york.ac.uk/phrc>>.

Final Report

Table of Contents

Executive Summary.....	5
1. Introduction and background	13
1.1. Healthy Start.....	13
1.2. The project.....	14
1.3. Assessing national policy interventions	15
1.4. Poverty and nutrition	16
1.5. Assessing nutrition-related outcomes.....	17
1.6. Assessing process-related outcomes.....	17
1.7. Local nutrition education services	17
1.8. Creating change in the short, medium or long term.....	18
1.9. Summary: Implications for the design of a national evaluation of Healthy Start.....	18
1.10. Our approach.....	20
2. Identifying priority outcomes	21
2.1. The importance of selecting the right outcomes	21
2.2. Methods.....	21
2.3. Results.....	23
2.4. Summary: priority outcomes	26
2.5. Next steps.....	26
3. Critique of methods to assess food and/or nutrient intake	27
3.1. Importance of nutritional assessment methods	27
3.2. Overview of dietary assessment methods used	27
3.3. Methodological issues related to Healthy Start.....	27
3.4. Summary: methods to assess food and/or nutrient intake	28
4. Comparison options	29
4.1. The fundamental importance of a comparative study	29
4.2. Methods.....	29
4.3. Results.....	29
4.3.1. Before-after study design - possible options:	29
4.3.2. Concurrent study design – possible options:.....	29
4.4. Summary: comparison options.....	31
4.5. Next steps.....	31
5. Routine data sources for potential baseline data.....	33
5.1. The potential contribution of routine data	33
5.2. Methods.....	33
5.3. Results.....	34
5.3.1. Type A data sources.....	34
5.3.2. Type B and C data sources	35
5.3.3. Routine data sources and priority outcomes	35
5.4. Summary: routine data sources for potential baseline data	39
5.5. Next steps.....	39
6. Routine data sources for feasible comparative data	40
6.1. Can routine data sources be used in comparative study designs?	40
6.2. Methods.....	40
6.2.1. Level at which data can be analysed	40
6.2.2. Adequate statistical power to estimate an appropriate size of effect.	40
6.3. Results.....	42
6.4. Summary: routine data sources for use in comparison options	47
7. Adapting routine data sources, and potential contribution of other data sources	49
7.1. The potential for developing existing data sources, and for using other sources of data	49

Final Report

7.2.	Adapting routine data sources	49
7.2.1.	Wider issues in adapting routine data collection	54
7.2.2.	Summary: adapting routine data collection	54
7.3.	Commercial retailer data	54
7.3.1.	Utility of supermarket data	56
7.3.2.	Utility of data from independent retailers	58
7.3.3.	Summary: Commercial retailer data sources	58
7.4.	Healthy Start Programme Data Sets	58
7.4.1.	Summary: Healthy Start programme data sets	61
7.5.	Complementary data sources	61
7.5.1.	'Local boosts' of national surveys	61
7.5.2.	Summary: Local boosts to routine data collection	62
7.5.3.	'Best practice' information systems	62
7.5.4.	Before-after study of Healthy Start in Sheffield	63
7.5.5.	Summary: Sheffield before-after study	64
8.	Purposive prospective studies	65
8.1.	Potential contribution of prospective studies	65
8.2.	Possible study designs	65
8.3.	Summary: purposive prospective studies	69
9.	Discussion of issues to be addressed in evaluation, with recommendations for action	70
9.1.	Background issues	70
9.1.1.	Context of the project	70
9.1.2.	Importance of comparison groups	70
9.1.3.	Priority outcomes	71
9.2.	Routine data sources	71
9.3.	Adapting routine data sources	73
9.4.	Commercial data sources	75
9.5.	Healthy Start data sets	77
9.6.	Complementary data sources	77
9.7.	Prospective studies	77
9.8.	Comparison options	78
10.	Options for evaluation	80
10.1.	Overview of potential data sources	80
10.2.	Evaluation options	82
11.	Report on progress against project objectives	89
	Acknowledgements	91
	References	92
Appendix 1	Staff and Advisory Group membership	100
Appendix 2	Content of Healthy Start programme at time of Devon and Cornwall evaluation and commissioning of scoping project	101
Appendix 3	Priority outcomes for national evaluation of Healthy Start	102
Appendix 4	Explanatory variables	109
Appendix 5	Critique of dietary assessment methods	111
Appendix 6	Information recorded on HS-relevant outcomes and HS- eligible groups for all Type 'A' data sources	116
Appendix 7	Information reported by HS-relevant outcomes for Types B and C data sources	127
Appendix 8	Routine data sources – comparison options	131
Appendix 9	Summary of relevant Type 'A' data sources reporting data to measure outcomes of effectiveness for each comparison option	132
Appendix 10	Sample size estimates for routine data sources in comparison options	134

Final Report

Index of Tables

Table 1: Comparison of national Healthy Start and Welfare Food Schemes	13
Table 2: Priority outcomes to measure effectiveness	24
Table 3: Priority outcomes to describe impact on target population	25
Table 4: Priority outcomes to describe health service activity	25
Table 5: Priority outcomes to describe impact on health and commercial sectors	26
Table 6: Priority outcomes recorded in Type A and B data sources by Healthy Start (HS) eligibility group	36
Table 7: Sample size estimates for four existing data sources DELETED	41
Table 8: Outcomes for potential evaluation through (Type A) routine data sources	43
Table 9: Outcomes which can NOT be evaluated through (Type A, B or C) routine data sources	44
Table 10: Outcomes amenable to potential evaluation through (Type B) routine data sources	46
Table 11: Potential routine data sources for prospective evaluation of Healthy Start (HS)	51
Table 12: Retailer use for expenditure of vouchers	55
Table 14: Potential 'local boosts' to support future national surveys	62
Table 15: Purposive data collection from recipients: priority outcomes	67
Table 16: Purposive data collection from health providers: priority outcomes	68
Table 17: Purposive data collection from commercial retailers: priority outcomes	68
Table 18: Potential of different approaches to contribute to evaluation of Healthy Start	81

Final Report

Executive summary

Background

Healthy Start is a new government scheme, the aim of which is to enhance nutrition for vulnerable pregnant women, breastfeeding women and children up to age four. It was implemented at a national level across the UK in November 2006. It replaced the longstanding Welfare Food Scheme, following a scientific review. The intention of these changes was to encourage pregnant women and families from low-income groups to eat a more nutritious diet, and to enable the identification of potentially vulnerable women by health professionals earlier in their pregnancy. It is as yet unclear what the positive or negative impacts of Healthy Start might be, and this project is intended to scope out options for monitoring and evaluation of the new programme.

The aim and objectives of the project, as specified by the Department of Health, were:

Aim: To advise the Department of Health on approaches to monitoring and evaluation of longer-term health and social outcomes of the Healthy Start scheme, including establishment of baseline data

Objectives:

1. To identify key criteria for evaluating the success of the Healthy Start policy
2. To propose a framework for monitoring the quality and performance of the Healthy Start scheme, and for establishing a system for collection of routine monitoring data
3. To map existing sources of data that could contribute to national policy evaluation of the Healthy Start scheme, and to review their relevance and potential value in yielding baseline data
4. To establish baseline data for Healthy Start policy evaluation by carrying out and reporting on secondary analyses of existing key datasets, commenting on the strengths, weaknesses and limitations of the datasets
5. To identify available standard data collection tools, and comment on their suitability and limitations for the purpose of a policy evaluation of Healthy Start

Policy-related factors and timing limited options for evaluation, and it was understood from the start of the project that none of the potential options for evaluation would be ideal. Identifying suitable comparison groups with which to compare outcomes was seen as a fundamental issue.

Final decisions about the design of a national evaluation will be dependent on the Department of Health's views on the primary purpose of such an evaluation, and on decisions about budget and timeframe.

Key criteria: assessing priority outcomes (Objective 1)

A two-stage assessment of relevant and potentially plausible outcomes, using existing literature, academic theory and expert opinion, resulted in a list of priority outcomes that could measure effectiveness; the impact on the target population; health service activity; and the impact on health and commercial sectors (Tables 2-5). These include measures of dietary intake, food-related behaviour, nutrition,

Final Report

health and education status, and infant feeding: programme acceptability, delivery and systems and infrastructure; and economic issues and potential broader effects of the Healthy Start programme.

Assessing data collection tools (Objective 5)

To assist in the final selection of outcomes, an overview of dietary assessment methods was conducted. No one method is ideal, and it is likely that a combination might be most accurate. Standard measures of food portion sizes for use in assessment of dietary intake for children living in England are not yet available, though work is ongoing.

Comparison options (Objective 2)

Several options for before-after and concurrent comparisons were explored and have been described (Chapter 4, Figure 1). Limitations identified at this stage include the potential for external confounding in both approaches, and the difficulty of measuring accurate outcomes for women and children eligible for the Welfare Food Scheme.

Mapping existing sources of data (Objective 3)

A systematic search was conducted to identify relevant data sources. These include three types of data source:

A Data collected by repeated cross-sectional or longitudinal surveys and, in most cases, available in the form of complete datasets on the UK Data Archive website

B Data collected on the general population or in specific settings and, in most cases, available on various websites

C Data collected as part of routine care, but not readily accessible at the individual level, unless one is involved in the routine care

Initial results suggested that routine data sources may have the potential to be useful for collection of baseline data among some eligible groups for most priority outcomes. However, we then examined whether or not data could be analysed at the level of women and children eligible for Healthy Start; and whether or not data were collected on large enough samples to meet sample size considerations. The findings from this stage suggested that existing data sources are very limited in their potential to support an evaluation of Healthy Start, regardless of study design (Table 8).

Adapting routine data collection (Objective 3)

The severe limitations identified in existing routine data (Chapters 5 and 6) led us to consider the potential for adapting and developing existing routine data collection. The inclusion of a flag for 'Healthy Start eligibility status' within three relevant datasets (Scottish Morbidity Record; Hospital Episode Statistics; Secondary Uses Service) would allow the collection of data on priority outcomes for infant feeding (initiation only), nutritional and health status. The relevant data sources shown in Table 11 (Infant Feeding Survey, Low Income Diet and Nutrition Survey, Health Survey for England; Maternal and Child Health Datasets) have the potential, if adapted, to report routine data on priority outcomes of effectiveness to measure reported changes in dietary, supplemental and nutrient intake, infant feeding and

Final Report

weaning practices, a range of nutritional and health status outcomes, and timely contact of eligible women with maternity services.

Other data sources (Objective 3)

Other potential sources of data examined included:

Commercial data sources to examine purchasing patterns

Important limitations of using data from commercial retailer sources were identified. However, till receipt data could have the potential to provide cross-sectional data to monitor household purchasing patterns. Reward schemes have the potential to provide cross-sectional and longitudinal data. These data could be used to monitor household purchasing patterns for all Healthy Start products across all beneficiary groups, as well as incremental changes over time.

Data sets held by government departments that may support evaluation of process outcomes

Measurement of some priority outcomes relevant to the process of Healthy Start, including programme coverage, and its related impact on various sectors may be feasible through use of these data sets.

Complementary data sources to support limited national data.

Local 'boosts' to routine data collection may have the potential to support national routine data collected by adapted, ongoing surveys.

Some regional information systems are relatively well developed and could be considered to represent 'best practice' in terms of their data capacity for monitoring and surveillance activities.

Data from the ongoing Sheffield Healthy Start study have the potential to 'stand-alone' as a detailed local evaluation, to support national data from adapted routine data sources, and for possible extrapolation to other comparable areas using synthetic estimate techniques.

Purposive studies to evaluate Healthy Start (Objective 2)

A range of possible options for purposive studies were examined. A cohort study could provide an opportunity to measure the potential incremental effect of Healthy Start over time. Sample groups for additional, small scale qualitative data would also be readily accessible for collection of process outcomes regarding the impact of Healthy Start on recipients. Surveys could measure the impact of Healthy Start on service providers and commercial retailers. Use of a small number of 'sentinel sites' could be a useful strategy for examining the range of priority outcomes in depth in different, low income settings.

Recommendations for any national evaluation of Healthy Start (Objective 2)

- At least part of any evaluation of Healthy Start should include some form of comparative study.

Final Report

- Framing of any national evaluation of Healthy Start should give serious consideration to the questions of primary interest and the associated priority outcomes to best answer those questions.
- Ongoing work on standard food portion sizes to assess dietary intake for children of different ages, and pregnant women, should be expedited and the results widely disseminated.
- Further assessment of feasibility of routine data sources for potential use for before-group / benchmark data
- Examination of governance issues regarding identification of individuals for concurrent comparison groups including:
 - Borderline non-eligibles
 - Equivalent non-eligibles

Options for evaluation (Objective 2)

Four options for evaluation are described. They are not mutually exclusive. Depending on the main aims, questions and associated outcomes, for the evaluation (to be decided by the Department of Health), we recommend a combination of approaches to capture the range of important outcomes in different population groups, and over time. The four options are:

Option 1: National monitoring and evaluation of core outcomes of effectiveness and coverage

- Five adapted ongoing national survey data sets (Low Income Diet & Nutrition Survey; Health Survey for England; Infant Feeding Survey; Maternal Health and Child Health Datasets) for outcomes of effectiveness: dietary intake; supplement intake; nutrient intake; infant feeding; nutritional and health status: plus explanatory variables
- Existing data source (Expenditure and Food Survey) for limited supporting purchasing data
- Benefits Agency data set for take-up data

Option 2: National monitoring and evaluation of comprehensive range of outcomes of effectiveness, coverage and impact of programme

- Purposive national cross-sectional surveys or cohort study of recipients within planned nationally representative sentinel sites for outcomes of effectiveness: dietary intake, supplement intake; potentially nutrient intake; infant feeding including weaning and introduction of cow's milk, purchasing data; process outcomes: impact of programme on recipients; and explanatory variables.
- One sentinel site could be based in Sheffield for extended cross-sectional and longitudinal data collection from existing cohort beyond May 2008.

Final Report

- Benefits Agency data set for take-up data

Option 3: National monitoring and evaluation of limited core outcomes of effectiveness and coverage

- Commercial multiple and independent retailers for household purchasing data for all relevant foods and drinks for all population groups of interest. This assumes the acceptability of household **purchasing** data as an alternative to core **intake** data.
- Benefits Agency data set for take-up data
- Purposive one-off local/regional study to describe impact of programme on target recipients and /or service providers. Extension of the Sheffield before-after study could provide longitudinal data for this purpose as well as data on additional core outcomes of dietary and nutrient intake.

Option 4: Local monitoring and evaluation of comprehensive range of outcomes of effectiveness, coverage and impact of programme for potential extrapolation of core outcomes to similar areas at national level

- Extension and possible expansion of existing purposive local before-after study in Sheffield for potential extrapolation to similar areas across England through geographical mapping techniques. Local data would report on outcomes of effectiveness (dietary and nutrient intake, infant feeding), process outcomes, impact of programme on recipients and some explanatory variables.

Options 1 and 2 are the most robust; Options 3 and 4 might be considered if the budget is severely limited.

The approach of choice is a combination of Options 1 and 2, if suitable adaptations are made.

In the absence of such adaptations to routine data collection, Option 2 is really the only feasible approach to provide good quality effectiveness data which is reliable and generalisable at the national level for a range of target population groups. The longitudinal nature of this evaluation option also has the potential to assess the incremental, long-term impact of Healthy Start to achieve lifestyle change toward healthier nutrition among low-income families.

Recommendations for further assessment, and/or implementation of evaluation options (Objective 2)

The following recommendations include action to further assess and examine all four evaluation options outlined above. Following agreement on the primary aims and associated outcomes for a national evaluation and an assessment of which evaluation option(s) may best achieve those aims, the relevant recommendations can be prioritised for implementation accordingly.

Final Report

Option 1

- To support the request to include a flag for 'Healthy Start eligibility or beneficiary status' within the Maternal Health and Child Health Datasets;
- To mandate these data fields for national collection and archiving.
- High level inter-departmental policy support to develop a cost-effective monitoring and evaluation system based on five modified routine data sets:
 - The Low Income Diet and Nutrition Survey
 - Infant Feeding Survey;
 - The Health Survey for England
 - The Maternal Health Dataset
 - The Child Health Dataset

Option 2

- A prospective study is the only way of collecting data on some important outcomes, namely, the impact of Healthy Start on recipients, service providers and the commercial sector. It is recommended that at least part of the evaluation of Healthy Start is conducted as a planned, prospective study
- The use of sentinel sites, based in areas of high deprivation, is an approach that has been shown to work in terms of collecting good quality, in depth data, with the potential to continue to collect longitudinal data or return to collect cross-sectional data over time. The existing before-after study to evaluate the impact of Healthy Start in Sheffield could be developed for ongoing data collection in one established sentinel site.

Option 3

- Identify individual multiple and independent retailers used by Healthy Start recipients to redeem their vouchers and investigate their willingness to collaborate in data sharing.
- Assess the number of retailers required to provide representative beneficiary data, including retailers serving recipients in rural and deprived inner city areas.
- Assess existing capacity of identified retailers to provide purchasing data at the level of individual Healthy Start eligibles and/or recipients.
- Negotiation for inclusion of a 'voucher notification' or 'flag' system to identify Health Start recipients within future multiple and independent retailer datasets;
- Development of 'best practice' systems with Tesco supermarket for potential replication to other retailers including examination of data protection issues.

Options 1, 2 and 3

- An audit of the Benefits Agency¹ and Registered Commercial retailer² data sets to identify if the following variables are currently extracted from the application form and recorded in an electronic format:
 - Individual postcode ^{1, 2};
 - Individual date of birth ¹;

Final Report

- National Insurance Number ¹.
- Assessment of the potential cost and feasibility to prospectively extract those variables for inclusion in the Benefits Agency and/or Registered Commercial retailer data sets.
- Examination of governance issues regarding data protection for use of this variable data at the level of the individual beneficiary.

Wider issues identified in the course of this work

Finally, we identified important issues related to programme evaluation and, particularly routine data collection, in general:

Consideration of evaluation options is best done before programmes are put in place; this is likely to result in more robust designs and more accurate assessment of impact.

We found no relevant datasets in which *a priori* sample size calculations had been conducted for specific population groups of interest. Such considerations at the planning stage of routine data collection would enhance the value of each survey, perhaps especially in regard to assessing inequalities in health.

Government departments and local agencies could benefit from incorporating measurements of uptake and possible outcomes of Healthy Start into service agreement and performance management metrics, particularly in relation to working in partnership across communities.

Inclusion of unique identifiers (e.g. NHS or National Insurance number) in routine data sources would enable potential record linkages between data sets for future evaluations of government programmes, including Healthy Start.

Final Report

1. Introduction and background

1.1. Healthy Start

Healthy Start is a new government scheme, the aim of which is to enhance nutrition for vulnerable pregnant women, breastfeeding women and children up to age four. It was implemented at a national level across the UK in November 2006. It replaced the longstanding Welfare Food Scheme, following a scientific review (COMA 2002), which recommended that the predominantly milk-based Welfare Food Scheme be replaced with one that promotes healthy eating more broadly. Table 1 below outlines the content of the two programmes at the time the Welfare Food Scheme was discontinued and Healthy Start established. In summary, the Welfare Food Scheme provided milk tokens to eligible women for the purchase of formula or cow's milk, while Healthy Start provides vouchers with which eligible women can purchase fresh fruit and vegetables as well as formula and cow's milk. Free vitamin supplements are an intrinsic part of both programmes, though the formulations have changed over time. Other significant changes are that women now register for Healthy Start with a health professional rather than through the benefits system, and Healthy Start is available to all teenagers under 18 years who are pregnant or mothers of young children, not just those from low-income backgrounds. The intention of these changes was to 'encourage pregnant women and families from low-income groups to eat a more nutritious diet' (DH 2006), and to enable the identification of potentially vulnerable women by health professionals earlier in their pregnancy. Some of the changes have, however, resulted in decreased availability of food support when compared with the Welfare Food Scheme; the value of the vouchers is not enough to purchase the 900g of formula milk for most brands previously available to bottle fed babies, and children are no longer offered support after their fourth birthday.

It is as yet unclear what the positive or negative impacts of Healthy Start might be and this project is intended to scope out options for monitoring and evaluation of the new programme.

Table 1: Comparison of national Healthy Start and Welfare Food Schemes

Welfare Food Scheme	Healthy Start
Means tested - apply via benefits office	Means tested - apply via health professional (midwife, health visitor or GP); ALL pregnant teenagers eligible
Weekly tokens to exchange for milk or infant formula, which could be exchanged for seven pints of milk per week from retailer, or 900g of infant formula (from child health clinic)	Weekly vouchers worth £2.80 to use at registered retailers to pay for milk, fresh fruit and vegetables, and infant formula
Pregnant women and children under 5 got one token per week	Pregnant women and children aged from 1 year up to end of third year get one voucher/week: Children under 1 get two vouchers/week: Children aged 4 and over get no vouchers
Free vitamin drops	Free vitamin drops (different formulation)

Final Report

1.2. The project

In September 2006, the Department of Health funded a project entitled '*A scoping review on the evaluation of Healthy Start*', commissioned by the Policy Research Programme via the Public Health Research Consortium. One preliminary meeting took place in May 2006 between the research team and the Department of Health, to agree the project protocol and funding and discuss a range of issues related to Healthy Start and its evaluation. A further meeting was held in December 2006 to discuss the interim report, which received positive feedback.

The work was conducted by a collaborative team based both in the Mother and Infant Research Unit, University of York, and the Institute for Child Health, University College London, supported by an Advisory Group drawn broadly from academic, NHS and service user communities (Appendix 1).

The aim and objectives of the project, as specified by the Department of Health, were:

Aim: To advise the Department of Health on approaches to monitoring and evaluation of longer-term health and social outcomes of the Healthy Start scheme, including establishment of baseline data

Objectives:

1. To identify key criteria for evaluating the success of the Healthy Start policy
2. To propose a framework for monitoring the quality and performance of the Healthy Start scheme, and for establishing a system for collection of routine monitoring data
3. To map existing sources of data that could contribute to national policy evaluation of the Healthy Start scheme, and to review their relevance and potential value in yielding baseline data
4. To establish baseline data for Healthy Start policy evaluation by carrying out and reporting on secondary analyses of existing key datasets, commenting on the strengths, weaknesses and limitations of the datasets
5. To identify available standard data collection tools, and comment on their suitability and limitations for the purpose of a policy evaluation of Healthy Start

Policy-related factors and timing limited options for evaluation from the start. In the first meeting to agree the protocol, the Department of Health clarified that any phased roll out to allow comparison between groups in different geographic areas would not be possible. As a further challenge, the Healthy Start programme was then rolled out across the UK in November 2006 (www.healthystart.nhs.uk), three months after the start of this project. Both of the most robust approaches to evaluation, a randomised controlled trial or a prospectively planned before-and-after study, were therefore ruled out from the start. Identifying suitable comparison groups, which we see as fundamental to evaluation, has been a serious challenge as a result.

A report of the rapid evaluation of the early impact of a pilot phase of the programme in Devon and Cornwall (Hills et al 2006) became available in the early stages of this project. The content of the Healthy Start programme was however modified before national roll-out of the programme, rendering some elements of that evaluation inapplicable. As the final content of the Healthy Start programme was still uncertain at the start of this work, in the first months we examined all the components of the programme as outlined in our commissioning discussions. The subsequent changes

Final Report

required some adaptations to be made to our work in its later stages. Appendix 2 outlines the differences between the programme content at the time of the Devon and Cornwall evaluation and at the commissioning stage of this project, and the programme as it was finally rolled out nationally.

As a result of these two serious limitations, it was understood from the start of the project that none of the potential options for evaluation would be ideal. The challenge for the team was to identify alternative approaches that could contribute to understanding of the process and outcomes of the scheme. Identifying suitable comparison groups with which to compare outcomes was seen as a fundamental issue.

It is understood by the research team that the findings of this work will be used to inform discussion, and we do not therefore offer one definitive design. Our approach has been to outline possible options for evaluation. Final decisions about the design of a national evaluation will be dependent on the Department of Health's views on the primary purpose of such an evaluation, and on decisions about budget and timeframe.

1.3. Assessing national policy interventions

The evaluation of large-scale national policy is complex and often subject to constraints including timing and budgetary limitations (Bamberger et al 2004). Whether a programme has an impact that can be measured will depend on a range of factors, including:

- Whether or not the content of the programme is appropriate to the target group
- Whether or not the programme reaches the target group
- Whether or not the target group can use the programme content effectively
- Whether or not those responsible for administering/disseminating the programme are motivated, informed and in touch with the target group
- Whether or not relevant outcomes can feasibly be affected by the programme, and can be measured
- Whether or not the evaluation is capable of examining the possibility that the programme may work well in some contexts, or for some population groups, better than others

Any proposed evaluation should consider all of these issues.

The design of such evaluation is especially challenging when the policy is already in place, and is further complicated when the policy is aimed at specific population groups who may be difficult to identify and contact (Rutter 2006). A policy that aims to have an impact on childbearing women, infants and children up to age four, and indeed on low-income families as a whole, has additional complexities. But it is essential to evaluate policy that may have an impact on such vulnerable groups (Coote et al 2004), to ensure that the impact is favourable and that all processes are as efficient and effective as possible. Unintended side effects should also be identified; these have been shown to occur with other national policy interventions. The evaluation of the School Fruit and Vegetable pilot scheme, for example, has shown that increased intakes in school have been accompanied by decreased intakes at home (Schagen et al 2005).

The evaluation of Healthy Start is also likely to be complicated by related policy initiatives introduced in the same time period. A series of cross-government

Final Report

approaches to enhancing healthier lifestyles and addressing inequalities in health have been introduced in recent months and years (e.g. Department of Health 2000, Department of Health 2003, Department of Health 2004a, Department of Health 2004b, Department of Health 2004c, Department of Health 2007). Related, concurrent initiatives include tackling obesity, stopping smoking, increasing breastfeeding initiation, extending maternity leave, and enhancing nutrition through programmes such as Five a Day and the School Fruit Scheme. It is likely to prove difficult to separate the impact of some of these programmes. Indeed, it is likely that their co-existence has an impact on their effectiveness, positively or negatively; this issue will be considered later in this report.

1.4. Poverty and nutrition

Poverty predisposes childbearing women and children to poor nutrition (Dowler et al 2001), whether that is measured in terms of food intake, nutrient intake, or nutritional status. The Avon Longitudinal Study of Parents and Children (ALSPAC) of 11,923 pregnant women in the south west of England found a strong relationship between difficulty in affording food and the quality of the diet (Rogers et al 1998). Studies have found low income women to be far below the reference values for most nutrients (Harrison and Lang 1997) and that their consumption of healthy foods such as fruit and vegetables, milk and fruit juice was low (Dallison and Lobstein 1995). A range of adverse health, developmental and education outcomes, with short and long term consequences for maternal, infant, child and ultimately, adult health, may result. In spite of the importance of this topic, knowledge of the eating habits of childbearing women is limited (Reid and Adamson 1997). One study has found that some women in low-income communities in the US have developed dietary behaviours that result in them meeting their nutritional requirements, though clearly others have not (Fowles et al 2005), and it has been reported that women see the time of pregnancy and new motherhood as an opportunity for introducing dietary change (eg Anderson et al 1995).

Food support programmes for low income pregnant and postnatal women, babies and children are intended to improve nutrition and reduce these adverse outcomes. Outside of the UK, the best known example of a national food support programme is the Special Supplemental Nutrition Programme for Women, Infants and Children (WIC), a federally-funded programme in the US (D'Souza et al, July 2006). This provides a generous basket of nutritious food, formula milk, and breastfeeding support. Similarly, the Healthy Start Scheme aims to encourage low income women and children under four to eat a more nutritious diet, although the value of the vouchers provided is considerably less than the value of the WIC package.

At the start of this project, some of the project team were in the final stages of compiling a series of six rapid reviews of nutrition interventions in the field of maternal and child nutrition, for the National Institute of Health and Clinical Excellence. These included reviews of the effectiveness of public health interventions to improve the nutrition of preconceptional women (McFadden et al 2006); pregnant women (D'Souza et al, June 2006a); postpartum women (McCormick et al, April 2006); young children aged 6-24 months (McCormick et al, June 2006) and 2 to 5 year old children (D'Souza et al, June 2006b), and a review of the effectiveness of public health interventions to promote safe and healthy milk feeding practices in babies, including breastfeeding counselling and support for low income women in pregnancy and postnatally (King et al 2006). All six rapid reviews searched particularly for studies including low income women, children and families. The studies identified in these reviews, and a range of previous relevant work (eg

Final Report

D'Souza et al, July 2006, Reid and Adamson 1997) have been used to inform this project.

1.5. Assessing nutrition-related outcomes

Creating change in nutritional behaviour is known to be difficult (Resnicow & Vaughan 2006) and the range of potential outcomes that might (or might not) result is extensive. These might be short-term behavioural outcomes (eg changes in purchasing patterns and nutritional intake, breastfeeding rates); short and medium-term health and development outcomes for both mother and child (e.g. maternal anaemia and tiredness, infant growth, obesity, subsequent pregnancy outcomes, educational development), or longer-term health outcomes (e.g. cardiovascular disease, educational attainment). In designing an evaluation of a nutrition-related programme, therefore, it is essential to consider a wide range of different types of outcome.

One of the most important outcomes that might change as a result of Healthy Start is food and/or nutrient intake and indeed, encouraging a more nutritious diet is the main aim of the scheme. Nutritional intake is however notoriously difficult to measure accurately (Wreiden et al 2003), and measuring intake in the population groups of interest (childbearing women, infants, and children up to age four) brings particular challenges (Cade et al 2006, Cockcroft et al 2005). Methods used to measure intake include weighed food records, 24 hour recall, and food frequency questionnaires. A critique of methods used to assess nutritional intake has been conducted as part of this work (Chapter 3).

1.6. Assessing process-related outcomes

With any public policy, there are important questions around whether or not it is reaching those whom it might benefit (Kane et al 2000). Information on how such programmes work is also essential to help in interpretation of any changes in health and developmental outcomes. As the registration and distribution systems have changed from the previous programme, process issues are especially important for Healthy Start, and discussions with the Department of Health in December 2006 indicated that uptake of the new scheme was lower than expected at that time. Any evaluation must therefore also consider questions such as the proportion of eligible women registering; gestational age at registration; the proportion using the vouchers; where they are used and what foods are purchased; and women's and health professionals' views of the system.

1.7. Local nutrition education services

Our work takes us into contact with a range of health and social care professionals, and voluntary organisations. We are aware as a result that some areas are adding or expanding existing local components to the Healthy Start scheme, including shopping and cooking classes, arrangements with local retailers to allow the purchase of individual items of fruit and vegetables, and bulk buying by a cooperative to reduce the cost; sometimes referred to as 'Healthy Start Plus'. Such variations, while small in themselves, have the potential to have a large impact on the effectiveness of the scheme. It will be important to consider such local variations in any evaluation, to examine effectiveness, as well as to describe examples of best practice.

Final Report

1.8. Creating change in the short, medium or long term

There are important questions about the purpose of the Healthy Start scheme and its evaluation that will need to be addressed by the Department of Health before the evaluation can be finalised. For example:

- Is Healthy Start intended to create short-term change in behaviour?
 - If so, it will be essential to examine purchasing patterns and food intake for women and children in receipt of the vouchers.
- Is it intended to contribute to long-term patterns of health outcomes in low-income groups, and thereby address inequalities in health?
 - If so, measures of relevant health outcomes for different groups over long periods of time will be needed.
- Is the scheme intended to lead to a positive effect in the longer term with an incremental effect on lifestyle change, similar to other public health programmes; and especially for those recipients who have benefited from the programme for an extended period?
 - If so, longitudinal data to measure the increased effect on nutritional behaviour and practice over time are required.
- Is the scheme likely to develop over time, with possible add-on components (i.e. Healthy Start Plus)?
 - If so, it will be important to seek examples of ways in which health and social care professionals and families have worked to maximise the impact of the scheme, to seek their views on what might be the most useful components to adapt or add, and to examine structural issues related to the way in which the scheme works (Attree 2006).

In considering possible approaches to evaluation, we have taken into account all of these issues. Before commissioning of the full evaluation, however, decisions about the primary aim(s) of the scheme will need to be expressed by the Department of Health.

1.9. Summary: Implications for the design of a national evaluation of Healthy Start

- The design of the definitive evaluation could not be a randomised controlled trial, or indeed any prospective design for equivalent comparison groups as the programme has already been put in place. This ruled out the most robust designs and seriously limited options for evaluation.
- Measures of effectiveness will need to include those related to the content of the programme, as well as the process of its delivery and health and other outcomes.
- The evaluation will need to consider short, medium and long term outcomes from the perspectives of:
 - Eligible women and their families
 - The communities in which they live
 - Health professionals who work with them
 - Retailers involved in the scheme
 - Programme commissioners and funders

Final Report

- It is likely that some communities (e.g. those where health professionals have been very pro-active versus those where they have not) and some sub-groups of eligible women (e.g. primiparous women, women from specific ethnic groups, women in rural areas) will respond differently to Healthy Start. Such variations in provision, support and response to the programme will be important and will need to be measured.
- It may be possible to use routine data to assess some of the important outcomes. However, these will have to meet standards of quality and sample size, and must be capable of being analysed at the level of programme recipients.
- The potential effects of the differences between the former Welfare Food Programme and the Healthy Start Scheme are fundamental to a national evaluation of Healthy Start.
- A wide range of different outcomes will be important, which are likely to need different approaches and time frames. It is likely therefore that any evaluation will be composed of several different approaches, including both comparative and descriptive approaches.
- Any design is likely to capture changes resulting not only from Healthy Start, but other related policy initiatives introduced in the same time period.
- It is possible that the content of the programme may continue to change over time, and indeed, vitamins have been introduced to the programme since it was launched. Any evaluation needs to be able to build in such changes over time.
- We are aware from talking with health professionals and voluntary groups that some areas are adding local components to the scheme. It will be important to consider such local variations as they may have an impact of effectiveness.
- The scoping of a 'national' evaluation is assumed to apply to England only, as other countries in the UK will determine the scope and method for separate independent evaluations.
- The budget for the evaluation was unknown, and likely to be limited.
- A fundamentally important point is that final decisions about the design of a national evaluation will be dependent on the Department of Health's views on the primary purpose of such an evaluation, and on decisions about budget and timeframe.

Final Report

1.10. Our approach

We have considered a range of designs, and have been informed by developments in evaluation methodology (eg Bamberger et al 2004, Pawson and Tilley 1998). We have considered the need for comparative and descriptive, and quantitative and qualitative approaches. Throughout, we have considered that some form of comparison is fundamental to an evaluation.

It was clear from very early in this work that no one study design would address the complex issues. We therefore took the approach that we should assess the different components, or 'building blocks', that might contribute different aspects of a national evaluation. Depending on the purpose, budget and timescale, one or more of these building blocks might be used in an evaluation. To support this work, we invited individuals with a wide range of backgrounds to join our Advisory Group to help design options that could be as rigorous as possible within the limitations imposed.

To address the aim and objectives, we outlined five tasks:

1. Scope outcomes of interest and identify priority outcomes.
This was based on the following criterion:
Plausible: what outcomes do the literature and expert opinion suggest might plausibly be changed (positively or negatively) by Healthy Start or the Welfare Food Scheme?
2. Critique existing relevant data collection tools
3. Identify sources of routine data, examine whether analysis is possible at the level of women and children eligible for Healthy Start, and identify any relevant baseline data.
This was based on the following criteria:
 - a. Measureable: can relevant outcomes be measured accurately using routine data or simple data collection?
 - b. Feasible: can change be detected in light of a priori sample size calculation; i.e. have outcomes been measured in enough women and children to rule out chance findings?
4. Identify sources of other relevant data, and examine whether analysis is possible at the level of women and children eligible for Healthy Start
5. Identify options for evaluation.

For each task we describe the method and results. We then discuss the overall findings and draw conclusions relevant to the design of a national evaluation. Finally, we provide an assessment of options for evaluation, using a 'building blocks' approach. These options are intended to inform discussion; final decisions will be related to the main purpose of the evaluation, policy considerations and the budget available.

Final Report

2. Identifying priority outcomes

2.1. The importance of selecting the right outcomes

Fundamental to the design of any evaluation is to agree which outcomes should be measured. This decision will be influenced by examining whether or not outcomes could plausibly be changed by the intervention (i.e. plausible); whether or not measuring such outcomes is possible (i.e. measurable); and consideration of the sample size needed to see any change, either positive or negative (i.e. feasible). It will also be affected by views on whether outcomes are important to policy makers, researchers and the public – are they issues that would be perceived as important? The first task therefore was to assess the wide range of outcomes of effectiveness and process that could possibly be affected by the Healthy Start programme, and to identify priority outcomes.

2.2. Methods

This work was undertaken in several interlinked stages.

In the first instance, a comprehensive list (the 'long list') of relevant and potentially plausible outcomes was developed including:

- a. Nutrition, health and social outcomes to evaluate the effectiveness of Healthy Start in the short, medium or long term
- b. Process outcomes to monitor and evaluate the impact of the delivery of Healthy Start
- c. Explanatory variables for appropriate analysis of effectiveness data¹
- d. The population source from whom data should be collected for each outcome / variable

A broad definition of plausibility was adopted at this stage to identify outcomes based on the following sources:

- Evidence of effectiveness (from intervention studies, identified from recent reviews: McFadden et al 2006, D'Souza et al June 2006a, D'Souza et al July 2006, McCormick et al April 2006, King et al 2006, McCormick et al June 2006, D'Souza et al June 2006b)
- Academic theory and expert opinion (epidemiological studies and academic knowledge of the field using the research team and Advisory Group expertise)
- Field experience of the Healthy Start programme (pilot evaluation report, Hills et al 2006)

This approach resulted in the identification and inclusion in the list of all outcomes studied in research of effectiveness, and relevant observational studies (e.g. birth cohorts). The 'long list' of outcomes and potential explanatory variables was detailed in the Interim Report (MIRU/ICH 2006, Appendix 3 of that report).

¹ Variables which are thought likely to have an explanatory and/or confounding effect on a primary outcome of interest.

Final Report

Priority outcomes were subsequently identified on the basis of being associated with a plausible change (positive or adverse) as a result of Healthy Start. This was assessed in two ways:

- a. Demonstrated positive or negative effect from evidence base of effectiveness from intervention studies identified from recent reviews
- b. Input from the Advisory Group and project team on outcomes of importance

The formal evidence base provided relatively little evidence, as the quality and quantity of studies examining effectiveness of food support or nutrition programmes is limited. It is also important to note that the intervention studies are not directly comparable to Healthy Start. For example, the USA Special Supplementation Nutrition Programme for Women, Infants and Children (WIC) provides a basket of foods across the food groups, combined with optional nutrition and breastfeeding counselling. Even on the assumption that all other characteristics are comparable, a reported effect of an intervention study cannot therefore be assumed to be replicable by Healthy Start.

Input from the Advisory Group and project team identified plausible outcomes of likely positive or adverse effect in three areas:

1. As a result of Healthy Start compared to the absence of a similar programme, for example, purchase of fruit and vegetables;
2. As a result of Healthy Start compared to the former Infant Welfare Food Scheme, for example, initiation of breastfeeding;
3. As a result of local best practice intended to support and enhance Healthy Start; for example, referral to local nutrition education and support services. This may be as a result, or independent of, the presence of Healthy Start.

The report of the pilot phase of Healthy Start (Hills et al 2006) was also used to prioritise outcomes.

It was agreed that to inform questions of uptake, equity and differences of effect, all agreed outcomes should be collected, where possible, from the different population groups of interest to Healthy Start as follows:

- a. Eligible target groups in terms of demographic characteristics:
 - i. pregnant women including teenagers under 18 years
 - ii. women and families with a child/children from birth to age 4 years
- b. Eligible target groups in terms of benefit status:
 - i. pregnant women in receipt of Income Support or income based Jobseeker's Allowance
 - ii. families in receipt of income-based Jobseeker's Allowance or Child Tax Credit with an income below £14155 per annum
- c. Eligible target groups who may be hardest to reach:
 - i. pregnant teenagers
 - ii. travelling communities
 - iii. women who do not speak English
- d. Eligible target groups who are likely to experience greater public health benefit from participation in Healthy Start:
 - i. Pregnant women who are heavy smokers and/or alcohol users

Final Report

- ii. Infants and children of mothers who are heavy smokers and/or alcohol users

The priority outcomes generated from this process are presented in Results (2.3) below. The evidence base or expert opinion underpinning the assessment of plausibility for each priority outcome is detailed at Appendix 3.

The same process was undertaken to identify explanatory variables for subsequent use in analysis of outcome data, including demographic variables such as age; dietary intake including normal diet (i.e. high fish intake); and health behaviours such as smoking and exercise. Some of these variables are likely to be confounding factors in any analysis.

2.3. Results

The priority outcomes identified by this process, that are seen as important for an evaluation of the national Healthy Start Programme, have been presented in four categories (Tables 2- 5 below). Table 2 relates to evaluation of the effectiveness of Healthy Start, and Tables 3 - 5 relate to describing the impact of Healthy Start on different target groups/sectors.

Explanatory variables identified are provided at Appendix 4. Data collection for these variables has been defined in relation to the primary outcome of interest. Variables which are also likely to be confounders at the point of analysis have not been classified separately at this stage. Such distinctions would be required, however, at the point of data analysis.

Final Report

Table 2: Priority outcomes to measure effectiveness

Dietary intake	<p>Intake of multivitamin / mineral supplements</p> <p>Intake of periconceptual folic acid</p> <p>Food intake for milk, fruit and vegetables</p> <p>Quality of diet including fruit and vegetables</p> <p>Nutrient intake for energy, protein, vitamins and minerals</p>
Food-related behaviour	<p>Types of foods and drinks purchased with vouchers, including fruit and vegetables</p> <p>Displacement of income, eg. increased expenditure on fruit/veg or other items such as alcohol</p>
Nutrition, health and education status	<p>Iron levels (pregnant women and infant)</p> <p>Maternal anaemia in pregnancy</p> <p>Weight gain in pregnancy</p> <p>Women's wellbeing including exhaustion, unhappiness, anxiety or depression</p> <p>Gestational age at birth</p> <p>Preterm births – early and very early</p> <p>Infant and child weight, length, height (including mean / low birth weight)</p> <p>Mortality</p> <p>Educational and behavioural outcomes</p>
Infant feeding	<p>Initiation rates of any and exclusive breastfeeding at birth and hospital discharge</p> <p>Duration rates of any and exclusive breastfeeding up to 12 months</p> <p>Use of cow's milk before 12 months as main milk drink</p> <p>Intake of formula milk</p> <p>Type, content and timing of introduction of weaning foods</p>

Final Report

Table 3: Priority outcomes to describe impact on target population

Food-related behaviour	Use of foods purchased by voucher including ease of use of fruit and vegetables
Programme acceptability	Women's views on the content and delivery of HS Embarrassment for recipients when using vouchers Total purchasing power for family / household compared to previous entitlements
Programme delivery	Number / proportion of recipients receiving entitlements, particularly hard to reach groups Early recruitment into, and length of participation in, scheme Equity of value of vouchers within and between regions Sources of HS information for existing IWFS and new recipients Types of information for eligibles and/or recipients including materials in different languages Access to local retailer registered with HS including range and quality of fresh fruit and veg Mechanisms for beneficiary to redeem full value of voucher

Table 4: Priority outcomes to describe health service activity

Programme delivery	Timing of first contact with maternity services including point of advice on HS Delivery of nutrition education and/or referral at point of contact with health professional advising on HS Ability of health professionals to identify, register, counsel and refer eligible recipients
Programme systems and infrastructure	Impact on workload for health professionals and their existing client base Sustainability of workload within existing resources

Final Report

Table 5: Priority outcomes to describe impact on health and commercial sectors

Economic	Cost effectiveness of HS compared to IWFS or other nutrition programmes
Broader effects of Healthy Start	Change in retailer behaviour to supply and/or promote fruit and vegetables Uptake of related nutrition education and breastfeeding activities

2.4. Summary: priority outcomes

This process identified priority outcomes that could measure effectiveness; the impact on the target population; health service activity; and the impact on health and commercial sectors, presented in Tables 2-5. These include measures of dietary intake, food-related behaviour, nutrition, health and education status, and infant feeding: programme acceptability, delivery and systems and infrastructure; and economic issues and potential broader effects of the Healthy Start programme.

2.5. Next steps

The next stages of the work examined issues related to measurability and feasibility of these priority outcomes. In order to do this, methods of dietary assessment, and possible comparison options for a national evaluation, were considered first. The comparison options provided a framework in which assessments of measurability and feasibility could be most usefully undertaken.

3. Critique of methods to assess food and/or nutrient intake

3.1. Importance of nutritional assessment methods

One of the most important and immediate outcomes of Healthy Start is likely to be a change in diet. Methodological issues for measurement of food and/or nutrient intake data need to be taken into account when considering the feasibility of data collection, and the utility of dietary, nutrient and supplement intake data. The quality of intake data may vary considerably depending on the methods used for each routine data source or purposive study. Decisions regarding the final selection of outcomes to be used in an evaluation and the most appropriate data source for collection of intake, should therefore include an appraisal of the method used or planned for that data source.

We therefore conducted a brief assessment of such methods. This was based on a rapid review of the literature and consultation with Prof Janet Cade, member of the Advisory Group and Director of the Nutritional Epidemiology Group, University of Leeds.

3.2. Overview of dietary assessment methods used

The most commonly used dietary assessment methods for large populations include food frequency questionnaires (FFQs) and household food surveys. These measurements are based on self-reported, self-completed survey tools and therefore have a low respondent burden and are relatively low cost. The potential sources of error through estimated portion sizes, memory and selective reporting are recognised weaknesses of such methods. Survey tools such as these should also be validated in relation to a reference method and for use among different population groups of interest.

Interview methods, such as 24 hour recall and dietary history are also used for relatively large populations. These methods can be implemented by telephone to limit costs and are considered more reliable than the completely self-reported method of FFQs. Errors due to estimation of portion sizes and memory and bias in over-reporting of 'good' or under-reporting of 'bad' foods still need to be taken into account.

Weighed food records and estimated food records are also widely used due to their increased precision for measurement of portion sizes. Indeed, the 7 day weighed food record is often referred to as the 'gold standard' for measurement of nutritional intake. The relatively high respondent burden and cost, however, are limiting factors for their use in large scale surveys.

Use of methods such as the 7 day weighed food record from a sub-group of a larger sample completing an FFQ for example, can achieve the required generalisability of adequate sample size whilst also increasing validity of findings through increased precision and reduced error or bias in reporting method.

3.3. Methodological issues related to Healthy Start

A further methodological issue for consideration in collection of food and/or nutrient intake data for an evaluation of Healthy Start is the lack of standard portion sizes for

Final Report

children. The development of such a standard portion size has been commissioned by the Food Standards Agency but work conducted has not yet been released for publication. This work extracted collated food portion size information from recent National Diet and Nutrition Surveys (NDNS) of children aged 1½ to 4½ years and young people aged 4-18 years combined with other available weighed dietary records. Information on portion sizes of packaged foods and fast foods commonly eaten by children has also been collated. A list of typical food portion sizes has been produced for each age range and tested using existing dietary survey data. The availability of this information for use in future child dietary intake data would aid comparison between data sources and increase reliability of child intake data.

Assessment of dietary and supplement intake in pregnancy also poses additional methodological challenges. The timing of data collection for nutrient intake at various stages of the pregnancy may have a bearing on recommended nutritional requirements. In addition, nausea and sickness or cravings may affect diet in pregnancy. Consequently, several dietary assessments may be required at different trimesters to provide a more accurate assessment of overall quality of diet. Pregnant women, as with breastfeeding women, may be more likely to experience guilt regarding their diet and therefore more likely to report more favourable accounts of their diet. Interviewer administered tools may therefore be less able to collect more reliable data than self-reported methods.

A more detailed critique of each food and/or nutrient intake assessment method, and a summary of issues regarding food portion sizes for children, is provided in Appendix 5.

3.4. Summary: methods to assess food and/or nutrient intake

To assist in the final selection of outcomes to be included in an evaluation of Healthy Start, an overview of methods to assess food and/or nutrient intake was conducted. No one method is ideal and it is likely that a combination might be most accurate. Standard methods to assess food and/or nutrient intake for children are not yet available, though work is ongoing.

Final Report

4. Comparison options

4.1. The fundamental importance of a comparative study

We assumed from an early stage that examining the impact of Healthy Start would involve the comparison of an intervention group (those receiving, or eligible for, Healthy Start) with another group. Without a relevant comparison group, it will be difficult or impossible to interpret any measures of effectiveness. Descriptive study designs may well be appropriate for some questions (such as what women spend the vouchers on, and whether the administrative systems are successful in reaching all population groups), but questions of effectiveness are fundamental.

As described in Chapter 1, suitable comparison options are very limited.

4.2. Methods

In this stage of the work, we examined several possible comparison options, drawing on examples of similar studies and the expertise of our research team and Advisory Group. We considered comparisons between:

- different population groups
- at different time periods, and
- in different geographical areas.

Please note: we refer to women and children eligible for Healthy Start or the Welfare Food Scheme as 'eligibles', and those who receive the vouchers or tokens as 'recipients'.

4.3. Results

We identified two main categories of suitable comparison:

4.3.1. Before-after study design - possible options:

- A. Individuals eligible for Healthy Start compared to individuals eligible for the Welfare Food Scheme:
 - a) Healthy Start eligibles (both women and children) compared to Welfare Food Scheme eligibles for outcomes relevant to both programmes, e.g. intake of cow's milk, formula or vitamin supplements;
 - b) Healthy Start eligibles compared to Welfare Food Scheme eligibles for outcomes not relevant to Welfare Food Scheme, e.g. intake of fruit and vegetables, expenditure on fruit and vegetables.

4.3.2. Concurrent study design – possible options:

- B. Individuals eligible for Healthy Start compared to similar non-eligibles:
 - a) Healthy Start eligibles compared to borderline non-eligibles,
 - i. e.g. pregnant women who are on low incomes but are not eligible for the income benefits required for Healthy Start registration;
 - b) Healthy Start eligibles compared to equivalent non-eligibles,
 - i. e.g. women who are eligible for these income benefits but are not pregnant; families who are eligible for the benefits but have no children aged under 4 years.

Final Report

We consider the comparison groups in option A to be generally equivalent, as eligibility has remained broadly similar in both schemes. Some differences in participants are likely however due to variations in specific eligibility criteria. For example, the Healthy Start programme does not include eligibility on the basis of the pension credit guarantee, but does include all pregnant teenagers regardless of benefit status (Hills et al 2006). Variations in net purchasing power of the tokens/vouchers between the two schemes might also generate differences between sub-population groups within the comparisons. For example, Healthy Start provides fixed-value vouchers (to the value of £5.60 in the first year postpartum, and £2.80 in pregnancy and up to age 4) instead of a volume based token previously used for purchasing cow's milk or formula (Hills et al 2006). As a result, the Healthy Start vouchers may not, at all times during the first year, pay for the bottle fed infant's full requirement for infant formula as was the case previously.

The before-after study design outlined for option A is subject to external confounding variables between the two periods of study, including other nutrition- and income-related developments, as described in Chapter 1.

Whilst the concurrent study design for option B has the advantage of limiting the potential for external confounding variables over time, it is subject to error as a result of differences between the comparison groups. In the case of option B a), Healthy Start eligibles compared to borderline non-eligibles, the comparison groups would be subject to differences in income / benefit status. In the case of option B b), Healthy Start eligibles compared to equivalent non-eligibles, the events of becoming pregnant and/or being a parent of a young child are likely to have an effect on attitudes and behaviour toward healthy eating and related lifestyle behaviours. In addition, infertility is related to both under-nutrition and to obesity, so there may be nutritional differences between low income women who are pregnant and those who are not pregnant.

The potential groups for comparison are presented in Figure 1 below. This illustrates the comparisons in terms of different time points (e.g. before and after Healthy Start); different population groups (e.g. Healthy Start eligibles compared to Healthy Start borderline non-eligibles); and different geographical areas of comparison (e.g. Healthy Start pilot region compared to region(s) without Healthy Start).

The geographical area for national comparison presented in Figure 1 below refers to England or, prior to the national roll-out of Healthy Start, England excluding Devon and Cornwall. Other national geographical comparisons might include other countries within the UK either prior to, or since, the UK roll-out of the Scheme. These comparisons have not been included however due to the complex external variables likely to confound any analysis of effectiveness of Healthy Start within each country.

Final Report

4.4. Summary: comparison options

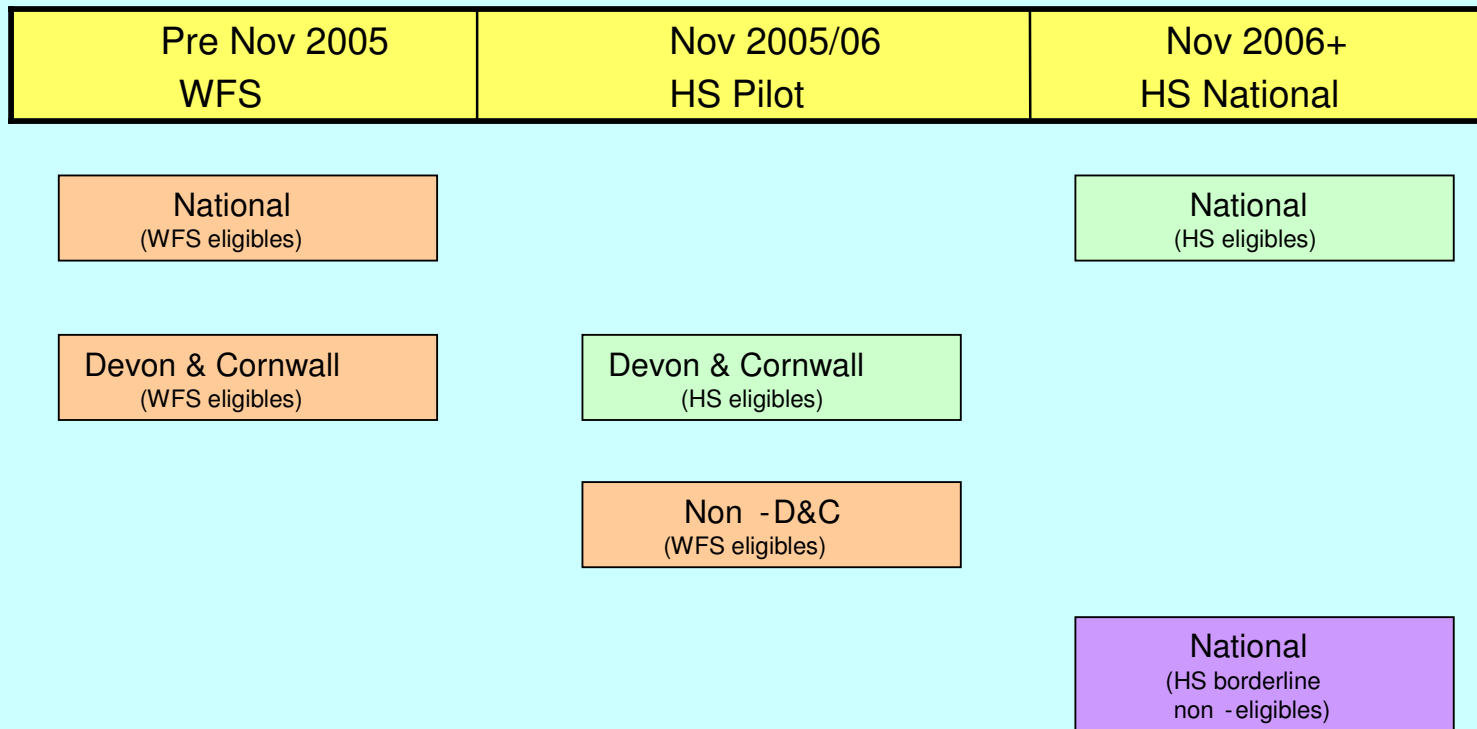
Several options for before-after and concurrent comparisons have been explored. Limitations identified at this stage include the potential for external confounding in both approaches, and the difficulty of measuring accurate outcomes for women and children eligible for the Welfare Food Scheme. We have, however, identified several possible approaches, including before-after and concurrent designs.

4.5. Next steps

Were data to be available for a range of priority outcomes from the years before the introduction of Healthy Start, this could be an important contribution to a before-after study. Were data to be available in the future for the population groups who might form a suitable comparison group, this could be of assistance for a concurrent study design. The next step was therefore to explore the potential for a range of data sources to contribute to these comparison options.

Figure 1

Potential comparisons



5. Routine data sources for potential baseline data

5.1. The potential contribution of routine data

The previous chapters have identified the important outcomes to be measured, and the possibility of both before-after and concurrent study designs. To understand better whether or not readily-available sources of data on these outcomes could contribute to a potential evaluation, we examined existing sources of routinely-collected data to see whether or not data related to these outcomes were available. If so, they could potentially contribute to either a before-after or a concurrent comparison, and to ongoing monitoring over time.

5.2. Methods

The aim of this work was to map existing sources of data that could contribute to a national policy evaluation of the Healthy Start programme; and to review their relevance and potential value in yielding baseline data to measure the priority outcomes.

This task entailed searching routine data sources to identify those that may report on priority outcomes of effectiveness.

For the purpose of this task we considered three types of data:

- A. Data collected by repeated cross-sectional or longitudinal surveys and, in most cases, available in the form of complete datasets on the UK Data Archive website (e.g. Expenditure and Food Survey, Health Survey for England);
- B. Data collected on the general population or in specific settings and, in most cases, available on various websites (e.g. General Practice Research Database, Hospital Episode Statistics);
- C. Data collected as part of routine care, but not readily accessible at the individual level, unless one is involved in the routine care (e.g. national and local child health computer systems).

Most priority outcomes of effectiveness and one outcome to describe the impact of health service activity, namely, 'Timing of first contact with maternity services including point of advice on Healthy Start' were selected for this mapping task². This selection aimed to reflect the majority of priority outcomes of effectiveness, whilst also reflecting the likelihood of change as a direct result of women/children participating in the Healthy Start programme. The searching process therefore included the following outcomes:

1. **Food outcomes:**

1a. Intake of milk, fruit and vegetables by pregnant women/ breastfeeding women/ children aged under 4 years.

1b. Proxy outcome of 'quality of diet' (e.g. poor, fair, good – to provide some detail on the pattern of different food groups being consumed on a daily/weekly basis) for pregnant women/breastfeeding women/children aged under 4 years..

² Priority outcomes of effectiveness which were not included in this mapping task include: weight gain in pregnancy; preterm births, early & very early and infant mortality

Final Report

- 1c.** Intake of nutrients from milk, fruit and vegetables by pregnant women/ breastfeeding women/ children aged under 4 years.
- 2. Infant feeding:**
- 2a.** Initiation and duration of any/exclusive breastfeeding for infants aged 0-1 years.
 - 2b.** Intake of formula milk by children aged under 4 years.
 - 2c.** Timing of the introduction of milk, other than breast or formula milk for infants aged 0-1 years.
 - 2d.** Timing of the introduction of weaning foods for infants aged 0-1 years.
 - 2e.** Type and content of weaning foods for infants aged 0-1 years.
- 3. Proxy measures for the timing of registration onto the Healthy Start programme (e.g. first contact with midwife) by age of the Healthy Start-eligible individual.**
- 4. Vitamin and mineral supplements:**
- 4a.** Intake of vitamin and mineral supplements by pregnant women/ breastfeeding women/ children aged under 4 years.
 - 4b.** Intake of periconceptional folic acid by pregnant women.
- 5. Household expenditure on food and drink, including the profile of household members.**
- 6. Nutrition, health and social status outcomes**
- 6a.** Maternal iron (haemoglobin or ferritin) levels /anaemia in pregnancy.
 - 6b.** Baby's gestational age at delivery.
 - 6c.** Baby's birth weight.
 - 6d.** Length/height and weight of children aged under 4 years.
 - 6e.** Maternal wellbeing and mental health in pregnancy/of mothers with children up to age 4.
 - 6f.** Educational and behavioural development of children aged 1-3 years.

In the first instance, we searched for data sources containing outcomes within groups 1-5 from 1996 onwards by browsing the following websites: Office for National Statistics, Association of Public Health Observatories, Clinical and Health Outcomes Knowledge Database, Department of Health, Department for the Environment, Food and Rural Affairs, UK Data Archive, and the Foods Standard Agency. We used the following search terms: food*, drink*, diet*, nutrition*, milk*, fruit*, vegetable*, vitamin*, feed*, breast?feed*, antenatal* and midwi?e*. The search for the remaining outcomes (group 6) involved browsing those data sources that had already been identified in the original search for groups 1-5.

Details of each dataset were extracted into a standardised data extraction and assessment form, which was then compiled into a project database.

5.3. Results

The results of the search for different types of data sources are presented below. A summary of data sources which appear to have the potential to yield baseline data for each outcome is presented at Table 6 below.

5.3.1. Type A data sources

Final Report

A total of 21 cross-sectional and longitudinal surveys were identified from the searches, with 13 containing at least one relevant outcome for pregnant women, breastfeeding women, or children aged under 4 years. Of these 13 surveys, it is expected that five will continue collecting Healthy Start-relevant outcome data in the future.

Of the eight data sources that were not suitable:

- Three contained relevant outcome variables, but did not collect these data for pregnant women, breastfeeding women, or children aged under 4
- Four did not contain variables that defined any of the Healthy Start eligibility groups
- One (the Low Income Diet and Nutrition Survey) contained relevant outcome variables, but at the time of searching, no details on variables relating to the Healthy Start eligibility groups were available

Details on the level and type of information recorded on relevant outcomes included in this search and eligible groups for all Type A data sources are provided at Appendix 6.

5.3.2. Type B and C data sources

In considering types B and C data sources, it is important to note that our search strategy was designed primarily to identify Type A sources. It is likely that other Type B and C sources exist in addition to those identified through our processes, but the internet-based search strategy which we used may not have been the most effective means of identifying and assessing the potential of these types for this project. Additional consultation with members of the Advisory Group aimed to address this limitation.

A total of 10 Type B sources were identified by the search strategy, three of which recorded data relating to relevant outcomes for one eligible group. All of these are expected to continue collecting relevant outcome data in the future.

A total of five Type C data sources were identified. Two of these collected data on relevant outcomes, but did not contain any variables relating to eligibility status.

In the case of four Type B and three Type C data sources, a complete list of their constituent variables was not available on the internet. It is unclear, therefore, as to whether or not these sources collected data relating to any of the relevant outcomes and/or eligibility status.

In contrast to Type A data sources, Type B and C sources are derived from information systems that cover a high percentage of the population. Data from Type B and C sources, where available, are therefore potentially very useful in terms of feasibility (ie sample size).

Details on the level and type of information recorded on relevant outcomes and eligible groups for all Type B and C data sources are provided in Appendix 7.

5.3.3. Routine data sources and priority outcomes

A summary of all data sources that reported relevant outcome data for one or more of the eligible groups is provided at Table 6 below.

Final Report

Table 6: Priority outcomes recorded in Type A and B data sources by Healthy Start (HS) eligibility group.

Priority outcome	Data source	HS eligibility group
Intake of milk	EFS (2001/02-2004/05)	HS eligible pregnant women and children aged under 4
	FES (1996/97-2000-01)	HS eligible children aged under 4
	FRS (1996/97-2004/05)	HS eligible children aged under 4
	HEMS (1996-97)	HS eligible pregnant women
	HSE	HS eligible pregnant women (1997-99, 2003-04) and children aged under 4 (1997)
	SHS	HS eligible pregnant women (1995-2003) and children aged under 4 (1998)
Intake of fruit and/or vegetables	FCS (1999-2004)	HS eligible children aged under 4
	HEMS (1996-97)	HS eligible pregnant women
	HSE	HS eligible pregnant women (1997-99, 2001-04), breastfeeding women (2002) and children aged under 4 (1997)
	MCS [Sweep 2, 2003/05]	HS eligible pregnant women and children aged under 4
	NIHSWS (1997)	HS eligible pregnant women
	SHS	HS eligible pregnant women (1995-2003) and children aged under 4 (1998)
Quality of diet including fruit and veg intake	FCS (1999-2004)	HS eligible children aged under 4
	HEMS (1996-97)	HS eligible pregnant women
	HSE	HS eligible pregnant women (1997-99, 2003-04), breastfeeding women (2002) and children aged under 4 (1997)
	NIHSWS (1997)	HS eligible pregnant women
	SHS	HS eligible pregnant women (1995-2003) and children aged under 4 (1998-2003)
Intake of nutrients from milk, fruit and vegetables	None	N/A

Final Report

Initiation of any/exclusive breastfeeding	CHS (2004/05)	HS eligible infants aged 0-1
	SMR02 (1996 onwards)	HS eligible infants aged 0-1
Duration of any/exclusive breastfeeding	CHS (2004/05)	HS eligible infants aged 0-1
	HSE (2002)	HS eligible infants aged 0-1
	MCS (Sweep 1, 2001/03)	HS eligible infants aged 0-1
	SHS (2003)	HS eligible infants aged 0-1
		HS eligible infants aged 0-1
Intake of formula milk	None	N/A
Timing of the introduction of milk other than breast or formula milk	MCS (Sweep 1, 2001/03)	HS eligible infants aged 0-1
Timing of the introduction of weaning foods	CHS (2004/05)	HS eligible infants aged 0-1
	MCS (Sweep 1, 2001/03)	HS eligible children aged under 1
Type and content of weaning foods	None	N/A
Timing of first contact with maternity services including point of advice on Healthy Start	MCS (Sweep 1, 2001/03)	HS eligible pregnant women
	HES (1996 onwards)	HS eligible pregnant women aged under 18
	SMR02 (1996 onwards)	HS eligible pregnant women aged under 18
	SUS (2005 onwards)	HS eligible pregnant women aged under 18
Intake of vitamin and mineral supplements	HSE (1997-2004)	HS eligible pregnant women and children aged under 4
	SHS	HS eligible pregnant women (1995-2003) and children aged under 4 (1998-2003)
Intake of periconceptual folic acid	HSE (2002)	HS eligible mothers with children aged under 1
Household expenditure on foods and drinks	EFS (2001/02-2004/05)	HS eligible pregnant women and children aged under 4
	FES (1996/97-2000/01)	HS eligible children aged under 4
	NFS (1996-2000)	HS eligible pregnant women and children aged under 4
Maternal iron (haemoglobin or ferritin) levels /anaemia in pregnancy	HSE (2002)	HS eligible mothers with children aged under 1
	MCS (Sweep 1, 2001/03)	HS eligible mothers with children aged under 1
	SMR02 (1996 onwards)	HS eligible pregnant women aged under 18
Baby's gestational age at delivery	BHPS (1999/2000-2004/05)	HS eligible newborns
	HSE (2002)	HS eligible newborns
	MCS (Sweep 1, 2001/03)	HS eligible newborns
	SHS (2003)	HS eligible newborns
	SMR02 (1996 onwards)	HS eligible newborns
	SUS (2005 onwards)	HS eligible newborns
Baby's birth weight	BHPS (1999/2000 – 2004/05)	HS eligible newborns
	HSE (2002)	HS eligible newborns
	MCS [Sweeps 1, 2001/03 and 2, 2003/05]	HS eligible newborns
	HES (1996 onwards)	HS eligible newborns
	SMR02 (1996 onwards)	HS eligible newborns
	SUS (2005 onwards)	HS eligible newborns

Final Report

Length/height and weight of child aged under 4 years	HSE [1996-2004]	HS eligible children aged under 4
	MCS (Sweeps 1, 2001/03 and 2, 2003/05)	HS eligible children aged under 4
	SHS [1998, 2003]	HS eligible children aged under 4
	SMR02 (1996 onwards)	HS eligible children aged under 4
Maternal wellbeing and mental ill health in pregnancy/of mothers with children aged under 4 years	BHPS [1996/97-2004/05]	HS eligible pregnant women and mothers with children aged under 4
	FCS (1999-2002)	HS eligible mothers with children aged under 4
	HSE [1997-2004]	HS eligible pregnant women and mothers with children aged under 4
	MCS [Sweeps 1, 2001/03, 2, 2003/05 and 3, 2006+]	HS eligible pregnant women and mothers with children aged under 4
	NIHSWS [1997, 2001]	HS eligible pregnant women and mothers with children aged under 4
	NDCHS [2002, 2004]	HS eligible mothers with children aged under 4
	SHS [1995, 1998, 2003]	HS eligible pregnant women and mothers with children aged under 4
	SMR02 (1996 onwards)	HS eligible pregnant women and mothers with children aged under 4
Educational and behavioural development of child aged 1 – 3 years	MCS [Sweeps 1, 2001/03 and 2, 2003/05]	HS eligible children aged 1-3

Notes.

Type A data sources:

BHPS = British Household Panel Survey; CHS = Continuous Household Survey; **EFS = Expenditure and Food Survey**; **FCS = Families and Children Study**; FES = Family Expenditure Survey; **FRS= Family Resources Survey**; HEMS = Health Education Monitoring Survey; **HSE = Health Survey for England**; **MCS = Millennium Cohort Study**; NDCHS = New Deal for Communities Household Survey; NFS = National Food Survey; NIHSWS = Northern Ireland Health and Social Wellbeing Survey; SHS = Scottish Health Survey.

Type B data sources:

HES = Hospital Episode Statistics; SMR02 = Scottish Morbidity Record; SUS = Secondary Uses Service.

Type A surveys highlighted in **bold** are expected to continue collecting HS-relevant outcome data in the future. All Type B data sources are expected to be ongoing.

Final Report

5.4. Summary: routine data sources for potential baseline data

These initial results suggest that routine data sources may have the potential to be useful for collection of baseline data among some eligible groups for most priority outcomes included in this search.

Outcomes for which no potential routine data source has been identified for any population group are: a) intake of nutrients from milk, fruit and vegetables; b) intake of formula milk; and c) type/content of weaning foods.

Whilst some data sources report relevant outcomes for one or more eligible groups, only one data source was identified which reported one Healthy Start-relevant outcome for the population group of eligible breastfeeding women. The Health Survey for England reported intake of fruit and/or vegetables for breastfeeding women in their 2002 survey. Subsequent surveys have not reported this outcome for this population group, however.

The seven data sources identified as expected to continue collecting relevant outcome data in the future also appear to provide the potential for collection of intervention group data for comparison in a before-after study design.

5.5. Next steps

When considering the usefulness of these routine data sources for either baseline or intervention group data, it is important to note that we have not yet taken into account the availability or quality of data at the individual level, the detail of how the outcome was measured, or the sample sizes available for each eligible population group. These issues will be considered in subsequent sections.

Final Report

6. Routine data sources for feasible comparative data

6.1. Can routine data sources be used in comparative study designs?

Having identified sources of some routine data on priority outcomes, the next stage was to assess the possibility of using these sources in possible comparisons, both for before-after and concurrent designs. This required examination of issues such as whether or not:

- data could be analysed at the level of women and children eligible for Healthy Start, and
- data were collected on large enough samples to meet sample size considerations

6.2. Methods

Findings from the earlier search for potential baseline data sources had identified the limited capacity of most Type B and C data sources to report on Healthy Start-relevant outcomes and/or eligibility status (Appendix 7). Consequently, when assessing data to be used for comparisons, we only examined the potential of data collected by repeated cross-sectional or longitudinal surveys (Type A data sources) as they were considered most likely to be useful.

Details of this assessment are presented in section 6.3 and at Appendix 8. A summary of relevant Type A data sources is presented at Appendix 9.

Feasibility of these data sources was then assessed in terms of eligibility and sample size. In particular, we were seeking to identify their potential for analysis at the level of women/children eligible for Healthy Start, and their feasibility in light of a sample size calculation.

6.2.1. Level at which data can be analysed

Relevant datasets were trawled to assess whether the available outcome data could be analysed at the level of women / children eligible for Healthy Start and if not, at what level they can be analysed. The inability to analyse data at the level of an individual eligible woman or child was a serious limiting factor in terms of its feasibility for use in any evaluation.

6.2.2. Adequate statistical power to estimate an appropriate size of effect.

An initial criterion to assess priority outcomes of effectiveness was feasibility in light of an a priori sample size calculation; i.e. if differences were to be observed between data collected at different times or between different groups, would the numbers of women or children for whom the outcomes were measured be adequate to rule out chance differences being mistakenly identified as real, or real differences not being detected? The search for potential routine data sources to provide baseline data demonstrated that for no relevant datasets was there any indication that they had conducted a priori sample size calculations for specific population groups of interest to Healthy Start.

Final Report

As an alternative, the feasibility of using data from relevant data sources was assessed according to its ability to achieve 80% statistical power to detect an appropriate size of effect within an appropriately defined period. Sample sizes were assessed using multiple methods (see Appendix 10). The estimates generated by the first method identified the very limited sample size for the population group of eligible pregnant women in the two data sources which reported outcomes for this target group (EFS = <5; HSE = <1) ³. Only one data source, the Health Survey for England, reported one outcome, intake of fruit and vegetables, in one survey for the population group of eligible breastfeeding women (2002). Data are limited however to enable an appropriate estimate of sample size for assessment of feasibility. This is exacerbated by the timing of data collection which could be at any point during the child's first year of life. The sample of breastfeeding mothers will therefore include mothers who may be breastfeeding at any point within that period. No other relevant outcomes for the population group of eligible breastfeeding women were reported by any data source. For the remaining population group of interest, eligible children aged 0-3 years inclusive, sample sizes appeared sufficient to warrant further investigation.

Our power calculations were based on the reported standard deviation (SD) for each outcome within each dataset in combination with the estimated sample size for eligible children aged 0-3 years inclusive. Figures were put into the "PS", the Power and Sample Size Calculation Programme and results reported in SDs. For example, if the SD intake of cow's milk is 1.26 pints a week for 102 children aged 1-3 years inclusive for each comparison group, we would be able to detect a change of 0.50 pints a week and any change higher than this with 80% power and a p-value of 0.05.

It is important to note the multiple methods used to estimate sample size generated an estimated sample *range* for eligible children aged 0-3 years inclusive within each dataset

Table 7: Sample size estimates for four existing data sources DELETED

Further, the recorded sample sizes for control groups in each of the concurrent comparison options are based on an estimate of the total number of non-eligibles. This represents a greater number than would be expected for those non-eligibles who are 'borderline' on the basis of income. This proxy method of sample size estimation for the control groups is not expected to effect the overall power calculation, however. This is due to the power calculation being determined by the smallest comparison group which is always likely to be smaller than the borderline control group within these data sources.

The estimated sample size range for each population group of interest, and power calculations, are mapped to the results of the search for Type A routine data sources for selected outcomes of interest at Appendix 8. The Comments sections in this table provide information on:

- The level at which the data can be analysed, particularly whether data can be analysed at the level of individual children under 4 years eligible for HS;
- Important limitations about the type of data collected; and
- Source of the Standard Deviation used in each power calculation.

³ EFS: Expenditure and Food Survey; HSE: Health Survey for England.

Final Report

The feasibility of routine data sources for selected outcomes of effectiveness was assessed on the basis of this information and is presented in section 6.3 below.

6.3. Results

The results of the search for, and feasibility of, Type A routine data sources which measure a selection of priority outcomes of effectiveness within some comparison options are presented at Appendix 8. The size of effect detectable at 80% statistical power was calculated for each outcome due to the relatively small sample sizes involved in these survey-based data sources.

Four of the Type A data sources were able to describe both the intervention and comparison groups for a number of the questions of interest:

- Expenditure and Food Survey (EFS)
- Families and Children Study (FCS)
- Family Resources Survey (FRS)
- Health Survey for England (HSE)

More detailed information on these sources is provided at Appendix 9.

Although the Healthy Start programme is intended to benefit three main groups (pregnant women, breastfeeding women, and children aged under 4), none of the four surveys collected data for breastfeeding women in the relevant time periods indicated for the intervention or control groups in the highlighted comparisons. In addition, the latest HSE dataset does not collect any relevant outcome data from children aged under 4 years.

The following tables present the results of feasibility assessments for most⁴ priority outcomes of effectiveness from all data sources.

The results have also been summarised in terms of their overall value for a comparative evaluation of Healthy Start. Table 8 presents outcomes which appear to have some potential in their current form within the routine data source to be used for evaluation purposes. Table 9 presents outcomes which appear to have no potential for use in an evaluation whilst Table 10 summarises those outcomes which could have potential for evaluation, subject to further development of how the data is collected in future data collections.

⁴ Priority outcomes not included in this table are: weight gain in pregnancy; early, very early and preterm births; and infant mortality as per original methodology detailed in Methods 2.1

Final Report

Tables 8-10: Use of routine data sources to provide comparative data to evaluate outcomes of effectiveness

Table 8: Outcomes for potential evaluation through (Type A) routine data sources

Outcome	Population group	Availability of baseline and intervention data	Adequate detection of effect @ 80% statistical power	Level of analysis		Relevance of data collected for HS outcome	Comment on adequacy of statistical power	Rating ++++ +++ ++ +
				Individual	Household			
Dietary intake of cow's milk	Infants aged 0-1 year	✓	✓		✓	Proxy variable of receipt, and not intake, of welfare milk	Adequacy of power has not been calculated for infants aged 0-1 year	+
	Children aged 1-<4 years	✓						
Dietary intake of fruit and/or vegetables	Infants aged 0-1 year	✓	✓		✓	Frequency of intake: 'on most days' No quantities	Power adequate for 0-<4s within family level data.	++
	Children aged 1-<4 years	✓						
Types of food and drinks purchased with vouchers	Infants aged 0-1 year	✓	✓		✓	Expenditure on Fruit, Veg, Milk/cheese/eggs & other categories but not specific to vouchers	Power adequate for 0-<4s within family level data	+++
	Children aged 1-<4 years	✓			✓			

Key:

++++ rating: Data available at appropriate* level of HS-eligible with adequate statistical power and direct variable for outcome of interest

+++ rating: Data available at appropriate* level of HS-eligible with adequate statistical power with proxy variable for outcome of interest.

++ rating: Data available at inappropriate* level of HS-eligible with adequate statistical power and direct variable for outcome of interest.

+ rating: Data available at inappropriate* level of HS-eligible with adequate statistical power with proxy variable for outcome of interest.

* **appropriate / inappropriate** refers to the level of data available for analysis. In most cases, data is required at the individual level for analysis with possible exceptions such as purchasing data which can be analysed at the household level.

Final Report

Table 9: Outcomes which can NOT be evaluated through (Type A, B or C) routine data sources

Outcome	Population group	Availability of baseline and intervention data	Adequate detection of effect @ 80% statistical power	Level of analysis		Comment
				Individual	Household	
Dietary intake of cow's milk	Pregnant women	✓	X	✓		Estimated sample size for pregnant women: n < 1
	Breastfeeding women	✓	?	✓		Not possible to estimate sample size for breastfeeding women
Timing of introduction of cow's milk	Infants aged 0-1 year	x				
Dietary intake of fruit and /or vegetables	Pregnant women	✓	X	✓		Estimated sample size for pregnant women: n < 1
	Breastfeeding women	x				
Quality of diet including intake of fruit and vegetables	Pregnant women	✓	X	✓		Estimated sample size for pregnant women: n < 1
	Breastfeeding women	x				
	Infants aged 0-1 year	x				
	Children aged 1-<4 years	x				
Nutrient intake for energy, protein, vitamins and minerals including calcium	Pregnant women	x				
	Breastfeeding women	x				
	Infants aged 0-1 year	x				
	Children aged 1-<4 years	x				
Intake of multivitamin / mineral supplements	Pregnant women	✓	X	✓		Estimated sample size for pregnant women: n < 1
	Breastfeeding women	x				
	Infants aged 0-1 year	✓	X	✓		Intake of any type of supplement to improve health not prescribed by GP.
	Children aged 1-<4 years	✓		✓		
Intake of periconceptional folic acid	Pregnant women	✓	X	✓		Estimated sample size for pregnant women: n < 1

Final Report

Types of food and drinks purchased with vouchers	Pregnant women	✓	X		✓	Estimated sample size for pregnant women: n < 5
	Breastfeeding women	X				
Displacement of income to other items, e.g. alcohol	Pregnant women	X				The displacement variable is not recorded directly in the EFS data set but can be derived from the recorded patterns of expenditure
	Breastfeeding women	X				
	Families with infants aged 0-1	✓	x		✓	
	Families with children aged 0-<4	✓			✓	
Duration of breastfeeding (any and/or exclusive)	Infants aged 0-1 year	X				
Intake of formula milk	Infants aged 0-1 year	X				
	Children aged 1-<4 years	X				
Type of weaning foods	Infants aged 0-1 year	x				
Timing of introduction of weaning foods	Infants aged 0-1 year	x				
Educational and behavioural development	Children aged 1-<4 years	x				Currently finalising utility of CHIC Core / RCPCH Core Dataset as possible Type C data source
Maternal iron (haemoglobin or ferritin) levels	Pregnant women	x				
Length of infant / child	Infants/ children aged 0-<4 years	x				

Final Report

Table 10: Outcomes amenable to potential evaluation through (Type B) routine data sources

Outcome	Population group	Availability of baseline and intervention data	Adequate detection of effect @ 80% statistical power	Level of analysis		Comment	Potential strategy to enable use of data source
				Individual	Household		
Initiation of breastfeeding (any and/or exclusive)	Infants aged 0-1 year	✓	Feasible based on high population coverage	✓		Limited data on HS status	Inclusion of HS eligible field into dataset
Timing of first contact with maternity services including advice about HS	Pregnant women	✓		✓			
Maternal anaemia in pregnancy	Pregnant women	✓		✓			
Maternal well being and mental health	Pregnant women	✓		✓			
	Mothers of children aged 0-<4 years	✓		✓			
Mean and/or low infant birth weight	Newborns	✓		✓			
Gestational age at delivery	Newborns	✓		✓			
Weight of infant / child	Infants aged 0-1 year	✓		✓			
	Children aged 1-<4 years	✓	✓				

6.4. Summary: routine data sources for use in comparison options

Table 8 illustrates the extremely limited scope of routine data sources to provide relevant and quality data of effectiveness for Healthy Start when using either a before-after or concurrent comparison option. Three outcomes of interest are reported with sufficient statistical power to measure an appropriate change of effect for the single population group of children aged under 4 years. However, the usefulness of the Type A routine data sources to evaluate these outcomes is severely curtailed by the nature of data collection for each variable. *As a result, none of the outcomes can be evaluated at the level of a four plus rating, whereby the data are available at the level of individual Healthy Start eligible with a direct variable for the outcome of interest.*

In all cases, the outcome is reported for the household only. The inability to disaggregate the data by eligible population groups precludes the use of routine data sources for a comparative evaluation of outcomes for dietary intake. *Any effect on dietary intake of cow's milk, fruit and/or vegetables by children under 4 might be attributable to a change in dietary intake of the father or any other member of the household.* The measure of dietary intake of cow's milk is further limited due to the proxy nature of this variable based on 'receipt' of milk rather than 'intake' per se.

The outcome of 'types of foods and drinks purchased with Healthy Start vouchers' is less problematic at the household level. Indeed, a measurable change of household expenditure on relevant foods and drinks as a result of Healthy Start is likely to be the only feasible measure of this outcome. The variable currently reporting data for this outcome reports total household expenditure and not expenditure specific to Healthy Start vouchers. Given the weekly frequency of the Healthy Start voucher, one could assume that any difference between total expenditure by Healthy Start recipients compared to non Healthy Start recipients is likely to be as a result of the additional purchasing power from the voucher. *In summary, the ability to measure a change in purchasing of relevant foods and drinks for eligible households who have children aged less than 4 years does appear to be feasible using an existing survey-based routine data source.*

Table 9 clearly illustrates the lack of availability of data for all priority outcomes relevant to the target population group of breastfeeding women for a comparative evaluation. This is to be expected given the absence of data for this population group in the original search for either baseline or comparative data. Of greater significance, none of the Type A sources which reported outcomes for pregnant women has adequate sample sizes for pregnant women who are eligible for Healthy Start. *Existing routine data sources are not considered feasible therefore for the evaluation of any dietary intake and food expenditure outcomes for pregnant and breastfeeding women.*

This table also highlights those priority outcomes for which data are not reported in any comparative routine data sources for any population group of interest, namely: a) timing of introduction of cow's milk; b) intake of nutrients from milk, fruit and vegetables; c) intake of periconceptional folic acid; d) intake of formula milk; e) type, and timing of introduction, of weaning foods; f) duration of any and/or exclusive breastfeeding; g) educational and behavioural development; and maternal iron levels.

Table 10 highlights the potential to use future routine Type B data sources to

Final Report

evaluate the impact of Healthy Start in a comparative study examining priority outcomes for infant feeding (initiation only), nutritional and health status. All these outcomes were reported with adequate statistical power. *However, none of these data sources are currently useful for the purposes of an evaluation of Healthy Start due to the limited data on eligibility status. The collection of appropriate data for this range of outcomes can be achieved however by the inclusion of a flag for 'Healthy Start eligibility status' within the three relevant datasets (SMR02, HES, SUS).*

Finally, in relation to the conduct of routine surveys in general; we found no relevant datasets in which *a priori* sample size calculations had been conducted for specific population groups of interest. This is an issue that has wider relevance than the conduct of this specific evaluation. Such considerations at the planning stage of routine data collection would enhance the value of each survey, perhaps especially in regard to assessing inequalities in health.

Final Report

7. Adapting routine data sources, and potential contribution of other data sources

7.1. The potential for developing existing data sources, and for using other sources of data

The severe limitations identified in existing routine data (Chapters 5 and 6) encouraged us to consider the potential for adapting and developing existing routine data collection.

Further, in searching for existing routine data sources, other potential sources of data were identified. These other sources identified included:

- The possibility of using commercial data sources to examine purchasing patterns
- Data sets held by government departments that may support evaluation of process outcomes
- Complementary data sources to support limited national data.

These sources were explored in the next stage of this work.

7.2. Adapting routine data sources

Several of the routine data sources examined had the potential to be used for an evaluation, but were lacking in some way, such as information about Healthy Start eligibility status, or an appropriate sample size. It is possible that relatively simple adaptations to ongoing, routine data collection could enable systematic reporting of data to monitor and evaluate the national Healthy Start programme at regular and frequent intervals as required, through concurrent comparisons or examination of trends over time.

Such adaptations could be beneficial for a variety of users involved in the fields of healthy eating and inequalities. They could address many of the fundamental gaps in routine data sources for core dietary intake and weaning food data, as well as providing routine data on infant feeding, food intake, weaning and nutritional/health status outcomes for the poorly sampled hard-to-reach groups experiencing low incomes and social disadvantage. The proposed adaptations would require policy level support and possibly, some funding considerations.

In order to achieve this advance towards enabling routine, cost-effective monitoring and evaluation of Healthy Start, relatively simple adaptation of five key data sources would be required: the Infant Feeding Survey, the Low Income Diet and Nutrition Survey, the Health Survey for England, and the Maternal Health and Child Health Datasets.

Subject to the status of the existing data source, one or several of the following adaptations may be necessary:

1. Inclusion of new variables within existing survey questionnaires to:
 - a. Identify individuals eligible for Healthy Start
 - b. Report a measure more precisely for the purposes of Healthy Start
 - c. Report an outcome for which data are not currently collected

Final Report

2. Increased sampling for identified population groups to:
 - a. Achieve adequate statistical power for currently under-represented groups
 - b. Include a new population group within the sampling frame

It is important to note that the new variable to 'identify individuals eligible for Healthy Start' (1a) will include data for the estimated 15% of individuals who are eligible for Healthy Start but do not register to benefit from the entitlements, and the further 15% who do not use the vouchers (Department of Health discussion, December 2006). This approach is considered suitable for two reasons: a) data analysis would be based on an 'intention to treat' model where any reported effect includes those participants who should have but did not receive the intervention; and b) the data protection issues associated with identifying individual recipients registered with Healthy Start are likely to be more complex than those for identifying individuals who are eligible on the basis of recorded income or benefit status.

A further adaptation for consideration is the inclusion of a unique identifier to enable records of individual 'Healthy Start eligibles and/or recipients' to be linked across data sets. A key example might include linkage between food and/or nutrient intake data reported in the Low Income Diet & Nutrition Survey with nutritional or health status outcome data reported in the Maternal Health and Child Health Datasets. Unique identifiers might include an individual's NHS number or National Insurance number. Examination of the governance issues related to data linkages would be required.

Table 11 details the specific adaptations required for each of the five routine data sources which could provide prospective data for ongoing monitoring and evaluation of Healthy Start.

NOTE: In the recently-published national survey of infant feeding in the UK (Bolling et al 2007, published 14/5/07 after this scoping work has been concluded), data are presented on whether or not mothers had received food vouchers. It may be that some of the key adaptations to this dataset have already been put in place, although sample size remains an issue.

Final Report

Table 11: Potential routine data sources for prospective evaluation of Healthy Start (HS)

Existing routine data source	Outcome	Requires HS-eligible variables	Requires increased sampling of target population groups	Comment
Infant Feeding Survey	Initiation of any & exclusive breastfeeding	✓	✓	This is the only known ongoing potential source for these priority outcomes, except initiation of breastfeeding which could be collected from Child Health Dataset (see below)
	Duration of any & exclusive breastfeeding			
	Type and content of weaning foods			
	Timing of introduction of cow's milk	✓	✓	Neither of these outcomes is currently reported in IFS or any known data source. Inclusion in the IFS is considered best option.
	Timing of introduction of weaning foods			
Low Income Diet & Nutrition Survey	Dietary intake of fruit, vegetables, cow's milk and infant formula	✓	✓	Urgent requirement for publication of this highly relevant survey to confirm which HS-eligible variables are reported and adaptations required. High quality intake & nutrient data expected from this source. LIDNS plans to collect detailed quantitative information on food consumption (by 4 x
	Quality of diet including fruit and vegetables		National Diet & Nutrition Survey did not include pregnant women, including teenagers. LIDNS might require specific inclusion of these population groups.	
	Nutrient intake of energy, protein, minerals and vitamins, including calcium		Variables on infant feeding may be reported. If not, requires inclusion to enable analysis for breastfeeding women. A priori sample sizes	

Final Report

	Nutritional status indices (details not yet available)		for pregnant women should allow for % expected to breastfeed to ensure adequate power for 'breastfeeding women' group.	multiple pass 24 hour recall) and nutrient intake, plus blood samples for analysis of nutritional status indices
Health Survey for England	Dietary intake of cow's milk for pregnant women, including teenagers	x	✓ Estimated sample size for HS-eligible pregnant women = <1. Increased sampling would also need to recruit adequate numbers of pregnant teenagers.	Adaptation of this dataset for these outcomes would not be required if the Low Income Diet & Nutrition Survey can provide intake data for these HS-eligible population groups.
	Dietary intake of cow's milk for breastfeeding women	✓	✓ Requires infant feeding status variable to enable analysis for breastfeeding women A priori sample sizes for pregnant women should allow for % expected to breastfeed to ensure adequate power for 'breastfeeding women' group.	
	Intake of vitamin supplements by pregnant women	✓	✓ Already reports on use of multivitamin and folic acid. Requires additional variable to identify if vitamin supplement was provided by Healthy Start. Estimated sample size for HS-eligible pregnant women = <1. Increased sampling would also need to recruit adequate numbers of pregnant teenagers.	This is the only known ongoing potential source for this priority outcome.
	Intake of vitamin supplements by breastfeeding women		✓ A priori sample sizes for pregnant women should allow for % expected to breastfeed to ensure adequate power for 'breastfeeding women' group.	

Final Report

	Intake of vitamin supplements by children aged under 4 years		✓ Statistical power was inadequate based on estimated sample size of n=94 HS-eligible children.	
	Intake of periconceptional folic acid by pregnant women			This outcome would be available from adapted Maternal Health Dataset (see below).
Maternal Health and Child Health Datasets	Mean and/or low birth weight	✓	X	Request for HS flag already submitted. Policy support required for inclusion of flag and mandating of relevant data for national collection & archive (as detailed in 2.4 above).
	Maternal anaemia in pregnancy			
	Maternal well being and mental health			
	Gestational age at delivery			
	Intake of folic acid prior to and during pregnancy			
	Timing of first contact with maternity services			
	Explanatory (demographic and health behaviour) outcomes including smoking and alcohol status			
	Length of infant / child for under 4 years	✓	X	This outcome is not planned to be reported in Child Health dataset. Inclusion in this single data source to routinely report all HS-relevant nutritional/ health status outcomes would be the best option.

Note: Outcome relates to all population groups of interest unless specified otherwise, i.e. pregnant women; pregnant teenagers; breastfeeding women; infants aged 0 - >1 year; children aged 1 - >4 years.

Final Report

7.2.1. Wider issues in adapting routine data collection

Our discussions with members of the research team, the Advisory Group and colleagues in the NHS and related agencies suggested that government departments and local agencies would benefit from incorporating measurements of uptake and possible outcomes of Healthy Start into service agreement (e.g. Local Delivery Plans) and performance management metrics, particularly in relation to working in partnership across communities.

7.2.2. Summary: adapting routine data collection

The five relevant data sources shown in Table 11 have the potential, if adapted, to report routine data on priority outcomes of effectiveness to measure reported changes in dietary, supplemental and nutrient intake, infant feeding and weaning practices, a range of nutritional and health status outcomes, and timely contact of eligible women with maternity services. The data would be high quality in terms of the representation of all target eligible population groups, and would be of sufficient size for useful analysis. The ongoing nature of data reporting by each data source would enable monitoring of trends over time for the intervention group based on repeat cross-sectional surveys. However, the data quality has not yet been assessed nor any data protection issues in enhancing the data sources.

Government departments and local agencies could benefit from incorporating measurements of uptake and possible outcomes of Healthy Start into service agreement and performance management metrics, particularly in relation to working in partnership across communities.

7.3. Commercial retailer data

The main strength of Healthy Start, compared to the former Welfare Food Scheme, is likely to be the shift from a milk token scheme towards a food support programme, delivered through the more flexible voucher component. The main detriment is likely to be the reduced financial support for the purchase of formula milk. One might argue, therefore, that the most critical function of a national evaluation of the Healthy Start Scheme is to measure any change in purchase, use and consumption of fruit and vegetables, cow's milk and formula milk. Further, one might expect increased access and routine use of some fruit and vegetables could lead to a long term lifestyle change in food-related behaviour and associated improvement in overall quality of diet.

Routine survey-based data sources have been found to be extremely limited for the purposes of measuring these outcomes (see Chapter 5). Commercial retailers registered with Healthy Start may provide a useful source of existing data to measure changes in patterns of purchasing of fruit, vegetables, cow's milk and formula for the same individuals over time.

Purchasing data from a commercial retailer would potentially be available at the household level for all target groups of eligibility within Healthy Start. Indeed, household level data are considered the only feasible measure of this outcome from existing data sources. Household level data are not a problem *per se* for monitoring changes in purchasing of foods and drinks. With the possible

Final Report

exception of formula milk, it would however be inappropriate for use as a proxy for intake of foods or drinks by individual recipients.

The following table illustrates which retailers have been used for expenditure of the vouchers by recipients of Healthy Start. Data from Devon and Cornwall represent actual proportions reported from the pilot phase of programme introduction whereas data from England are indicative only following the relatively recent roll-out in November 2006 (Department of Health correspondence 2007).

Table 12: Retailer use for expenditure of vouchers

Retailers where vouchers are being used	% of voucher use: Phase 1 (Devon & Cornwall)	% of voucher use: Phase 2 (England)
Multiples	63	75
Independents	22	12
Milk roundsmen	11	9
Chemists	4	2.5
Wholesalers	-	0.8
Box schemes	-	0.4
Market traders	-	0.15

These data suggest that 'multiples' (i.e. supermarkets) is the main category of retailer being used for expenditure of Healthy Start vouchers. Multiple retailers appear to have a greater penetration in England as compared to Devon and Cornwall. This may reflect the higher proportion of rural and remote areas in Devon and Cornwall whereby multiple retailers are less accessible (Kaufman et al 1999). Access to large supermarkets may also be limited in many deprived urban areas despite being the preferred choice of food retailer outlet for the majority of consumers (Caraher et al 1998). This may account for the relatively extensive use of independent retailers which tend to provide a more limited range of fresh produce at a relatively higher price (Chung & Myers 1999).

While noting these potential limitations to generalisability, it appears that supermarkets represent approximately 70% of the commercial sector in which vouchers are redeemed by Healthy Start recipients. Multiple retailers have the potential therefore to be a useful existing data source to measure a change in household purchasing patterns on fruit, vegetables, milks and formula for over two thirds of Healthy Start recipients.

An analysis of individual supermarkets used by Healthy Start recipients to redeem their vouchers is not available for the purposes of this scoping project. The current market share for the main supermarket chains in the UK for all population groups, however, is dominated by Tesco at 31% (Evening Standard 2007). This represents nearly double that of Asda, the second largest supermarket with 17% market share (Evening Standard 2007). In comparison, Morrisons held 6% of market share in January 2003 (Guardian 2003). Tesco also appears to have experienced considerably greater market growth in recent years with its share increasing from 26% in 2003 to 31% in 2007 compared to Asda which has retained its share of 17% during the same period. Other major supermarkets in the UK which may be used by Healthy Start recipients include: Safeway; Sainsbury, Netto; Lidl; Somerfield; Kwik Save; and Iceland (frozen foods). Supermarkets such as Marks & Spencer and Waitrose are considered less relevant for the purposes of data collection for Healthy Start due to their market focus on relatively expensive premium quality products.

Final Report

Data on foods and drinks purchased by Healthy Start recipients at Tesco supermarkets would therefore provide approximately 30% of product expenditure for the approximate 70% of recipients who have redeemed their vouchers. It is important to note any data for these recipients would not include the estimated 15% of recipients who have not redeemed their vouchers or the further 15% of women and families who are likely to be eligible, but have not registered, for Healthy Start vouchers (Department of Health correspondence 2006). Data from Tesco supermarkets could provide purchasing data for approximately:

- 30% of all Healthy Start registered recipients who redeem their vouchers at a multiple retailer
- 21% of all Healthy Start registered recipients who redeem their vouchers at a registered retailer
- 18% of all Healthy Start registered recipients (regardless of voucher redemption)
- 16% of all Healthy Start eligibles (regardless of uptake)

The volume of data potentially available from a single multiple retailer dataset is likely to be extremely large and more than adequate to achieve appropriate statistical power to detect a relatively small size of effect for all eligibility population groups in the Healthy Start Scheme. For example, Morrisons supermarket is reported to have over nine million customers visiting their stores each week (Morrisons 2007). However, the limited proportions of recipients represented by a single multiple retailer highlights the need for an analysis of the main supermarkets used by Healthy Start recipients. This would inform the number of multiple retailers from whom purchasing data should be collected in order to achieve an appropriate level of representation in a national evaluation of Healthy Start.

It is important to also consider the limitations of such information. First, with no baseline measures, they are unlikely to contribute to an evaluation of Healthy Start vs. the Welfare Food Scheme. Second, if data are available only from large supermarkets, they will tell us little about families who shop in smaller, local shops. Third, there will be important issues of data protection. Finally, it is as yet unknown whether or not supermarkets would be willing to cooperate in such work, or what the costs would be.

7.3.1. Utility of supermarket data

Most supermarket chains report store expenditure data at two levels:

1. Till receipts: expenditure on all items for all consumers
2. Reward scheme: expenditure on all items for consumers who have registered with the reward point scheme and show their card at the point of purchase.

Till receipt data could potentially be accessed for single and/or repeat cross-sectional surveys. Reward Scheme data have the potential to provide both cross-sectional and longitudinal data on household food purchasing patterns.

Use of either of these datasets would require the ability to identify Healthy Start recipients. The capacity to do this through a proxy variable of postcode or income could be explored within existing till receipt and reward scheme datasets for key multiple retailers.

The large sample sizes potentially available from either of these types of dataset would improve the precision of the estimate of purchasing patterns. A proxy variable of income would be likely to produce a more precise identification method than that of

Final Report

postcode, thereby increasing confidence that any measured change in purchasing patterns is a result of Healthy Start. These datasets would not include any specific data on use of Healthy Start vouchers at each point of sale. Therefore, any change in household purchasing patterns for identified Healthy Start recipients would be assumed to be as a result of expenditure of the vouchers.

Alternatively, both till receipt and reward scheme datasets could be linked to a record of when the Healthy Start voucher is used at each point of sale. Such a system might exist or be relatively simple to establish as for other discount vouchers accepted in supermarket stores.

This system would have two advantages: a) to identify Healthy Start recipients, and b) to provide purchasing data which are directly linked to use of Healthy Start vouchers in the weekly shop. This would remove the source of error generated from the assumption that a Healthy Start beneficiary has used their voucher for that particular shopping basket and at that specific retailer. This is particularly relevant for recipients who use multiple retailers to spend their vouchers, and who are less likely to 'spend' their voucher at each visit to the retailer of interest. The relatively limited value of the Healthy Start vouchers increases confidence however that reported frequent and regular expenditure of the voucher at the retailer of interest does represent total expenditure of vouchers by the beneficiary.

The Reward Scheme datasets also have the potential for inclusion of a flag to identify an individual Healthy Start beneficiary. This system would have two distinct advantages: a) the ability for data linkage with relevant demographic data held within existing supermarket datasets for the purposes of analysis of explanatory variables; and b) the ability to collect longitudinal data to measure the incremental effect of Healthy Start over time. Discussions with the Public Health Observatory (Yorkshire & Humber) have highlighted this as an option currently under consideration by Tesco.

In the event of a flag to identify individual Healthy Start recipients, purchasing data could also potentially be linked to other data sets, such as the Maternal Health and Child Health Datasets, for analysis of associated changes in nutritional and/or health status. Such linkages would also facilitate adjustment for the effects of key explanatory variables such as smoking and/or alcohol consumption.

Recent discussions with senior representatives from Tesco supermarket suggested a linkage between expenditure of Healthy Start vouchers and club-card data would be fairly straightforward and is currently under consideration. This would enable analysis of purchasing data over time for individual Healthy Start recipients who have Tesco club-cards. Retrospective analysis of purchasing patterns for those same individuals who had a club-card prior to becoming recipients of Healthy Start would also enable a before-after comparison of purchasing patterns for those individuals. This approach could provide a model for replication in other multiple or independent retailers who employ both Electronic Point of Sale (EPOS) and reward scheme systems.

The potential of both systems to identify Healthy Start recipients could be explored. The inclusion of a system which reports use of Healthy Start vouchers and a flag to identify individual recipients would enable Reward Scheme data to provide feasible, high quality, longitudinal data from ongoing data sources to measure:

1. Changes over time in purchasing patterns for all relevant Healthy Start products, namely, fruit, vegetables, milk and infant formula

Final Report

2. Changes over time in purchasing patterns for all target groups of Healthy Start recipients including pregnant women and pregnant teenagers
3. Changes over time in purchasing patterns for the total food basket as an indirect result of Healthy Start on healthy eating
4. Before-after comparison of purchasing patterns as detailed in 1-3 above.

7.3.2. Utility of data from independent retailers

Independent retailers represent approximately 12% of expenditure of Healthy Start vouchers in England. This proportion is likely to be relatively higher in rural and remote areas as indicated by the Devon and Cornwall data detailed in Table 12 above and reported in the most deprived urban areas (Caraher et al 1998; Chung & Myers 1999). Purchasing data from independent retailers is likely to be important therefore to represent the potentially 'most deprived' sectors of the target populations in terms of income and/or access to healthy food choices.

Till receipt data are potentially available from independent retailers as well as larger supermarkets. Independents may have the existing capacity to identify Healthy Start eligibles or recipients through a proxy variable of postcode or income or through records of use of Healthy Start vouchers at the point of sale as for other discount vouchers.

Analysis of the number and type of independent retailers utilised by Healthy Start recipients is required. The feasibility of collection of till receipt data from independent retailers can then be explored.

7.3.3. Summary: Commercial retailer data sources

Important limitations of using data from commercial retailer sources have been described: they could not be used in a comparison of Healthy Start with the Welfare Food Scheme; there are important issues of representativeness and governance; and the willingness of retailers to cooperate is not known.

However, till receipt data could have the potential to provide cross-sectional data to monitor household purchasing patterns for all Healthy Start products across all Healthy Start beneficiary groups. The collection of till receipt data from all multiple and independent retailers would provide purchasing data for over 80% of Healthy Start recipients, including those likely to be most disadvantaged.

Reward schemes have the potential to provide cross-sectional and longitudinal data. These data could be used to monitor household purchasing patterns for all Healthy Start products across all beneficiary groups, as well as incremental changes over time. Reward schemes may not be available for all multiple and particularly, independent retailers. Therefore, the proportion of Healthy Start recipients for whom purchasing data can be collected from Reward schemes is likely to be less than 80% and may have lower representation from the most disadvantaged beneficiary groups.

7.4. Healthy Start Programme Data Sets

We are aware of four data sets held within the relevant government department for use in the delivery of the Healthy Start programme:

1. Benefits agency dataset (Department of Inland Revenue)
 - a. Data on eligible and actual recipients registered on Healthy Start

Final Report

- b. Former data on eligible and actual recipients of the Welfare Food Scheme
2. Voucher agency dataset (Token Distribution Unit, Chelmsford)
 - a. Data on distribution and possibly receipt and use of vouchers
3. NHS fraud dataset (NHS Fraud Unit)
 - a. Data on appropriate and fraudulent use of vouchers
4. Registered commercial retailers dataset (?Department of Health)

We have limited knowledge of these data sets and the types of data stored within them. It is assumed however that measurement of some priority outcomes relevant to the process of Healthy Start and its related impact on various sectors may be feasible through use of these data sets.

Some of the data linkages within a single data set may be subject to governance issues regarding data protection, for example, linking of individual postcode or date of birth data to registration on Healthy Start. Other data linkages between data sets are likely to be subject to governance issues, for example, linking of data regarding length of participation in the Scheme with health service data sets via a unique identifier such as National Insurance Number. These issues may limit the feasibility of more detailed analysis by population group or region as well as the potential to map process outcomes with outcomes of effectiveness at the level of the individual beneficiary.

The following table identifies the potential data set for monitoring the impact of Healthy Start for some process outcomes on the target population:

Final Report

Table 13: Potential existing data sets to measure outcomes reporting the impact of Healthy Start on the target population

Priority outcome	Data set	Comment
Number / proportion of individuals eligible for Healthy Start	Benefits Agency	These combined data would inform the take-up rate for Healthy Start.
Number / proportion of recipients registered for Healthy Start	Benefits Agency	Additional analysis for take-up rates by pregnant teenagers could be undertaken using the 'date of birth' variable reported in the application form. Variations in take-up rates by region or locality could be assessed based on the 'postcode' variable reported in the application form using geographical mapping techniques such as spatial analysis (Smith et al 2006, APHO 2005)
Early recruitment into Healthy Start	Benefits Agency	Assumes data on 'expected date of delivery' is extracted from application form to assess stage of pregnancy at point of registration
Length of participation in Healthy Start	Benefits Agency	Assumes data-linkages are available to track individuals who move through pregnancy to motherhood and possible further pregnancies. This outcome data could potentially be linked to individual nutritional and health status outcome data reported in the proposed Maternal & Child Services data set. This would require linkage via a unique identifier such as National Insurance No.
Access to local registered retailer	Registered commercial retailers	Assumes 'postcode' data on application form can be extracted for spatial analysis using geographical mapping techniques (Smith et al 2006, APHO 2005)
Equity of value of vouchers within and between regions	Registered commercial retailers	Assumes 'postcode' data on application form can be extracted for linking with regional food pricing data using geographical mapping techniques such as spatial analysis (Smith et al 2006, APHO 2005)
Mechanisms for beneficiary to redeem full value of voucher	NHS fraud	Possible reported cases of 'book', 'change' or other systems to redeem full value of voucher

7.4.1. Summary: Healthy Start programme data sets

Measuring process outcomes is an essential part of any evaluation. The process outcomes which may potentially be measured using data reported in one of the Healthy Start Programme data sets are detailed in Table 13 above. These all relate to the category of measuring the impact of Healthy Start on the target population.

The feasibility of measuring these outcomes is subject to the assumptions outlined in the Table. In turn, these assumptions are subject to governance issues regarding data protection requirements.

7.5. Complementary data sources

Other data sources could be useful to improve the overall quality of existing national evaluation data, to support national data, and/or as an alternative data source in the face of no available national data.

In the first instance, regional data may be useful to provide more detailed data on specific outcomes, for example, collection of weighed food records to provide a more rigorous assessment of dietary intake collected by estimated food records. Regional data may also be useful to boost limited data at the national level, for example, intake data from specific population groups of interest such as pregnant teenagers or women and children from minority ethnic groups to support data from the Low Income Diet & Nutrition Survey.

Some of the more potentially useful sources of complementary data are discussed briefly below.

7.5.1. 'Local boosts' of national surveys

Additional data can be collected at the local level to support existing national data. 'Local boosts' are usually undertaken to oversample the national survey at a local level to increase the sample size to generate more robust local results (APHO 2005). 'Local boosts' of the Health Survey for England (HSE) have been undertaken for this purpose. Examples include a local boost survey of residents in Camden & Islington Healthy Authority in 1999 and six Local Authority areas in Merseyside in 2003-4 (APHO 2005).

The Association of Public Health Observatories has undertaken a broad assessment of data sources for surveillance of lifestyle measures, including use of local boosts to provide monitoring data for dietary behaviours (APHO 2005). The APHO suggests the primary utility of data from 'local boosts' is for comparison with national and regional benchmarks and with other Local Authorities and Primary Care Trusts. Very large boosts would be required, however, to enable analysis of within-area inequalities by age, ethnicity or area of residence, particularly where the size of change is likely to be small. The suitability of 'local boosts' to monitor *trends over time* is dependent on plans to repeat the related national survey (2005).

'Local boosts' could, therefore, be used for the purposes of increasing sample sizes to collect food and drink intake and all types of infant feeding data among specific population groups of interest for Healthy Start. Additional local data could be used to support three of the five national surveys identified for potential adaptation for the

Final Report

purposes of Healthy Start. This is due to the current limiting factor in terms of adequate sample size for specific population groups.

It is important to note that the potential of data from either the 'local boosts' or the national surveys themselves is wholly dependent on the inclusion of variables to identify individuals 'eligible for Healthy Start'. Local boosts would be of limited value per se if these adaptations were not implemented for the relevant ongoing national surveys.

The following table details the population groups which would benefit from boosting of sample size by additional local data collection for each survey of interest.

Table 14: Potential 'local boosts' to support future national surveys

Existing national survey	Population groups for targeting by local boost
The Infant Feeding Survey	All low income groups potentially eligible for Healthy Start
The Health Survey for England	Pregnant women Breastfeeding women
The Low Income Diet & Nutrition Survey	To be confirmed following publication of the recent survey

The methods used by each national survey would need to be replicated for any local data collection. This would enable aggregation of the data and ensure comparability and rigour.

The ability to use these data for monitoring and evaluation of Healthy Start is therefore dependent on the inclusion of 'Healthy Start eligible' variables for both the national and local surveys. Comparison options for the cross-sectional data generated from a single time-point would include a national benchmark or a concurrent comparison group. Comparison options generated from repeat cross-sectional surveys would enable monitoring of trends over time with the potential for additional comparison with benchmark data.

7.5.2. Summary: Local boosts to routine data collection

Local boosts have potential value to support national routine data collected by adapted, ongoing surveys. They may be particularly useful in the event of a reduction among a relevant population group due to a change in sampling strategy for that particular survey.

7.5.3. 'Best practice' information systems

Some regional information systems are considered to be relatively well developed and could be considered to represent 'best practice' in terms of their data capacity for monitoring and surveillance activities. Examples include the former NW Thames region and the West Midlands information systems.

These regional information systems may have the potential to provide more detailed data on the effects of Healthy Start for different types of regions or population groups to complement available national data. Such information systems may also report measures for outcomes not included in national data sources. In this case, an

Final Report

essential source of regional outcome data could be used for potential extrapolation to the national level, thereby filling a core gap in outcome data.

The actual potential of these sources could be further explored in the short term in the event of gaps for core outcome data at the national level. Alternatively, these data sources may have potential utility in the medium term to investigate regional differences in the effects of Healthy Start identified by national data sources.

7.5.4. Before-after study of Healthy Start in Sheffield

A local evaluation of the impact of Healthy Start on low-income pregnant women and post partum women and their infants is currently being implemented in Sheffield. The before-after design of this study has the potential to provide data for several 'priority outcomes' for recipients of the Welfare Food Scheme compared to the Healthy Start Scheme. This includes outcomes of effectiveness (for example, dietary and nutrient intake) and outcomes to describe the impact of Healthy Start on target recipients and health providers.

Research questions addressed by this study include:

1. Will the introduction of the 'Healthy Start' Scheme affect the dietary intake of pregnant women and new mothers in Sheffield?
2. How do household income, ethnicity, maternal age and education level, dietary intake, cooking ability and shopping behaviour of mothers in Sheffield, influence the feeding of their infants?
3. Do health and social care practitioners in Sheffield have the expertise, confidence and capacity to provide the dietary information recommended under Healthy Start, to low-income pregnant women and new mothers?

Eligibility criteria included 'receipt of milk tokens', 'being a teenager', 'residency at Sure Start areas of Sheffield' and 'residency at most deprived electoral wards according to the Index of Multiple Deprivation'. These criteria reflected the differences in eligibility criteria between the two Schemes and therefore include future recipients of Healthy Start who were not entitled to receive benefits under the WFS.

The 'before' or baseline study period ran from November 2005 to November 2006 during which, a total of 282 pregnant women and 221 postpartum women were recruited. This includes approximately 80% White, and 20% Pakistani, women and a sub-sample of pregnant teenagers and women living in Sure Start areas. The sample comprises 'before' data for 35% of pregnant women and 41% of mothers who were WFS recipients for comparison with recipients of Healthy Start. Conversely, 'baseline' data are available for 65% of pregnant women and 59% of mothers who were not entitled to WFS but have become recipients of Healthy Start. Data collection for the one year 'after' study phase began in May 2007.

All participants completed a 'Subject Information Questionnaire' during pregnancy and at monthly intervals from 1 – 9 months postpartum. An 'Infant Feeding Questionnaire' was also completed by all mothers at the same time points.

Methods to measure dietary and nutrient intake for Caucasian women comprised a semi-quantified Food Frequency Questionnaire (FFQ) and 24 hour dietary recall. The FFQ had been validated amongst low-income women in Sheffield for the

Final Report

ALSPAC study. Intake data were collected from Pakistani women by 24 hour dietary recall and food diaries. All measures were implemented during pregnancy and at monthly intervals from 1-9 months postpartum.

Sample sizes for mothers within this study are comparable to those estimated to be available for new mothers eligible for Healthy Start within existing national routine data sources. All participants within the Sheffield study are also 'recipients' of Healthy Start as opposed to being 'eligible' for benefits, as in the case of routine data sources. The strength of these data for evaluation of outcomes for pregnant and breastfeeding women is particularly marked in the absence of any outcomes being reported in existing routine data sources for these population groups.

7.5.5. Summary: Sheffield before-after study

This study has the potential to provide good quality, before-after data on dietary intake, infant feeding and a range of descriptive outcomes for all eligible groups within Healthy Start, including a sub-group of Pakistani women and service providers. Indeed, the availability of potentially unique baseline data to enable a comparison of Healthy Start with the former WFS warrants further examination of this potentially rich data source. The ability to collect further longitudinal data for the cohort children as they progress to 4 years of age and beyond and from 'new' pregnant women within the cohort due to subsequent pregnancies should also be explored. Data collection is currently due to be completed by May 2008.

These data have the potential to 'stand-alone' as a detailed local evaluation, to support national data from adapted routine data sources and for possible extrapolation to other comparable areas using synthetic estimate techniques. It could also be included as a sentinel site within a larger cohort study (see 8 below) for a national evaluation specific to the purposes of Healthy Start.

8. Purposive prospective studies

8.1. Potential contribution of prospective studies

Previous chapters have indicated that the contribution of existing routine data sources is limited. There are also some outcomes where data are simply not collected, such as women's, health professionals' and retailers' views of the two programmes.

Prospective studies to collect data for the specific purpose of monitoring and evaluation of Healthy Start could therefore have two important functions:

1. As a stand-alone method to evaluate Healthy Start

In this scenario, a purposive study might be considered the best evaluation option compared to the other data sources detailed above. This option could include the majority of priority outcomes to measure both the effectiveness and/or impact of Healthy Start.

2. As a complementary evaluation method

In this scenario, a purposive study could be used to provide supporting outcome data for those outcomes not reported through any other identified data source.

8.2. Possible study designs

The most suitable study design and method of data collection would depend on the outcome of interest, and on the budget available. Approaches to collection of quantitative or qualitative data could include:

- a) Single or repeat cross-sectional surveys (postal questionnaire or interview based) of a random sample of target population groups⁵ at a national, regional or local level;
- b) Single or repeat cross-sectional surveys (postal questionnaire or interview based) of a cohort of Healthy Start recipients across selected 'sentinel sites';
- c) Surveys, interviews and/or focus groups among targeted population groups of particular interest in selected sentinel sites, e.g., pregnant teenagers, breastfeeding women, minority ethnic groups.

We have used the 'sentinel site' approach in previous studies (e.g. Dyson et al 2006, Renfrew et al 2006). In this design, a small number of centres, selected according to pre-specified criteria, were recruited to test out approaches and support local data collection. Inclusion criteria included: a health economy based in area of deprivation; serving a diverse population; with support from local staff and service commissioners. Using such an approach allows for examination of cross-sectoral working; the inclusion of different areas of the country (eg metropolitan, small town,

⁵ Target population groups might include individual recipients of Healthy Start, service providers related to Healthy Start or commercial retailers registered with Healthy Start.

Final Report

rural); supports in-depth work with families, health professionals and retailers; and would support repeated surveys.

Before-after comparison options would be limited to benchmark data and/or baseline data available from national surveys or the before-after study in Sheffield, as baseline data prior to the introduction of Healthy Start would not be available due to the timing of the roll-out of the national programme.

Concurrent comparisons could however be conducted:

First, a traditional cohort method could be used, to include a group of people who are both exposed and unexposed to Healthy Start for cross-sectional and/or longitudinal follow-up. In this scenario, data for both the intervention and control groups would be collected from the cohort.

Alternatively, a cohort approach could recruit only eligible individuals for Healthy Start for longitudinal follow-up. Whilst this approach would obviously be cheaper, comparison options would be very limited, as above. It could however yield important and interesting descriptive data on some outcomes.

Importantly, either cohort approach has the potential to evaluate incremental changes experienced by individual recipients over time. This may be particularly useful to assess the 'real' impact of Healthy Start, which like many programmes aimed at improving lifestyle changes, is likely to be demonstrated in the medium to long term. A further advantage of the cohort method would be the potential to collect more detailed qualitative data from sub-groups of existing participants.

The main limitation of both approaches is the feasibility of achieving adequate sample size given the difficulties in recruitment of 'hard-to-reach' groups. The cohort method would also need to over-sample in the initial recruitment phase to allow for subsequent losses to the cohort. If this were considered suitable, the sampling frame for the cohort option could be focused on a smaller number of suitable sites, as described above, which provide appropriate representation of regional and sub-population groups.

The following tables detail priority outcomes which are not reported in any other identified data source or may be considered difficult to collect from the identified potential data source. This can be used to inform the primary aim and design of any prospective study/studies.

Final Report

Table 15: Purposive data collection from recipients: priority outcomes

Type of outcome	Outcome	Comment
Effectiveness	Duration of breastfeeding	If not included in future adapted Infant Feeding Survey (IFS).
	Use of cow's milk before 12 months as main milk drink	
	Type, content and timing of introduction of weaning foods	The latter two outcomes are proposed 'new' additions to the IFS rather than existing variables which require increased sampling and a flag for eligibility status. They may therefore be less feasible for inclusion in IFS
	Educational and behavioural outcomes	Qualitative data only Finalising scope of CHIC core data set as possible Type C source which could provide quantitative data if adapted for eligibility status variables
	Dietary intake data for fruit, vegetables, cow's milk and infant formula	If not included in future adapted Low Income Diet & Nutrition Survey
Intake data for vitamin supplements	If not included in future Health Survey for England.	
Describe impact on target population	Use of foods purchased by voucher including ease of fruit and vegetables	Not reported in any other source
	Women's views on content and delivery of Healthy Start	
	Embarrassment for recipients when using vouchers	
	Actual sources of information for existing IWFS and new recipients	
	Types of information for recipients including materials in different languages	

Final Report

Table 16: Purposive data collection from health providers: priority outcomes

Type of outcome	Outcome	Comment
Describe health service activity	Delivery of nutrition education and/or referral at point of contact with health professional advising on Healthy Start	Not reported in any other source. Could potentially be collected from health service records if data field included in routine service provision forms
	Ability of health professionals to identify, register, counsel and refer eligible recipients	Not reported in any other source
	Impact on workload for health professionals and their existing client base	
	Sustainability of workload within existing resources	
Describe impact on health sectors	Uptake of related nutrition education and breastfeeding activities	Could potentially be collected from health service records (e.g. by Children's Centres) if data field included in routine service provision forms

Table 17: Purposive data collection from commercial retailers: priority outcomes

Type of outcome	Outcome	Comment
Describe impact on commercial sectors	Change in retailer behaviour to supply and/or promote nutrition programmes	Not known to be reported in any other source

Benchmark population group data from some routine data sources could potentially provide a comparison option for the cross-sectional or longitudinal data collected for the purposes of either a stand-alone evaluation or, for specific outcomes of effectiveness, to complement data from other collection methods.

Comparison options would not be necessary if using purposive data collection methods to describe the impact of Healthy Start on target population groups.

Final Report

8.3. Summary: purposive prospective studies

Purposive studies for specific monitoring and evaluation of Healthy Start have the potential to provide directly relevant national data for a comprehensive range of effectiveness and descriptive outcomes. This would be particularly useful as an alternative, or adjunct, to the adaptation of three of the five national survey datasets discussed in 6.1 above. Adaptation of the planned Maternal Health and Child Health Datasets would still be recommended, however, for reporting of most nutritional and health status outcomes.

The cohort study design provides a unique opportunity to measure the potential incremental effect of Healthy Start over time. Sample groups for additional, small scale qualitative data would also be readily accessible for collection of process outcomes regarding the impact of Healthy Start on recipients.

Surveys for use in data collection to measure the impact of Healthy Start on service providers and commercial retailers could be based on those used for the evaluation of phase 1 in Devon and Cornwall (Hills et al 2006). These particular surveys are considered to provide useful additional descriptive data at relatively minimal cost.

Using a small number of sentinel sites could be a useful strategy for examining the range of priority outcomes in depth in different, low income settings.

Final Report

9. Discussion of issues to be addressed in evaluation, with recommendations for action

9.1. Background issues

9.1.1. Context of the project

The new Healthy Start scheme, which replaced the predominantly milk-based Welfare Food Scheme, has widened the range of healthy foods that can be bought, and encourages women to book with a health professional earlier in their pregnancy. However, the value of the vouchers is not enough to buy the 900g of formula milk for most brands of formula as previously available through the Welfare Food Scheme; children are not eligible for support after their fourth birthday; and some of the changes may have unintended side effects. It is as yet unclear what the positive or negative impacts of Healthy Start might be.

The aim of this work was to advise the Department of Health on approaches to monitoring and evaluation of longer-term health and social outcomes of the Healthy Start scheme. Evaluation of large-scale national policy programmes is always challenging. This work is particularly complex as it addresses a nutritional intervention for both mothers and children, and because the programme is already in place. It is also complicated by the parallel development of other programmes intended to address inequalities in health, promote breastfeeding, and improve nutrition. It is possible that these different programmes may work in synergy, enhancing their impact; or alternatively, slightly different messages or emphasis could result in confusion. We have not looked in depth at this issue, but we note that it is an important consideration for discussion before the final evaluation is commissioned. For example, a national evaluation of Healthy Start could potentially contribute to a longer term evaluation of the impact of the various healthy eating / nutrition / infant feeding programmes on the general population and specific population groups.

Recommended action

- Consideration of evaluation options is best done before programmes are put in place; this is likely to result in more robust designs and more accurate assessment of impact.

9.1.2. Importance of comparison groups

It was understood from the start of the project that none of the potential options for evaluation would be ideal. The challenge for the team was to identify alternative approaches that could contribute to understanding of the process and outcomes of the scheme. Identifying suitable comparison groups with which to compare outcomes was seen as fundamental to an evaluation that might inform policy makers about the scheme's effectiveness or otherwise, and contribute to future development of the scheme. Descriptive approaches were also considered, as they have an important role to play in examining some outcomes.

Final Report

Several options for before-after and concurrent comparisons were explored. No comparison option is ideal. Limitations include the potential for external confounding, and the difficulty of measuring accurate outcomes for women and children eligible for the Welfare Food Scheme.

Recommended action

- At least part of any evaluation of Healthy Start should include some form of comparative study.

9.1.3. Priority outcomes

Fundamental to the design of any evaluation is to agree which outcomes should be measured. The first task therefore was to assess the wide range of outcomes, health as well as process-related, that could possibly be affected by the Healthy Start programme, and to identify priority outcomes. We identified priority outcomes that could measure effectiveness; the impact on the target population; health service activity; and the impact on health and commercial sectors, presented in Tables 2-5. These include measures of dietary intake, food-related behaviour, nutrition, health and education status, and infant feeding: programme acceptability, delivery and systems and infrastructure; and economic issues and potential broader effects of the Healthy Start programme.

To assist in the final selection of outcomes to be included in an evaluation of Healthy Start, an overview of dietary assessment methods was conducted. No one method identified is ideal, and it is likely that a combination might be most accurate. Methods to assess dietary intake for children are not yet available, though work is ongoing.

The identification of these priority outcomes is an important contribution in its own right, and will help policy makers, academics, health professionals and the public to consider which of a range of outcomes are most important to them.

Recommended actions

- Framing of any national evaluation of Healthy Start should give serious consideration to the questions of primary interest and the associated priority outcomes to best answer those questions.
- Ongoing work to assess dietary intake for children of different ages, and pregnant women, should be expedited and the results widely disseminated.

9.2. Routine data sources

Existing routine data sources appear to have reported most priority outcomes of effectiveness among most population groups of interest for a national evaluation of Healthy Start. The notable exception is for the specific population group of 'Healthy Start eligible breastfeeding women' for whom only one data source has reported one outcome of interest in a single survey; namely, the Health Survey for England (2002) which reported intake of fruit and vegetables.

Final Report

On further examination, however, the feasibility of utilising existing routine data sources to measure priority outcomes of effectiveness among any population group of interest presents a far bleaker picture. Existing routine data sources cannot provide directly relevant data with sufficient statistical power to enable evaluation of a single priority outcome at the level of the individual Healthy Start beneficiary.

One potential use of existing routine data sources is to measure the outcome of 'purchasing of fruit and vegetables'. This is due to the adequacy of household level data for this particular outcome. Data would only be available, however, for households which include children eligible for Healthy Start, and not households which include pregnant or breastfeeding women.

These findings are based on variables reported within data sources identified as potentially useful to evaluate relevant outcomes within a comparison option. The data sources (n=7) were relatively limited in number compared to those identified for potential use to provide baseline data (n=16) for priority outcomes. However, we consider the remaining 8 Type A routine data sources are also unlikely to provide appropriate baseline data for most, if not all, priority outcomes.

This is due to the complex conditions required of a dataset which yields suitable data for the purposes of an evaluation of Healthy Start. Even if a relevant variable has been reported in these datasets, the likelihood that it will also include variables to identify individuals eligible for Healthy Start, in sufficient numbers to detect an appropriate change, as well as reporting the exact variable of interest at the level of the eligible individual is extremely low. Indeed, these difficulties have been clearly demonstrated for the Type A data sources assessed in detail for the purposes of a comparative evaluation.

The absence of all outcomes relevant to the complex relationship of the intake of formula, timing of weaning foods and the introduction of cow's milk are of particular concern. Whilst Healthy Start represents an increase in purchasing power for women who breastfeed their baby, women who exclusively formula feed will experience a net decrease in their purchasing power compared to the milk tokens in the former Welfare Food Scheme. It is important therefore for an evaluation of Healthy Start to be able to evaluate any potential increase in the early introduction of weaning of foods and/or cow's milk alongside a possible reduction in intake of formula. In addition, data are not available through existing routine sources for the outcome of 'duration of breastfeeding' which could increase in the face of reduced purchasing power for formula milk.

Existing Type B data sources have also proved to be limited for evaluation of nutritional and health status outcomes. This is due to the absence of variables to identify eligible individuals for Healthy Start but not in terms of reporting relevant variables or adequate statistical power.

Recommended actions: routine data collection – wider issues

- In relation to the conduct of routine surveys in general; we found no relevant datasets in which *a priori* sample size calculations had been conducted for specific population groups of interest. This is an issue that has wider relevance than the conduct of this specific evaluation. Such considerations at the planning stage of routine data collection would enhance the value of each

Final Report

survey, perhaps especially in regard to assessing inequalities in health.

- Government departments and local agencies could benefit from incorporating measurements of uptake and possible outcomes of Healthy Start into service agreement and performance management metrics, particularly in relation to working in partnership across communities.
- Inclusion of unique identifiers (e.g. NHS or National Insurance number) in routine data sources would enable potential record linkages between data sets for future evaluations of government programmes, including Healthy Start. Governance issues would need to be examined.

9.3. Adapting routine data sources

As an alternative to existing Type B data sets, the planned Maternal Health Dataset (MHD) and Child Health Dataset (CHD) are expected to report nearly all outcomes on nutritional and health status within the single routine data source. The MHD will also report on the priority outcome, 'intake of periconceptional folic acid', including intake prior to pregnancy. This outcome was not reported in any existing routine data source (Table 9 above). Further, the MHD will report on all relevant explanatory variables to enable appropriate analysis of primary outcome data to evaluate the effectiveness of Healthy Start (see Appendix 4).

Work with the Yorkshire & Humber Public Health Observatory (YHPHO)⁶ for this project has resulted in a request for the inclusion of a flag specific to 'Healthy Start eligibility or beneficiary status' in the Maternal Health and Child Health Datasets. If this were accepted, data could be available for this range of outcomes for the intervention group from June 2009 (Maternal health data) and August 2009 (Child health data), the expected dates for implementation of these datasets into data systems.

The ability to use these data would, however, depend on the relevant Healthy Start field(s) being mandated for national collection and archiving in a central database, accessed via the Secondary Uses System. This project therefore recommends the Department of Health provides the essential policy level support to enable national mandating of this data field. In this event, the short, medium and long term effects of Healthy Start for nearly all these priority nutritional and health status outcomes could be evaluated for all relevant population groups of interest to the national programme within a single routine data source. Use of this data source for concurrent comparison group data would require separate consideration.

Relevant outcomes which are not planned to be reported in the MHD or CHD include 'maternal anaemia in pregnancy', 'timing of first contact with maternity services' and 'length of child from 1-4 years'. The 'length of child from 1-4 years' has not been identified in any existing routine data source. 'Maternal anaemia in pregnancy' and 'Timing of first contact' are reported in the SMR02 dataset. The lack of variables to identify 'Healthy Start-eligibles' currently limits their feasibility for an evaluation of Healthy Start. The potential to include a flag for 'Healthy Start eligibility status' within this data source may warrant further investigation.

⁶ Jake Abbas, Deputy Director of the YHPHO, is a member of the Advisory Group for this Scoping project. The YHPO is the national lead for diabetes, children and young people and health economics.

Final Report

There is therefore potential for future routine data sources to be useful and cost-effective sources of ongoing evaluation data, especially in the case of the broad range of nutrition, infant feeding and health status outcomes for all population groups of interest. These are currently reported in three Type B data sources (SMR02, SUS, HES) which do not include variables to identify eligible individuals, and the inclusion of variables to identify such individuals within these data sources would enable their use as future intervention group data. The recommended approach, however, is to extract data for these outcomes, and other priority primary and explanatory variables, from the planned Maternal Health and Child Health Datasets.

Achieving the significant potential for the use of adapted routine data sources is largely dependent on policy support to facilitate the proposed adaptations. Specifically, policy support would be needed as follows:

Recommended action

- To support the request to include a flag for 'Healthy Start eligibility or beneficiary status' within the Maternal Health and Child Health Datasets;
- To mandate these data fields for national collection and archiving.

The realisation of the potential of all five data sources (detailed in box below) would provide a highly cost-effective approach to monitoring and evaluation of the effectiveness of the national Healthy Start Scheme comparable with other national food support systems. Indeed, data collection methods for dietary and other lifestyle surveillance data used in these major national surveys are often regarded as "gold standard" (APHO 2005). Such action would also be consistent with recommendations detailed in the Government Action plan 'Delivering Choosing Health' which specifically included an action "to develop appropriate systems for recording lifestyle measures" (Department of Health, 2005).

One potential limitation of these adapted national data sources is the uncertainty regarding future sampling strategies within each survey. For example, proposals were put forward to increase the sample of children within the 2006 Health Survey for England from 2000 to 6000. This would have been accompanied however by halving the adult sample to around 8000 individuals (APHO 2005). Whilst this is not considered to negate the potential value of these adapted data sources, it does highlight the need to monitor proposed survey plans and make provision for complementary data collection options as required. These could include local boosts to national surveys, use of existing best practice information systems and purposive studies specific to Healthy Start as discussed in Chapters 7 and 8.

For these reasons, the following recommendation is considered to be of the greatest importance in terms of implications for a national evaluation of Healthy Start:

Final Report

Recommended action

- High level inter-departmental policy support to develop a cost-effective monitoring and evaluation system based on five modified routine data sets:
 - Infant Feeding Survey;
 - The Low Income Diet and Nutrition Survey
 - The Health Survey for England
 - The Maternal Health Dataset
 - The Child Health Dataset

Additional options for evaluation which include a comparison group could potentially be built onto the cross-sectional data available through these five data sets. These might include either a before-after study design or a concurrent comparison with a either a control group or a benchmark population.

In the case of a before-after design, a full examination of the feasibility of reported outcome data for all data sources reporting baseline data (as detailed in Section 4.3) would be required. The feasibility assessments undertaken for the purposes of this scoping work included only those data sources which reported outcomes of interest for both a baseline and a comparison group. A full examination of any feasible baseline data sources would be useful for the particular purpose of enabling comparisons between the Healthy Start and the former Welfare Food Scheme.

A concurrent comparison with a control group would require further assessment of the feasibility of identifying either, borderline non-eligibles or, equivalent non-eligibles who are not pregnant or have no children under 4 years.

A concurrent comparison with a benchmark population might be particularly useful in the absence of baseline or control group data. This would enable an assessment of whether any reported change in priority outcomes of effectiveness is likely to be attributable to the effect of Healthy Start rather than a natural change occurring across the general population. Benchmark data are likely to be available for many of the priority outcomes of effectiveness through existing national survey-based data sources. The feasibility of these data sources to report outcomes for the general population is not constrained by the requirements for 'Healthy Start eligibility' variables or limited sample sizes. The direct relevance of the variable reported to measure the outcome relevant to Healthy Start would require further examination.

In conclusion, the most comprehensive, feasible and cost-effective option for a national evaluation of effectiveness is based on intervention group data from the five adapted data sets for comparison with benchmark data from existing routine data sources. Both data sources would draw on cross-sectional survey data and would enable either a snap-shot of effectiveness at a single point in time or monitoring of trends over time.

9.4. Commercial data sources

Both till receipts and reward scheme data have some advantages to data available from existing survey-based datasets for the following reasons:

1. Ability to report on all relevant food and drinks within the Healthy Start Scheme

Final Report

2. Ability to report household data for all eligible and/or beneficiary groups within Healthy Start including pregnant women and pregnant teenagers
3. Increased reliability of outcome data as a result of large sample sizes
4. Increased reliability of variable data based on prospective, objective purchasing records compared to self-reported survey data
5. More comprehensive representation of Healthy Start eligibles / recipients across the UK including the most disadvantaged

They are, however, possibly limited in their generalisability.

The following action is recommended to *assess the feasibility* of measuring national changes in purchasing patterns from data sets held by multiple and independent retailers:

Recommended action

- Identify individual multiple and independent retailers used by Healthy Start recipients to redeem their vouchers and investigate their willingness to collaborate in data sharing.
- Assess the number of retailers required to provide representative beneficiary data, including retailers serving recipients in rural and deprived inner city areas.
- Assess existing capacity of identified retailers to provide purchasing data at the level of individual Healthy Start eligibles and/or recipients.
- Negotiation for inclusion of a 'voucher notification' or 'flag' system to identify Health Start recipients within future multiple and independent retailer datasets;
 - Development of 'best practice' systems with Tesco supermarket for potential replication to other retailers.
- Explore data protection issues raised.

Before making a final decision on the use of such data, further consideration is required in relation to the possible adaptation of routine data sources (see chapters 7 and 8). In the event of future adaptation of the recommended routine data sources, including the Low Income Diet and Nutrition Survey, retailer data may be less desirable.

Action to facilitate the collection of purchasing data from commercial retailers would be considered low priority in the event of intake data being available from the adapted LIDNS. In this scenario, the limited purchasing data available on fruit and vegetables for eligible households who have children under 4 years would provide useful supporting outcome data. These data are available from an existing and ongoing routine data source (Expenditure and Food Survey) with adequate statistical power. Therefore, these data would provide baseline and prospective data through the most cost-effective and accessible source.

In the event of intake data not being available from the adapted LIDNS, good quality and large scale purchasing data from commercial retailers would be considered high priority. These data could potentially become the default core outcome on which the

Final Report

success of Healthy Start to improve access to fruit, vegetables, cow's milk and infant formula for low income families is measured.

9.5. Healthy Start data sets

These process outcomes are considered fundamental to the ongoing planning and delivery of the Healthy Start Scheme. This might be for the purposes of assessing actual coverage of the programme through to identification of potential legal concerns regarding fraudulent use of the vouchers.

The government programme data sets represent a unique data source which may currently, or could potentially, report relevant process data for all programme recipients and registered retailers. The following action is recommended, therefore, in order to assess the feasibility of a process evaluation using these datasets:

Recommended action

- An audit of the Benefits Agency and Registered Commercial retailer data sets to identify if the following variables are currently extracted from the application form and recorded in an electronic format:
 - Individual postcode ¹;
 - Individual date of birth ²;
 - National Insurance Number ².
- Assessment of the potential cost and feasibility to prospectively extract those variables for inclusion in the Benefits Agency and/or Registered Commercial retailer data sets.
- Examination of governance issues regarding data protection for use of this variable data at the level of the individual beneficiary.

¹ Benefits Agency and Registered Commercial Retailer data sets

² Benefits Agency data set only.

9.6. Complementary data sources

Some potentially useful complementary data sources have been identified at national and regional levels. In the event of adequate funds, the complementary data sources have the potential to improve the overall quality and/or coverage of national data.

Conversely, where funding constraints limit the scope for national data, regional data sources may have the potential for extrapolation to the national or local levels. Appropriate use of geographical mapping techniques and synthetic estimates require careful consideration for each outcome of interest.

9.7. Prospective studies

A prospective study specifically for the purposes of evaluating Healthy Start could be planned to achieve one of two primary aims: one, as a stand-alone data collection method to provide relatively comprehensive outcome data for a national evaluation; or two, to provide additional, primarily descriptive, data for the purposes of monitoring the impact of Healthy Start.

A stand-alone purposive study might be considered more feasible than adaptation of the five proposed national survey data sets to provide national level data on core

Final Report

outcomes in the short term. In this scenario, repeat cross-sectional surveys of a random sample of recipients could provide monitoring and evaluation data to assess reported changes at single points in time. Each purposive survey data set could be compared with outcome data from a benchmark population where available from existing routine data sources. The option for comparison with a concurrent comparison group would be largely dependent on budgetary constraints and governance issues regarding identification of potential participants.

A cohort study design could also be used to provide stand-alone, comprehensive evaluation data. This would have the unique advantage of providing data on changes over time for individual recipients who have continued to benefit from Healthy Start. Indeed, this may be the most appropriate measure to assess the 'real' effect of a programme promoting changes in lifestyle which tend to be demonstrated in the medium to longer term (Avenell et al 2004, Foxcroft et al 2003, West et al 2000) and in association with increased length of participation in the programme (Metcoff et al 1985 and Rush et al 1988, in review by D'Souza et al July 2006).

Both designs could benefit from use of a sentinel site approach, in which sites selected according to pre-specified criteria are used to support high quality data collection, and where data collection could be continued over time.

In the event of national data on core outcomes of effectiveness and coverage being available from adapted data sets, a purposive study would be the most suitable data collection option for descriptive data. Data to monitor the impact of Healthy Start on target recipients could be collected by interviews and focus group methods among small samples of different population groups. Descriptive data to measure the impact of Healthy Start on health providers and the commercial sector could be collected by postal questionnaires based on surveys used by the evaluation of phase 1 in Devon and Cornwall (Hills et al 2006). These purposive data collection methods would be relatively low cost despite their potential to provide rich outcome data.

Recommended actions

- A prospective study is the only way of collecting data on some important outcomes. It is recommended that at least part of the evaluation of Healthy Start is conducted as a planned, prospective study
- The use of sentinel sites, based in areas of high deprivation, is an approach that has been shown to work in terms of collecting good quality, in depth data, with the potential to continue to collect longitudinal data or return to collect cross-sectional data over time.

9.8. Comparison options

The potential for existing routine survey based sources to provide useful baseline data is extremely limited on the basis of assessments of some of those sources for the purposes of comparison option data.

The absence of any national baseline data prior to the implementation of Healthy Start also limits the scope for comparison of the effect of Healthy Start compared to the former Welfare Food Scheme. Given the potential importance of these

Final Report

comparisons for some outcomes of effectiveness, e.g. intake of formula, cow's milk and breastfeeding rates, examination of the remaining relevant routine data sources is warranted. For example, other potential routine sources of comparison data for Welfare Food Scheme eligibles to report the outcome of the intake of cow's milk include Health Education Monitoring Survey and the Scottish Health Survey. Details of these and other potential sources of baseline and / or before-group comparison data are provided in Table 6 above.

In the likely event of no national baseline or before-group comparison data being available, national comparison options are limited to concurrent comparison groups and/or benchmark data.

The potential to identify individuals who are either 'borderline non-eligibles' in terms of income or benefit status or 'equivalent non-eligibles' who are not pregnant or do not have any children under 4 is subject to data protection considerations. Given the timing constraints which have limited the collection of prospective baseline data and the potential value of alternative comparative data, examination of these governance issues should be considered.

An alternative, albeit relatively limited, comparison option is with benchmark data from the general population. This would help to assess whether any reported change of effect for the intervention group is as a result of Healthy Start and the extent to which Healthy Start may be reducing the inequalities gap regarding access to healthy foods. In the potential event that a benchmark provides the only comparison option for a national evaluation, further examination of all identified routine data sources (see Table 6) to report appropriate measures of relevant outcomes is required.

In conclusion, the following actions are recommended to assess the most appropriate and/or feasible comparison options for a national evaluation:

Recommended actions

Once key questions and priority outcomes have been identified:

- Further assessment of feasibility of routine data sources for potential use for baseline / before-group / benchmark data is conducted
- Examination of governance issues regarding identification of individuals for concurrent comparison groups is conducted for:
 - Borderline non-eligibles
 - Equivalent non-eligibles

It is anticipated these assessments may provide a limited number of potentially useful data sources for a small number of outcomes. The scope for potential sources reporting benchmark data may be more feasible given this type of comparison does not require data sources to identify individuals on the basis of their eligibility.

Final Report

10. Options for evaluation

10.1. Overview of potential data sources

As we indicated in Chapter 9, a national evaluation of Healthy Start should include a combination of data sources to collect effectiveness and descriptive data for different population groups at a variety of geographical levels; we call this a 'building blocks' approach. Policy and budget considerations will influence the best package of data sources and collection methods suited for a national evaluation and the final design of the study will depend on the main aim of the evaluation.

In summary, the possible data sources are:

1. Existing routine, publicly available data sets for collection of national data for baseline, intervention group and/or benchmark data.
2. Routine, publicly available data sets adapted for the purposes of Healthy Start for collection of intervention group, possible concurrent comparison group, and benchmark national data.
3. Commercial retailer national and/or regional data sets:
 - a. Till receipt data;
 - b. Reward scheme data.
4. Healthy Start Programme-specific national data sets
5. Complementary data sets:
 - a. 'Local boost' data sets
 - b. Best practice information systems
 - c. Sheffield study for local monitoring of Healthy Start
6. Purposive national and/or regional studies designed for Healthy Start

Geographical mapping techniques may also provide the potential to extrapolate existing but limited national, regional or local data for improved representation for some outcomes.

An overview of the outcomes which could potentially be measured through each of these approaches is provided in Table 18 below. Further details about individual outcomes and assumptions related to use of each data source are provided. This list is not exhaustive as some outcomes can be collected from multiple sources. Outcomes have been broadly mapped to the data source considered most suitable on the basis of availability and feasibility. For example, dietary intake data could potentially be reported by the Health Survey for England. This would not be necessary however if these outcomes were reported by the Low Income Diet & Nutrition Survey. The latter source is considered superior in terms of its likely sample size and reported methods for collection of dietary intake data.

Final Report

Table 18: Potential of different approaches to contribute to evaluation of Healthy Start

Approach to be used	Data set	Groups of outcomes measured	Reference to relevant section of report
1. Existing routine data source (EFS)	Expenditure and Food Survey	Purchasing data on fruit and vegetables for households with eligible children.	7.2
2. Adapted routine data sources (dependent on implementation of recommended adaptations)	Infant Feeding Survey	Infant feeding data including breastfeeding and weaning for all population groups.	7.2
	Low Income Diet & Nutrition Survey	Dietary and nutrient intake data for relevant foods and drinks for all population groups. Possible nutritional status data.	
	Health Survey for England	Intake data for vitamin supplements for pregnant women.	
	Maternal Health and Child Health Datasets	Nutritional and health status data for all population groups. Explanatory variable data.	
3. Commercial data sources	Multiple and independent retailer' data sets	Purchasing data for all relevant foods and drinks for households with eligible recipients	7.3
4. Healthy Start Programme national data sets	Benefits Agency data set	Take-up rates for Healthy Start; Early recruitment into Healthy Start; Length of participation in Healthy Start	7.4
	Registered commercial retailers' data set	Access to local registered retailer; Equity of value of vouchers	
	NHS fraud data set	Mechanisms for beneficiary to redeem full value of voucher	
5. Purposive studies designed for monitoring and evaluation of Healthy Start	National random sample for cross-sectional survey(s) or cohort for cross-sectional and longitudinal data	Effectiveness outcomes for all infant feeding outcomes; dietary intake data and intake data for vitamin supplements	8

Final Report

	As above or local/ regional samples of target groups	Descriptive outcomes for impact of Healthy Start on recipients	
	National random sample or local /regional samples of target groups	Descriptive outcomes for impact of Healthy Start on service providers and other health sectors	
	As above	Descriptive outcome for impact of Healthy Start on commercial sector	
6. Complementary regional data sources	Local boost of national surveys	Effectiveness outcomes on dietary intake and infant feeding to support national survey data	7.5
	Best Practice information systems	Possible effectiveness outcomes on nutritional and/or health status outcomes.	
	Before-after Healthy Start study in Sheffield	Range of effectiveness and descriptive outcomes on dietary intake, take-up rates and the impact of Healthy Start on target populations	

10.2. Evaluation options

A range of options for monitoring and evaluation of Healthy Start are proposed here, based on our assessment of the range of possible approaches. The strengths and weaknesses of each option are discussed. We have given an estimate of the likely scale of the budget for each (i.e. low, moderate, high) but without knowing the main aim of the study or the workload implications of the suggested adaptations, we cannot provide any more detailed information on cost. We would also note that a high-cost option may yield very valuable information and prove to be very cost-effective.

We considered allocating a 'value for money' rating, in terms of the anticipated associated costs compared to the robustness and quality of each evaluation option, but decided not to do so in the light of the limitations described above. We are confident that each of the proposed options would be valuable components of an evaluation.

We also include an estimate of the likely complexity of the governance issues to be addressed in conducting each option; again, we would need to know more about the final design before being able to understand this in detail.

The options are not mutually exclusive, as we outlined above. Indeed, depending on the main aims of the evaluation, we would recommend a combination of approaches to capture the range of important outcomes in different population groups, and over time.

Final Report

Option 1: **National monitoring and evaluation of core outcomes of effectiveness and coverage**

Data sources: Five adapted ongoing national survey data sets (Low Income Diet & Nutrition Survey; Health Survey for England; Infant Feeding Survey; Maternal Health and Child Health Datasets) for outcomes of effectiveness: dietary intake; supplement intake; nutrient intake; infant feeding; nutritional and health status: plus explanatory variables

Existing data source (Expenditure and Food Survey) for limited supporting purchasing data

Benefits Agency data set for take-up data

Cost: Low to Moderate

Governance issues: Minimal problem

Comparison groups:

This approach would enable monitoring of trends over time for the intervention group based on repeat cross-sectional surveys (see **Chapter 7.2**). Comparisons would be limited to benchmark data available from existing routine data sources and/or possible before-group data for recipients of the WFS for some outcomes. In both cases, it is likely the comparison group would be limited to the **whole** target population for Healthy Start or the sub-group of families with children under 4 years but would not be possible for **individual** target groups of interest such as pregnant teenagers or breastfeeding women. The potential for such comparisons requires further assessment of routine data sources to provide feasible before-group or benchmark data as detailed in **Chapter 9.8**.

Option 2: **National monitoring and evaluation of comprehensive range of outcomes of effectiveness, coverage and impact of programme**

Data sources: Purposive national cross-sectional surveys or cohort study of recipients within planned nationally representative sentinel sites for outcomes of effectiveness: dietary intake, supplement intake; potentially nutrient intake; infant feeding including weaning and introduction of cow's milk, purchasing data; process outcomes: impact of programme on recipients; and explanatory variables.

One sentinel site could be based in Sheffield for extended cross-sectional and longitudinal data collection from existing cohort beyond May 2008.

Benefits Agency data set for take-up data

Final Report

Option to include:

Adapted national Maternal Health and Child Health Datasets for nutritional and health status outcomes

Cost: Moderate to High

Governance issues: Moderate, but achievable

Comparison groups:

For the purposes of outcomes of effectiveness, the more expensive, traditional cohort approach would enable comparison between the intervention and concurrent control groups at various time points and over time. A 'streamlined' cohort approach comprising only eligible individuals for Healthy Start would be limited to monitoring of trends over time for the intervention group based on repeat cross-sectional surveys (see **Chapter 8.2**). National before-after comparisons would be limited to benchmark data and/or data for WFS recipients available from national surveys. The potential for these comparisons requires further assessment of routine data sources to provide feasible before-group or benchmark data as detailed in **Chapter 9.8**.

The longitudinal element of either cohort approach has the potential to evaluate incremental changes experienced by recipients over time to assess the impact of Healthy Start to achieve lifestyle change toward healthier nutrition among low-income families.

Option 3: National monitoring and evaluation of limited core outcomes of effectiveness and coverage

Data sources: Commercial multiple and independent retailers for household purchasing data for all relevant foods and drinks for all population groups of interest. This assumes the acceptability of household **purchasing** data as an alternative to core **intake** data.

Benefits Agency data set for take-up data

Purposive one-off local/regional study to describe impact of programme on target recipients and /or service providers. Extension of the Sheffield before-after study could provide longitudinal data for this purpose as well as data on additional core outcomes of dietary and nutrient intake.

Option to include:

Adapted national Maternal Health and Child Health Datasets for nutritional and health status outcomes

Adapted national Infant Feeding Survey for all outcomes for breastfeeding, weaning and introduction of cow's milk

Final Report

Cost: Low to Moderate

Governance issues: Minimal problem

Comparison groups:

Till receipt data from commercial retailers have the potential to enable monitoring of trends of purchasing patterns over time using cross-sectional data. Reward scheme data have the potential to provide cross-sectional and longitudinal data to both monitor household purchasing patterns and evaluate incremental changes over time. The latter is subject, however, to the presence of reward schemes for each retailer and their willingness and ability to establish links between expenditure of Healthy Start vouchers and Reward scheme data.

Comparisons of household purchasing patterns with benchmark data and some target populations for before-groups of WFS recipients are likely to be feasible using existing routine data sources (see **Chapters 5 and 6**). Sample sizes from these sources for before-group comparisons are likely to be relatively small however and would severely limit the value of the overall comparison. The potential for these comparisons requires further assessment of routine data sources to provide feasible before-group or benchmark data as detailed in **Chapter 9.8**.

Option 4: **Local monitoring and evaluation of comprehensive range of outcomes of effectiveness, coverage and impact of programme for potential extrapolation of core outcomes to similar areas at national level**

Data sources: Extension and possible expansion of existing purposive local before-after study in Sheffield for potential extrapolation to similar areas across England through geographical mapping techniques. Local data would report on outcomes of effectiveness (dietary and nutrient intake, infant feeding), process outcomes, impact of programme on recipients and some explanatory variables.

Option to include:

Benefits Agency data set for national take-up data

Adapted national Maternal Health and Child Health Datasets to measure nutritional and health status outcomes for cohort of recipients in Sheffield

Cost: Low

Governance issues: Moderate, but achievable

Comparison groups:

Final Report

This approach would enable comparison of outcome data with before-groups who were both WFS and non-WFS recipients prior to becoming eligible for Healthy Start. No further action would be required to facilitate this comparison although data collection for the Sheffield intervention group is due for completion in May 2008. The potential for extrapolation to similar areas through England through geographical mapping techniques would require further expert consideration.

10.3 Discussion of options

We consider Option 1 to be the most robust option for sustainable and systematic monitoring and evaluation of a comprehensive range of core outcomes of Healthy Start, if our recommended adaptations to routine data collection can be implemented. This is due to the routine nature of these data sources and their relative sustainability to provide ongoing national data for all population groups of interest. These adaptations would also represent significant improvements in recording of lifestyle surveillance data for use by other dietary related programmes and related work in reducing inequalities. It is important to note, this is subject to the actual feasibility of routine data sources to provide appropriate before-group data for comparison with prospective intervention data from the adapted routine data sources.

The Government Benefits Agency data set could be good value for money as a source of core data on take-up rates. Further data collection options to support potential variations in national data or to measure additional priority outcomes could also be considered in the medium term.

We consider the cohort approach as detailed in Option 2 to be the second most robust option for monitoring and evaluation of a comprehensive range of core outcomes of Healthy Start. If adaptations cannot be made to routine data collection as above, it would become the main, or indeed the only, feasible option.

The more expensive, 'traditional' cohort approach of Option 2 is considered to be the more robust of the two cohort approaches due to its inherent collection of concurrent comparison data. The comparison would be limited to Healthy Start recipients with non-Healthy Start recipients and would not include before-after comparisons of Healthy Start recipients with WFS recipients. The main limitation of this approach is likely to be the relative cost compared to the 'streamlined' cohort approach or adaptation of future routine data sources.

Both these approaches have the considerable advantage of being able to include a range of additional outcomes, such as the views of women and health professionals, and the experiences of retailers. Extension of the existing before-after study in Sheffield would be an efficient use of an existing, good quality local data source from one sentinel site.

The option to include data collection from the adapted Maternal Health and Child Health Datasets would also provide valuable nutritional and health status outcome data at a relatively minimal cost. This would be achieved through data linkages between individual recipients within each sentinel site, including recipients within the Sheffield before-after study.

The cohort study methodology has the unique advantage of providing longitudinal data to measure the incremental effect of Healthy Start over time. Indeed, this might

Final Report

be the measure of effectiveness which demonstrates the real effect of Healthy Start consistent with other lifestyle programme initiatives (Avenell et al 2004, Foxcroft et al 2003, West et al 2000).

The Government Benefits Agency data set is also considered extremely good value for money to provide essential programme coverage data.

We consider Option 3 to be the most suitable option for national monitoring and evaluation of limited core outcomes for Healthy Start in the event of major budget constraints. This assumes however that commercial retailer data can be purchased at relatively low cost for the purposes of a national evaluation of a government health programme.

An evaluation of effectiveness for the primary function of Healthy Start, namely, increased access to fruit and vegetables, would be measured however through household purchasing data as an alternative to individual dietary intake. The potential to use purchasing data as a direct proxy for intake of formula milk could be explored.

Use of outcome data from the Sheffield before-after study would provide core local data on dietary intake, infant feeding and process outcomes to support the national level purchasing data.

Programme coverage data could be collected at relatively low cost from the Government benefits agency data set.

The inclusion of the adapted, planned Maternal Health and Child Health Datasets would be relatively low cost to achieve and would provide essential core data on nutritional and health status outcomes. The value of this, however, is subject to the feasibility of data linkages at the level of individual recipients between the commercial and health services datasets.

Option 4 may be useful in the event of major budget constraints and feasibility issues for alternative options. Its usefulness at the national level, however, is dependent on the ability for extrapolation of outcome data. The scope for such extrapolation through geographical mapping techniques would need to be assessed by experts before this option is given serious consideration. The current study period would need to be extended beyond May 2008 for use in an ongoing monitoring and evaluation.

Data from the before-after Sheffield study is considered most valuable if incorporated into a broader approach such as Options 2 or 3.

All four evaluation options could potentially be enhanced at various time points by inclusion of additional option components. Further inclusions might include one or several of the complementary data sources discussed in Section 6.4.

Final Report

Summary – Options for evaluation

Four options for evaluation have been outlined. None is ideal, but each has the potential for measuring a range of important outcomes, if suitable adaptations to routine data collection can be put in place. Options 1 and 2 are the most robust; Options 3 and 4 might be considered if the budget is severely limited.

The approach of choice is a combination of Options 1 and 2, if suitable adaptations are made.

In the absence of such adaptations to routine data collection, Option 2 is really the only feasible approach to provide good quality effectiveness data which is reliable and generalisable at the national level for a range of target population groups.

Final Report

11. Report on progress against project objectives

Objective 1. To identify key criteria for evaluating the success of the Healthy Start policy

This objective was addressed by Task 1: Scope outcomes of interest and identify priority outcomes. Relevant work is described in Chapters 2 and 9. We identified a list of priority outcomes, including outcomes that could assess effectiveness, impact on target populations, health service activity, and impact on health and commercial sectors. We also identified key explanatory variables. This list represents an output in its own right, and will be of value to policy makers, academics, the health service, and voluntary groups working in this field.

Objective 2. To propose a framework for monitoring the quality and performance of the Healthy Start scheme, and for establishing a system for collection of routine monitoring data

This objective was addressed in Task 5: Identify options for evaluation. Relevant work is reported in Chapters 8, 9, and 10. Four options for evaluation have been identified, to measure different kinds of outcomes. These include the use and adaptation of existing routine data, and the conduct of a planned, prospective study. Our approach would be to combine different options to enable examination of a suitable range of priority outcomes. Final decisions are dependent on decisions by the DH on the main purpose of an evaluation; priority outcomes; the extent to which routine data collection can be modified; and the budget available.

Objective 3. To map existing sources of data that could contribute to national policy evaluation of the Healthy Start scheme, and to review their relevance and potential value in yielding baseline data

This objective was addressed in Tasks 3 and 4: Identify sources of routine data, examine whether analysis is possible at the level of women and children eligible for Healthy Start, (and identify any relevant baseline data); and Identify sources of other relevant data, and examine whether analysis is possible at the level of women and children eligible for Healthy Start. Relevant work is reported in Chapters 5, 6, 7, and 9. We found virtually no data from any source on priority outcomes with adequate sample sizes to inform an evaluation of Healthy Start. As a result, we identified very limited suitable baseline data, rendering before-after comparisons very difficult.

Objective 4. To establish baseline data for Healthy Start policy evaluation by carrying out and reporting on secondary analyses of existing key datasets, commenting on the strengths, weaknesses and limitations of the datasets

As a result of our work on Objective 3 (described above), we found that there were virtually no sources of relevant baseline data. As a result, our work concentrated on ways of adapting routine data collection. Adaptations to existing routine data collection that would support an evaluation have been outlined. Relevant work is described in Chapters 5, 6, 7 and 9.

Final Report

Objective 5. To identify available standard data collection tools, and comment on their suitability and limitations for the purpose of a policy evaluation of Healthy Start

This objective was addressed in Task 2: Critique existing relevant data collection tools. Relevant work is reported in Chapters 3 and 9. A rapid review and expert consultation identified tools for assessing dietary and/or nutrient intake. No one method is ideal and no information is yet available on assessing intake in children, or pregnant women.

Final Report

Acknowledgements

We are grateful for advice from all members of the Advisory Group: Jake Abbas, Deputy Director, Yorkshire & Humber Public Health Observatory; Martin Bland, Professor of Health Statistics, University of York; Professor Janet Cade, Nutritional Epidemiology Group, University of Leeds; Liz Dowler, Reader in Food and Social Policy, University of Warwick; Dr David Elliman, Consultant in Community Child Health, Great Ormond Street Hospital; Lorna Farr, Senior Nurse - Equality & Diversity Manager, Newcastle PCT; Alison Macfarlane, Professor of Perinatal Health, City University; Christine McGuire, Principal Research Officer, Policy Research Programme, Department of Health; Jenny McLeish, Freelance Researcher/Campaigner; Nigel Rice Health, Econometrics and Data Group, University of York; Helen Roberts, Professor of Child Health, City University; Catherine Shaw, Acting Director of Research and Evaluation, National Children's Bureau; Dr Dagmar Zeuner, Assistant Director of Public Health, Islington Primary Care Trust, and from Hilary Graham, Director of the Public Health Research Consortium.

Secretarial support was provided in the early stages of the work by Linda Baillie and in the later stages by Jenny Brown. The work was funded by the Policy Research Programme of the Department of Health, through the Public Health Research Consortium.

Final Report

References

Anderson AS, Campbell DM and Shepherd R (1995) The influence of dietary advice on nutrient intake during pregnancy. *British Journal of Nutrition* 73, 163-77

APHO: Association of Public Health Observatories (2005) Sources of data on lifestyle risk factors in local populations. Technical Briefing No.1. November 2005. University of York

Attree P (2006) A critical analysis of UK public health policies in relation to diet and nutrition in low income households. *Maternal and Child Nutrition* 2, 67-78

Avenell A, Broom J, Brown TJ, Poobalan A, Aucott L, Stearns SC, Smith WCS, Jung RT, Campbell MK, Grant AM (2004) Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement. *Health Technology Assessment* Vol 8 No 21

Bamberger M, Rugh J, Church M, Fort L (2004) Shoestring evaluation: designing impact evaluations under budget, time and data constraints. *American Journal of Evaluation* 25 (1) 5-37

Bolling K, Grant C, Hamlyn B, Thornton A (2007) Infant Feeding Survey 2005. The Informaiton Centre, London

Cade JE, Frear L, Greenwood DC (2006) Assessment of diet in young children with an emphasis on fruit and vegetable intake: using CADET – Child and Diet Evaluation Tool. *Public Health Nutrition* 9(4):501-508

Final Report

Cade J, Thompson R, Burley V, Warm D. (2001) Development, validation and utilisation of food-frequency questionnaires – a review. *Public Health Nutrition* 5(4), 567-587

Caraher M, Dixon P, Lang T, Carr-Hill R (1998) Access to healthy foods: part I. Barriers to accessing healthy foods: differentials by gender, social class, income and mode of transport. *Health Education Journal* 57(3),191-201

Chung C & Myers SL (1999) Do The Poor Pay More For Food? An analysis of Grocery Store Availability and Food Price Disparities. *Journal of Consumer Affairs* 33(2), 276-296

Cockcroft JE, Durkin M, Masding C, Cade JE (2005) Fruit and vegetable intakes in a sample of pre-school children participating in the 'Five for All' project in Bradford. *Public Health Nutrition*. 8(7):861-869

Committee on Medical Aspects of Food and Nutrition Policy (COMA); Panel on Child and Maternal Nutrition of the Committee on Medical Aspects of Food and Nutrition Policy (2002) *Review of the Welfare Food Scheme*. The Stationery Office, London

Coote A, Allen J, Woodhead D (2004) Finding Out What Works. King's Fund, London

Dallison J, Lobstein T (1995) *Poor expectations: poverty and undernourishment in pregnancy*. London: NCH Action for Children and the Maternity Alliance

Final Report

D'Souza L, King SE, McFadden A, Moreton JA, Wright K, McCormick FM, Renfrew MJ, Dyson L, with Dowler E. The effectiveness of public health interventions to improve the nutrition of pregnant women. Draft Rapid Review (June 2006a)

D'Souza L, King SE, Glanville J, Fox D, McCormick FM, McFadden A, Renfrew MJ, with Mulvihill C. The effectiveness of public health interventions to improve the nutrition of 2 to 5 year old children. Draft Rapid Review (June 2006b)

D'Souza L, Renfrew MJ, McCormick FM, Dyson L, Wright K, Henderson J, Thomas J. Food-support programmes for low-income and socially disadvantaged childbearing women in developed countries: systematic review of the evidence. National Institute for Health and Clinical Excellence (July 2006)

Department of Health (2000) The NHS Plan. The Stationery Office, London

Department of Health (2003) Tackling health inequalities – a programme for action. The Stationery Office, London

Department of Health (2004a) Choosing Health; making healthy choices easier. The Stationery Office, London

Department of Health (2004b) Every Child Matters: change for children in the health services. Department of Health, London

Department of Health (2004c) National Service Framework for Children, Young People and Maternity Services: Executive Summary. Department of Health, London (4 October)

Final Report

Department of Health (2005). Delivering Choosing Health: Making Healthier Choices Easier. Department of Health

Department of Health (2006) Delivering Healthy Start: a guide for health professionals. Department of Health, London

Department of Health (2007) Review of the Health inequalities infant mortality PSA target. Department of Health, London

Dowler E, Turner S, Dobson B (2001) Poverty bites: food, health and poor families. London: Child Poverty Action Group

Dyson L, Renfrew MJ, McFadden A, McCormick F, Herbert G, Thomas J (2006) Promotion of breastfeeding initiation and duration. Evidence into practice briefing. National Institute for Health and Clinical Excellence: London

Evening Standard (2007) www.thisislondon.co.uk; News and current affairs, Tuesday 01 05 07

Fowles ER, Hendricks JA, Walker LO (2005) Identifying Healthy Eating Strategies in Low-Income Pregnant Women: Applying a Positive Deviance Model. Health Care for Women International 26 (9) 807-820

Foxcroft DR, Ireland D, Lister-Sharpe DJ, Lowe G, Breen R (2003) Longer-term primary prevention for alcohol misuse in young people: a systematic review. Addiction 98 397-411

Guardian (2003) www.business.guardian.co.uk; Monday January 13 200

Final Report

Harrison M, Lang T (1997) Running on empty. Demos Collection, Issue 12, pp 25-27

Hills D, Child C, Junge K, Wilkinson E, Sullivan F. Healthy Start: Rapid evaluation of early impact on recipients, health professionals, retailers and contractors. Symbia, Tavistock Institute (9th June 2006)

Kane R, Wellings K, Free C, Goodrich J (2000) Uses of routine data sets in the evaluation of health promotion interventions: opportunities and limitations. Health Education 100 33-41

Kaufman PR (1999) Rural Poor Have Less Access to Supermarkets, Large Grocery Stores. Journal of Rural Development Perspectives 13(3);19-26

King SE, D'Souza L, Glanville J, Fox D, Renfrew MJ, McFadden A, McCormick FM, Moreton JA. The effectiveness of public health interventions to promote safe and healthy milk feeding practices in babies. Draft Rapid Review (May 2006)

Margetts BM, Nelson M (1997) Design concepts in Nutritional Epidemiology, 2nd ed. Oxford: Oxford University Press

Margetts BM, Thompson RL, Speller V, McVey D. (1998). Factors which influence healthy eating patterns: results from the 1993 Health Education Authority health and lifestyle survey in England. Public Health Nutr. 2: 193-8

Final Report

McCormick FM, Glanville J, Moreton JA, Fox D, King SE, D'Souza L, Renfrew MJ.

The effectiveness of public health interventions to improve the nutrition of postpartum women. Draft Rapid Review (April 2006)

McCormick FM, King SE, Glanville J, Fox D, Moreton JA, Renfrew MJ, McFadden A, D'Souza L, with Peploe, K. The effectiveness of public health interventions to improve the nutrition of young children aged 6-24 months. Draft Rapid Review (June 2006)

McFadden A, Wright K, King SE, Moreton JA, McCormick FM, Renfrew MJ, D'Souza L, with Mulvihill C. The effectiveness of public health interventions to promote nutrition of pre-conceptual women. Draft Rapid Review (September 2006)

Metcoff J, Costiloe P, Crosby WM, Dutta S, Sandstead HH, Milne D, Bodwell CE, Majors SH (1985) Effect of food supplementation (WIC) during pregnancy on birth weight. *American Journal of Clinical Nutrition* 41(5):933-947

Morrisons supermarket (2007) <http://www.morrisons.co.uk/>

Mother and Infant Research Unit, University of York, with The Institute of Child Health, University College London (MIRU/ICH) Scoping review on evaluation of Healthy Start: Interim Report. Submitted to the Department of Health 8 December 2006

Pawson R and Tilley N (1998) *Realistic evaluation*. Sage Publications, London.

Final Report

Prevost AT, Whichelow MJ, Cox BD (1997) Longitudinal dietary changes between 1984-5 and 1991-2 in British adults: association with socio-demographic, lifestyle and health factors. *British Journal of Nutrition* 78: 873-888

Reid M and Adamson H (1997) Opportunities for and barriers to good nutritional health in women of childbearing age, pregnant women, infants under 1 and children aged 1 to 5. Health Education Authority, London

Renfrew MJ, Herbert G, Wallace LM, Spiby H, McFadden A (2006) Developing practice in breastfeeding *Maternal and Child Nutrition*. 2(4):245-261

Resnicow K and Vaughan R (2006) A chaotic view of behaviour change: a quantum leap for health promotion. *International Journal of Behavioural Nutrition and Physical Activity* 3(25), 5868-3-25

Rush D, Sloan NL, Leighton J, Alvir JM, Horvitz DG, Seaver WB, Garbowski GC, Johnson SS et al (1988) The National WIC Evaluation: evaluation of the Special Supplemental Food Program for Women, Infants and Children. V. Longitudinal study of pregnant women. *American Journal of Clinical Nutrition* 48 (2 Suppl):439-483

Rutter M (2006) Is Sure Start an Effective Preventive Intervention? *Child and Adolescent Mental Health* 11(3) 135-141

Schagen, S., Blenkinsop, S., Schagen, I., Scott, E., Teeman, D., White, G., Ransley, J., Cade, J. and Greenwood, D. (2005). *Evaluation of the School Fruit and Vegetable Pilot Scheme: Final Report*. London: Big Lottery Fund

Final Report

Smith AM, Smith C. (1994) Dietary intake and lifestyle patterns: correlates with socio-economic, demographic and environmental factors. *J Hum Nutr Diet.* 7: 283-94

Smith DM, Clarke GP, Ransley J & Cade J. (2006) Food Access and Health: A Microsimulation Framework for Analysis. *Studies in Social Science*, 35(4); 909-927

West R, McNeill A, Raw M (2000) Smoking cessation guidelines for health professionals: an update. *Thorax* 2000;55;987-999 doi:10.1136/thorax.55.12.987

Wreiden W, Peace H, Armstrong J, Barton K. (2003) A short review of dietary assessment methods used in National and Scottish Research Studies. Briefing Paper prepared for Working Group on Monitoring Scottish Dietary Targets Workshop, September 2003

Appendix 1: Staff and Advisory Group membership

Senior investigators

Prof Mary Renfrew	PI and project lead for York
Dr Catherine Law	Project lead for UCL

Staff

York:

Lisa Dyson	Senior research officer (0.2 wte)
Felicia McCormick	Research fellow (0.8 wte)
James Thomas	Database manager (0.2 wte)
Linda Baillie/Jenny Brown	Project secretary (0.2 wte)

UCL:

Richard Jenkins	Research support officer (0.4 wte)
Anna Pearce	Research fellow (0.1 wte)

Advisory Group membership

Name	Title
Jake Abbas	Deputy Director, Yorkshire & Humber Public Health Observatory
Prof Martin Bland	Professor Health Statistics, University of York
Prof Janet Cade	Director, Nutritional Epidemiology Group, University of Leeds
Dr Liz Dowler	Reader in Food and Social Policy, University of Warwick
Dr David Elliman	Consultant in Community Child Health, Great Ormond St Hospital
Lorna Farr	Senior Nurse – Equality & Diversity Manager, Newcastle PCT
Prof Hilary Graham	Director of Public Health Research Consortium, University of York
Prof Alison Macfarlane	Professor of Perinatal Health, City University
Christine McGuire	Principal Research Officer, Policy Research Programme, Department of Health
Jenny McLeish	Freelance Researcher / campaigner
Dr Nigel Rice	Health Economist, Econometrics and Data Group, University of York
Dr Helen Roberts	Professor of Child Health, City University
Catherine Shaw	Acting Director of Research and Evaluation, National Children's Bureau
Dr Dagmar Zeuner	Assistant Director of Public Health, Islington Primary Care Trust

Appendix 2: Content of Healthy Start programme at time of Devon and Cornwall evaluation and commissioning of scoping project

1. At time of Devon and Cornwall evaluation and commissioning scoping project

- Vitamin supplements for pregnant women and children up to age 4
- Food vouchers for fruit and vegetables (or formula milk for bottle fed babies) for
 - pregnant women (£2.80 per week)
 - breastfeeding women (£5.60 per week up to 12 months)
 - bottle fed babies (£5.60 per week up to 12 months)
 - children up to age 4 (£2.80 per week)
- Counselling and support for breastfeeding in pregnancy and postnatally (from midwives and health visitors)
- A public education and information campaign on the importance of nutrition
- Registration onto the scheme by the community midwife is intended to promote earlier contact with antenatal services, possibly resulting in an impact on pregnancy/postnatal/perinatal/infant outcomes more broadly

2. As Healthy Start programme rolled out, November 27th 2006

- Food vouchers for milk, formula milk, fruit and/or vegetables for:
 - All pregnant women under 18 (£2.80 per week)
 - Pregnant women aged 18 and over* (£2.80 per week)
 - Each baby aged under one** (£5.60 per week to 12 months)
 - Each child aged one up to 4 years** (£2.80 per week)

* Pregnant women in receipt of Income support or Income-based Job Seeker's Allowance;

** Families in receipt of Income-based Job-Seeker's Allowance or Child Tax Credit with an income below £14155 per annum

- Free vitamin supplements as follows:
 - Currently, up to 2 bottles of Abidec every 8 weeks;
 - At future date, a new Healthy Start vitamin product containing vitamins A, C and D.
- Registration onto the scheme by a midwife or health visitor who should provide routine and opportunistic nutrition and infant feeding education at the point of contact as well as referral to local nutrition and infant feeding initiatives.

Appendix 3: Priority outcomes for national evaluation of Healthy Start

Each outcome has been mapped to the population group from whom data should be collected (and not the population group for whom that variable may necessarily have an impact). For example, intake of folic acid should be collected from the pregnant mother although it is clearly associated with perinatal outcomes.

Each outcome is coded to reflect its source(s); a key is provided at the end of the Table.

Appendix 3, Table 1: Outcomes to evaluate effectiveness

Type of outcome	Outcome	Population group				Evidence base of effectiveness		
		Maternal	Peri-natal	0- 12 months	1-4 years	Likely effect (if known) including source	Population group	Type of intervention
Dietary intake	Intake of multivitamin / mineral supplements	•	•	•	•	4		
	Intake of periconceptional folic acid	•				4		
	Food intake for milk, fruit and vegetables (amount and frequency) for individual: a) Pregnant woman; b) Breastfeeding mother; c) Child of 0-1 year; d) Child of 1-4 years.	•	•	•	•	2b, 2c, 2d, 4		
	Overall quality of diet, including drinks for: a) Pregnant woman; b) Breastfeeding mother; c) Child of 0-1 year; d) Child of 1-4 years.	•	•	•	•	4		
	Nutrient intake for energy, protein, vitamins and minerals including	•	•	•	•	+ve Increased	Low income women	WIC food vouchers and

Final Report

	calcium.					energy, protein, minerals and vitamins ^{1b, 2b}		optional nutrition counselling
Food behaviour, attitudes and knowledge	Types of foods and drinks purchased with vouchers, including fresh fruit and vegetables	•				+ve Increased purchase of fruit and veg ^{3, 4}	HS beneficiaries particularly with children over one year	Healthy Start pilot scheme in Devon & Cornwall
	Displacement of income, eg. increased overall expenditure on fruit/veg or other items such as alcohol or cigarettes	•				-ve Retailer exchanging voucher for alcohol and cigarettes before manager intervened. ³		Healthy Start pilot scheme in Devon & Cornwall
Nutrition and health status	Iron (haemoglobin and ferritin) levels a) maternal: pre, during and post pregnancy; b) infant: birth and 6 mo postpartum	•	•			+ve Raised levels of iron and folate ^{1c, 1x, 2c, 2b}	Women with poor diets and planning a pregnancy	Multivitamin / mineral supplements
	Maternal anaemia in pregnancy	•				⁴		
	Rate of, and actual, weight gain in pregnancy	•				+ve Increased weight gain ^{1b}	Low income women	WIC food vouchers and optional nutrition counselling
	Women's wellbeing, particularly young women & potential links with diet: a) Exhaustion; b) Unhappiness; c) Anxiety and depression.	•				^{2c, 4}		

Final Report

	Gestational age at birth		•			No effect ^{1b} 4	Pregnant women	Nutrition advice / counselling
	Early, very early and preterm births		•			+ve Reduced rates of preterm births ^{1b}	Pregnant women who smoke < 15 cigarettes / day	Community and home based health, social and nutritional support
	Anthropometry including weight, length, height (including mean / low birth weight and length at birth)		•	•	•	+ve Increase in mean birth weight ^{1b, 2c}	Pregnant women who smoke < 15 cigarettes / day	WIC food vouchers and optional nutrition counselling
	Mortality	•	•	•	•	4		
	Educational and behavioural outcomes (routine health visitor assessments and school attainment)			•	•	4		
Infant Feeding	Initiation rates of any and exclusive bf at birth and hospital discharge		•			+ve Non-significant increases 1d, 2d, 3, 4	Pregnant women	Antenatal group education
	Duration rates of any and exclusive bf at 6 & 12 weeks and any bf at 6, 9 & 12 months.		•	•		+ve Non-significant increases 1d, 2d, 3, 4	Pregnant women	Antenatal group education
	Use of cow's milk before 12 months as main milk drink		•			-ve Some mothers putting child onto cow's milk earlier due to relative value of vouchers 3, 4	HS beneficiaries, particularly lowest income groups	Healthy Start pilot scheme in Devon & Cornwall
	Intake of formula milk		•	•		-ve Possible shift to	HS beneficiaries,	Healthy Start pilot scheme in

Final Report

						cheaper brands &/or reduction in intake ^{3,4}	particularly lowest income groups	Devon & Cornwall
	Optimum weaning practices including: a) timing of introduction of complementary foods; and b) type / content of weaning foods.		•			1e, 2d, 4		

1 = Intervention studies: 1a NICE RR Preconception; 1b NICE Food Support Review; 1c NICE RR Postpartum nutrition; 1d NICE RR 0-6 months; 1e NICE RR 6-24 months; 1f NICE RR 2-5 years; 1x Mahomed 1999 Cochrane review (Iron supplementation in pregnancy); 2 = Cohorts: 2a ALSPAC; 2b NDNS; 2c SWS, 2d MCS; 3 = Devon and Cornwall Healthy Start pilot evaluation; 4 = Advisory Group for 'Scoping national evaluation of Healthy Start'.

Appendix 3, Table 2: Outcomes to describe impact on target population(s)

Type of outcome	Outcome	Population group				Studies describing impact		
		Maternal	Peri-natal	0-12 months	1-4 years	Likely impact including source	Population group	Type of intervention
Food behaviour, attitudes and knowledge	Use of foods bought by voucher, including ease of use of fruit and vegetables in diet, including: a) maternal knowledge of meal planning, budgeting and preparation skills;	•				Limited effect due to lack of food preparation skills ^{3,4}	HS beneficiaries with particularly poor diets	Healthy Start pilot scheme in Devon & Cornwall
Programme acceptability	Women's views on: a) the content and delivery of HS; b) ways of improving HS.	•				+ve & -ve Effective awareness of HS but lack of clarity around eligibility ^{3,4}	HS beneficiaries	Healthy Start pilot scheme in Devon & Cornwall
	Embarrassment for beneficiaries in using vouchers including reason (e.g. retailer challenged	•				+ve & -ve Depends on retailer ^{3,4}	HS beneficiaries	Healthy Start pilot scheme in Devon &

Final Report

	use of voucher for non-HS items)							Cornwall
	Total purchasing power for family / household compared to previous entitlements, including distinction between formula feeders and breastfeeders and travel costs to access local retailer					⁴		
Programme delivery	Number / proportion of beneficiaries receiving entitlements, including: a) change of eligibility status; b) mechanisms to reach hardest to reach groups	•	•	•	•	Variation across areas and particular difficulties in reaching most vulnerable groups ^{3, 4}	HS beneficiaries	Healthy Start pilot scheme in Devon & Cornwall
	Early recruitment into, and length of participation in, scheme for each beneficiary					+ve Greater effect on weight gain in pregnancy with increased participation ^{1b, 4}	Low income women	WIC food vouchers and optional nutrition counselling
	Equity of value of vouchers within and between regions	•	•	•	•	⁴		
	Sources of HS information for existing IWFS and new beneficiaries, eg: midwives, health visitors, GP surgery, direct transfer from milk tokens, family and friends	•				+ve & -ve Good info for IWFS beneficiaries but difficulties for new beneficiaries ³	More difficulties among new beneficiaries in younger age groups.	Healthy Start pilot scheme in Devon & Cornwall
	Types of information for beneficiaries including availability in different languages, e.g. leaflet, user guide, referral to benefits office, verbal discussion	•				Info from health professional seen as handing over leaflets but limited		Healthy Start pilot scheme in Devon & Cornwall

Final Report

						discussion ³		
	Access to local retailer registered with HS, including range and quality of fresh fruit and vegetables	•				Poor quality fresh fruit and veg in deprived urban areas and remote rural areas. Possible increased travel to registered retailer ³		Healthy Start pilot scheme in Devon & Cornwall
	Mechanisms for beneficiary to redeem full value of voucher	•				Cash change of book system not permitted due to fraud concerns. ³		Healthy Start pilot scheme in Devon & Cornwall

1 = Intervention studies: 1a NICE RR Preconception; 1b NICE Food Support Review; 1c NICE RR Postpartum nutrition; 1d NICE RR 0-6 months; 1e NICE RR 6-24 months; 1f NICE RR 2-5 years; 1x Mahomed 1999 Cochrane review (Iron supplementation in pregnancy); 2 = Cohorts: 2a ALSPAC; 2b NDNS; 2c SWS, 2d MCS; 3 = Devon and Cornwall Healthy Start pilot evaluation; 4 = Advisory Group for 'Scoping national evaluation of Healthy Start'.

Appendix 3, Table 3: Outcomes to describe health service activity

Type of outcome	Outcome	Population group				Studies describing impact		
		Maternal	Peri-natal	0-12 months	1-4 years	Likely impact including source	Population group	Type of intervention
Programme delivery	Timing of first contact with maternity services, including point of advice on HS, eg at booking, prior to booking	•				⁴		
	Delivery of nutrition education and support at point of contact with health professional informing beneficiary of HS	•	•	•	•	Limited delivery of nutrition education ^{3,4}	HS beneficiaries	Healthy Start pilot scheme in Devon & Cornwall
	Ability of health professionals to	•				Health	Hard to reach	Healthy Start

Final Report

	identify, register, counsel and support eligible women, including: a) mechanisms to reach hardest to reach groups; b) addressing changes of eligibility status					professionals report hard to reach groups visit less regularly ^{3,4}	HS beneficiary groups: e.g. young women, ethnic groups, refugees, asylum seekers..	pilot scheme in Devon & Cornwall
Programme systems and infrastructure	Impact on workload for health professionals and their existing client base	•	•	•	•	⁴		
	Sustainability of workload within existing resources					⁴		

3 = Devon and Cornwall Healthy Start pilot evaluation; 4 = Advisory Group for 'Scoping national evaluation of Healthy Start'.

Appendix 3, Table 4: Outcomes to describe impact on health and commercial sectors

Type of outcome	Outcome	Population group				Studies describing impact		
		Maternal	Peri-natal	0-12 months	1-4 years	Likely impact including source	Population group	Type of intervention
Economic	Cost effectiveness of HS compared to IWFS or other nutrition programmes					⁴		
Broader effects of HS	Change in retailer behaviour to supply and/or promote fruit and veg					+ve change in purchasing decisions ³	Some retailers	Healthy Start pilot scheme in Devon & Cornwall
	Uptake of related nutrition education and breastfeeding activities including local child health promotion programme	•	•	•	•	Few referrals to nutrition promotion services by health professionals. ³		

3 = Devon and Cornwall Healthy Start pilot evaluation; 4 = Advisory Group for 'Scoping national evaluation of Healthy Start'.

Appendix 4: Explanatory variables

Variables which, on the basis of the evidence, are thought likely to have an explanatory and/or confounding effect on a primary outcome of interest are listed below. An evaluation of Healthy Start needs to ensure data for these variables is also collected to enable appropriate analysis of the actual effect of Healthy Start on a primary outcome of interest. The population group from whom data should be collected is indicated in Column 3 whereas the population group(s) for whom that variable may have an explanatory effect are detailed in Column 4. For example, data for the variable of 'maternal smoking' should be collected from the mother, this is likely to have an effect on both maternal and perinatal outcomes. The source of evidence from which each explanatory variable has been derived is indicated by the superscript note as detailed in the code at the end of the table.

Type of outcome / variable	Outcome	Population group				Potential relevance to outcomes
		Maternal	Perinatal	0-12 months	1-4 years	
Demographic	^{2a, 2b, 2c, 2d} Age	•				All outcomes across all population groups
	^{2a, 2b, 2c, 2d} Education	•				As above
	^{2a, 2b, 2c, 2d} Ethnicity	•				As above
	^{2a, 2b, 2c, 2d} Income / SES proxy	•				As above
	^{2a, 2b, 2c, 2d} Number of pregnancy/birth	•				As above, particularly failure to thrive and duration of breastfeeding
	^{2a, 2b, 2c, 2d, 4} Location within and between region(s) or inner city, urban, rural and remote areas	•				Access to HS foods, dietary intakes and related health outcomes for all groups.
	^{2d} Variation between households based on benefit entitlements	•				As above, particularly use of cow's milk before 12 months related to groups experiencing most disadvantage
	⁴ Social support networks, eg. single parent, single parent living with parents	•				Potential impact on uptake of HS
	⁴ Employment status including childcare mechanisms for working mothers	•				Potential impact on uptake of HS
Dietary intake	^{2b} Overall diet and/or food sources, other than Healthy Start	•	•	•	•	Outcomes across all groups

Final Report

	^{2b} Nutrient intake, including dietary supplements, other than Healthy Start	•	•	•	•	As above
	^{2c} High fish intake and/or low intake of green vegetables	•				Related to high blood pressure in childhood
	^{2a} Intake of fruit and other drinks	•				Related to duration of breastfeeding
Health behaviours	^{2d} Maternal smoking	•				Maternal and perinatal outcomes including weight gain in pregnancy, foetal growth and birth weight
	^{2d} Alcohol consumption	•				As above
	Infant feeding method(s) and duration	•				Relative increase or decrease in financial status as a result of Healthy Start could affect all outcomes as well as relevance to perinatal and child health outcomes, eg infections, IQ.
	^{2a, 2d} Pre-birth mental health	•				Perinatal and child health outcomes
	^{2a, 2c} Physical activity during pregnancy	•				As above
	^{2c, 2d} Anthropometry (height, weight, including pre-pregnancy weight, birth weight)	•				Perinatal outcomes particularly birth weight and length at birth
	^{2c} Fat mass	•				Low maternal fat mass related to poorer rates of growth in late gestation
	^{2c} BMI	•				Mother's slimness and unbalanced diet may be related to risk of cardiovascular and metabolic disease in child's later life

1 = Intervention studies: 1a NICE RR Preconception; 1b NICE Food Support Review; 1c NICE RR Postpartum nutrition; 1d NICE RR 0-6 months; 1e NICE RR 6-24 months; 1f NICE RR 2-5 years; 1x Mahomed 1999 Cochrane review (Iron supplementation in pregnancy); 2 = Cohorts: 2a ALSPAC; 2b NDNS; 2c SWS, 2d MCS; 3 = Devon and Cornwall Healthy Start pilot evaluation; 4 = Advisory Group

Appendix 5: Critique of dietary assessment methods

A summary of the main strengths and weaknesses of recognised dietary assessment methods to collect dietary and/or nutrient intake data is provided in Section A below. For the purposes of Healthy Start, intake data would be collected from female adults, including teenagers, and children aged less than 4 years. Additional methodological considerations for dietary assessment methods for pre-school children are detailed in Section B.

A. Dietary Assessment methods

1. Weighed Food Records

An individual weighs every food and drink item prior to consumption and records the weight in a pre-designed booklet. Leftovers are recorded also. Weighed records can be kept for 3,4,5 or 7 days, the 7 day often been referred to as the 'gold standard'. It is now considered necessary to use complementary physiological and biochemical methods to check reliability of method of measuring food intake being used.

Strengths:

- Widely used method
- Precision of portion sizes

Weaknesses:

- High respondent burden
- Mis-reporting
- Expensive
- Food composition data limited

Eg. of study using Weighed Food Records:

- National Diet and Nutrition Surveys

2. Estimated Food Records

Similar to weighed food record method except the quantification of food and drink is estimated, not weighed. Estimation is done using: household measures (eg. cups, spoons); food photographs, food models. The estimates are converted into weights by an investigator to calculate food and nutrient intake.

Strengths:

- Widely used method
- Lower respondent burden than weighed food diaries

Weaknesses:

- Estimation of portion sizes
- Mis-reporting
- Expensive
- Food composition data limited

Eg. of study using Estimated Food Records:

- The EPIC study (European Prospective Investigation of Cancer)

3. 24 Hour Recall

A trained interviewer asks the respondent to remember, retrospectively, all the food and drink consumed during a period of time in the recent past (often previous 24 hours). The interviewer may use prompts to: i) remind the respondent of eating and drinking episodes by time periods, links to day time activities; and ii) to assist estimation of portion sizes consumed. The information is recorded and coded by the interviewer.

Strengths:

- Low respondent burden
- Suitable for large-scale surveys
- Can be administered by telephone

Weaknesses:

- Estimation of portion sizes
- Single observation provides poor measure of individual intake
- Bias in recording 'good/bad' foods
- Memory dependent

4. Multiple Pass Recall

The diet is assessed over a period of 3-5 days during which the respondent is asked to recall all food and drinks consumed in the 24 hour period prior to the interview. Interviews can be a combination of face-to-face and telephone. The 'multiple pass' refers to the steps involved in the interview to check the dietary information: in the 'first pass', a quick list of foods consumed is obtained; in the 'second pass', information about the meal / snacks consumed (including time and place) are recorded. The 'third pass' prompts for foods that may have been forgotten. Finally a review of the record and further details of foods consumed and portion sizes are completed.

Strengths:

- Improved precision compared to 24 hour recall
- Low respondent burden
- Suitable for large-scale surveys
- Can be administered by telephone

Weaknesses:

- Estimation of portion sizes
- Bias in recording 'good/bad' foods
- Memory dependent

Eg. of study using Multiple Pass Recall:

NHANES (National Health and Nutrition Examination Study)

LIDNS (UK wide Low Income Diet and Nutrition Survey)

5. Food Frequency Questionnaires (FFQs) and semi-quantitative FFQs

The FFQ consists of a list of foods and a selection of options relating to the frequency of consumption of each of the foods listed (e.g. times per day, daily, weekly, monthly). FFQs normally ask about intake within a given time frame (eg. In the past 2-3 months, 1 year or longer) and aim to capture habitual intake. The food list can vary in length from just 9 food items to assess a single nutrient (eg. Calcium in a study of osteoporosis) to a list of 190 foods or more in studies on cancer.

FFQs are designed to collect dietary information from large numbers of people (eg. 100 individuals or more) and are normally self-administered, though interviewer administered and telephone interview methods are used.

Many FFQs also attempt to collect information about portion size in addition to frequency of consumption, the semi-quantitative FFQ. Where portion size information is not obtained standard food portion sizes are used to calculate nutrient intakes.

FFQs are useful for gathering information on groups of individuals as well as habitual intake of a range of foods. A primary aim of FFQs can be to characterize participants according to their position in the distribution of intake for the purposes of grouping or ranking.

Food lists, a type of FFQ, are brief questionnaires designed to measure specific dietary behaviours. It is not possible to measure nutrient intake from these questionnaires.

5.1 Use of FFQs in Cross-sectional surveys

FFQs have been used in cross-sectional studies to provide group comparisons, ranking of individuals and an assessment of usual dietary intake. "If the questionnaire aims to look at the percentage failing to meet nutritional requirements then issues of sensitivity and specificity also need to be addressed" (Cade et al, 2001).

Brief questionnaires designed to measure specific dietary behaviours (eg fruit and vegetable consumption) may be useful in lifestyle type surveys in which the number of dietary questions needs to be limited (Margetts et al 1998; Prevost et al 1997; Smith & Smith 1994 in Cade et al 2001). "If the cross-sectional study aims to compare different subgroups of the population, for example the effects of age or gender, then the food frequency questionnaire should be validated for each of the important sub-groups." (Cade et al 2001)

Strengths:

- Low respondent burden
- Suitable for large-scale surveys
- Can be self-completed
- Can be posted

Weaknesses:

- Estimation of portion sizes (food photographs may improve precision)
- Possible over-reporting of 'healthy' foods
- Requires validation in relation to reference method
- Requires validation for use among different sub- population groups
- Requires large numbers of participants

Egs. of studies using FFQ:

MONICA study (MONItoring trends and determinants in Cardiovascular disease)
Ca&VitDFFQ (Calcium and Vitamin D FFQ)

6. Dietary history

Usually conducted by trained interviewers to obtain detailed information on usual foods consumed, portion sizes, recipes and frequency of food consumption over the recent past.

Strengths:

- Low respondent burden

Weaknesses:

- Estimation of portion sizes
- Cost limits use for large-scale surveys
- Memory dependent

7. Household Food Surveys

Surveys to collect information about dietary intake at the household level. Some market research surveys relating to food purchases trends are conducted at the household level. Till receipts are also collected as part of the new Expenditure and Food Survey.

Strengths:

- Suitable for large-scale surveys
- Designed for monitoring diet trends at the population level

Weaknesses:

- Data not collected at the individual level

Egs. of studies using Household Food Surveys:

- NFS (the UK National Food Survey)
- EFS (the UK Expenditure and Food Survey)

B. Portion sizes for children

A national standard for portion sizes for children is not currently available in England. This work has been commissioned by the FSA and conducted by the University of Dundee although methodological issues have delayed publication of this work.

The project extracted collated food portion size information from recent National Diet and Nutrition Surveys (NDNS) of children aged 1½ to 4½ years and young people aged 4-18 years combined with other available weighed dietary records. Information on portion sizes of packaged foods and fast foods commonly eaten by children has also been collated. A list of typical food portion sizes has been produced for each age range and tested using existing dietary survey data.

1. Studies using food portion sizes for children

- a. Scottish Executive have developed national guidance for the early years to promote better food choices for children aged 1-5 years in early education and childcare settings. Children's portion sizes for some fruit and vegetables have been derived from the portion size guide for adults used in the Scottish Health Survey 2004 and the Health Survey for England 2003. The portion size for pre-school age (1-5) children is approximately 2/3 of an adult portion, eg. vegetables (fresh, frozen or canned) = 50g / 2 tablespoons.

- b. Paediatric advice via the US Food and Drugs Administration states the average toddler portion size is approximately $\frac{1}{4}$ of an adult portion.
- c. USDA (Dept of Agric) Children's Nutrition Research Center suggests one tablespoon per year of life is a 'good rule of thumb' for children aged 1-6 years.
- d. In England, average portion weights have been developed for primary school children aged 4-11 years (n=149 schools = n7975 portions) and secondary school children aged 11-18 years (n=79 schools = 3354 portions) school meals and grouped into foods or food groups (in confidence as in peer review).
- e. Use of food photographs (photographic food atlas) and self-reported standard descriptions of portion sizes were found to be unreliable compared to actual weights and comparisons with standard measures for adults (n=47). The food atlas provided higher median estimated weights for the majority of items. The differences were greater among children aged 6-16 years (n=37).

2. Methodological issues affecting quality of existing or planned food and/or nutrient intake data for pre-school children:

- a. Availability / use of standard measures for portion sizes;
- b. Use of validated measures for portion sizes;
- c. Availability / use of food composition tables for frequently eaten 'child' foods
- d. Relevance and validation of measures to different socio-economic and ethnic groups.

Appendix 6: Information recorded on HS-relevant outcomes and HS-eligible groups for all Type ‘A’ data sources

A number of cross-sectional and longitudinal surveys containing information about the prioritised outcomes were identified by the search strategy and are listed below by outcome group. For each group, surveys that are highlighted in bold text are expected to continue collecting HS-relevant outcome data for one or more of the HS-eligible groups.

1. Food outcomes

1a: Intake of milk, fruit and vegetables/ 1b: proxy outcome of ‘quality of diet’

Avon Longitudinal Study of Parents and Children – ALSPAC (1998-99, 2002-03)

- HS eligibility group variables = pregnant women under age 18 (except 2001).
- Collects HS-relevant outcome data (intake of milk [except 2002], fruit and vegetables; quality of diet) for pregnant women. However, it is unlikely that any of this data from 1998 onwards relate to pregnant women under age 18, given the longitudinal design of the study beginning in 1991/92. Additional HS-relevant data are collected from the cohort child, but by 1996, all are aged 4 and over.

British Household Panel Survey (UK, Wave 14, 2004/05)

- HS eligibility group variables = families with children aged under 4 and receiving Income Support/Job Seeker’s Allowance/Child Tax Credit and annual income of <£14155.
- Although HS-relevant outcome data (intake of fruit and vegetables; quality of diet) are collected for respondents aged 11-15 years, there are no data for pregnant women (no pregnancy variable included), breastfeeding women (no infant feeding status variable included), or children aged under 4.

Expenditure and Food Survey (UK, 2001/02-2004/05)

- Contains variables relating to 5 of the 6 HS eligibility groups (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155) from 2001/02-2002/03 and all 6 groups from 2003/04-2004/05.
- Collects HS-relevant outcome data (intake of free welfare milk) for pregnant women and children aged under 4, although the relevant variable refers to the receipt of milk and not actual intake, and data are available from the UK Data Archive (UKDA) at the household level only.

Families and Children Study (GB, 1999-2004)

- Contains variables relating to 2 of the 6 HS eligibility groups in 1999 and 3 groups from 2000 onwards (families with children aged under 4 and receiving Income Support/income-based Job Seeker’s Allowance/Child Tax Credit and annual income of <£14155).
- Collects HS-relevant outcome data (intake of fruit and vegetables; quality of diet) at the family level only, and the data do not provide details on the quantity of food consumed.

Family Expenditure Survey (UK, 1996/97-2000/01)

- Contains variables relating to 1 of the HS eligibility group variables in 1996/97 and 2 groups from 1997/98 onwards (families with children aged under 4 and receiving Income Support/income-based Job Seeker’s Allowance).

- Collects HS-relevant outcome data (intake of free welfare milk) for children aged under 4, although the relevant variable refers to the receipt of milk and not actual intake, and data are available from the UKDA at the household level only.

Family Resources Survey (UK, 1996/97-2004/05)

- Contains variables relating to 1 of the HS eligibility group variables in 1996/97, 2 groups from 1997/98-2000/01, and 3 groups from 2001/02 onwards (families with children aged under 4 and receiving Income Support/income-based Job Seeker's Allowance/Child Tax Credit and annual income of <£14155).
- Collects HS-relevant outcome data (intake of free welfare milk) for children aged under 4, although the relevant variable refers to the receipt of milk and not actual intake, and includes both cows and powdered milk and does not distinguish between the two. Data are available from the UKDA at the household level only.

Health Education Monitoring Survey (England, 1996-1998)

- Contains variables relating to 3 of the 6 HS eligibility group variables in 1996 and 1997 (pregnant women under age 18; pregnant women aged 18 and over and receiving Income Support; families with children aged under 4 and receiving Income Support) and one group (families with children aged under 4 and receiving Income Support) in 1998.
- Collects HS-relevant outcome data (intake of milk [type consumed only], fruit and vegetables [frequency consumed]; quality of diet) for pregnant women (1996-97 only).

Health Survey for England (England, 1997-99, 2001-04)

- Contains variables relating to 3 of the 6 HS eligibility groups in 1996, 5 groups from 1997–2003 (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155), and all 6 groups in 2004.
- Collects HS-relevant outcome data on intake of milk for pregnant women (type consumed = 1997-99 and 2003-04, quantity consumed = 1998-99 and 2003-04) and children aged under 4 (type consumed, 1997 only).
- Collects HS-relevant outcome data on intake of fruit and vegetables for pregnant women (1997-99 and 2001 onwards), breastfeeding women (2002 only), and children aged under 4 (1997 only).
- Collects HS-relevant outcome data on quality of diet for pregnant women (1997-99 and 2003 onwards), breastfeeding women (2002 only), and children aged under 4 (1997 only).

Millennium Cohort Study (UK, second [2003/05] and third [2006+] sweeps)

- Contains variables relating to all 6 HS eligibility groups.
- Collects data on fruit and vegetables in second sweep (2003/05), but the variable assesses only the availability of these foods to the family and not the frequency or quantity consumed. The third sweep (2006+) includes data on the intake of milk, fruit and vegetables and quality of diet for the cohort child, but all children are by this time aged 4 and over.

National Diet and Nutrition Survey Aged 4-18 (GB, 1997)

- HS eligibility group variables = families with children aged under 4 and receiving Income Support/income-based Job Seeker's Allowance.
- Although HS-relevant outcome data (intake of milk, fruit and vegetables; quality of diet) are collected for respondents aged 4-18 years, there are no

data for pregnant women (no pregnancy variable included), breastfeeding women (no infant feeding status variable included), or children aged under 4.

National Diet and Nutrition Survey Aged 19-64 (GB, 2000/01)

- HS eligibility group variables = families with children aged under 4 and receiving Income Support/income-based Job Seeker's Allowance.
- Although HS-relevant outcome data (intake of milk, fruit and vegetables; quality of diet) are collected for respondents aged 19-64 years, there are no data for pregnant women (excluded from the sample), breastfeeding women (excluded from the sample), or children aged under 4.

New Deal for Communities Household Survey (selected areas of England, 2002, 2004)

- HS eligibility group variables = families with children aged under 4 and receiving Income Support/Job Seeker's Allowance.
- Although HS-relevant outcome data (intake of fruit and vegetables) are collected for respondents aged 16 and over, there are no data for pregnant women (no pregnancy variable included), breastfeeding women (no infant feeding status variable included), or children aged under 4.

Northern Ireland Health and Social Wellbeing Survey (Northern Ireland, 1997)

- Contains variables relating to 5 of the 6 HS eligibility groups (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155).
- Collects HS-relevant outcome data on food outcomes (intake of fruit and vegetables; quality of diet) for pregnant women.

Scottish Health Survey (Scotland, 1995, 1998, 2003)

- Contains variables relating to 3 of the 6 HS eligibility groups in 1995, 5 groups in 1998 (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155), and all 6 groups in 2003.
- Collects HS-relevant outcome data on intake of milk for pregnant women (type consumed = 1995-2003, quantity consumed = 1998 only) and children aged under 4 (type and quantity consumed, 1998 only).
- Collects HS-relevant outcome data on intake of fruit and vegetables for pregnant women (1995-2003) and children aged under 4 (1998 only).
- Collects HS-relevant outcome data on quality of diet for pregnant women (1995-2003) and children aged under 4 (1998-2003).

1b: Intake of nutrients from milk, fruit and vegetables

National Diet and Nutrition Survey Aged 4-18 (GB, 1997)

- HS eligibility group variables = families with children aged under 4 and receiving Income Support/income-based Job Seeker's Allowance.
- Although HS-relevant outcome data are collected for respondents aged 4-18 years, there are no data for pregnant women (no pregnancy variable included), breastfeeding women (no infant feeding status variable included), or children aged under 4.

National Diet and Nutrition Survey Aged 19-64 (GB, 2000/01)

- HS eligibility group variables = families with children aged under 4 and receiving Income Support/income-based Job Seeker's Allowance.

- Although HS-relevant outcome data are collected for respondents aged 19-64 years, there are no data for pregnant women (excluded from the sample), breastfeeding women (excluded from the sample), or children aged under 4.

Four other surveys (*Consumer Attitudes Survey 2000-05*, *Health Education Population Survey 1996-2005*, *Infant Feeding Survey 2000-05* and *Welsh Health Survey 1998-2005*) collected data on food outcomes but did not contain any variables relating to the 6 HS eligibility groups. One other data source, the *Low Income Diet and Nutrition Survey* (UK, 2003-05), has collected information on food outcomes but no details on variables relating to the HS eligibility groups are currently available (as of April 2007).

2. Infant feeding

2a: Initiation and duration of any/exclusive breastfeeding

Continuous Household Survey (Northern Ireland, 2004/05)

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data from parents with child/children under 2 years old.

Health Survey for England (England, 2002)

- HS eligibility group variables = pregnant women under 18; pregnant women aged 18 and over and receiving Income Support/Job Seeker's Allowance; families with children aged under 4 and receiving Income Support/Job Seeker's Allowance.
- Collects HS-relevant outcome data (age of baby when stopped breastfeeding) from mothers with child under 1 year old who no longer breastfeed.

Millennium Cohort Study (UK, first [2001/03], second [2003/05], and third [2006+] sweeps)

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data on the cohort child from the main respondent, although by the time of the second and third sweeps all children are aged over 1 year.

Scottish Health Survey (Scotland, 2003)

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data (age of baby when stopped breastfeeding) from parents with child/children aged 0-1 years who no longer breastfeed.

2b: Intake of formula milk

Family Resources Survey (UK, 1996/97-2004/05)

- Contains variables relating to 1 of the HS eligibility group variables in 1996/97, 2 groups from 1997/98-2000/01, and 3 groups from 2001/02 onwards (families with children aged under 4 and receiving Income Support/income-based Job Seeker's Allowance/Child Tax Credit and annual income of <£14155).
- Collects HS-relevant outcome data (intake of free welfare milk, including powdered milk), although it is not possible to determine whether or not children are exclusively bottle-fed (no infant feeding status variable included). Furthermore, the relevant variable refers to the receipt of milk and not actual

intake, includes both powdered and cows milk and does not distinguish between the two, and is available from the UKDA at household level only.

2c: Timing of the introduction of milk other than breast or formula milk

Millennium Cohort Study (UK, first sweep [2001/03])

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data on the cohort child from the main respondent.

2d: Timing of the introduction of weaning foods

Continuous Household Survey (Northern Ireland, 2004/05)

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data from parents with child/children under 2 years old.

Millennium Cohort Study (UK, first sweep [2001/03])

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data on the cohort child from the main respondent.

2e: Type and content of weaning foods

One survey (*Infant Feeding Survey 2000-05*) collected data on this and all of the other infant feeding outcomes (2a, 2b, 2c, 2d) but did not contain any variables relating to the 6 HS eligibility groups.

3. Proxy measures for the timing of registration onto the HS programme

None of the cross-sectional surveys identified in the searches contained proxy measures for HS registration. However, one of the longitudinal data sources, the Millennium Cohort Study included a question in its first sweep of data collection (2001/03) on the number of weeks pregnant when the mother first saw a doctor or midwife to confirm her pregnancy or had her first antenatal visit.

4. Vitamin and mineral supplements

4a: Intake of vitamin and mineral supplements

Avon Longitudinal Study of Parents and Children – ALSPAC (1996-97, 2000-01, 2003)

- HS eligibility group variables = pregnant women under age 18.
- Collects HS-relevant outcome data for pregnant women. However, it is unlikely that any of this data from 1996 onwards relate to pregnant women under age 18, given the longitudinal design of the study beginning in 1991/92.

Health Survey for England (England, 1997-2004)

- Contains variables relating to 5 of the 6 HS eligibility groups from 1997-2003 (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155) and all 6 groups in 2004.
- Collects HS-relevant outcome data for pregnant women (1997 onwards) and children aged under 4 (1997 onwards), but the relevant variable does not provide details on the type, quantity or frequency consumed.

National Diet and Nutrition Survey Aged 4-18 (GB, 1997)

- HS eligibility group variables = families with children aged under 4 and receiving Income Support/income-based Job Seeker's Allowance.
- Although HS-relevant outcome data are collected for respondents aged 4-18 years, there are no data for pregnant women (no pregnancy variable included), breastfeeding women (no infant feeding status variable included), or children aged under 4.

National Diet and Nutrition Survey Aged 19-64 (GB, 2000/01)

- HS eligibility group variables = families with children aged under 4 and receiving Income Support/income-based Job Seeker's Allowance.
- Although HS-relevant outcome data are collected, there are no data for pregnant women (excluded from the sample), breastfeeding women (excluded from the sample), or children aged under 4.

Scottish Health Survey (Scotland, 1995, 1998, 2003)

- Contains variables relating to 3 of the 6 HS eligibility groups in 1995, 5 groups in 1998 (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155), and all 6 groups in 2003.
- Collects HS-relevant outcome data (type consumed only) for pregnant women (1995-2003) and children aged under 4 (1998-2003).

4b: Intake of periconceptional folic acid

Health Survey for England (England, 2002)

- HS eligibility group variables = pregnant women under 18; pregnant women aged 18 and over and receiving Income Support/Job Seeker's Allowance; families with children aged under 4 and receiving Income Support/Job Seeker's Allowance.
- Collects HS-relevant outcome data from mothers with child/children aged under 1.

Two other surveys (*Infant Feeding Survey 2000-05* and *Welsh Health Survey 1998-2005*) collected data on vitamin and mineral supplements but did not contain any variables relating to the 6 HS eligibility groups.

5. Household expenditure on food and drink

Expenditure and Food Survey (UK, 2001/02-2004/05)

- Contains variables relating to 5 of the 6 HS eligibility groups (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155) from 2001/02-2002/03 and all 6 groups from 2003/04-2004/05.
- Collects HS-relevant outcome data at the household level.

Family Expenditure Survey (UK, 1996/97-2000/01)

- Contains variables relating to 1 of the HS eligibility group variables in 1996/97 and 2 groups from 1997/98 onwards (families with children aged under 4 and receiving Income Support/income-based Job Seeker's Allowance).
- Collects HS-relevant outcome data at the household level.

National Food Survey (UK, 1996-2000)

- HS eligibility group variables = pregnant women under age 18; pregnant women aged 18 and over and receiving Income Support; families with children aged under 4 and receiving Income Support.
- Collects HS-relevant outcome data at the household level.

6. Other nutrition, health and social status outcomes

6a: Maternal iron (haemoglobin or ferritin) levels/anaemia in pregnancy

Health Survey for England (England, 2002)

- HS eligibility group variables = pregnant women under 18; pregnant women aged 18 and over and receiving Income Support/Job Seeker's Allowance; families with children aged under 4 and receiving Income Support/Job Seeker's Allowance.
- Collects HS-relevant outcome data (anaemia in pregnancy) from mothers with child/children aged under 1.

Millennium Cohort Study (UK, first [2001/03] sweep)

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data (anaemia in pregnancy) from the natural mother about her last pregnancy.

6b: Baby's gestational age at delivery

British Household Panel Survey (UK, Waves 9-14, 1999/2000-2004/05)

- Contains variables relating to 2 of the 6 HS eligibility groups in Waves 9-10, 5 groups in Waves 11-12 (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155), and all 6 groups in Waves 13-14.
- Collects HS-relevant outcome data on newborns from mothers who gave birth in the preceding year.

Health Survey for England (England, 2002)

- HS eligibility group variables = pregnant women under 18; pregnant women aged 18 and over and receiving Income Support/Job Seeker's Allowance; families with children aged under 4 and receiving Income Support/Job Seeker's Allowance.
- Collects HS-relevant outcome data from mothers with child/children aged under 1.

Millennium Cohort Study (UK, first [2001/03] sweep)

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data on the cohort child from the natural mother.

Scottish Health Survey (Scotland, 2003)

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data from mothers with child/children aged 0-1 years.

6c: Baby's birth weight

British Household Panel Survey (UK, Waves 9-14, 1999/2000-2004/05)

- Contains variables relating to 2 of the 6 HS eligibility groups in Waves 9-10, 5 groups in Waves 11-12 (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155), and all 6 groups in Waves 13-14.
- Collects HS-relevant outcome data on newborns from mothers who gave birth in the preceding year.

Health Survey for England (England, 2002)

- HS eligibility group variables = pregnant women under 18; pregnant women aged 18 and over and receiving Income Support/Job Seeker's Allowance; families with children aged under 4 and receiving Income Support/Job Seeker's Allowance.
- Collects HS-relevant outcome data from mothers with child/children aged under 1.

Millennium Cohort Study (UK, first [2001/03] and second [2003/05] sweeps)

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data on the cohort child from the natural mother (sweep 2 = data from new families).

6d: Length/height and weight of children aged under 4 years

Health Survey for England (England, 1996-2004)

- Contains variables relating to 3 of the 6 HS eligibility groups in 1996, 5 groups from 1997–2003 (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155), and all 6 groups in 2004.
- Collects HS-relevant outcome data for infants aged 0-1 years (length = 2002-04) and children aged 2 and over (height and weight = 1996-2004).

Millennium Cohort Study (UK, first [2001/03] and second [2003/05] sweeps)

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data (first sweep = weight, second sweep = height and weight) on children aged under 4.

Scottish Health Survey (Scotland, 1998-2003)

- Contains variables relating to 5 of the 6 HS eligibility groups in 1998 (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155) and all 6 groups in 2003.
- Collects HS-relevant outcome data for infants aged 0-1 years (length = 2003) and children aged 2 and over (height and weight = 1998-2003).

6e: Maternal wellbeing and mental ill health in pregnancy/of mothers with children aged under 4 years

Avon Longitudinal Study of Parents and Children – ALSPAC (1996-2000, 2002-03)

- HS eligibility group variables = pregnant women under age 18.
- Collects HS-relevant outcome data for pregnant women. However, it is unlikely that any of this data from 1996 onwards relate to pregnant women under age 18, given the longitudinal design of the study beginning in 1991/92.

British Household Panel Survey (UK, Waves 6-14, 1996/97-2004/05)

- Contains variables relating to 2 of the 6 HS eligibility groups in Waves 6-10, 5 groups in Waves 11-12 (except families with children aged under 4 and

receiving Child Tax Credit and annual income of <£14155), and all 6 groups in Waves 13-14.

- Collects HS-relevant outcome data for pregnant women (Waves 8 and 11-14) and mothers with children aged under 4 (Waves 6-14).

Families and Children Study (GB, 1999-2002)

- Contains variables relating to 2 of the 6 HS eligibility groups in 1999 and 3 groups from 2000 onwards (families with children aged under 4 and receiving Income Support/income-based Job Seeker's Allowance/Child Tax Credit and annual income of <£14155).
- Collects HS-relevant outcome data for mothers with children aged under 4.

Health Survey for England (England, 1997-2004)

- Contains variables relating to 5 of the 6 HS eligibility groups from 1997–2003 (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155), and all 6 groups in 2004.
- Collects HS-relevant outcome data for pregnant women and mothers with children aged under 4 years.

Millennium Cohort Study (UK, first [2001/03], second [2003/05] and third [2006+] sweeps)

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data for pregnant women and mothers with children aged under 4.

New Deal for Communities Household Survey (selected areas of England, 2002, 2004)

- HS eligibility group variables = families with children aged under 4 and receiving Income Support/Job Seeker's Allowance.
- Collects HS-relevant outcome data for mothers with children aged under 4.

Northern Ireland Health and Social Wellbeing Survey (Northern Ireland, 1997, 2001)

- Contains variables relating to 5 of the 6 HS eligibility groups (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155).
- Collects HS-relevant outcome data for pregnant women and mothers with children aged under 4.

Scottish Health Survey (Scotland, 1995, 1998, 2003)

- Contains variables relating to 3 of the 6 HS eligibility groups in 1995, 5 groups in 1998 (except families with children aged under 4 and receiving Child Tax Credit and annual income of <£14155), and all 6 groups in 2003.
- Collects HS-relevant outcome data for pregnant women and mothers with children aged under 4.

6f: Educational and behavioural development of children aged 1-3 years

Millennium Cohort Study (UK, first [2001/03], second [2003/05] sweeps)

- Contains variables relating to all 6 HS eligibility groups.
- Collects HS-relevant outcome data on children aged 1-3 years from the main and partner respondents.

Two other surveys (*Infant Feeding Survey 2000-05* and *Welsh Health Survey 1998*) collected data on one or more of the nutrition, health and social status outcomes but did not contain any variables relating to the 6 HS eligibility groups.

Additional details on the number of sources identified are shown in Appendix 6, Table 1 below.

Appendix 6, Table 1: Number of Type ‘A’ data sources by Healthy Start eligibility group and relevant outcome

HS eligibility group	HS-relevant outcome						
	Food outcomes	Infant feeding	Timing of HS registration (proxy measure)	Vitamin and mineral supplements	Household expenditure on food and drink	Other nutrition, health and social status outcomes	Total number of sources
Pregnant women under age 18	6 (2)	4 (0)	1 (0)	2 (1)	2 (1)	5 (3)	9 (4)
Pregnant women age 18+ and IS	6 (2)	4 (0)	1 (0)	2 (1)	2 (1)	5 (3)	9 (4)
Pregnant women age 18+ and IB-JSA	5 (2)	4 (0)	1 (0)	2 (1)	1 (1)	5 (3)	7 (4)
Families with children <age 4 and IS	9 (4)	5 (1)	1 (0)	2 (1)	3 (1)	7 (3)	13 (6)
Families with children <age 4 and IB-JSA	8 (4)	5 (1)	1 (0)	2 (1)	2 (1)	7 (3)	11 (6)
Families with children <age 4, CTC and AI <£14155	6 (4)	4 (1)	1 (0)	2 (1)	1 (1)	5 (3)	8 (6)
Total number of sources	9 (4)	5 (1)	1 (0)	2 (1)	3 (1)	7 (3)	13 (6)

HS = Healthy Start

IS = Income Support

IB-JSA = Income-based Job Seeker’s Allowance

CTC = Child Tax Credit

AI = Annual Income

(#) = number of sources that are expected to continue collecting HS-relevant outcome data in the future

Appendix 7: Information reported by HS-relevant outcome for Types ‘B’ and ‘C’ data sources

Type B data sources

A total of 10 data sources were identified by the search strategy

Type ‘B’ data sources

CHSP	Child Health Surveillance Programme (Pre-School)
DIN	Doctors’ Independent Network
GPRD	General Practice Research Database
GC	Guthrie Card (Inborn Errors Neonatal Screening Programme)
HES	Hospital Episode Statistics
LDPR	Local Delivery Plan Returns
QR	QResearch
SMR02	Scottish Morbidity Record (SMR02) – Maternity Inpatient and Day Care
SUS	Secondary Uses Service
THIN	The Health Improvement Network

In the case of the DIN, GPRD, QR and THIN, a complete list of their constituent variables was not available on the internet. Therefore, it is unclear as to whether or not these sources collected data relating to any of the HS-relevant outcomes and/or HS eligibility status. They are included in Table ? for reference purposes, on the grounds that their data are derived from general practice records and could, therefore, potentially contain some of the HS-relevant outcomes (e.g. infant feeding). The remaining six sources recorded data relating to the following HS-relevant outcomes:

Infant feeding

Initiation and duration of any/exclusive breastfeeding

Scottish Morbidity Record (SMR02) (Scotland, 1996 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = first feed given and feeding on discharge from hospital (response options include breast, bottle, other).

Three other sources (*CHSP*, *GC* and *LDPR*) collected data on infant feeding but did not contain any variables relating to HS eligibility status.

Proxy measures for the timing of registration onto the HS programme)

Hospital Episode Statistics (England, 1996 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = gestation period in weeks at the date of the first antenatal assessment.

Scottish Morbidity Record (SMR02) (Scotland, 1996 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = date of booking (antenatal booking clinic).

Secondary Uses Service (England, 2005 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = first antenatal assessment date.

Other nutrition, health and social status outcomes

Maternal iron (haemoglobin or ferritin) levels/anaemia in pregnancy

Scottish Morbidity Record (SMR02) (Scotland, 1996 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = anaemia can be coded in the diagnostic/clinical record section of SMR02.

Baby's gestational age at delivery

Scottish Morbidity Record (SMR02) (Scotland, 1996 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = gestational age at delivery can be derived from date of delivery (record of labour/delivery section of SMR02) and last menstrual period (current pregnancy section of SMR02).

Secondary Uses Service (England, 2005 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = gestation length (labour onset).

Baby's birth weight

Hospital Episode Statistics (England, 1996 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = birth weight (maternity tail section)

Scottish Morbidity Record (SMR02) (Scotland, 1996 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).

- HS-relevant outcome data = birth weight (record of baby section of SMR02).

Secondary Uses Service (England, 2005 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = birth weight.

Baby’s APGAR score

Scottish Morbidity Record (SMR02) (Scotland, 1996 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = APGAR score at 5 minutes (record of baby section of SMR02).

Length/height and weight of children aged under 4 years

Scottish Morbidity Record (SMR02) (Scotland, 1996 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = crown-heel length (record of baby section of SMR02).

Maternal wellbeing and mental health in pregnancy/of mothers with children aged under 4 years

Scottish Morbidity Record (SMR02) (Scotland, 1996 onwards)

- Contains variables relating to 1 of the HS eligibility groups (pregnant women under 18, derived from age and antenatal care variables).
- HS-relevant outcome data = mental health conditions can be coded in the diagnostic/clinical record section of SMR02.

Educational and behavioural development of children aged 1-3 years

One other source (*CHSP*) collected data on this and other nutrition, health and social status outcomes but did not contain any variables relating to HS eligibility status.

Type ‘C’ data sources

A total of 5 data sources were identified by the search strategy (see Appendix 7, Table 1).

Appendix 7, Table 1: Type ‘C’ data sources

CHICC	Child Health Informatics Centre Core/RCPCH Updated Essential Core Dataset
NCHCS	National Child Health Computer System
RICHES	Regional Interactive Child Health System

SBR	Scottish Birth Record
SMMIS	St Mary's Maternity Information System

In the case of the NCHCS, RICHS and SMMIS, a complete list of their constituent variables was not available on the internet. Therefore, it is unclear as to whether or not these sources collected data relating to any of the HS-relevant outcomes and/or HS eligibility status. They are included in Appendix 7, Table 1 for reference purposes, on the grounds that their data are derived from maternity- or child-based data records and could, therefore, potentially contain some of the HS-relevant outcomes (e.g. infant feeding).

Infant feeding

Two sources (*CHICC* and *SBR*) collected data on infant feeding but did not contain any variables relating to HS eligibility status.

Other nutrition, health and social status outcomes

All five Type 'C' data sources (*CHICC*, *NCHCS*, *RICHS*, *SMMIS* and *SBR*) collected data on one or more of these outcomes but it was unclear as to whether any included any variables relating to HS eligibility status.

Appendix 8: Routine data sources – comparison options

Explanatory notes

The four Type A data sources which were able to describe both the intervention and comparison groups for a number of the questions of interest are highlighted in green in the table.

Where a cell in the table is asterisked, this indicates that the intervention or comparison group can be described by some or all of the potential data sources, but the comparison is not possible due to a lack of data sources for the other group. However, these surveys may still provide useful baseline data for the particular relevant outcome as detailed in Table 5.

Comparisons are arranged by question of interest and related outcome. Each outcome is accompanied by a list of Type A data sources that are of potential use to the comparison (i.e. they contain variables relating to the relevant outcome and one or more of the Healthy Start eligibility groups). Each row contains details on the intervention and comparison groups, including group characteristics (e.g. pregnant women, breastfeeding women, children aged under 4 years), year of data collection, place (geographical area) of data collection, data sources that can describe the group, an estimate of their sample sizes and the size of the change detectable at 80% statistical power.

It should be noted that although the 'year' column for the intervention group in each of the highlighted comparisons features the '2005/06' or '2006+' time periods, the most recent publicly available datasets for the relevant surveys are from 2004 (in the case of the FCS and HSE) or 2004/05 (the EFS and FRS). However, these sources are considered eligible for the comparisons, as they are expected to continue collecting relevant outcome data in the future.

The estimated sample size and the size of effect calculated with 80% statistical power for each outcome are reported in Columns K and L respectively. The level at which the data can be analysed and any limitations about the relevance of the reported variable to the priority outcome are reported in Column M.

Appendix 9: Summary of relevant Type ‘A’ data sources reporting data to measure outcomes of effectiveness for each comparison option

Expenditure and Food Survey (UK; 2001/02-2004/05; ongoing)

- Collects data from two of the three main HS eligibility groups: pregnant women and children aged under 4.
- In the latest survey year, EFS collects HS-relevant outcome data on the dietary intake of cows’ milk, although the relevant variable refers to the receipt of milk and not actual intake, and the data available from the UK Data Archive (UKDA) are at the household level only.
- Collects HS-relevant outcome data on the type of foods and drinks purchased and the displacement of income to other items, although expenditure using HS vouchers is not specifically recorded, and the data held at the UKDA are at the household level only.
- HS-relevant outcome variables have remained unchanged since the first survey in 2001/02.
- Provides detail on the following borderline ‘non-eligible’ groups = pregnant women on low incomes but not in receipt of the income benefits required for HS registration; women who are in receipt of these income benefits but are not pregnant; families who are in receipt of these benefits but have no children aged under 4.
- Samples private households only and will, therefore, exclude many people, such as those who are homeless or living in temporary accommodation, who are likely to be eligible for HS.
- The sample size estimate for the intervention group at the national level is small (less than 200 individuals for the latest survey year).
- Data held at the UKDA are coded at the government office region level only, which precludes any comparisons involving Devon and Cornwall. However, the EFS questionnaire records area and address number, and there remains the possibility that data could be accessed at this level from another source and then aggregated to the level of Devon and Cornwall, although numbers are likely to be very small.

Families and Children Study (GB; 1999-2004; ongoing)

- Collects data from one of the three main eligibility groups: children aged under 4.
- In the latest survey year, FCS collects HS-relevant outcome data on intake of fruit and vegetables and quality of diet, but at the family level only, and the variables do not provide details on the quantity of food consumed.
- HS-relevant outcome variables have remained unchanged since the first survey in 1999.
- Provides detail on the following borderline ‘non-eligible’ groups = families who are in receipt of the income benefits required for HS registration but have no children aged under 4.
- Samples parents with dependent children, identified from Child Benefit records.
- The sample size estimates for the intervention group at the national level are between 400 and 800 for the latest survey year.
- The FCS dataset held at the UKDA does not contain any spatial unit information, which precludes any comparisons below the national level, and the FCS questionnaire does not include any geographical identifiers.

Family Resources Survey (UK; 1996/97-2004/05; ongoing)

- Collects data from one of the three main eligibility groups: children aged under 4.
- In the latest survey year, FRS collects HS-relevant outcome data on the dietary intake of cows milk, although the relevant variable refers to the receipt of milk and not actual intake, and includes both cows and powdered milk and does not distinguish between the two. Furthermore, the data held at the UKDA are at the household level only.
- Relevant outcome variables have remained unchanged since 1996/97.
- Provides detail on the following borderline 'non-eligible' groups = families who are in receipt of the income benefits required for HS registration but have no children aged under 4.
- Samples private households and will, therefore, exclude many individuals, such as those who are homeless or living in temporary accommodation, who are likely to be eligible for the HS programme.
- The sample size estimates for the intervention group at the national level are between 400 and 700 for the latest survey year.
- Data held at the UKDA are coded at the government office region level only, which precludes any comparisons involving Devon and Cornwall. However, the FRS questionnaire includes local authority and district council codes, and there remains the possibility that data could be accessed at these levels from another source and then aggregated to the level of Devon and Cornwall, although numbers are likely to be very small.

Health Survey for England (England; 1997-99, 2001-04; ongoing)

- Collects data from two of the three main eligibility groups: pregnant women and children aged under 4.
- In the latest survey year, HSE collects HS-relevant outcome data on the dietary intake of cows' milk, fruit and vegetables, and the quality of diet including overall assessment of fruit and vegetable intake, but for pregnant women only. Also collects data on intake of vitamin and mineral supplements, but the variable records only whether or not they are consumed and does not detail the type, quantity or frequency of consumption.
- Variables on milk consumption have remained unchanged since 1998; variables on quality of diet have remained broadly the same since 1997; variables on fruit and vegetable consumption from 1997-99 detailed frequency of consumption, and from 2001 onwards have measured the quantity consumed.
- Provides detail on the following borderline 'non-eligible' groups = pregnant women on low incomes who are not in receipt of the income benefits required for HS registration, and women who are in receipt of these income benefits but are not pregnant.
- Samples private households and will, therefore, exclude many individuals, such as those who are homeless or living in temporary accommodation, who are likely to be eligible for the HS programme.
- The sample size estimates indicate that with regard to dietary-related outcomes, the HSE is not useful for an evaluation of the HS programme. Relevant outcome data have been collected for only one of the HS eligible groups (pregnant women) in the time periods featured in the highlighted comparisons, and the latest HSE dataset from 2004 includes only 6 pregnant women. With regard to the intake of vitamin and mineral supplements, the sample size estimates for the intervention group at the national level are small (around 100 individuals for the latest survey year).

Appendix 10: Sample size estimates for routine data sources in comparison options

Background:

4 datasets have been identified as potential sources for an evaluation of the Healthy Start scheme, on the basis that they contain the relevant variables to identify individuals or households eligible for the scheme. The potential data sources are the Expenditure and Food Survey (EFS), the Families and Children Study (FCS), the Family Resources Survey (FRS), Health Survey for England (HSE).

Eligibility for Healthy Start is based on the following groups:

1. Pregnant women
2. Breastfeeding women
3. Children aged 0-3

None of the data sources, however, included variables relating to breastfeeding status in their latest datasets (2004 or 2004/05), and are therefore unlikely to do so in the future (to provide an intervention group). Therefore our sample size estimation involved estimating the number of individuals in groups 1 and 3 for each of the data sources.

Individuals in group 1 are eligible for registration onto Healthy Start in one of three ways:

- Under age 18
- In receipt of income support
- In receipt of income-based Job Seeker's Allowance

Individuals in group 3 are also eligible in one of three ways:

- Families receiving income support
- Families receiving income-based Job Seeker's Allowance
- Families receiving of Child Tax Credit, and an annual income of <£14155

We estimated the proportion of individuals or households within the surveys who would be eligible for Healthy Start according to the above criteria using two different methods.

1. The first used numbers provided in survey reports outlining key results and demographics. Where the relevant data were not available estimations were made using national figures from, for example, the census.
2. The second accessed one of the datasets (FRS) and identified the actual number of individuals and households eligible for the Healthy Start scheme. These numbers were converted to proportions and then applied to the remaining datasets, as it would have been too time consuming to access all of them.

These two methods give differing estimates because they are based on different assumptions. In using the two in tandem it is hoped that we will gain an insight into the approximate numbers which are available from the potential data sources.

Shown below are ranges, based on the two different methods, within which we would expect the true numbers to fall (shown below).

FRS: 489 - 619

EFS: 107 – 198

FCS: 435 - 719

HSE: 94 – 114