An exploration of the UK Healthy Start vitamin supplementation programme in North West England

This thesis is submitted in accordance with the requirements of the University of Liverpool for the degree of Doctorate in Medicine

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Declaration

This thesis is my own work. The material contained in this thesis has not been presented, nor is currently being presented, either wholly or in part for any other degree or qualification.

Dedication

I would like to dedicate this thesis to my mother and father who instilled in me that we live in an unjust society, but that there is something each of us can do to influence the world around us in a positive way through knowledge and action, driven by commitment, compassion and integrity.

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Abstract

Background: The UK Healthy Start (HS) programme is a means-tested nutritional supplementation programme providing food (FV) and vitamin vouchers (VV) for children under the age of four years and pregnant and breastfeeding women. FV can be used for fruit, vegetables, fresh cow's milk, and infant formula. VV can be exchanged for women's tablets (folic acid, vitamin C and D) and children's drops (vitamin A, C and D). The gap in the prior evidence-base since the launch of the HS programme was that no comparison was made in the take-up of vitamins between areas that used the universal versus targeted approach.

Aim and objectives: The overarching aim of this study was to investigate the effect of a targeted versus universal implementation approach on the take-up of vitamins amongst the population 'targeted' by the Department of Health, i.e. low-income families. Thesis objectives: 1) identify differences in HS VV uptake between a demographically similar targeted and universal area and 2) explore the explanatory factors as perceived by potentially eligible mothers, HS healthcare professionals, and commissioners for similarities and differences in vitamin take-up between these two areas.

Design: Sequential explanatory mixed-methods within a pragmatism paradigm. Secondary analysis of DH routine data of HS VV uptake for areas using a universal and targeted implementation approach. Findings from the quantitative data analysis drove the design of the study's second-phase, which used semi-structured interviews.

Setting: Two local health administrative areas (LHA) in North West England (NWE).

Participants: Analysis - quantitative data for 22 LHA in NWE. Purposive samples of 25 potentially eligible mothers, 11 HS healthcare providers, three HS commissioners, and three DH HS unit coordinators.

Results: Overall, VV uptake was low, with FV take-up consistently higher. The highest FV take-up recorded was 80.3%; the highest VV take-up was 7.3% and 3.6% for women and children, respectively. The uptake of both women's and children's VV in the universal area was significantly higher compared with the targeted area: 6.3% versus 1.6%, $p < 0.001$ and 3.2% versus 1.2%, $p < 0.001$, respectively. Mothers reported that HS vitamins were more accessible and healthcare professionals were more aware of the provision of HS vitamins in the universal area. Healthcare professionals in the universal area found it easier to remember to discuss HS vitamins at every consultation with a mother. Commissioners experienced the HS vitamin implementation process as bureaucratically cumbersome; the commissioner from the universal area had more engagement from key stakeholders.

Conclusion: The take-up of the UK HS vitamin programme was very low, albeit significantly higher in the universal area. A UK-wide universal implementation approach will not on its own increase vitamin uptake to meaningful levels. Implementation process-steps and environmental factors need to be addressed to achieve meaningful progress in reducing health inequalities in vitamin D-related health.

1 Chapter 1: Introduction and background

1.1 Introduction to this thesis

In England, there is a high prevalence of vitamin D deficiency across all ethnic groups (Hyppönen and Power, 2007) with a higher prevalence amongst black and minority ethnic communities. To reduce the prevalence of vitamin D deficiency, vitamin D supplementation via vitamin tablets or drops has been proposed (Pearce and Cheetham, 2010). To make vitamin D supplements accessible to mothers and preschool children from lower socio-economic backgrounds, the UK government introduced means-tested Heathy Start vitamins. Healthy Start vitamins are part of the UK-wide Healthy Start programme, which provides means-tested food vouchers and vitamin vouchers. The take-up of Healthy Start food vouchers has been high since the launch of the Healthy Start programme whilst the take-up of Healthy Start vitamins has been low (McFadden et al., 2014, McFadden et al., 2015). This is despite encouragement from the UK chief medical officers (Chief Medical Officers UK., 2012). It has been suggested in the literature that the take-up of Healthy Start vitamins could increase if the vitamins were offered universally, i.e. to all mothers and preschool children (Moy et al., 2012, Jessiman et al., 2013). This thesis explores this hypothesis through two objectives:

- To identify differences in Healthy Start vitamin voucher take-up between a demographically similar targeted and universal area
- To explore the explanatory factors as perceived by potentially eligible mothers, Healthy Start healthcare professionals, and commissioners, for similarities and differences in vitamin take-up between these two areas and explore barriers at the point of supply to participants

1.2 Relevance of the issue

Vitamin D deficiency is a public health issue that has been pursued since the Victorian era with varying levels of public attention. Rickets was once considered a disease of the 19th century, but with the recommendation to ensure children were exposed to sunlight, known as 'airing' of children, in the 1920s, and the addition of ergocalciferol to milk during World War II, a major decrease in disease incidence occurred (Rajakumar, 2003). From the early part of the 21st century, there has been a resurgence of rickets and other medical conditions associated with vitamin D deficiency, thought to be due to a reduced exposure to sunlight (to prevent certain skin cancers) and an increased indoor-lifestyle (Bivins, 2007).

To address this issue, in 2006, the Department of Health launched a nutritional safety-net for low income families for: pregnant women, lactating women, and preschool children. These supplements, widely known as the 'Healthy Start vitamins', contain vitamin D (Lucas et al., 2015). Despite this initiative, it is estimated that, after adjustment for socio-economic status, preschool children in the UK currently receive only one-third of the recommended daily intake of vitamin D (Feeding For Life Foundation, 2012), with fewer than 10% of young children from low-income families receiving Healthy Start vitamins. This raises four key issues:

- From the launch of the Healthy Start vitamin programme in 2006, what implementation approach has been used by the Department of Health to make Healthy Start vitamins accessible?
- How effective is the implementation approach chosen by the Department of Health at reaching target-levels of take-up?
- What is wrong with the chosen implementation approach?
- What alternative implementation approach would improve the take-up of Healthy Start vitamins?

The first issue will be discussed in the background; the second and third issue will be discussed in the literature review; the final issue will be discussed towards

the end of the thesis when bringing together the background, literature review, and research findings. To understand the need for Healthy Start vitamin D supplementation, the first part of this chapter will give an overview of the current healthcare issues associated with vitamin D deficiency and how UK nutrition policies have addressed some of these issues. From the outset, however, it is important to highlight the core concepts that underpin this thesis.

1.3 Core concepts underpinning this thesis

1.3.1 Universal implementation

The term universal implementation in this study is used to refer to a public health policy implementation approach where all individuals in a specific population are provided with equal access to the policy's provisions or services. For this thesis, the universal implementation of the Healthy Start vitamin voucher programme indicates that all pregnant and lactating women and preschool children have equal access to the vitamins. Universalism is the concept underpinning access to the National Health Service overall.

1.3.2 Targeted implementation

The term targeted implementation in this study reflects that the relevant public health policy has been offered to only a subset in the population of interest who meet a predefined selection criterion. In this thesis, targeted implementation reflects that only pregnant and lactating women and preschool children from low-income families have access to Healthy Start vitamins. The selection criteria used have been defined by the Department of Health Healthy Start Unit.

1.3.3 Health inequality

The term health inequality in this thesis is used to describe systematic, avoidable, and unfair differences in health outcomes or determinants between groups of people either within or between countries (World Health Organization, 2014). One way of understanding how health inequalities arise is through the social

determinants of health (SDH) approach (Dahlgren and Whitehead, 1991). This approach recognises that the differences in conditions in which "people are born, grow up, live, work and age" (p.16), i.e. their social conditions, result in differences in health outcomes, giving rise to health inequalities (Marmot et al., 2010). The social conditions are in turn influenced by wider policy decisions (for example in welfare, health services, and education) at the government level (Dahlgren and Whitehead, 2007).

1.3.4 Rose's prevention paradox

In 1985, Geoffrey Rose compared two prevention strategies, highlighting the pros and cons of each approach. Using Rose's analysis (Rose, 1985, p.37), the 'high risk' strategy addressed the needs of a minority population already at high risk, e.g. of developing complications of hypertension, neglecting the rest of the population who had a lower risk. The 'high risk' strategy, Rose argued, was suitable for the person who already had the problem but did not address the underlying cause of the disease. The 'population' approach, the second strategy identified by Rose, sought to "control the determinants of incidence, to lower the mean level of risk factors (and) to shift the whole distribution of exposure in a favourable direction" (Rose, 1985, p.37). A complementary mix of both the 'high risk' and 'population' approach is often required to assist individuals and communities to avoid disease.

1.3.5 Take-up of Healthy Start vitamins

The Healthy Start Unit (Healthy Start Unit, 2018) measures take-up by low-income families of Healthy Start vitamin (of supplements of vitamin D, C, and folic acid for pregnant women and lactating mothers and vitamin D, C, and A for preschool children). Vitamin take up from this programme is measured by the number of vitamin claim-forms that it receives from a health administrative area compared with the estimated number of eligible programme-beneficiaries in that area. The Department of Health Healthy Start Unit collects monthly data from the Department of Work and Pensions and Job Centre Plus to estimate the number of

eligible beneficiaries of the programme. Take-up data are reported quarterly as a percentage. Criteria for the targeted Healthy Start programme are:

Women who were at least 10 weeks pregnant and families with children under four years old qualify for Healthy Start if the family is getting (2011/12):

- Income Support, or
- Income-based Jobseeker's Allowance, or
- Income-related Employment and Support Allowance, or
- Child Tax Credit (but not Working Tax Credit unless the family is receiving Working Tax Credit run-on only*) **and** has an annual income of £16,190 or less (2014/15)

Mothers under the age of 18 years and pregnant also qualified for Healthy Start even if they did not get any of the above benefits.

1.4 Background

This section describes the issues surrounding the clinical manifestations, diagnosis and treatment of vitamin D deficiency, sources of vitamin D, and an overview of the epidemiology of vitamin D within the UK. This is followed by a description of the demographics of vitamin D deficiency.

1.4.1 Current issues associated with a lack of vitamin D

Clinical manifestations: Poor bone health, manifested as rickets in children and osteomalacia in adults, is one of the well-known consequences of vitamin D deficiency. In the last decade, evidence has accumulated to link a number of medical conditions with vitamin D deficiency, including some of the most important public health issues. Obesity, breast cancer, cardiovascular diseases, multiple sclerosis, and tuberculosis are some of the conditions associated with low vitamin D levels that the medical literature has documented (Theodoratou et al., 2014).

Theodoratou et al. (2014) conducted an 'umbrella review' of the evidence to evaluate the associations of vitamin D and 137 diverse outcomes including skeletal,

cardiovascular, autoimmune, and malignant diseases. The umbrella review identified 107 systematic reviews, 74 meta-analyses of observational studies of plasma vitamin D concentrations, and 87 meta-analyses of randomised controlled trials of vitamin D supplementation. Comparisons of syntheses of observational versus randomised evidence were possible for only 14 of the 137 outcomes. The review found that vitamin D supplementation is probably linked to a decrease in dental caries in children and an increase in birthweight and in maternal vitamin D concentrations at term. Evidence suggested an association between high vitamin D concentrations and low risk of small head circumference at birth, small-for-gestational-age at birth, and gestational diabetes mellitus. Evidence from observational studies or randomised controlled trials was insufficient and inconclusive about the relationship between vitamin D concentrations and: childhood infections (maternal vitamin D status); pre-eclampsia in pregnant women; bone health in pregnant and lactating women; and rickets. One of the main reasons a relationship could not be found between vitamin D concentrations and rickets was because of the variability of the evidence available to review.

Diagnosis and treatment of a low level of vitamin D: Vitamin D status is determined by an assay of serum 25-hydroxyvitamin D (25-OHD). There is currently no consensus between North American countries and the UK about the thresholds for defining vitamin D deficiency and vitamin D insufficiency (Table 1.1); the USA and Canada advocate higher thresholds (Munasinghe et al., 2017). Within the UK, concerning levels of 25-OHD, the medical community has agreed that a level less than 25 nmol/l represents vitamin D deficiency, a level at which symptomatic rickets and osteomalacia occur. A level between 25-50 nmol/l signifies vitamin D insufficiency that is associated with disease risk for many chronic diseases, including cardiovascular diseases, diabetes mellitus, and cancer (Wang et al., 2017). Even if Vitamin D status is adequate, lifestyle advice is required, with the aim of optimal levels exceeding 75 nmol/l (Table 1).

Sources of vitamin D The skin produces most of the body's vitamin D via sunlight exposure; vitamin D has been called the 'sunshine vitamin' (The Association of UK Dieticians, 2016). Dietary sources of vitamin D include oily fish, egg-yolk, and fortified foodstuffs (Table 1.2). The Government's Scientific Advisory Committee on Nutrition advised in 2016 that everyone over one year of age, including pregnant women, breastfeeding women, and those at risk of vitamin D deficiency (people with minimal exposure to sunshine and those from minority ethnic groups with dark skin) should have 10.0 micrograms of vitamin D every day. Children under one year should have 8.5-10.0 micrograms/day whether they are exclusively or partially breastfed (Scientific Advisory Committee on Nutrition, 2016).

Table 1.1 UK serum vitamin D categories
Serum vitamin D as measured by 25-hydroxyvitamin D (25-OHD) and the respective vitamin D status assigned, clinical manifestations and treatment. Source: (Pearce and Cheetham (2010)

Serum 25-OHD	Vitamin D status	Manifestation	Management
<25 nmol/l	Deficient	Rickets, osteomalacia	Treat with high-dose calciferol
25-50 nmol/l	Insufficient	Associated with disease risk	Vitamin D supplementation
50-75 nmol/l	Adequate	Healthy	Lifestyle advice
>75 nmol/l	Optimal	Healthy	None

Table 1.2 Dietary and other sources of vitamin D and risk factors for inadequate 25-OHD levels
Source: Pearce and Cheetham (2010)

Sources of vitamin D	Risk factors
Ultraviolet B sunlight exposure	Lack of sunlight exposure frequently due to increased indoor activity (including the institutionalised), skin-concealing garments, meticulous use of sunscreen
Oily fish, e.g. mackerel, sardines, salmon and trout, cod liver oil, and other fish oils	Vegetarian diet
Egg yolk	Malabsorption
Supplemented margarine and infant formula, statutory in the UK. Supplemented breakfast cereals	Exclusively breastfed Pigmented skin

Epidemiology of low levels of vitamin D: In the UK, 50% of adults have insufficient levels (25-50 nmol/l, 25-OHD) of vitamin D, with 16% having severe deficiency (<25 nmol/l, 25-OHD) during winter and spring. Groups in the population who are at higher risk of vitamin D deficiency include the elderly, obese, those who cover their skin with garments or sun cream, non-white people, and those who do not have adequate exposure to ultraviolet B light.

1.4.2 Demographics of vitamin D deficiency

Geographical differences: A clear geographical gradient of prevalence exists, with those living in Scotland and northern England having statistically significantly lower vitamin D levels compared with those living in the south of England independent of seasonal variation (Hyppönen and Power, 2007). It is thought that the difference in latitude explains the gradient (Ginde et al., 2009). More than 90% of an individual's vitamin D supply comes from ultraviolet-B light exposure. Vitamin D synthesis is almost exclusive to the months of April to September, due to the

latitude of the UK, and predominantly between the hours of 11am and 3pm (Pearce and Cheetham, 2010).

Ethnicity: It has been established that non-white people are at a higher risk of vitamin D deficiency compared with their white counterparts, due to their pigmented skin (Pearce and Cheetham, 2010). A recent study conducted in Birmingham, UK, sought to establish the extent of this problem amongst South-Asian and Black African-Caribbean groups (Patel et al., 2013). From 1,904 participants (South Asian = 1,122, Black African-Caribbean = 782), most had deficient or severely deficient vitamin D levels, independent of age and the presence of osteoporosis. Though this study added to the evidence that low levels of vitamin D are found in South Asian and Black African-Caribbean ethnicities, the question of the relationship between vitamin D levels in these groups and its clinical relevance remains.

Socio-economic status and low vitamin D: Vitamin D deficiency has been found to be associated with low socio-economic status amongst developed countries. In the Netherlands, a large multi-ethnic cohort study of 4,167 6-year-old children was conducted to examine sociodemographic, lifestyle, and dietary determinants of vitamin D deficiency (Voortman et al., 2015). As previously reported, the prevalence of vitamin D deficiency [25(OH)D <50 nmol/L] was higher in winter (51.3%) than in summer (10.3%) and higher in children with black minority ethnicities (54.5%) than in those children with a Dutch or other Western ethnic background (17.6%) (Pearce and Cheetham, 2010). Using multivariable models, the study found that household income was associated with vitamin D deficiency (odds ratio (OR): 1.74; 95% confidence interval (CI): 1.34 to 2.27 for low versus high income). In a British cross-sectional study survey of 1,102 children aged 4-18 years living in private households (January 1997 to January 1998), an association was found amongst children whose families were on income support (OR = 2.2; 95% CI 1.3 to 3.9) (Absoud et al., 2011). A study commissioned by the Scottish Food Standards Agency found a significant association between mean vitamin D levels

and area deprivation, with average levels of 45.7nmol/l for those living in the least deprived 20% of areas in Scotland to 31.3nmol/l for those living in Scotland's most deprived areas. The mean vitamin D levels for those living in Scotland's most deprived 15% of areas were significantly lower than those living in the 85% least deprived areas (29.1nmol/l compared with 39.1nmol/l; $p \leq 0.001$) (Scottish Food Standards Agency, 2013).

1.4.3 Vitamin D levels in the UK

Hyppönen and Power (2007) conducted a large cohort study in which 25-hydroxyvitamin D was measured from 7,437 white people from the 1958 British Birth Cohort when they were 45 years-old. The study found that 3.2%, 15.4%, and 60.9% of the cohort had 25(OH) D concentrations of <25, <40, and <70 nmol/l, respectively, during summer and autumn, with the time spent outdoors being strongly associated with 25-OHD. The proportions were much higher during the winter and spring, with 15.5%, 46.6%, and 87.1% of the cohort having <25, <40, and <70 nmol/l, respectively. Other notable findings were: 1) the obese were twice as likely to have 25-OHD concentrations of <40 nmol/l ($p < 0.001$) compared with the non-obese, 2) Scottish participants were twice as likely to have 25-OHD concentrations of <40 nmol/l ($p < 0.001$) compared with participants from other parts of the UK, and 3) no significant difference was observed between those who used vitamin D supplements or oily fish compared with those who consumed vitamin D-fortified margarine. In that paper, the intermediate threshold for vitamin D status was <40 nmol/l, 10nmol/l less than the level recommended by recent guidelines (Pearce and Cheetham, 2010). The authors stated that the cut-off of <40nmol/l was informed by laboratories conducting vitamin D assays. If <50 nmol/l was used, a higher percentage of the study's population may have been below the intermediate threshold in both summer and winter. Amongst the 154 non-white people who were excluded from the study, 50%, 80%, and 100% had 25(OH) D concentrations of <25, <40, and <70 nmol/l, respectively, during winter and spring.

That large cohort study conducted by Hyppönen and Power (2007) showed that clinically low vitamin D levels are not confined to ethnic minorities or older people, being also found in the White middle-age British population. With 50% of the UK population having inadequate levels of vitamin D, which is preventable, vitamin D deficiency is a public health challenge as well as opportunity that should be seized. One method of tackling this issue is with nutritional policies.

1.4.4 History of vitamin D supplementation in UK nutrition policies

The first UK social policy with nutritional objectives was the provision of free school meals in 1914 (UK Parliament, 1914). Before the discovery of vitamin D in 1914 (Rajakumar, 2003), many in the UK population understood that exposure to summer sunshine or the intake of cod liver oil prevented and cured rickets. Upon the discovery of vitamin D, mothers were advised to 'air' their children through exposure to sun-baths as a preventive and therapeutic measure for rickets (Rajakumar, 2003). By the 1940s, rickets was virtually eradicated due to sunlight exposure, the use of cod liver oil, and mandatory fortification of margarine with vitamin D (Berry, 1959, p335).

To help ensure that pregnant and breastfeeding mothers and young children received an adequate diet during the World War II period of rationing, the Welfare Food Programme was introduced in 1940 under the then Prime Minster, Sir Winston Churchill, who advocated for investing in infants through milk subsidies (Committee on Medical Aspects of Food and Nutrition Policy; Panel on Child and Maternal Nutrition of the Committee on Medical Aspects of Food and Nutrition Policy, 2002). Ergocalciferol was subsequently added to National Dried Milk during World War II, with vitamin D supplementation being recommended during pregnancy from then onwards. The Welfare Food Programme was initially implemented using a universal approach; by the 1950s, a targeted approach was, however, in place, with the criteria for entitlement being based on family income (Belton, 2005).

Until the late 1950s, the medical community encouraged cod liver oil intake but, by the 1960s, due to vitamin A toxicity being attributed to cod liver oil intake, discontinuation was recommended with no alternative vitamin D supplementation being made available (Bivins, 2007). Vitamin drops and tablets containing vitamins A, C, and D were subsequently introduced in 1975 into the targeted Welfare Food Programme (Jackson, 2009). The Department of Health continued using a targeted implementation approach with the introduction of the Healthy Start vitamin programme, recommending that those from higher socio-economic backgrounds seek vitamin D supplementation independently.

1.4.5 Healthy Start vitamins and vitamin D supplementation

In 2002, the UK government requested a review of the Welfare Food Programme by the Committee on Medical Aspects of Food and Nutrition Policy (COMA) Panel on Maternal and Child Nutrition; no review of the programme had been conducted since its inception in 1940 (Committee on Medical Aspects of Food and Nutrition Policy; Panel on Child and Maternal Nutrition of the Committee on Medical Aspects of Food and Nutrition Policy, 2002). This resulted in the Healthy Start programme replacing the Welfare Food Programme in 2006. The COMA panel concluded that the Welfare Food Programme provided a nutritional safety-net that exceeded the daily milk requirements of children, did not provide a varied diet as a source of other nutrients, and needed to promote breastfeeding and access to healthcare professionals (Belton, 2005). The Healthy Start programme was therefore designed to provide a more comprehensive safety-net for nutritionally vulnerable pregnant women, mothers, and young children. The programme differed from the Welfare Food Programme in both nutritional and administrative aspects. The Healthy Start programme:

1. provided food vouchers for the purchase of fresh and frozen fruit and vegetables as well as milk and infant formula

2. provided vitamin vouchers for Healthy Start vitamins containing vitamins A, C, and D for children aged from six months to four years and folic acid and vitamins C and D for pregnant and breastfeeding women
3. was available only to pregnant and lactating women and children aged six months to four years from low-income families; the rest of the population received no subsidisation
4. transferred the application process from the benefits system to registered healthcare professionals including midwives, health visitors, and general practitioners
5. included dietary and lifestyle advice during pregnancy

Notably, COMA highlighted that the take-up of the vitamins available under the Welfare Food Programme was low and recommended that this be improved by increasing the provision of vitamins. Since the launch of the Healthy Start programme, take-up of vitamins amongst the eligible population has been low (Jessiman et al., 2013, Moy et al., 2012).

The chief medical officers of the United Kingdom have acknowledged vitamin D deficiency as an urgent public health problem (Chief Medical Officers UK, 2012). As Healthy Start vitamin take-up was low, a letter was issued to the healthcare professionals who were able to register mothers (Appendix 1): general practitioners, practice nurses, and health visitors. Community pharmacists were also included, as it was hoped that Healthy Start vitamins would be available from local pharmacies (Chief Medical Officers UK, 2012). The group that principally distribute the Healthy Start vitamins and have frequent contact with the Department of Health-defined target-group are, however, the healthcare workers and nursery staff in Sure Start children centres.

In 2012, the Chief Medical Officer for England, Professor Dame Sally Davies, called for a review of the cost-effectiveness of making the Healthy Start programme universal , offering all children under the age of four years free vitamins (Davies, 2013). The National Institute for Health and Care Excellence published this review

in August 2015 (National Institute for Health and Care Excellence, 2015). The economic model indicated that, compared with current provision:

- "It is **not** cost effective to offer Healthy Start supplements universally to the current target group – that is, to extend the offering to all:
    - pregnant women from 10 weeks
    - women with a child aged under 12 months
    - children over 6 months and under 4 years.

    This is because the best estimate of the incremental cost-effectiveness ratio [ICER] is £620,898 per quality-adjusted life year [QALY] gained, compared with the current programme.

- It **is** cost effective to extend the offering of Healthy Start supplements universally to the current target group if it is also extended to all:
    - women who are planning a pregnancy
    - women less than 10 weeks pregnant
    - infants aged 0–6 months
    - children aged from 4 to 5 years"

    This is because the best estimate of the ICER is £6528 per QALY gained compared with the current scheme."

The latter ICER is much lower because of the large gain in QALYs due to women taking folic acid in the first 10 weeks of pregnancy and the reduction in future costs of caring for those with neural tube defects.

The Scientific Advisory Committee on Nutrition (SACN) published its update on vitamin D in 2016 (Scientific Advisory Committee on Nutrition, 2016).
SACN reviewed the evidence on vitamin D and health to determine if the dietary recommendations, set in 1991 for the UK, were still appropriate. SACN stated in its report, "in a change to previous advice, SACN is now recommending:

- a reference nutrient intake (RNI) of 10 micrograms of vitamin D per day, throughout the year, for everyone in the general population aged 4 years and older
- an RNI of 10 micrograms of vitamin D per day for pregnant and lactating women and population groups at increased risk of vitamin D deficiency
- a 'safe intake' of 8.5 to 10 micrograms per day for all infants from birth to 1 year of age
- a 'safe intake' of 10 micrograms per day for children aged 1 to 4 years

The RNI and safe intakes were developed to ensure that most of the UK population has enough vitamin D to protect musculoskeletal health, all year round."

Healthy Start vitamins, which will be detailed more in the section below, contain 10 micrograms of vitamin D in the tablets for mothers and 7.5 micrograms of vitamin D in the children vitamin drops (Healthy Start Unit, 2018).

1.5 Healthy Start programme

1.5.1 Healthy Start: eligibility criteria, food vouchers, vitamin vouchers

The Healthy Start programme is a statutory, means-tested nutrition programme that offers dietary advice as well as food and vitamin supplementation to low-income pregnant women, new mothers, and preschool children up to their fourth birthday, according to income-related eligibility criteria (Figure 1.1) (Healthy Start Unit, 2018). From the tenth week of gestation, women can register for the programme if they receive welfare or tax credits with a household income of £16,190 or less (2011/12). Additionally, any pregnant female under the age of 18 years can register, irrespective of income, benefits, or tax credits.

Mothers registered for Healthy Start received weekly food vouchers worth £3.10, which could be used to purchase fresh and frozen fruit and vegetables, plain

cow's milk, and infant formula from registered retailers. During the first year of the child's life, the mother was eligible for £6.20 weekly vouchers (£0.89 per day); the cost of a frequently-used brand of infant formula was £8.99 in 2011/12, which lasts for six days (£1.49 per day). This contrasted with and was considerably less than what was available under the Welfare Food Programme, i.e. 900g of infant formula per week for a child up to the age of twelve months (Belton, 2005). Of note, the family had to register an address to which the vouchers could be sent (Healthy Start Unit, 2018); this is challenging for families with no fixed abode. To ensure that expectant mothers and mothers of young children have access to someone who can give healthy lifestyle advice and support their access to healthcare, a health professional must sign the registration-forms. It is estimated that approximately 80% of eligible beneficiaries are registered with the programme.

In addition to food vouchers, registered recipients receive vitamin vouchers, which can be exchanged for vitamin drops and tablets. Pregnant women receive vitamin supplementation containing vitamin C and D, plus folic acid to reduce the probability of neural tube defects. Children from the age of six months to their fourth birthday receive vitamin supplementation containing vitamin A, C, and D to prevent scurvy, promote normal vision, and prevent vitamin D deficiency, respectively. The Government has commissioned industry to manufacture Healthy Start vitamins since 2005.

Figure 1.1 Healthy Start eligibility – how mothers and preschool children qualify for food and vitamin vouchers
Figure describes Healthy Start eligibility criteria. Used with permission from source (Healthy Start Unit, 2009)

For Health Professionals

Healthy Start is a a UK-wide government scheme to improve the health of low-income pregnant women and families on benefits and tax credits.

Women who are at least 10 weeks pregnant and families with children under four years old qualify for Healthy Start if the family is getting:

- Income Support, or
- Income-based Jobseeker's Allowance, or
- Income-related Employment and Support Allowance, or
- Child Tax Credit (but not Working Tax Credit unless the family is receiving Working Tax Credit run-on only*) **and** has an annual income of £16,190 or less (2014/15).

*Working Tax Credit run-on is the Working Tax Credit received in the 4 weeks immediately after a person has stopped working for 16 hours or more per week (single adults) or 24 hours a week (couples).

Women also qualify during the whole of their pregnancy if they are under 18 when they apply, even if they don't get any of the above benefits or tax credits. To continue getting support from the scheme for their babies, they must meet the same qualifying criteria as other Healthy Start families. It is therefore important that pregnant women under 18 years old tick any qualifying benefits or tax credits they or their family are getting when they first apply, or contact the Healthy Start Issuing Unit to let them know if they start claiming any later in their pregnancy. They must also claim Child Tax Credit as soon as they can after their baby is born.

What do Healthy Start beneficiaries get?

- Pregnant women get one Healthy Start voucher a week worth £3.10
- Babies under the age of one get two vouchers a week worth a total of £6.20
- Children aged over one and under four get one voucher a week worth £3.10.

Vouchers are posted out every four weeks. They can be spent on milk, plain fresh or frozen fruit and vegetables (fruit and vegetables with nothing added), or infant formula milk in a wide variety of local shops and supermarkets and with milkmen that have registered to take part in the scheme.

Healthy Start vitamins

Every eight weeks, beneficiaries also get green vitamin coupons with their vouchers, which they can swap for Healthy Start vitamins in their local area. The coupons are either for Healthy Start women's tablets or Healthy Start children's drops. It is the responsibility of primary care and health trusts and health boards to make both of these vitamin products available locally to Healthy Start beneficiaries.

1.5.2 Healthy Start programme: implementation approaches

Since the Department of Health launched the Healthy Start programme in 2006, the take-up of vitamins by the target low-income population of pregnant and lactating women and preschool children has been modest, with only 7%-14% of infants receiving vitamin drops (Alderton, 2014). The next section gives an overview of implementation approaches commonly used in public health policy, followed by alternative Healthy Start vitamin programme implementation approaches.

1.5.3 Implementation approaches used for public health policy

Public health services aim to protect and improve the nation's health and wellbeing and reduce health inequalities (Public Health England, 2013). The concept of 'equity in health' implies that, ideally, everyone could attain their full health potential, and no one should be disadvantaged from achieving this potential because of their social position or other socially determined factors (Whitehead and Dahlgren, 2007). The converse - social inequalities in health – refer in the UK and in this thesis to systematic differences in health status between socio-economic groups, commonly measured by income, education, occupation or deprivation of area of residence. All systematic social inequalities in health are socially produced, modifiable, and considered unfair (Dahlgren and Whitehead, 2007). A second phrase – social *inequities* in health – is sometime used in other countries, particularly in World Health Organization documents, but it carries the same connotation as the term social *inequalities* in heath in the UK, i.e. systematic health differences between socio-economic groups that are modifiable and unfair. This thesis uses the term social inequalities in health, or 'health inequalities' for short, throughout with the meaning explained above.

Universalism and targeting are two contrasting approaches to implementing public health policy. Universalism is based on the principle that we all have the same set of rights or entitlements. Eligibility for a universal service is based on simply being part of a defined population, for example, all persons living in a certain geographical area, e.g. all women and all preschool children. Current UK examples include: 1) Every individual residing in the UK has access to healthcare services, and 2) All children have access to primary and secondary education. The universal provision of healthcare via the NHS has been shown to reduce

health inequalities. For example, in a whole-population small area longitudinal study based on 32,482 neighbourhoods of 1,500 people, in England from 2004/2005 to 2011/2012, Asaria et al. (2016) reported slope indices of inequality for; 1) patients per family doctor, 2) primary care quality, 3) preventable emergency hospital admissions and 4) mortality from conditions considered amenable to healthcare. For all indicators there were larger absolute improvements in more-deprived neighbourhoods. The modelled gap between the most-deprived and least-deprived neighbourhoods in England decreased by; 1) 193 patients per family doctor (95% CI 173 to 213), 2) 3.29 percentage points of primary care quality as measured by the clinical performance in the quality and outcomes framework (95% CI 3.13 to 3.45), 3) 0.42 preventable hospitalisations per 1,000 people (95% CI 0.29 to 0.55), and 4) 0.23 amendable deaths per 1,000 people (95% CI 0.15 to 0.31) (Asaria et al., 2016). The reductions in inequalities were achieved in a large part through investments made by the UK Government in 2003 in primary care.

The contrasting public health policy implementation approach of 'targeting' is based on the principle of concentrating resources on those at highest risk. The targeted approach is often used to concentrate resources on disadvantaged members within society. Criteria such as being part of a 'high risk' group, a specific neighbourhood, or socio-economic status have been used to determine access to services. UK examples have included tuberculosis immunisation for babies in 'high risk' groups, area-based initiatives such as Health Action Zones, and welfare benefits such as income support (based on low-income status).

The universal and targeted policy implementation approach can be viewed as two approaches on different ends of a spectrum. Increasingly, a blended approach between these two approaches has been seen in the literature as 'progressive universalism', 'targeted universalism', and 'proportionate universalism' (Hatherley, 2011, Marmot et al., 2010).

'Progressive universalism' offers universally accessible services with enhanced access across the social gradient to those who have increased need. It has been described by HM Treasury and the Department for Education and Skills as support for all, with the greatest support being given to those who need it most (Department of Education and Skills, 2005).

Support for families bringing up children is one example of 'progressive universalism', with all families being given financial support through Child Benefit, and families with low-incomes having access to additional financial support.

Professor Sir Michael Marmot (former Chair of the World Health Organization Commission on the Social Determinants of Health) advocated for proportionate universalism to level up the health gradient. Professor Marmot encouraged that programmes and policies must include a range of responses for different levels of disadvantage experienced within the population and argued that in order to reduce the steepness of the health gradient, "actions must be universal, but with a scale and intensity this is proportionate to the level of disadvantage" (Marmot et al., 2010, p15). An example of this is the introduction of smoking cessation services in the NHS, which were available for all groups within the population, but at the same time, extra clinics were set up in disadvantaged areas to cater for the higher prevalence of smoking in these areas.

Reflecting on the spectrum of public health policy implementation approaches highlighted potential alternative intervention approaches for Healthy Start vitamins. Whether an alternative approach would improve the take-up of Healthy Start vitamins will be explored in this research.

1.6 Previous research and gaps in the literature

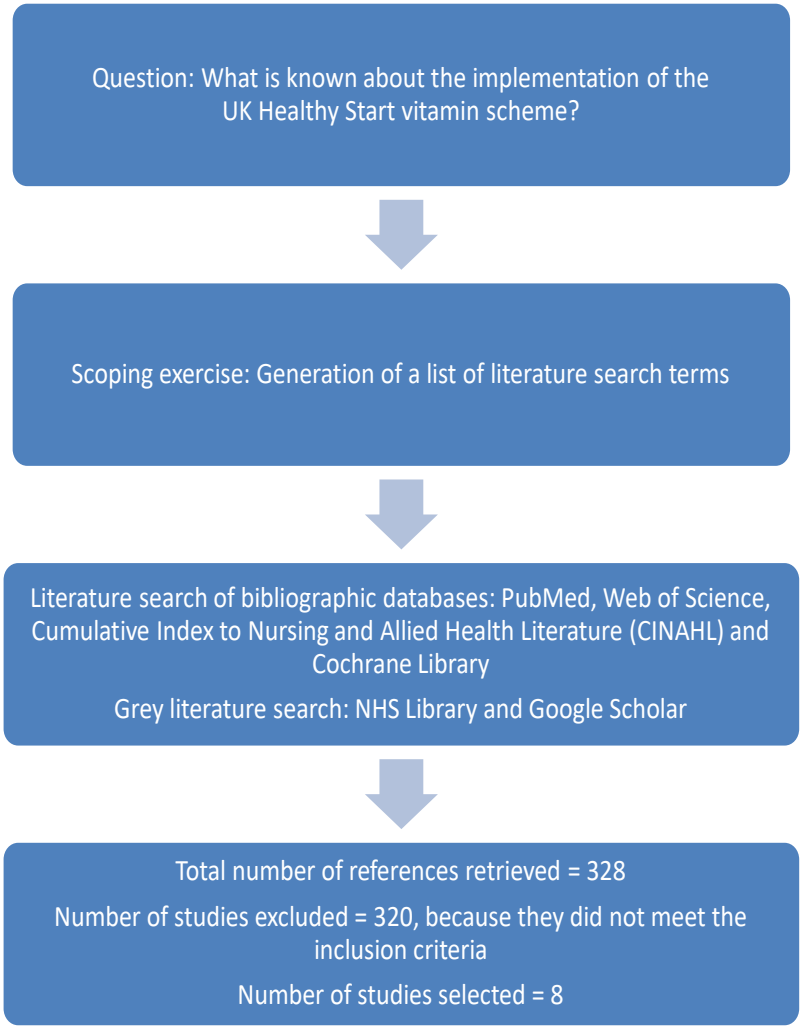
1.6.1 Structured review: What is known about the implementation of the Healthy Start programme and its take-up in the UK

Since the launch of the Healthy Start vitamin programme in 2006, take-up of vitamins has remained low. It is important to ask which aspects of the design and implementation of the vitamin programme may present barriers to access and take-up. The objective of the review was to examine evidence from quantitative, qualitative, and mixed methods research concerning the implementation of the Healthy Start vitamin programme and its take-up within the UK to understand the barriers present.

The search strategy for the search question "What is known about the implementation of the UK Healthy Start vitamin programme?" was developed with the support of a specialty librarian at the University of Liverpool (Figure 1.2). After supervisory discussion with supervisors about the pros and cons of various timespans to limit the search, it was decided that due to numerous changes made by governments in welfare policies relating to the provision of vitamins for preschool children, there was no added-value in pursuing a literature review before 1990. A scoping search on different bibliographic databases generated search-terms for the review; the most frequently indexed keywords were selected. MEDLINE, PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Cochrane Library were the bibliographic databases searched for published literature. The NHS Specialist Library and Google Scholar were searched for grey literature. Using the inclusion-criteria, articles from the retrieved collection of references were selected and entered into a reference database using Endnote (Version 7) software. Inclusion-criteria were:

- Language: English
- Countries: UK
- Timespan: January 1990 – March 2018
- Population: mothers and preschool children
- Key-words:
    - Take-up: impact, effect, coverage, take-up, access, use
    - Mothers: maternal, antenatal, pregnant, woman, women
    - Preschool children: child, children, infants, toddler, babies

Figure 1.2 Flow diagram for search strategy: "What is known about the implementation of the UK Healthy Start vitamin programme?" (January 1990 – March 2018)
Steps taken in identifying the available literature about the implementation of the Healthy Start vitamin programme, with a focus on identifying the barriers to access and take-up.



Since the launch of the Healthy Start programme in 2006, few studies have been conducted to evaluate the effectiveness of the food and vitamin components of the programme. Eight articles met the inclusion-criteria (Table 1.3). The studies demonstrated poor vitamin take-up was related to:

- Lack of awareness of the importance of vitamin D supplementation in the early years and current vitamin D recommendations amongst healthcare professionals (Moy et al., 2012, Jessiman et al., 2013, McFadden et al., 2014)
- Poor awareness amongst parents (Ford et al, 2009)
- Lack of knowledge about where to obtain supplements (McFadden 2015)
- Poor promotion of the Healthy Start programme by healthcare professionals and poor access to vitamins (Jessiman et al., 2013)
- Consistently low take-up of Healthy Start vitamins in low-income groups (Jessiman et al., 2013, Lewis, 2014)
- Logistically complex distribution process of Healthy Start vitamins (McFadden et al., 2015)

Ford et al. (2009) examined the effect of the introduction of the Healthy Start food voucher programme on dietary intakes and eating patterns of low-income, white, pregnant and postpartum women living in Sheffield, UK. Dietary intakes were measured using a validated semi-quantified questionnaire. They found that a high proportion of women on the Healthy Start food voucher programme met the recommended intakes for calcium, folate, iron, and vitamin C. None of the women (n=160) had received Healthy Start vitamins.

Mouratidou et al. (2010) conducted a before-and-after study comparing the nutritional behaviour of postpartum women who were either beneficiaries of or eligible for the Welfare Food Programme with postpartum women who were either beneficiaries of or eligible for the Healthy Start food vouchers programme. The aim was to examine whether the differences in nutritional intake between women on the Healthy Start food voucher programme and the Welfare Food Programme observed at four weeks postpartum were sustained over a period of twelve weeks. There was a significantly higher fruit and vegetable intake amongst the Healthy Start recipients compared with the Welfare Food Programme participants ($P = 0.023$), with the differences being sustained over twelve weeks. The Healthy Start food programme appeared to influence fruit and vegetable consumption; the potential mechanism/s was not discussed in the paper.

Moy et al. (2012) evaluated the effectiveness of the universal provision of Healthy Start vitamins in reducing the number of symptomatic cases of vitamin D deficiency amongst the Heart of Birmingham Primary Care Trust population, 75% being from ethnic minorities. The study found that the incidence rate of symptomatic vitamin D deficiency decreased by 59% between 2004 and 2009 (29 to 12 cases) from 120 cases per 100,000 children under the age of 5 to 49 cases per 100,000 children. Between 2004 and 2009, the take-up of Healthy Start was no greater than 17%. A key difference between the universal and national targeted programme, besides the vitamins being offered to all pregnant and lactating women and preschool children, was that children received vitamins from the age of two weeks versus six months and up to their fifth birthday versus their fourth birthday, as per the national criteria. Additionally, since the Healthy Start programme was launched in 2006, the population may have been more aware of the importance of vitamin D on their children's health through national media and campaigns. It is not known whether the incidence of symptomatic vitamin D deficiency continued to decrease or was sustained after 2009.

Lucas-Herald et al. (2012) reported on the awareness of mothers about the Healthy Start vitamin programme. A questionnaire was distributed to 37 mothers attending a health visitor clinic in a deprived area of Glasgow between February and March 2012; all the women were eligible for the vitamins and 97% were white with English as their primary language. The study highlighted the poor awareness of the Healthy Start vitamin programme amongst mothers as none had taken Healthy Start vitamins during their pregnancy and 29% of the mothers paying for over-the-counter antenatal vitamins. Only 8% and 24% of mothers recalled receiving written or verbal information, respectively, about Healthy Start vitamins. Only one child was taking Healthy Start vitamins.

Jessiman et al. (2013) explored, through 13 purposively selected primary care trusts across England, why eligible families were not accessing free Healthy Start vitamins. In-depth interviews were conducted with 15 Healthy Start coordinators, 50 frontline health and children professionals, and 107 parents. The reported barriers to Healthy Start vitamin take-up were: 1) parents' lack of awareness about the programme and benefits of the vitamins, 2) midwives not routinely discussing eligibility with families at their first contact, 3)

midwives not routinely mentioning Healthy Start vitamins when discussing the Healthy Start programme, 4) the administrative load of the application process, and 5) lack of availability of vitamins. The study mentioned that three of the areas offered the vitamins universally and that this approach supported a higher take-up of vitamins. No quantitative data were reported.

McFadden et al. (2014) reported an evaluation of Healthy Start from the perspectives of women and health practitioners. The study explored whether the Healthy Start food vouchers reached the families who needed them and whether the food vouchers had the potential to improve nutrition for low-income women and children. The study design included focus group discussions with 49 health practitioners, participatory workshops with 85 low-income ('eligible and borderline-eligible') women, and a national online consultation with 620 health and social care practitioners, service managers, commissioners, and advocacy groups. Efforts were also made to have interviews with non-English speaking women and women from traveller communities. Yorkshire and the Humber and London were the two English regions chosen for the interviews and focus groups, as both regions had large and diverse populations from which both urban and rural perspectives could be gathered. One-third of women and practitioners found that the eligibility criteria were confusing and limited. Women and practitioners found that the household income threshold for families receiving tax credits discriminated against those in low-paid work, as well as those whose employment status varied dependent on the availability of work. Practitioners in particular were "concerned that those with uncertain immigration status (e.g. seeking asylum), some of the most vulnerable groups of women and children in the UK, were not eligible for Healthy Start vouchers" (p.6) Other barriers to the registration of women to the Healthy Start food vouchers programme were: 1) poor awareness of the programme by women, 2) practitioners already had to give a lot of information during the first antenatal visit, 3) practitioners were unforthcoming about asking about a woman's financial circumstances, 4) both women and practitioners found the application process cumbersome Weaknesses of this study: 1) middle and high-income women were not interviewed, 2) the online consultation sent to user representatives relied on access to internet facilities and capability, 3) two out of the eleven planned participatory workshops

had only one participant; no information was given about the numbers in the other nine workshops, 4) the findings from the national online consultation with 620 health and social care practitioners, service managers, commissioners, and advocacy groups were grouped together; there may have been barriers unique to each professional group. There was no mention of staff from local authority owned children centres, which in practice host many ante and post-natal practitioners and come into contact with several eligible women and children. No one-to-one interviews (which may have uncovered some unexpected findings) were conducted. Additionally, the perspectives from the Healthy Start policy coordinators from the Department of Health Healthy Start Unit were not sought.

McFadden et al. (2015) evaluated and provided a real-life view of the operation of the Healthy Start vitamin programme, with 49 healthcare professionals participating in focus group discussions, 620 healthcare professionals participating in an online consultation, and 56 participants, which included policymakers and service commissioners together with healthcare professionals, for a stakeholder workshop. The professional groups represented were: health visitors, midwives, public health practitioners, general practitioners, paediatricians, and support staff. Participants described the Healthy Start vitamin distribution process as logistically complex and contended that for this reason the universal provision of vitamin supplements would be more cost-effective.

Lucas et al. (2015) conducted a qualitative study using in-depth interviews with 107 participants recruited from thirteen research sites across England. Participants were purposively selected, and all were parents using the Healthy Start programme. The study focused on the use of Healthy Start food vouchers. From the 107 participants interviewed though the majority found the food vouchers easy to use, some vulnerable groups were unable to access the programme. The food vouchers were viewed as playing an important role in supporting families to access fruit and vegetables. Only going to retailers known to accept the food vouchers and using self-service tills were two strategies used by parents to reduce stigma.

Overall, using the Colthart et al. (2008) grading criteria, these eight studies are clear and very likely to be true; Grade 4 (Colthart et al., 2008). The studies highlight that the Healthy

Start programme has benefited pregnant, postnatal women, and preschool children through increasing their intake of essential vitamins and nutrients either through vitamin supplements or the consumption of fruits and vegetables, with one study reporting a reduction in the incidence of symptomatic vitamin D deficiency (Moy et al., 2012). Though each study had its own limitations whether it be self-reporting through the use of questionnaires (Ford et al., 2009, Mouratidou et al., 2010) or the numbers included in the study (Moy et al., 2012), overall, the studies lended support to the potential benefit of the Healthy Start programme for pregnant women, postnatal women, and preschool children.

Table 1.3 An overview of quantitative and qualitative studies conducted in the UK investigating the effectiveness of the UK Healthy Start (HS) vitamin programme since its launch in 2006: "What is known about the UK Healthy Start vitamin programme?" (January 1990 – March 2018). Databases searched: PubMed and Cumulative Index to Nursing and Allied Health Literature (CINAHL)

*Beneficiaries: Pregnant and postpartum women from low-income families; WFS: Welfare Food Scheme

Study	Design & setting	Population groups	Ethnicity	Language spoken	N	Outcomes
Ford et al., 2009	Before-and-after group-level study, Sheffield.	WFS beneficiaries* (before), HS beneficiaries (after)	White	English	WFS=163 HS=149	HS women ate more fruits and vegetables and were more likely to meet the recommended nutrient intakes for iron, folate, calcium, and vitamin C in the short-term
Mouratidou et al., 2010	Before-and-after, primary data collected, Sheffield.	WFS beneficiaries* (before), HS beneficiaries (after)	White	English	142	The increased take-up of fruit and vegetables amongst HS beneficiaries was sustained at 3 months postpartum
Moy et al., 2012	Cross-sectional data, Heart of Birmingham Primary Care Trust	Children under 5 years with symptomatic vitamin D deficiency identified through case-finding	Multi-ethnicity; 75% of population are from at-risk ethnic minority groups	English	29 cases in 2005, 12 cases in 2009	Comparing incidence of vitamin D deficiency at baseline (targeted provision of supplements containing vitamin D) and five years post-implementation of universal vitamin provision: Number of cases of symptomatic vitamin D deficiency fell by 59% over 5 years (29 to 12), with a supplement take-up of 17%
Lucas-Herald	Audit	Mothers	97% white	English	34	No eligible mother took HS vitamins during

et al., 2012	questionnaire, Glasgow	attending a health visitor clinic				pregnancy
Jessiman et al., 2013	Qualitative study using in-depth interviews	HS coordinators, frontline health and children professionals, parents	Multi-ethnicity	English	15 coordinators, 50 frontline health and children professionals, 107 parents	Poor accessibility of vitamins, lack of awareness and lack of parental motivation to take vitamins found to be barriers to vitamin take-up
McFadden et al., 2014	Multi-method evaluation: focus groups, online consultation, participatory workshops. Yorkshire and the Humber and London; online consultation throughout England	Health practitioners, service managers, commissioners, advocacy groups, low-income women, including from traveller communities	Multi-ethnicity	Diverse; interpreter used		HS food vouchers can provide a nutritional safety-net. Erosion of voucher value, lack of access to registered retailers, and barriers to programme registration could compromise its impact
McFadden et al., 2015	Primary care community settings in Yorkshire and the Humber, and London	Rural, urban and ethnically diverse populations	Ethnically diverse; no further information given	English and the use of translators	669 health and social care practitioners participated in 49 focus group discussions; 620 participants took part in an online consultation; 56	Participants experienced HS vitamin distribution as logistically complex. Participants were concerned about the low take-up of HS vitamins. Many participants suggested a universal implementation approach

					participated in stakeholder workshops	
Lucas et al., 2015	Purposive sampling; 13 research sites to achieve geographical and demographic variation	13 areas in England	Ethnically diverse		107 parents	Most parents found the food voucher scheme easy to use; some vulnerable groups were unable to access the scheme. Food vouchers provided vital financial support. Parents used strategies to reduce stigma

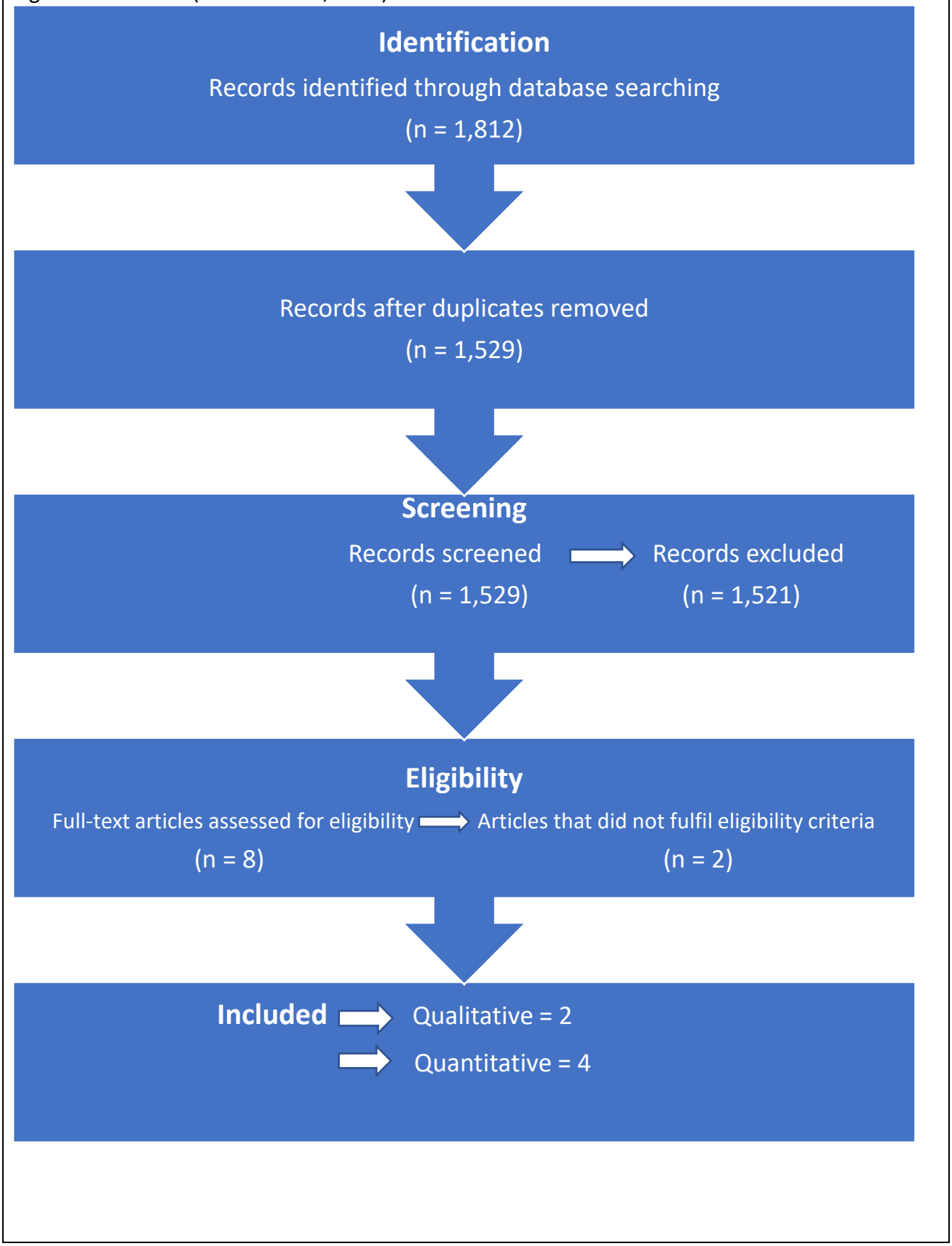
1.6.2 What is known about the take-up of universal and targeted implementation approaches to dietary supplementation programmes for children in the UK?

The main findings of the first literature review were that Healthy Start vitamin take-up was very low whilst Healthy Start food voucher take-up was simultaneously very high. This left the researcher wondering whether the concept of food itself, a basic physiological need understood by the public, was one of the factors contributing to the high take-up of Healthy Start food vouchers. The researcher was also keen to explore if there were any similarities to the barriers or facilitators influencing the take-up of dietary supplemental programmes compared with those found in empirical research about the implementation of the Healthy Start programme.

The researcher explored what is known about the take-up of dietary supplementation programmes offered to children in the UK where a universal or targeted implementation approach was adopted (Figure 1.3). The second literature review was undertaken after the researcher's data collection had been completed; it informed interpretation of the findings rather than the design of this study.

The brief structured review identified five studies relating to the provision of free school meals; one study related to the provision of Healthy Start vitamins. The findings from this brief structured review (table 1.6) provided potential insights into how the Healthy Start vitamin programme could be improved and vitamin take-up increased. The findings also informed potential areas of further research (p.164).

Figure 1.3 PRISMA (Liberati et al., 2009) flow-chart of the brief structured review



With supervisory support, the search strategy for the search question was developed and refined. A scoping search on MEDLINE and Web of Science bibliographic databases (January 1990 to February 2018, Figure 1.4) used specific search-terms (Figure 1.5).

Table 1.4 Criteria used to select studies for data collection of the brief structured review: What is known about the take-up of universal and targeted implementation approaches to dietary supplementation programmes for children in the UK?

Study design: Primary and secondary empirical studies **Participants/population:** Children (0-16 years) in the UK from January 1990 to February 2018 **Intervention:** Universal and/or targeted (means-tested) implementation of dietary supplementation programmes **Outcome measures:** Take-up or participation **Publication characteristics**: English language, UK, humans

Table 1.5 Search-terms used and how key-terms were combined to answer the brief structured review question:
What is known about the take-up of universal and targeted implementation approaches to dietary supplementation programmes for children in the UK? (January 1990 and February 2018)

MEDLINE, ran via OVID 02-01-2018

N°	Terms/syntax	Results
1	school meal*.ti,ab.	567
2	(diet* OR nutrition* OR vitamin*) **ADJ2** (supplement*).ti,ab	4,8263
3	(pre-school OR toddler OR infant OR preschool OR nursery OR child* OR pupil*).ti,ab	1,222,927
4	(target* OR universal OR means test* OR barriers OR facilitators OR take part OR take-up OR taking-up OR access* OR participat* OR adherence OR compliance OR acceptab* OR inequal*).ti,ab.	2,353,459
5	OR 1-2	4,8824
6	3 AND 4 AND 5	1,220
7	limit 6 to (english language and humans and yr="1990 -Current")	**1,081**

Social Science Citation Index Via Web of Science, ran 02-02-18

N°	Terms/syntax	Results
1	TS=”school meal*”	443
2	TS=((diet* OR nutrition* OR vitamin*) NEAR/2 (supplement*))	3,850
3	TS=(pre-school OR toddler OR infant OR preschool OR nursery OR child* OR pupil*)	6,00,252
4	TS=(target* OR universal OR means test* OR barriers OR facilitators OR “take part” OR take-up OR taking-up OR access* OR participat* OR adherence OR compliance OR acceptab* OR inequal*)	750,748
5	OR 1-2	4,290
6	3 AND 4 AND 5	747
8	Limit #6 to English and 1990-2018	**731**

Overall search results after deduplication in Endnote = **1,529** unique records (Figure 1.3).

The six studies included two qualitative and four quantitative publications about dietary supplementation programmes for children in the UK (Table 1.6)

Sahota et al. (2014): This study sought to explore the factors that influence free school meals (FSM) registration and the take-up of FSM in England. The findings were from a scoping review and qualitative research. The local authority provided data. Schools with high FSM entitlement levels compared with the local authority overall were selected. Data were collected from four primary and four secondary schools. Convenience sampling was used to identify individuals for interview. One-to-one interviews were conducted with the headteacher, school meal administrator, and parents. Focus groups were conducted with groups between the ages of 11-14 years and 14-16 years. For children aged 7-11 years, a participatory classroom activity was undertaken. Participating pupils included those eating paid or free school meals and packed lunches. Data were collected over two months.

Limitations were that the study sample only included parents who claimed their FSM entitlement. The parents in the study were therefore more likely to be familiar with FSM entitlement and the FSM registration process. Stigma may not have emerged as a finding as the use of FSM may have been normalised due to the high level of FSM entitlement within the schools.

Headteachers reported that the bureaucracy involved in claiming FSM acted as a barrier to FSM-registration. Headteachers also perceived that a lack of awareness to the entitlement of FSM was another barrier to registration for socially isolated or marginalised families. Conversely, parents who were interviewed reported that the FSM claiming process was straightforward but that secondary schools did not encourage the take-up of FSM. Supportive and effective home-school relationships were thought to be vital to the take-up of FSM from the perspective of school meal administrators. Parents of pupils from both primary and secondary schools preferred systems, such as a cashless system, through which their children could not be identified as receiving FSM. Factors that affected pupils' attitudes towards school lunches included choice, familiarity, taste of foods, and whether the foods were culturally 'safe'. Parents expressed that their priority was that their children did not go hungry whilst at school, with many preferring to send their child to school with a

packed lunch. The latter catered for 'fussy eaters' and pupils who viewed the portion-sizes of the school meals as too small. A packed lunch also avoided pupils having to queue for school meals, giving pupils more time with their friends. Pupils' views of lunchtime as a social time emerged as an important theme.

Implications for the Healthy Start vitamin programme were that: 1) complex administrative processes act as a barrier to the take-up of nutritional supplementation programmes, 2) supportive relationships between healthcare professionals and mothers are important in encouraging the take-up of Healthy Start vitamins, 3) mothers may wish to have a choice about the brand of antenatal, postnatal, and children vitamins.

Day et al. (2015): This qualitative study explored the perceptions of pupils, catering managers (n = 6), and headteachers (n = 5) about school meal provision in primary schools in Leeds, England, via 32 single-sex focus groups. The focus groups comprised 188 Year 3 and 170 Year 5 pupils. Interviews were conducted with the catering managers and headteachers. The participating schools represented a range of demographic backgrounds, ethnicities, and socio-economic backgrounds. Limitations were the small number of interview participants and that the pupils in the study came from only eight primary schools in one region of England.

Pupils from Year 3 and Year 5 perceived that school meals were regularly unhealthy. Choice, variety, taste, and perceived quality of food emerged as important factors in determining pupils' attitudes towards school lunches. Catering managers indicated that meals were prepared according to nutrient-based standards. Headteachers discussed various strategies being used to encourage pupils to adopt healthy eating behaviours. This included workshops with parents and parents being invited to dine with pupils at lunch. Involving pupils in the design of school meals was a key recommendation, as well as using a multi-component approach involving the key stakeholders to improve the take-up of school meals.

Implications for the Healthy Start vitamin programme were that: 1) mothers and children may wish to have a choice about the brand of vitamin supplement they take, 2) mothers may need reassurance about the quality of the vitamin supplements, and 3)

workshops with healthcare professionals, parents, and children focusing on the health benefits of Healthy Start vitamins may encourage vitamin take-up.

Keyte et al. (2012): This population-based, cross-sectional study aimed to assess whether engagement with the National Healthy Schools Programme (NHSP) had an impact on fruit and vegetable consumption from a random sample of schools in South West Hampshire, England. Engagement with the NHSP characterized the intervention group and schools not engaged in the NHSP characterized the control group. The NHSP promoted the link between good health, behaviour, and achievement through four key areas: healthy eating; physical activity; personal, social and health education (PSHE); and emotional health and well-being. Data were collected from 511 children aged 7-9 years using a validated 24-hour recall questionnaire designed to measure fruit and vegetable consumption. Free School Meal Entitlement was used as a proxy for socio-economic status. Of the 511 children: 410 children attended seven schools, three of which had achieved NHSP status and four of which were working towards NHSP status; 101 attended three schools not engaged with the NHSP.

Limitations: Though Free School Meal Entitlement is commonly used as a proxy for socio-economic status in the UK, it has been shown not always to capture children living in poverty (Taylor 2017). Some of the recall questionnaires may therefore have been from children not entitled to Free School Meals, but who were living in poverty. As with many cross-sectional studies, the recall questionnaire only provided a snapshot of pupils' food intake; their habitual fruit and vegetable intake may have been different.

There was a 10-15% Free School Meal Entitlement within the three schools not engaged with NHSP. Of the children attending schools engaged with the NHSP, 20.0% ate fruit or vegetables compared with 10.9% not engaged with the NHSP [p = 0.043; 95% CI 0 to 14.6%]. Children attending schools engaged with the NHSP ate a median of two portions of fruit and vegetables compared with one portion consumed by pupils attending a school not engaged with the NHSP [p = 0.001; 95% CI for the median difference 0 to 1.0]. Of children attending a school engaged with NHSP, 36.6% consumed more than 2.5 portions of fruit and vegetables compared with 18.8% of children attending a school not engaged (p = 0.001; 95%

CI 8.0% to 25.8%). This study contributed evidence about how the school environment influences the consumption of fruit and vegetables amongst primary school children.

Implications for the Healthy Start programme were that: 1) Healthy Start vitamins need to be offered in an environment that encourages healthy behaviours, 2) the take-up of Healthy Start vitamins may be encouraged through offering them to all mothers and children under the age of four years, and 3) the providers of Healthy Start vitamins need to offer both health and social education to encourage take-up.

Moy et al. (2012): This study evaluated the effectiveness of the universal provision of Healthy Start vitamins in reducing the number of symptomatic cases of vitamin D deficiency amongst the Heart of Birmingham Primary Care Trust population, 75% being from ethnic minorities.

Limitations were that the numbers in the study were small and no p values were calculated to identify whether the difference observed was statistically significant.

The study found that the incidence rate of symptomatic vitamin D deficiency decreased by 59% between 2004 and 2009 (29 to 12 cases) from 120 cases per 100,000 children under the age of 5 to 49 cases per 100,000 children. No p values or CI accompanied the data. Between 2004 and 2009, the take-up of Healthy Start was no greater than 17%. In this study, children received vitamins from the age of two weeks versus six months as recommended by the Healthy Start Unit, and up to their fifth birthday versus their fourth birthday as per national criteria. Additionally, since the Healthy Start programme was launched in 2006, the population may have been more aware of the importance of vitamin D for their children's health through national media and campaigns. It is not known whether the incidence of symptomatic vitamin D deficiency continued to decrease or was sustained after 2009.

Implications for the Healthy Start programme were that the universal provision of Healthy Start vitamins accompanied by a media campaign may increase the awareness of the importance of vitamin D and its health benefits and also increase the take-up of vitamins.

Moore et al. (2014): This cluster-randomised controlled trial measured the take-up of healthy items for breakfast in schools offering the Primary School Free Breakfast Initiative to all pupils, with 111 primary schools located in Wales participating: 55 in the intervention group and 56 in the control group. A dietary and recall questionnaire were used; responses were anonymously linked to Free School Meal Entitlement as a proxy-measure of deprivation. Other measures analysed were: attitudes towards eating breakfast; dietary recall questionnaire; classroom cognitive tests; and behavioural problems.

Limitations were that the recall questionnaire, reliant on self-reported measures, could have been subject to social desirability biases.

The percentage of Free School Meal Entitlement amongst the study participants within each school ranged from 0 to 61.0% (mean 22.8%; SD 13.2%, *n* = 108). Children in schools randomised to receive the Primary School Free Breakfast Initiative consumed significantly more healthy items at breakfast and had more positive attitudes towards breakfast than children in control schools in school-level analysis [*b* = 0.25, < 0.01; 95% CI 0.07 to 0.44; P < 0.01] at the 12-month follow-up point. Larger increases were observed in deprived schools. The *b* coefficient was the difference between groups in the average number of healthy items consumed; a *b* coefficient of 0.25 indicated that, on average, pupils in intervention schools ate 0.25 more servings of healthy items than those in the control schools. No intervention effect was observed at school-level FSM entitlement or intervention status and hyperactivity. This study provided support that universal food supplementation programmes for children can improve their consumption of fruit and vegetables.

Implication for the Healthy Start programme: any potential universal implementation of Healthy Start vitamins should be accompanied by changes to the environment that encourages healthy behaviours; this may support an increase in Healthy Start vitamin take-up.

Holford (2015): The aim was to identify and quantify endogenous peer-effects in take-up of free school meals. A dataset on every primary school for children aged 4-11 years in Scotland, UK, from 2003 to 2013, was used for secondary data analysis. The take-up of Free School Meals was modelled using the 'linear-in-means' framework. Economic demand

equations were used to quantify peer-effects. *Note – this is an economics paper, which is not one of the disciplines of the researcher here. As such, no further constructive comment is made on the limitations of this study.*

The paper identified significant positive endogenous peer effects in take-up of Free School Meals; a 10-percentage point rise in peer-group take-up of school meals increased take-up among Free School Meal-registered individuals by 3.3-4.0 percentage points, equivalent to reducing non-participation by between 29%-35%. Holford (2015) suggested that reforming Free School Meal using a universal implementation strategy would reduce non-participation amongst Free School Meal-registered children by at least 28% and up to 93% in the first year, with Free School Meal-registered individuals more likely to participate in their welfare entitlement because more of their peers' Free School Meal take-up.

The implication for the Healthy Start vitamin programme is that reforming it to universal provision may reduce non-participation.

The researcher acknowledged that the context in which the free school meals were offered differed compared with the Healthy Start vitamins. Differences included; 1) the age group of the children, i.e. over four years for the former and under four years for the latter, and 2) the potential role of direct peer pressure influencing the take-up of free school meals experienced by children vs. indirect peer pressure influencing the take-up of children's Healthy Start vitamins, i.e. the peer pressure would be felt by the mothers but not the children themselves. Other limitations included the small size of some of the studies, with some being limited to one region of England and one quantitative study not providing a p value. One study fell outwith the expertise of the researcher for this thesis.

In summary, the findings from this brief structured review (table 1.6), provided potential insights into how the Healthy Start vitamin programme could be improved and vitamin take-up increased, which the Discussion chapter reviews. Overall, the evidence-base suggested that:

- Reducing the bureaucracy surrounding the local delivery of Healthy Start vitamins may increase the take-up of vitamins

- The environment in which Healthy Start vitamins are offered may affect the take-up of the vitamins; this includes the effect of peers
- Giving parents choice and informing them that the Healthy Start vitamins are culturally safe may increase the take-up of Healthy Start vitamins
- Increasing the awareness of both preschool children and their parents of the health benefits of Healthy Start vitamins may increase take-up

Table 1.6 A synopsis of a brief structured review on dietary supplementation programmes for children in the UK (January 1990 and February 2018):
What is known about the take-up of universal and targeted implementation approaches to dietary supplementation programmes for children in the UK?

First author, year published	Setting (country)	Aim of intervention, and population	Study design, sampling type, number in sample, data collection method	Comparator	Main findings	Limitations	Quality of evidence: Grade*	Date data collected	Comments
Qualitative studies									
Sahota et al., 2014	Leeds, England, UK	To explore factors that influence registration for Free School Meals (FSM) and its take-up following registration	Qualitative, purposive sampling of schools, convenience sampling of participants, semi-structured interviews with head teachers, school meal administrators, parents, and eight focus groups with pupils aged 11-16 years. A participatory activity with children 7-11 years.	Nil	Perceived barriers to the take-up of FSM by head teachers were: bureaucracy involved in claiming free school meals, lack of awareness, low parental literacy, a sense of pride, and a right to privacy. In secondary schools, head teachers did not actively encourage the take-up of free school meals. Cashless systems in secondary schools were preferred by parents and head teachers aimed at reducing stigma and bullying. In primary schools, effective home-school relationships were considered crucial in encouraging the take-up of FSM. Choice, familiarity, the taste of foods and knowing which foods were culturally 'safe' were important in pupils' attitudes to	Some feelings, such as stigma, may not have emerged during focus-group interviews as individuals may have been less open about their feelings.	4	Not stated	Parents eligible for, but not FSM-registered, were not interviewed. Other factors that influence registration for FSM may have emerged if this group was interviewed.

					FSM. The social aspect of queuing for school meals, leaving less time to socialise with friends, was a major influence against the take-up of school meals for both paying and non-paying pupils.				
Day et al., 2015	Leeds, England, UK	To explore perceptions of pupils, catering managers, and head teachers of the implementation of universal free school meals (FSM)	Qualitative, purposeful sampling, 32 focus groups from 128 pupils from eight primary schools, six catering managers, five heads of school. Digitally recorded interviews with additional field-notes.	Nil	Quality of the school meal, variety of fruit and vegetables, and the ability to choose the food themselves versus their parents via a food-card affected pupils' intake of the FSM. Caterers believed that choice was an important factor in encouraging school meal take-up. Some head teachers expressed concern over access to funding for the (at the time) imminent, universal infant free school meal programme in September 2014.	Selection bias may have been introduced as teachers selected pupils. Pupils may have given socially desirable answers, potentially concealing some of their views.	4	May to July 2014	Social desirability bias could have been addressed through conducting 1:1 semi-structured interviews with primary school children.
					Quantitative				
Keyte et al., 2012	South West Hampshire, England, UK	To assess the impact of engagement with the National Healthy Schools Programme (NHSP) on fruit and vegetable consumption in children aged 7-	Quantitative population-based, cross-sectional study. Schools were chosen from a list of previously randomly selected schools; schools were selected based on availability (non-probability sampling of a random sample); 511 pupils	Control group was not engaged with the NHSP	Three schools were not engaged in the NHSP, three had achieved NHSP status, and four were working towards NHSP status. 20.0% compared with 10.9% of children attending schools engaged with the NHSP ate fruit or vegetables [p = 0.043; 95% CI 0 to 14.6%]. Children attending schools engaged with the NHSP ate a median of two portions of fruit and vegetables compared with one portion consumed by	The questionnaire may not have captured the children's habitual intake of fruit and vegetables.	4	Not stated	The paper did not state which component/s of the NHSP was/were particularly emphasised by the schools, if any. The NHSP is a multi-component intervention that

		9 years	aged 7-9 years from ten different schools, Validated 24-hr recall questionnaire of dietary assessment used.		pupils attending a school not engaged with the NHSP [p = 0.001; 95% CI for the median difference, 0 to 1.0].				includes staff and teacher training, increasing availability of fruit and vegetables during the day, parent education sessions, cookery lessons.
Moy et al., 2012	Birmingham, England, UK	To reduce the number of cases of vitamin D deficiency in those under 5 years through the universal provision of vitamin D supplements to all under-5s and all pregnant and lactating women resident in the inner-city health area. A public-awareness campaign took place simultaneous to the universal intervention.	Quantitative before-and-after study. Identification of children under five years resident in the inner-city area attending hospital paediatric departments or community paediatric clinics; data were collected at the start of the intervention (January to December 2005) and four years later (March 2009 to February 2010). Incidence rates were calculated.	Post-intervention	A 59% decrease in the absolute numbers of symptomatic vitamin D deficiency; 29 cases in 2005 versus 12 cases in 2010. Incidence rate reduced from 120/100,000 children under the age of five years to 49/100,000. Vitamin take-up reached 17%. Public awareness about the importance of vitamin D for bone health rose from 21% in 2007 to 79% in 2011. Of note, no p values or confidence intervals were given in this paper.	The national Healthy Start programme launched in 2006. Media coverage and visits to local health administrative areas by the national Healthy Start Unit could have contributed to the improvements observed by this study.	4	2005 to 2011	P values and confidence intervals should have been calculated on the results of this paper. Supplementation of infants started from 2 weeks of age; health visitors provided families with their first bottle of children drops at the first new baby home visit. GPs, health visitors, community and hospital midwives, pharmacists, paediatricians, and obstetricians

									were educated about the importance of vitamin D supplementation in their continuing professional education.
Moore et al., 2014	Wales, UK	To measure the take-up of healthy items for breakfast in schools offering the Primary School Free Breakfast Initiative to all pupils	Cluster-randomised control trial of 111 schools, 55 in the intervention group. Dietary and recall questionnaire was used for pupils.	Control group (n = 56) was not involved in the Primary School Free Breakfast Initiative	Pupils in intervention schools ate more healthy items at breakfast compared with children from schools in the control group [*b* = 0.25, < 0.01; 95% CI 0.07 to 0.44; P < 0.01] at the 12-month follow-up point. Larger increases were observed in deprived schools. A *b* coefficient (difference between groups in the average number of healthy items consumed) of 0.25 indicated that, on average, pupils in intervention schools ate 0.25 more servings of healthy items than those in control schools.	The recall questionnaire could have been subject to social desirability biases. Inferences could not be made at the individual level.	4	Not stated	Study provided evidence that universal interventions that involve changing the environment to facilitate healthier behaviours may be more likely to reduce inequalities.
Holford, 2015	Scotland, UK	To identify and quantify endogenous peer effects in take-up of Free School Meals (FSM). Primary schools, children aged 4-11 years.	Analysed dataset on every primary school, for children aged 4-11 years, in Scotland from 2003 to 2013. Take-up of FSM was modelled using the 'linear-in-means' framework. Economic demand equations are used to quantify peer effects.	Take-up of FSM amongst FSM-registered and FSM-unregistered individuals in schools offering FSM universally (as part of a	A 10-percentage point rise in peer-group take-up of school meals increased take-up among FSM-registered individuals by 3.3-4.0 percentage points; this was equivalent to reducing non-participation by between 29%-35%. The evidence suggested that reforming FSM using a universal implementation strategy would reduce non-participation amongst	The researcher is unable to comment on the limitation of this economics paper (outwith expertise).	4	Not stated	This economics paper is not one of the researcher's core disciplines. From what the researcher could ascertain, the paper provided Grade 4 evidence.

			Secondary data analysis of routine datasets.	pilot) versus schools not part of the pilot	FSM-registered children by at least 28% and up to 93% in the first year. FSM-registered individuals were more likely to participate in their welfare entitlement because more of their peers take up FSM.				

Grade*: Grade 1 – No clear conclusion can be drawn; Grade 2 – Results are ambiguous, but there appears to be a trend; Grade 3 – Conclusions can probably be based on the results; Grade 4 – Results are clear and very likely to be true; Grade 5 – Results are unequivocal (Colthart et al., 2008)

1.7 This thesis

1.7.1 Research aim and objectives

The overarching aim of this study was to investigate the effect of a targeted versus universal implementation approach to the Healthy Start vitamin programme on the take-up of vitamins in the eligible population 'targeted' by the Department of Health, i.e. low-income families, and reasons for any observed differences. The main objectives of this thesis were:

- To identify differences in Healthy Start vitamin voucher take-up between a demographically similar targeted and universal area
- To explore the explanatory factors as perceived by potentially eligible mothers, Healthy Start healthcare professionals, and commissioners for similarities and differences in vitamin take-up between these two areas and explore barriers at the point of supply to participants

1.7.2 Structure of thesis

This thesis spans five chapters:

- Chapter 1 (Introduction and literature) sets out what is known about vitamin D supplementation and gaps in the literature, leading to the aims of this thesis
- Chapter 2 (Methods) describes the quantitative and qualitative methods used to answer the research objectives and outlines their limitations
- Chapter 3 and 4 (Results) present and discuss the findings from the quantitative and qualitative arms of the study respectively
- Chapter 5 (Discussion) pulls together the key findings and describes the contribution of this study to the existing literature. This is followed by a discussion of the strengths and limitations of the overall approach and study design. The chapter ends with policy recommendations and proposes areas for further research.

The following chapter describes the methods used to collect the empirical findings in this thesis.

2 Chapter 2: Methods

2.1 Overall design of study

To address the thesis objectives, a sequential explanatory mixed-methods design was employed (Ivankova et al., 2006). This comprised three main elements:

- Secondary analysis of Department of Health routine data on Healthy Start Vitamin Programme take-up for England and for two areas in the North West, with contrasting approaches to implementation of the Programme: universal and targeted (to address objective 1)
- Observation of everyday provision/availability of vitamins under the Programme in the two contrasting areas, concurrent with the interviews (to address objective 2).
- Qualitative research, involving primary data collection through semi-structured, one-to-one interviews with healthcare providers of the Programme, commissioners, and potentially eligible women in the two contrasting areas (to address objective 2)

2.2 The rationale for using 'mixed methods'

Typically, a qualitative research approach is useful for exploring and understanding the meaning that individuals or groups assign to a social phenomenon, and a quantitative research approach is good for analysing the relationship of variables through hypothesis-testing. To address the overarching aim and research objectives, the study adopted a mixed-methods approach. The research procedure involved the collection, analysis, and integration (or 'mixing') of both quantitative and qualitative data to answer the research objectives (Creswell and Plano Clark, 2011) and gain a more complete picture. A sequential mixing was required to focus the collection of rich data (about the processes involved in the take-up of Healthy Start vitamins) on issues highlighted by the routine quantitative data and to contextualize the interpretation. While focus groups are generally suitable for studying people's beliefs and attitudes in a more natural environment (Krueger and Casey, 2000), the

semi-structured interview is particularly apt when exploring a person's experiences and views in-depth, with structure and flexibility (Ritchie and Lewis, 2003), hence the choice of semi-structured interviews for data collection.

The interviews were analysed using a framework approach. This approach was chosen to compare themes between and within groups of interviewees. The interviewees were from either a universal area or targeted area, and within each area, commissioners, healthcare professionals, and potentially eligible participants were interviewed. The framework approach ensured that "the integrity of individual respondents' accounts (is) was preserved throughout analysis" (Green and Thorogood, 2004, p.184). The study was also examining aspects of a UK-maternal and child health policy, and it was hoped to make policy recommendations. Being specifically geared towards generating policy recommendations (Green and Thorogood, 2004), framework analysis was therefore particularly suitable.

2.3 Sequential explanatory mixed methods design

The sequential explanatory mixed methods approach was chosen to meet the research objectives of this two-phase study. The findings from the analysis of quantitative data, together with the research questions in objective 2, drove the selection of the most appropriate method (qualitative interviewing) to answer questions about 'why' and 'how' differences in take-up arise.

In this study, the Department of Health Healthy Start Unit provided quantitative data for descriptive analysis of the take-up of vitamins for pregnant women and preschool children across the nine English regions. Data available for North West England primary care trusts were then analysed. The results from the quantitative phase of the study informed the selection of interview participants as well as the development of the semi-structured interview topic-guides for the qualitative phase. This intentional linking of the quantitative and qualitative phases reflected the 'mixing' that occurred.

2.4 Epistemology and positionality

Quantitative and qualitative methods were required to explore comprehensively the overarching research aim, viewed as two complementary sources of knowledge within the pragmatism paradigm, combining aspects of both a post-positivist and social constructionist worldview to inform the study design.

2.5 Pragmatism and personal reflection ('I')

As 'the researcher', I used the 'pragmatism' perspective with primacy being given to the overarching aim, i.e. the problem, rather than a specific worldview. Combining aspects of the diverse stances of post-positivist and social constructionist epistemological positions reflected that I valued both objective and subjective knowledge in exploring the research question (Morgan, 1998). Post-positivism would cast reality as universal, objective, and quantifiable (Silverman, 2005). Aspects of this philosophical position were evident when attempting to understand 'what' was occurring with the take-up of vitamins, i.e. what percentage of the vitamins available to a primary care organisation was being claimed. Through observing the trends in vitamin-take-up, a hypothesis was developed deductively for statistically testing, i.e. that vitamin-take-up was higher in universal compared with targeted areas.

The social constructionist worldview would concede that reality is socially constructed by and between the persons who experience it (Gergen and Gergen, 2003) (i.e. there is no absolute truth). Furthermore, through social interactions, reality exists as multiple truths based on our understanding and experiences of the world around us. This epistemological position was evident in the approach to qualitative data.

Consequently, I acknowledge that I have only collected representations of the interviewees' views and experiences, i.e. what is subjectively real to them, and that only accounts of reasoning are given, not 'explanations' in themselves. I also acknowledge that I interpret the behaviour of interviewees and attribute meaning to the behaviours based on my own experiences and tacit knowledge.

My background as a medical physician, then public health doctor (in both service and academic roles), and my life-experiences such as supporting vulnerable communities will have affected decisions and interpretations that I have applied in this research. During my time as a specialty registrar on the North West England NHS public health training programme, I was asked to support the Healthy Start lead at the primary care trust I was assigned to work. The support was specific to increasing the take-up of Healthy Start vitamins. It was through this work that the Healthy Start/vitamin D issue came to prominence.

Whilst undertaking the doctorate part-time, I pursued a Master of Quality Improvement and Patient Safety in Toronto. Two modules, "Leading and managing change" and "Human Factors", reinforced my ideas about the challenges faced when trying to implement a national policy at a local level, which influenced my interpretations of my data. The former highlighted three pertinent issues in particular. Implementation will fail (Kotter, 2007):

1) unless a vision is clearly communicated by the policy-makers to the implementers, in this case communication of the Department of Health vision to reduce vitamin D deficiency through the provision of Healthy Start vitamins to those locally responsible for the implementation of the policy,

2) unless the local implementers are empowered to act on the vision by being given the freedom to remove system obstacles and support from local leaders, and lastly

3) unless the implementers are allowed to try different ways of implementing the policy, being supported to learn from every action that did not work as much as to build on the actions that did work.

I also became a mother during the research process.

Human Factors "encompass all those factors that can influence people and their behaviour. In a work context, human factors are the environmental, organisational and job factors, and individual characteristics which influence behaviour at work" (Clinical Human Factors Group, 2016). Whilst studying this area, questions arose for me around the local implementation of the Healthy Start programme: What would vitamin take-up be like if a

pregnant woman or carer with a child less than five years could not leave a Sure Start centre without being offered a bottle of Healthy Start vitamins? Would vitamin take-up be higher if the brief discussion about the importance of vitamin D during pregnancy and children early years was not cramped into a 60-minute booking-in appointment, the first contact a pregnant woman has with a midwife?

My familiarity with qualitative research approaches had developed when I undertook a Master of Public Health dissertation about the experiences of former dependent alcoholics whose dependency focused on alcohol use at home, a topic that explored health issues in a vulnerable group. Semi-structured interviews were used to explore those experiences.

The lenses through which I have undertaken and interpreted data collection will have been shaped by such previous experiences as a medical doctor, a public health specialist, supporting the implementation of the Healthy Start vitamin programme, a healthcare service user, a manager in the NHS, and a mother.

2.6 Ethical considerations

2.6.1 The University of Liverpool

As the study was being conducted for a Doctor of Medicine degree from the University of Liverpool, the University of Liverpool's Faculty of Health and Life Sciences acted as a Sponsor the study; the Sponsor is the organisation responsible for a project's administration and management (Health Research Authority, 2014). This was granted in June 2011 (Appendix 1).

2.6.2 NHS

As the research project being undertaken involved NHS-employed healthcare professionals, ethical approval from both National Research Ethics Service (NRES) (Appendix 2) and local research and development committees had to be obtained before participant recruitment commenced. The Proportionate Review Sub-Committee of the NRES

Committee East Midlands – Derby 1 Research Ethics Committee reviewed the initial application and requested that:

- The participant only signs the consent form once
- A tear off slip be included at the bottom of the participant information-sheet for contact details
- It was made more explicit that two specific primary care trusts (PCTs) were selected for the study and the reasons for this
- The committee received an explanation and assurance about how the confidentiality of the transcripts would be maintained

A 'favourable opinion' was given following these changes.

The following are organizations from which local ethical approval was sought:

- Liverpool Research & Development (R&D): This covered NHS employees in both Liverpool and Sefton Primary Care Trust (Appendix 3)
- Blackburn with Darwen Teaching Care Trust Plus (Appendix 4)
- Liverpool Women's NHS Foundation Trust (Appendix 5)

All three organisations provided a favourable ethical opinion; no further changes were requested to the NRES-revised consent form (Appendix 6) and participant information-sheet (Appendix 7).

2.6.3 Local authority

As the children centres were local authority buildings and some of the healthcare professionals within them were employed via the local authority, the researcher sought guidance for ethical approval from both Sefton and Liverpool local authorities. The respective policy unit heads advised seeking permission for interview from each local authority health professional directly; neither local authority was aware of any formal research governance process for its organisation.

2.6.4 Healthy Start Unit 'take-up' data

The Department of Health Healthy Start Unit co-ordinator gave the researcher access to the regional vitamin voucher 'take-up' data. Individual primary care trust data were limited to those located within North West England, as this is where the researcher was based and also participated in a Healthy Start vitamin working-group (Liverpool). Permission to use the nationally collected data were given on the proviso that the limitations of the data were acknowledged, i.e. that the cross-sectional, quarterly, take-up data reflected the financial claims by primary care trusts for vitamin vouchers. Take-up was defined by the Healthy Start Unit as the number of recipients divided by the number of eligible recipients at a single point of time in each yearly quarter, where the number of sets of vitamins claimed by a primary care trust was used as a proxy for beneficiaries. The take-up was reported as a percentage. The researcher was explicit with the Department of Health Healthy Start Unit co-ordinator that the data were being used for a doctoral study.

2.7 Quantitative data collection and analysis

2.7.1 Routine data source

Data from the Department of Health Healthy Start Unit were obtained from the Healthy Start Unit co-ordinator and analysed with non-parametric statistics. Though the Healthy Start programme started in 2006, percentage 'take-up' data were only available from July 2009 (yearly quarter (Q) 2, 2009/10) to December 2012 (Q3, 2012/13). The number of beneficiaries and the number of those eligible from each primary care trust in North West England were only available from July 2009 (Q2 2009/10) to September 2010 (Q2 2010/2011) (Appendix 8). A total of 398,476 beneficiaries from targeted areas and 50,357 beneficiaries from universal areas were eligible for Healthy Start vouchers.

2.7.2 Statistical analysis

Basic descriptive epidemiology was used (i.e. by time, place, and person) to describe trends and patterns of the percentage 'take-up' of vouchers for food and mother and

children vitamins observed in the nine English regions. SPSS v20 (IBM, New York) was used for the statistical analyses between targeted and universal areas. As the data were not Normally distributed, established through the Kolmogorov-Smirnov test and the Shapiro-Wilk test, the non-parametric Chi-squared test was used.

Null hypothesis: There is no difference in the take-up[1] of Healthy Start vitamins between areas employing a targeted approach and those employing a universal approach.

2.8 Qualitative methods

2.8.1 Setting

The interviews were conducted in the metropolitan boroughs of Sefton, the universal area, and Liverpool, the targeted area, in North West England.

Liverpool was chosen as one of the health administrative areas (primary care trust at the time of data collection) for the study due to its level of deprivation and targeted approach to the provision of the Healthy Start vitamin programme. Sefton was found to be the only health administrative area in Merseyside with similar levels of deprivation and low life expectancies to offer Healthy Start vitamins universally, to all pregnant and lactating women and preschool children independent of income at the time of the study (Public Health England, 2013).

[1] 'Take-up' is defined by the Healthy Start Unit as the number of recipients divided by the number of eligible recipients at a single point of time in each yearly quarter, where the number of vitamins claimed for by a primary care trust is used as a proxy for beneficiaries. The 'take-up' is reported as a percentage.

2.8.2 Design

The qualitative data were collected between February and September 2012 using semi-structured, one-to-one interviews. The development of the interview-schedules was influenced by the research objectives and findings from the quantitative data. Pilot interviews were conducted and modified as fieldwork developed. The participant-information-sheet, covering an overview of the research topic and ethical issues, was developed concurrently. A semi-structured interview-schedule was designed for potentially eligible mothers (Appendix 9) and healthcare providers and commissioners (Appendix 10).

The topic-guides in the interview-schedule allowed a balance to be achieved between using a standard approach to data collection whilst allowing flexibility in the ordering of the issues pursued (Pope, 2007). Any unanticipated issues raised by an interviewee could also be pursued in more detail.

2.9 Sampling methods

2.9.1 Potentially eligible recipients of Healthy Start vitamins

The interview-sample for potentially eligible recipients[2] of Healthy Start vitamins was drawn from women who attended children centres within "Area T" and "Area U" using a purposive sampling strategy. The researcher attended morning and afternoon activities for mothers of preschool children on a variety of weekdays at children centres in both areas. This strategy aimed to capture a diverse sample of mothers who were a) on the Healthy Start programme, b) were not on the Healthy Start programme but fulfilled the Department of Health eligibility criteria, and c) mothers who did not fulfil the Department of Health eligibility criteria. The researcher was aware that this pragmatic sampling strategy would have missed parents who were not fluent in English, migrant populations, and those who did not have accessible transport links. For the researcher's safety, home visits were not conducted. Interpreters were not considered due to the cost implications.

[2] A potentially eligible recipient is a mother with a child less than five years of age

The researcher firstly contacted the Healthy Start co-ordinators for “Area T” and “Area U” primary care trusts, discussed the aim of the research, shared the participant information-sheet in paper and electronic format, and requested that the co-ordinators identify potential children centre managers who may be interested in the study. The researcher contacted the identified children centre managers via email and shared the participant information-sheet and interview-schedule for potentially eligible recipients; none of the managers declined to support the research.

Each children centre manager approached individual mothers, gave an overview of the research, asked whether they would be willing to participate, and then gave the researcher the telephone-number of the mothers who agreed. Upon telephoning each mother, the researcher discussed the purpose of the research and interview-process in detail and asked whether the mother would be willing to be interviewed, either by telephone or face-to-face, in the morning or afternoon.

The children centre managers also approached infant and toddler groups held within the centre. After giving each group an overview of the research, s/he asked the group’s permission for the researcher to describe the research in more detail and potentially to interview mothers. It was emphasised by the managers, at the researcher’s request, that refusal to be interviewed would not in any way affect mothers’ access to the centre’s services. The manager invited the researcher to the centre at a date and time convenient to both the manager and the group. At the groups, after describing the research in more detail, the researcher approached individual mothers and asked whether each was willing to be interviewed. Lack of time was the primary reason given by the mothers who declined to be interviewed; 25 mothers agreed to be interviewed, three declined to be interviewed.

2.9.2 Healthcare providers

The sampling strategy aimed to explore in depth issues raised by healthcare providers who were involved in the provision of Healthy Start vitamins through children centres. This included midwives, health visitors, and health promotion officers. Each children centre manager supplied an initial list of healthcare providers to contact in “Area T” and “Area U”. Initial contact with each healthcare provider was via email with the participant information-

sheet attached. No healthcare provider declined to be interviewed. Most midwives and health visitors opted for a telephone-interview, whilst health promotion officers preferred to be interviewed at their respective children centre. After each interview, the researcher asked if any other healthcare providers working from the respective centre may be willing to be interviewed at a future date and then received the email address of other potential healthcare providers, repeating the process described above.

2.9.3 Commissioners and national Healthy Start Unit staff

The respective commissioners of the local Healthy Start vitamin programme in "Area T" and "Area U" agreed to be interviewed. One commissioner was interviewed after s/he left the PCT (due to NHS reorganisations that occurred in 2012). To obtain a broader understanding of the universal implementation of the Healthy Start vitamin programme, two employees who worked on the commissioning and provision of the universal implementation approach in a different universal area, in North West England, were also interviewed. The three members of staff at the national Healthy Start Unit were also approached for interview. No individual declined the request.

Table 2.1 Number of interviewees by job role and implementation area for the Healthy Start vitamin study 2012

Category of interviewee	Number
Mothers in "Area T"	13
Mothers in "Area U"	12
Healthcare providers	11
Commissioners	3
Department of Health Healthy Start Unit staff	3

2.10 Data collection

2.10.1 Consent and confidentiality

Interviewees gave consent and received reassurance about confidentiality before each interview. After going through the participant information-sheet with interviewees, the researcher reminded them that they had the opportunity of not answering a question, taking a break, or discontinuing the interview at any point. Potentially eligible recipients received reassurance that their participation in the research would not affect their access to services provided at the children centre. It was made clear that the research was for a Doctor of Medicine degree. For face-to-face interviews, consent was obtained in the presence of the researcher to indicate each participant's willingness to be interviewed and for digital voice-recording. For telephone-interviews, the interviewee scanned and sent a signed consent form via email before the interview.

At the end of the interview, with the recording off, interviewees were asked how they felt and if they thought they required any support following the interview. They were made aware of the researcher's contact-details on the information-sheet should they need future support. No interviewee requested support.

Each participant received a unique identifier (numerical code) known only to the researcher. At the start of the interview, participants were introduced by their unique identifier. The transcripts were kept on a work computer and personal computer, each password-protected. The digital voice-recordings were wiped once the transcription was complete.

2.10.2 Interview-process

The one-to-one interviews focused on covering the breadth of interviewee experiences related to the issues covered in the semi-structured topic-schedule as well as exploring any new or exceptional experiences in depth.

During the one-to-one interviews, questions and prompts were included or omitted according to what the interviewee said and how the interview flowed. The study explored

understanding of the experiences and views of the three groups of interviewees concerning the Healthy Start vitamin programme. All face-to-face interviews were conducted on NHS or local authority sites. For the convenience of the interviewee, the option of telephone-interviews allowed healthcare providers and commissioners to fit the interview into their schedules.

2.10.3 Data transcription

Each interview was transcribed by a professional transcriptionist from the University of Liverpool within three working days after the interview. The researcher checked each transcript against the original recording for accuracy. The anonymised transcripts were then imported into a qualitative data analysis software package (NVivo version 9.2; QRS International 2011).

2.11 Qualitative data analysis

The five stages of the framework approach (Lacey and Luff, 2009) to analysis were applied to the current study as described below.

2.11.1 Stage 1: Familiarisation

The familiarisation stage (to immerse oneself in the raw data so that key ideas and recurrent themes can be drawn (Pope 2007)) was initially accomplished through the process of conducting the interviews and checking the transcripts for accuracy before importing them into NVivo 9.2. At the midpoint in the data collection, the researcher undertook a specific familiarisation exercise, re-reading five transcripts and the accompanying field-notes, noting key topics and recurring themes. These were then discussed with two of the doctoral supervisors who independently also coded the five transcripts. These 'initial' key topics and recurring themes informed the next stage of analysis by contributing to the 'initial' framework.

2.11.2 Stage 2: Identifying a thematic framework

The key topics and recurring themes that emerged in the familiarisation stage as well issues that emerged during the quantitative phase were used to develop a thematic framework. The thematic framework was developed using NVivo 9.2.

2.11.3 Stage 3: Indexing

The thematic framework formed in stage 2 was systematically applied to all the remaining transcripts. Each sentence was coded and assigned to particular theme(s) or categor(y)(ies). The thematic framework was refined as new topics and themes emerged over the course of data collection; groups of codes formed categories and categories were grouped into themes. Key-words used by interviewees were applied as the title of a code or category where possible. The 'final' framework emerged after all interviews were coded, reflecting the iterative nature of this qualitative research.

2.11.4 Charting

Using the final thematic framework, thematic and case-charts were developed for the main themes. For case-charts, a row was allocated to each interviewee and a column for each category. For theme-charts, a row was allocated to each theme and a column for each case. NVivo 9.2's framework matrix function was used to develop the charts. Preliminary relationships and connections between and within transcripts were sought.

2.11.5 Mapping and interpretation

Before the start of this stage, the researcher was aware that a step back was required to appreciate the complexities within the data. After a couple of weeks of not being immersed in the data (not thinking of or looking at the data), with a refreshed mind, the researcher analysed each thematic chart in order to identify patterns or associations, range of experiences, and contrasting views.

2.12 Observations of everyday practice

At the end of the whole interview held at a children centre, the researcher asked the centre's manager or his/her deputy for permission to see the number of Healthy Start vitamins available in their locked cupboard. The researcher documented the number of non-expired bottles of Healthy Start vitamins available for women and preschool children. Afterwards, the researcher walked to the nearest pharmacy to determine whether any vitamins similar to Healthy Start vitamins were available and at what cost. All documentation for this observational study was made in field-notes, including personal reactions to the situations observed (findings reported at the end of Chapter 3).

2.13 Chapter summary

This chapter presents an overview of the research design employed in this study. The overarching aim of this study was to investigate the effect of a targeted versus universal implementation approach to the Healthy Start vitamin programme on the take-up of vitamins in the eligible population 'targeted' by the Department of Health, i.e. low-income families, and reasons for any observed differences. In particular, the objectives of the research were to identify differences in Healthy Start vitamin voucher take-up between a demographically similar targeted and universal area and to explore the explanatory factors as perceived by Healthy Start healthcare professionals, commissioners, and potentially eligible participants for similarities and differences in vitamin take-up between these two areas.

A mixed methods approach was used and a sequential explanatory design employed to complement the quantitative and qualitative nature of the research objectives. The first part of the study analysed quantitative data from the Department of Health Healthy Start Unit to identify differences in the take-up of Healthy Start food and vitamin voucher take-up across England and especially North West England, complemented by direct observation of vitamin availability on-site at children centres and their local pharmacies. The second part of the study involved qualitative analysis of interview data generated from one-to-one semi-

structured interviews to explore the explanatory factors for similarities and differences in vitamin voucher take-up.

The remaining three chapters of the thesis put forward the findings using the methods employed, as described above, and a discussion about how the findings may influence the future implementation of the national Healthy Start vitamin voucher programme.

3 Chapter 3: Results – Quantitative and observational findings

This chapter addresses the first objective of this study:

- To identify differences in Healthy Start vitamin voucher take-up between a demographically similar targeted and universal area.

In addition to describing the vitamin voucher take-up from routine data, the take-up of Healthy Start food vouchers is also described. Findings from systematic observations (to explore barriers at the point of supply to participants) and field-notes made at the time of the interviews are also presented.

3.1 Voucher take-up: Quantitative results

(Department of Health 'Healthy Start Unit' data-set)

This section describes the take-up of Healthy Start vouchers in England between June 2009 and December 2012 (Q2 2009/10 to Q3 2012/13).

To recap from Methods: Data were reported by the Healthy Start Unit in yearly quarters:

- Q1: April-June
- Q2: July-September
- Q3: October to December
- Q4: January to March

Comparisons were made between the take-up of Healthy Start food vouchers versus vitamin vouchers:

- in England;
- by English region;
- by health administrative area in North West England; plus
- take-up of Healthy Start vitamin vouchers in universal versus targeted areas.

The eligible population was defined as a mother or preschool child from a family that met the following Department of Health Healthy Start eligibility criteria, i.e. the family received:

- Income Support, or
- Income-based Jobseeker's Allowance, or
- Income-related Employment and Support Allowance, or
- Child Tax Credit (but not Working Tax Credit unless the family is receiving Working Tax Credit run-on only) **and** has an annual family income of £16,190 or less (2014/15) (Healthy Start Unit, 2014)

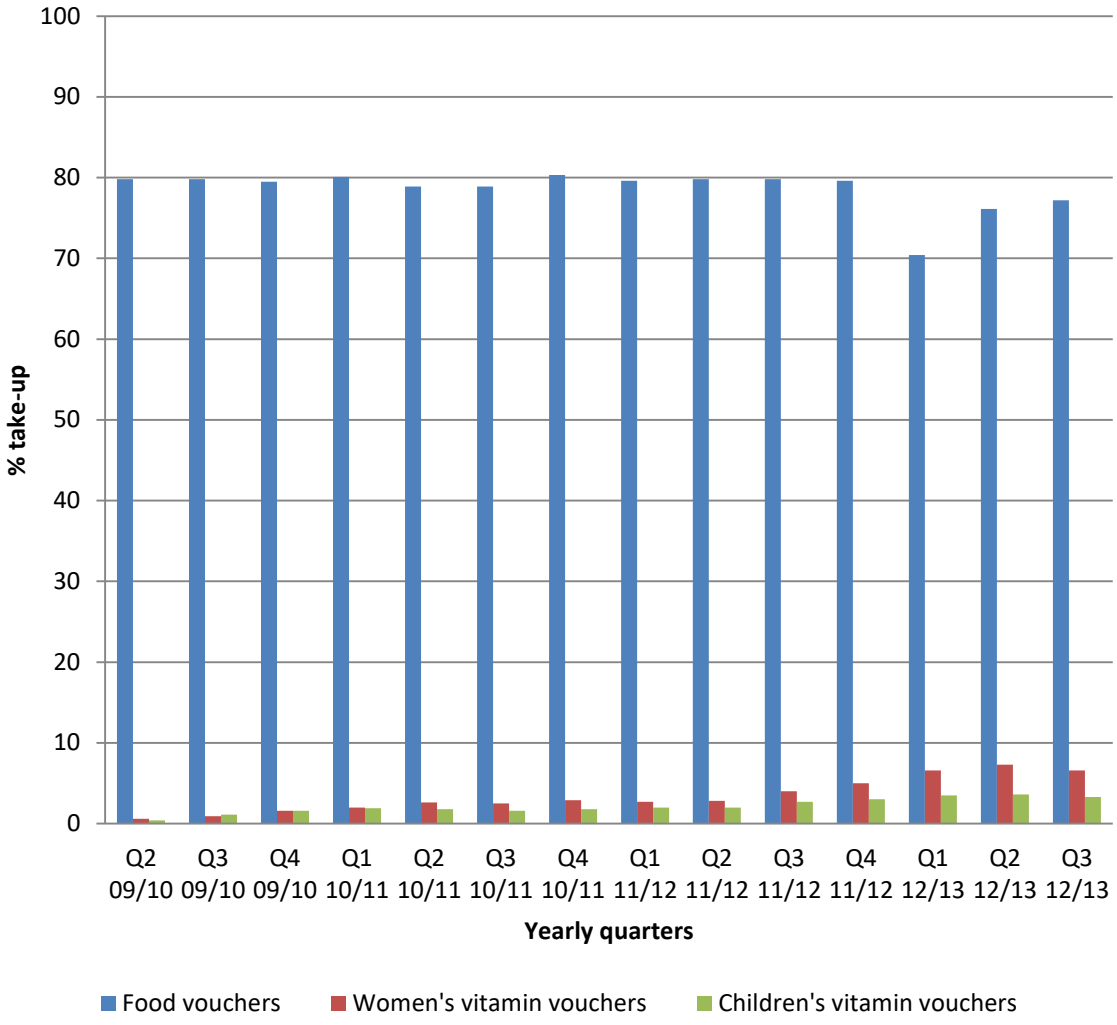
Each food voucher represented a £3.10 voucher used by a mother at a grocery store, which in turn sends the voucher to the Healthy Start. Each vitamin voucher for women and children represented a bottle of vitamin tablets and vitamin drops, respectively, which lasted eight weeks. The number of vouchers claimed represented the numerator when calculating quarterly 'percentage take-up'.

The section ends with a description of the caveats considered when using the data.

3.1.1 Take-up of Healthy Start food vouchers versus vitamin vouchers in England

Between June 2009 and December 2012 (14 quarters: Q2, 2009/10 – Q3, 2012/13) amongst the eligible population, the recorded take-up of Healthy Start food vouchers was higher than the take-up of women's and children vitamin vouchers for each yearly quarter in England. The lowest recorded percentage take-up of Healthy Start food vouchers in England was 70.4% between April and June 2012 (Q1 2012/13) and highest at 80.3% between January and March 2011 (Q4 2010/11) (Figure 3.1). The lowest recorded percentage take-up of Healthy Start women's and children vitamin vouchers was 0.6% and 0.4% respectively between July and September 2009 (Q2 2009/10). The highest recorded percentage take-up of Healthy Start women's and children vitamin vouchers was 7.3% and 3.6% respectively between July and September 2012 (Q2 2012/13) (Figure 3.1).

Figure 3.1 Percentage take-up of Healthy Start vouchers amongst the eligible population in England between July 2009 and December 2012 (Q2 2009/10 and Q3 2012/13)
Source: The researcher's calculations from Department of Health Healthy Start Unit database



3.1.2 Take-up of Healthy Start food vouchers versus vitamin vouchers by English region

The trend of a higher take-up of food vouchers compared with women's and children vitamin vouchers was observed in all nine English regions between June 2009 and December 2012. The regional percentage take-up of food vouchers was lowest in London at 65.3% between April and June 2012 (Q1 2012/13) and highest in North East England at 85.6% between July and December 2011 (Q2 and Q3 2011/12) (Table 3.1). The lowest recorded regional percentage take-up of Healthy Start women's and children vitamin vouchers was 0% in London and 0% in the East of England respectively between July and September 2009 (Q2 2009/10). The highest recorded regional percentage take-up of Healthy Start women's and children vitamin vouchers was 14.7% and 6.4% respectively in the West Midlands between July and September 2012 (Q2 2012/13) (Table 3.2 and 3.3). The absolute number of total beneficiaries for Q2 09/10 gave a sense of the scale of the eligible population (Table 3.1 to 3.6).

Table 3.1: Percentage take-up of food vouchers amongst the eligible population by English region between Q2 2009/10 and Q3 2012/13
Source: The researcher's calculations from Department of Health Healthy Start Unit database

Region	Absolute number of potential beneficiaries Q2 09/10	Q2 09/10	Q3 09/10	Q4 09/10	Q1 10/11	Q2 10/11	Q3 10/11	Q4 10/11	Q1 11/12	Q2 11/12	Q3 11/12	Q4 11/12	Q1 12/13	Q2 12/13	Q3 12/13
North East	29,191	84.4	8	8	8	8	8	8	8	8	8	8	7	8	8
North West	70,683	81.0	8	8	8	8	8	8	8	8	8	8	7	7	7
Yorkshire and the Humber	51,410	81.8	8 1.7	8 1.3	8 2.4	8 1.2	8 1.2	8 2.8	8 2.1	8 2.5	8 2.5	8 2.5	7 2.6	7 8.6	8 0.1
East Midlands	37,486	80.1	8	8	8	7	7	8	8	8	8	8	7	7	7
West Midlands	60,783	82.1	8	8	8	8	8	8	8	8	8	8	7	7	8
East of England	38,945	75.0	7	7	7	7	7	7	7	7	7	7	6	7	7
London	95,080	80.4	8	7	7	7	7	7	7	7	7	7	6	7	7
South East	51,873	74.9	7	7	7	7	7	7	7	7	7	7	6	7	7
South West	33,601	78.0	7	7	7	7	7	7	7	7	7	7	7	7	7

Table 3.2: Percentage take-up of women's vitamin vouchers amongst the eligible population by English region between Q2 2009/10 and Q3 2012/13
Source: The researcher's calculations from Department of Health Healthy Start Unit database * The Healthy Start Unit reported only percentages from Q2 11/12

Region	Absolute number of potential beneficiaries Q2 09/10	Q2 09/10	Q3 09/10	Q4 09/10	Q1 10/11	Q2 10/11	Q3 10/11	Q4 10/11	Q1 11/12	Q2 11/12	Q3 11/12	Q4 11/12	Q1 12/13	Q2 12/13	Q3 12/13
North East	3,519	0.1	0.1	0.6	0.8	0.4	0.2	0.3	1.1	0.8	1.2	0.7	2.2	1.5	1.5
North West	8,552	1.5	1.3	1.9	3.5	2.2	3.1	4.8	2.8	2.7	3.3	4.1	4.5	6.2	4.3
Yorkshire and th Humber	6,255	0.1	1.0	1.6	1.1	2.5	1.7	1.9	2.8	2.4	3.0	3.7	4.2	4.6	4.4
East Midlands	4,563	0.3	0.7	1.6	1.5	2.7	2.0	2.3	4.5	4.5	5.5	6.9	7.3	9.3	10.5
West Midlands	7,339	1.9	1.5	2.7	4.5	6.5	6.7	6.3	4.0	5.8	7.4	8.4	13.2	14.7	13.3
East of England	4,737	0.1	1.6	3.7	2.0	1.5	1.9	1.6	2.5	3.0	3.7	6.9	9.0	5.5	6.4
London	11,267	0.0	0.3	0.4	0.8	0.8	1.0	1.6	2.0	2.3	3.7	4.8	7.5	9.3	8.3
South East	6,299	0.2	0.2	0.5	1.8	2.4	2.2	1.8	2.2	1.6	2.9	3.9	5.5	5.1	5.6
South West	4,059	0.3	0.9	1.5	0.6	4.4	2.8	3.4	2.1	0.7	4.4	4.1	2.7	4.4	1.6

Table 3.3: Percentage take-up of children vitamin vouchers amongst the eligible population by English region between Q2 2009/10 and Q3 2012/13
Source: The researcher's calculations from Department of Health Healthy Start Unit database * The Healthy Start Unit reported only percentages from Q2 11/12

Region	Absolute number of potential beneficiaries Q2 09/10	Q2 09/10	Q3 09/10	Q4 09/10	Q1 10/11	Q2 10/11	Q3 10/11	Q4 10/11	Q1 11/12	Q2 11/12	Q3 11/12	Q4 11/12	Q1 12/13	Q2 12/13	Q3 12/13
North East	40,470	0.	0.2	0.	0.7	0.	0.1	0.3	0.6	0.4	0.8	0.4	1.3	0.	0.8
North West	98,347	0.	1.1	1.	2.1	1.	1.9	2.3	2.1	1.8	2.3	3.0	2.7	3.	2.5
Yorkshire and the Humber	71,935	0.1	1.7	2.7	1.7	1.7	1.4	1.5	2.0	1.7	1.8	2.3	2.3	2.3	3.0
East Midlands	52,470	0.	1.1	1.	1.3	2.	1.5	1.4	2.6	2.3	2.9	3.6	3.2	3.	3.8
West Midlands	84,395	1.	1.9	2.	4.1	3.	3.5	3.6	2.8	3.5	5.0	4.9	6.2	6.	6.3
East of England	54,470	0.	2.0	2.	1.6	1.	1.5	1.1	2.1	2.5	2.5	3.4	5.1	3.	3.3
London	129,574	0.	0.6	1.	1.3	1.	1.1	2.0	2.2	2.3	3.4	3.5	4.0	4.	3.8
South East	72,435	0.	0.4	0.	2.2	2.	1.8	1.2	1.3	1.2	2.3	2.2	2.9	2.	3.0
South West	46,676	0.	1.0	1.	0.7	0.	0.6	0.8	0.5	0.6	1.3	1.8	1.6	1.	1.1

3.1.3 Take-up of Healthy Start food vouchers versus vitamin vouchers by local health administrative area in North West England

Between the period of July 2009 and December 2012 (Q2 2009/10 and Q3 2012/13), the recorded percentage take-up of food vouchers by local health administrative area (known as primary care trusts at the time of data collection) in North West England, amongst the 'eligible' population, was lowest in Oldham at 63.6% between April and June 2012 (Q1 2012/13) and highest in Blackburn with Darwen at 88.0% between October and December 2011 (Q3 2011/12) (Table 3.4).

Between July 2009 and December 2012 (Q2 2009/10 and Q3 2012/13), all 24 local health administrative areas in North West England had a recorded percentage take-up of Healthy Start food vouchers. In contrast, nine and eight local health administrative areas did not record a take-up of women's and children vitamin vouchers respectively for at least six months after the start of data collection by the national Healthy Start Unit (Table 3.5 and 3.6). Of these, one area had no record of any take-up of women's vitamin vouchers; this same area only had one record of the take-up of children vitamin vouchers. Only one local health administrative area recorded a take-up for both women's and children vitamins from the start of data collection.

The take-up of women's vitamin vouchers (3,399/160,710) was statistically significantly higher than the take-up of children vitamin vouchers (7,052/497,236) amongst the eligible population in North West England (2.1% versus 1.4%, $\chi^2 = 377.2$; $p \leq 0.001$) (Figure 3.2).

Table 3.4: Take-up of food vouchers amongst the eligible population by North West primary care trust between Q2 2009/10 and Q3 2012/13
Source: The researcher's calculations from Department of Health Healthy Start Unit database * The Healthy Start Unit reported only percentages from Q2 11/12

% take-up of food vouchers by primary care trust	Absolute number of potential beneficiaries Q2 09/10	Q2 09/10	Q3 09/ 10	Q4 09/ 10	Q1 10/ 11	Q2 10/ 11	Q3 10/ 11	Q4 10/ 11	Q1 11/ 12	Q2 11/ 12	Q3 11/ 12	Q4 11/ 12	Q1 12/ 13	Q2 12/ 13	Q3 12/ 13
Ashton, Leigh & Wigan	3,705	7	7	7	7	7	7	7	7	7	7	7	7	7	7
Blackburn with Darwen	2,493	8	8	8	8	8	8	8	8	8	8	8	6	8	8
Blackpool	2,465	8	8	8	8	8	8	8	8	8	8	8	7	8	8
Bolton	3,791	8	8	8	8	8	8	8	7	7	8	8	6	7	7
Bury	2,047	7	7	7	7	7	7	7	7	7	8	8	6	7	7
Central & Eastern Cheshire	3,627	7 5.6	7 5.4	7 6.0	7 7.1	7 8.1	7 8.7	7 8.5	7 8.9	7 8.0	7 7.2	7 7.7	7 0.7	7 4.6	7 3.9
Cumbria	4,523	7	7	7	7	8	8	8	7	7	8	8	7	7	7
East Lancashire	3,913	8	8	8	8	8	7	8	7	8	8	7	6	7	7
Halton & St. Helens	4,833	7	7	7	7	8	8	8	8	8	8	8	8	8	8
Heywood, Middleton & Rochdale	4,811	8 1.6	8 2.4	8 2.0	8 3.6	8 4.4	8 1.0	8 0.9	7 9.4	8 0.9	8 0.5	7 9.8	7 0.3	7 8.4	7 9.2
Knowsley	3,588	7	8	8	8	8	8	8	8	8	8	8	8	8	8
Lancashire Care	2,867	8	8	8	8	8	7	7	7	7	7	7	6	7	7
Liverpool	7,502	8	8	8	8	8	8	8	8	8	8	8	7	8	8
Manchester	10,257	8	8	8	8	8	8	8	8	8	8	8	7	7	8
North Lancashire	2,544	7	7	7	7	7	7	7	7	7	7	7	6	7	7
Oldham	3,793	8	8	8	8	8	8	8	8	8	8	8	6	7	8
Sefton	4,024	8	8	8	8	8	8	8	8	8	8	7	7	7	7
Salford	2,687	8	8	8	8	8	8	8	8	8	8	8	7	7	8
Stockport	2,643	7	7	7	7	7	7	7	7	7	7	7	7	7	7
Tameside & Glossop	3,531	7	7	7	7	7	7	7	7	7	7	7	6	7	7
Trafford	1,809	7	7	7	7	8	8	8	7	7	7	7	7	7	7
Warrington	1,700	7	7	7	7	7	7	7	7	7	7	7	7	7	7
Western Cheshire	1,819	7	7	7	7	7	7	8	7	8	8	7	7	7	7
Wirral	4,445	8	8	8	8	8	8	8	8	8	8	8	8	8	8

Note: Areas shaded in grey delivered the Healthy Start programme using the universal implementation approach

Table 3.5: Take-up of women's vitamin vouchers amongst the eligible population by North West primary care trust between Q2 2009/10 and Q3 2012/13
Source: The researcher's calculations from Department of Health Healthy Start Unit database* The Healthy Start Unit reported only percentages from Q2 11/12

% take-up of women's vitamin vouchers by primary care trust	Absolute number of potential beneficiaries Q2 09/10	Q2 09/10	Q3 09/10	Q4 09/10	Q1 10/11	Q2 10/11	Q3 10/11	Q4 10/11	Q1 11/12	Q2 11/12	Q3 11/12	Q4 11/12	Q1 12/13	Q2 12/13	Q3 12/13
Ashton, Leigh & Wigan	338	3.4	2.4	3.5	3.5	4.4	3.4	9.8		4.2	3.7	8.7	6.0	2.8	3.2
Blackburn & Darwen	249	2.9	7.5	8.9	15.4		22.6	64.5	6.6	6.6	7.4	6.0	6.6	9.3	
Blackpool	248		1.9			4.0				11.3	8.5		14.4	20.2	23.9
Bolton	366							2.7	3.3		2.6		2.6	6.7	5.2
Bury	185	0.9	3.6	4.2	8.0	8.8	4.9	16	13.1	7.3	8.8	7.5	13.4	7.3	8.8
Central & Eastern Cheshire	327														
Cumbria	417					0.5			0.5						
East Lancashire	372	12.7	4.9	5.9	8.6	7.1	4.1		3.6						
Halton & St. Helens	445	0.6	0.8	1.6	2.1	2.5	3.1	3.1	3.3		2.0	4.5	2.8	3.8	
Heywood, Middleton & Rochdale	464			1.5	2.3	4.7	4.0		5	6.1	5.4	7.7	6.6	7.8	7.1
Knowsley	345								1.7	1.8			1.8	2.8	2.3
Lancashire Care	293	0.1	0.6	1.1	0.6	0.7	0.6	0.4							
Liverpool	735	5.9	2.3	4.8	14.7	1.7		4.9	7.1	5.0	7.9	6.6	3.4	12.5	
Manchester	1023						7.6	7.1	3.6	4.6	4	5.8	6.6	6.1	4.4
North Lancashire	230		1.0	1.5	1.8	2	2.1	1.4	1.6	3.5	3.7	1.3	1.6		0
Oldham	364	1.6	2.6		3.5	3.7	6.5	4.9		6.0	5.6	5.7	4.9	10.4	7.3
Salford	390			0.2		0.4		2.9	1.5	1.5		3.5	4.0	2.7	9.4
Sefton	256		1.1	3.4	6.9	3.9	5.1		8.7		10.2	18.1	15.5	15.7	12.2
Stockport	241			3.5						2.9	3.4	3.4	6.5	7.9	5.5
Tameside & Glossop	326	0.4	0.7	2.5	2.4	3.2	2.9	2.1					3.2	5.5	4.3
Trafford	165		2.0	4.5	6.4	5.2	4.9	6.1	5.8			7.9	9.3	10.9	8.3
Warrington	156				3.4	4.5	2.5	1.9			1.8		5.4	19.7	4.7
Western Cheshire	169		3.3	0.6											17.7
Wirral	447	0.1	0.6	1.5	2.0	2.2		2.4		2.2	3.1	5.1	4.6	4.9	3.8

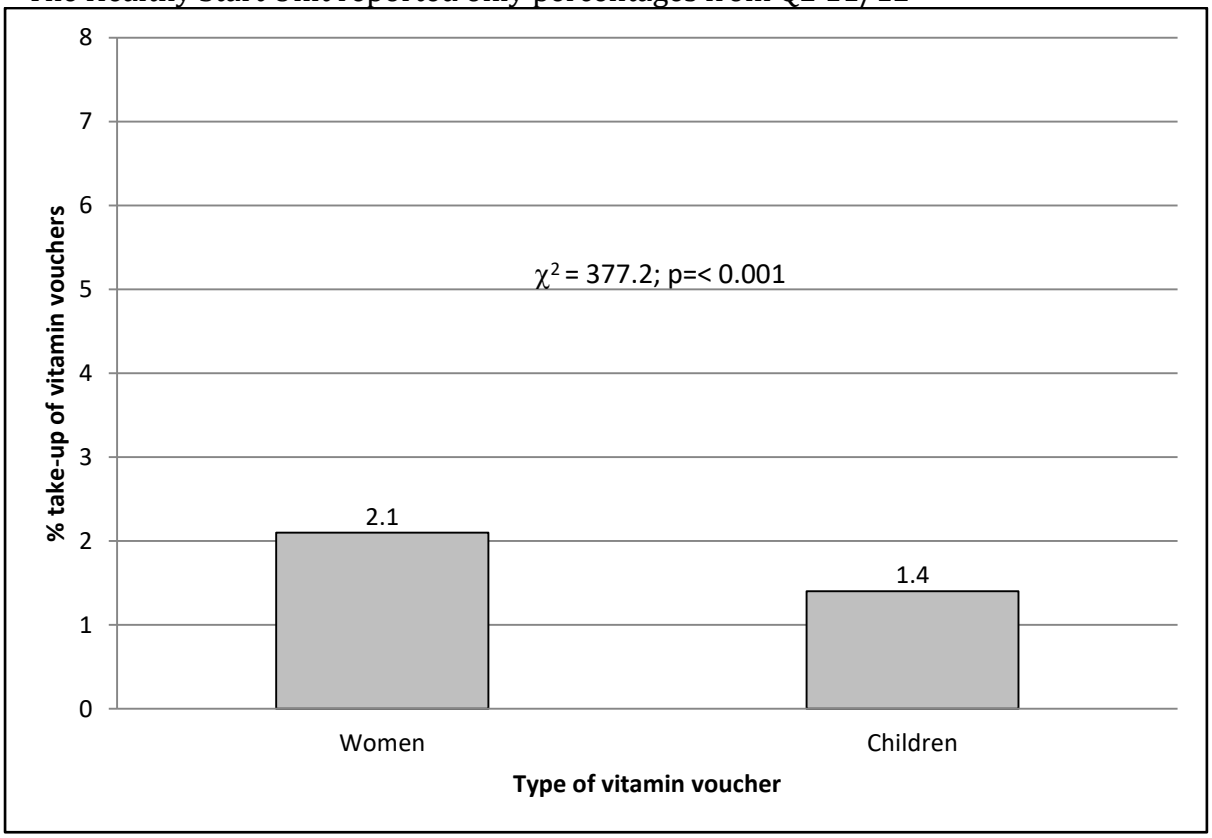
Note: Areas shaded in grey delivered the Healthy Start programme using the universal implementation approach

Table 3.6: Take-up of children vitamin vouchers amongst the eligible population by North West primary care trust between Q2 2009/10 and Q3 2012/13
Source: The researcher's calculations from Department of Health Healthy Start Unit database * The Healthy Start Unit reported only percentages from Q2 11/12

% take-up of children's vitamin vouchers by primary care trust	Absolute number of potential beneficiaries Q2 09/10	Q2 09/10	Q3 09/10	Q4 09/10	Q1 10/11	Q2 10/11	Q3 10/11	Q4 10/11	Q1 11/12	Q2 11/12	Q3 11/12	Q4 11/12	Q1 12/13	Q2 12/13	Q3 12/13
Ashton, Leigh & Wigan	3,889	1.5	1.5	2.6	2.2	2.6	2.5	2.1		2.6	3.0	6.8	2.2	1.5	0.8
Blackburn & Darwen	2,864	2.8	4.5	5.4	6.4		6.8	10.3	7.3	9.9	9.2	5.1	8.5	8.4	
Blackpool	2,848		1.1			1.1				4.8	8.1	6.0	5.5	9.8	13.7
Bolton	4,205							2.6	3.3		1.9		2.4	5.2	4.3
Bury	2,132	1.2	2.0	2.8	0.4	3.0	1.2	4.2	8.5	1.3	2.8	4.4	4.3	4.3	4.1
Central & Eastern Cheshire	3,761		1.3												
Cumbria	4,794					0.5			0.2						
East Lancashire	4,275	3.8	2.6	2.2	2.3	1.3	0.7		0.3						
Halton & St. Helens	5,118	0.5	1.2	1.3	1.2	1	1.9	1.8	0.3		1.1	2.5	1.6	1.2	
Heywood, Middleton & Rochdale	5,338			2.3	3.1	4.4	3.1		3.9	4.2	4.4	3.7	5.3	6.0	5.7
Knowsley	3,965								0.7	0.6			0.5	0.9	0.7
Lancashire Care	3,369	0.1	0.8	1.0	1.3	0.7	0.8	0.9							
Liverpool	8,451	1.6	1.7	3.7	8.4	1.8		5.3	4.7	2.0	2.9	3.8	1.9	4.5	
Manchester	11,759						6.1	5.2	3.8	3.9	3.6	4.5	4.3	4.9	4.0
North Lancashire	2,641		1.7	1.5	2.0	2.5	1.2	1.4	1.3	1.7	2.2	1.8	1.0		
Oldham	4,191	1.9	2.7		3.5	3.1	3.7	3.9		3.5	3.2	4.8	2.8	6.1	4.8
Sefton	4,489		1.9	5.3	6.2	6.7	5.1		10.5		7.7	12.6	6.6	6.4	4.0
Salford	2,945			0.1		0.4		0.4	0.9	1.6		3.6	2.4	2.0	1.7
Stockport	2,777			3.6						2.5	3.0	2.7	3.9	4.2	4.2
Tameside & Glossop	3,954	0.2	0.9	3.1	2.2	2.6	2.4	1.8					2.4	3.6	2.6
Trafford	1,902		3.2	5.0	6.7	5.0	4.9	4.3	4.7			6.3	6.1	8.1	6.2
Warrington	1,797				0.4	2.9	1.6	1.4			0.9		3.4	3.0	2.5
Western Cheshire	1,901		3.3	3.8											10.0
Wirral	5,146	0.4	0.8	2.1	2.1	1.7		1.9		1.6	2.5	2.6	2.6	2.7	2

Note: Areas shaded in grey delivered the Healthy Start programme using the universal implementation approach

Figure 3.2: Percentage take-up of women's vitamin vouchers compared with the take-up of children vitamin vouchers in North West England between Q2 2009/10 and Q3 2012/13 among the eligible population
Source: The researcher's calculations from Department of Health Healthy Start Unit database
* The Healthy Start Unit reported only percentages from Q2 11/12



3.1.4 Take-up of Healthy Start vouchers in universal versus targeted areas

The take-up of Healthy Start food vouchers was statistically significantly higher in targeted (320,727/398,476) versus universal (39,277/50,357) areas of in North West England (80.5% versus 78.0%, χ^2 = 174.8; p≤ 0.001).

The proportion of claimed women's vitamin vouchers amongst the eligible population from universal areas was significantly more than the proportion of claimed women's vitamin vouchers amongst the eligible population from targeted areas (6.3% versus 1.6%, χ^2 = 1,707.0; p ≤ 0.001) (Figure 3.3). Out of 17,968 eligible beneficiaries in the universal area,

1,131 women's vouchers were claimed. Out of 142,742 eligible beneficiaries in the targeted areas, 2,268 women's vitamin vouchers were claimed.

The proportion of children vitamin vouchers claimed in universal areas was more than twice that of targeted areas amongst the eligible population (3.2% versus 1.2%, χ^2 = 1,493.2; p≤0.001) (Figure 3.4). From the universal areas, 1,803/55,560 vitamin vouchers were claimed, and 5,249/441,676 vitamin vouchers were claimed from the targeted areas. Overall, the take-up of Healthy Start vitamin vouchers for both women and children was very low.

Figure 3.3: Percentage take-up of women's vitamin vouchers in universal versus targeted areas in North West England between Q2 2009/10 and Q3 2012/13 among the eligible population
Source: The researcher's calculations from Department of Health Healthy Start Unit database
* The Healthy Start Unit reported only percentages from Q2 11/12

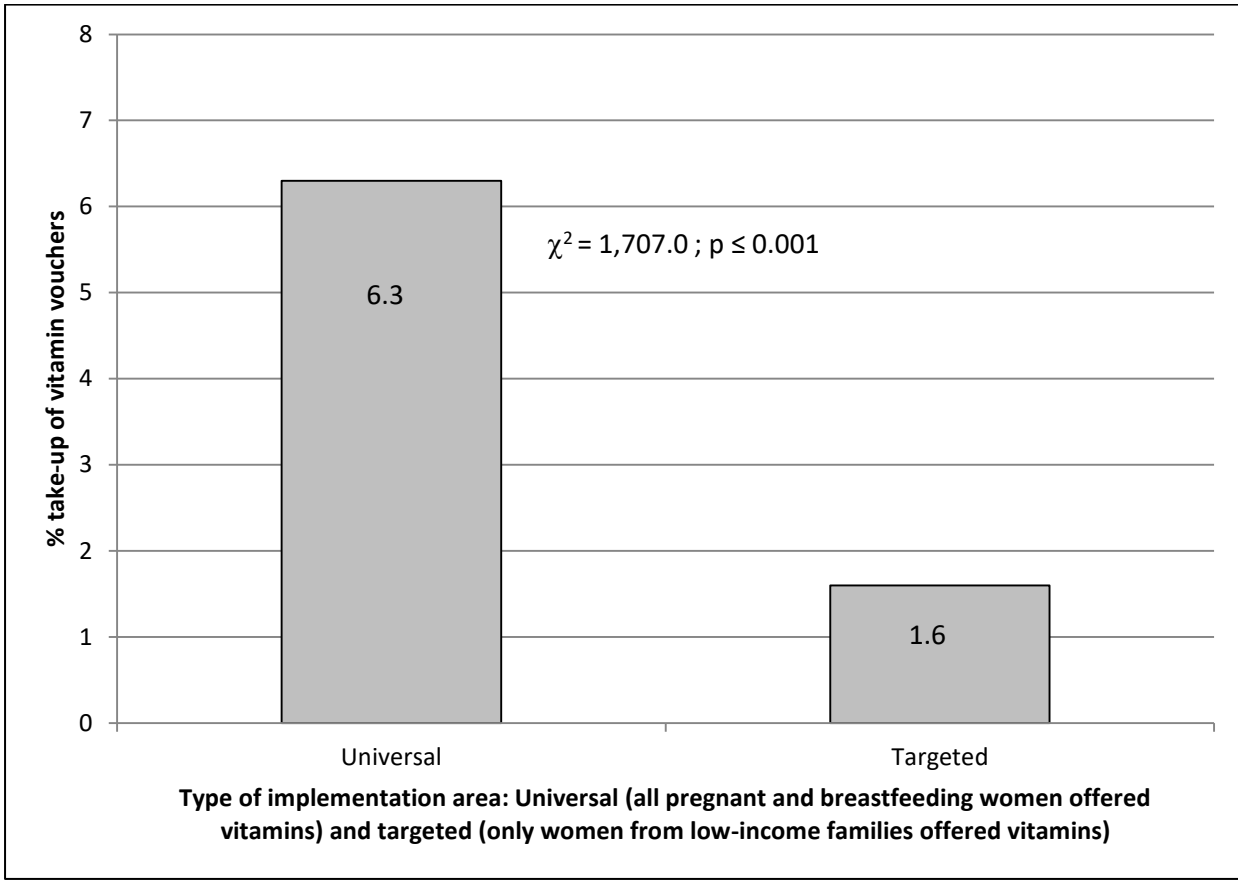
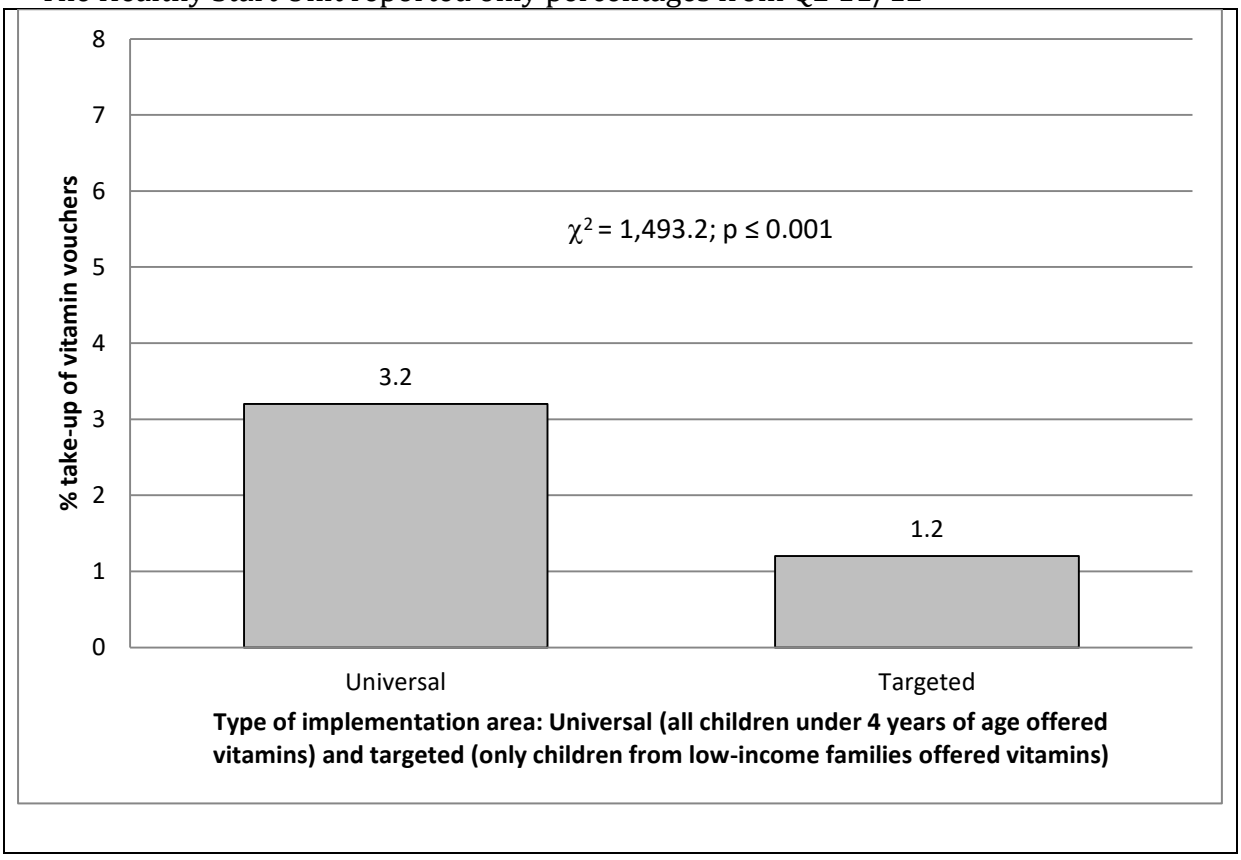


Figure 3.4: Percentage take-up of children vitamin vouchers in universal versus targeted areas in North West England between Q2 2009/10 and Q3 2012/13 among the eligible population
Source: The researcher's calculations from Department of Health Healthy Start Unit database
* The Healthy Start Unit reported only percentages from Q2 11/12



3.1.5 Caveats about the data

The Department of Health Healthy Start Unit reported the *number* of vitamin vouchers invoiced between July 2009 and September 2010 (Q2 09/10 and Q2 10/11). After this, only 'percentage' data were reported in the quarterly reports. As such, the chi-squared results presented in figures 2, 3 and 4 above are from five yearly quarters; the smallest denominator was 23,439 and smallest numerator was 206.

The Healthy Start Unit reported episodic data. One vitamin voucher was exchanged for one bottle of vitamins, which lasted for two months; therefore, within each yearly quarter,

it was possible for the same mother to claim twice for herself. Indeed, a mother claiming regularly would be appearing twice per quarter. The same applied for children vitamin vouchers; one child could potentially represent two episodes in each quarter, and this would be what would happen with the regular intended use. Between July 2009 and September 2010 (Q2 09/10 and Q2 10/11), therefore, an individual could exchange a maximum of 10 vouchers and a minimum of zero vouchers.

Possible reasons for missing data were that: 1) the local health administrative area did not implement the Healthy Start vitamin programme; 2) the local health administrative area's Healthy Start data did not reach the Department of Health Healthy Start Unit in time for quarterly reporting; 3) data collection was not sustained during times of leadership changes in the local health administrative areas.

The Department of Health Healthy Start Unit collected data about food vouchers directly from the Healthy Start-registered food retailers, e.g. ASDA, Tesco, and 'corner shops'. For the collection of vitamin voucher data, local health administrative areas claiming reimbursement had to send quarterly reports to the Healthy Start Unit about the number of vitamin bottles dispensed, with each bottle equivalent to one vitamin voucher. Local health administrative areas had to collate these data from all registered vitamin distributors within their area.

3.1.6 Vitamin supply: Findings from systematic observations of everyday practice

This section presents findings from systematic observations during visits to children centres and field-notes made at the time of the interviews as part of the data collection process, addressing this part of the second objective: *to explore barriers at the point of supply to participants*.

Physical accessibility: During the collection of the study's semi-structured interview data (May and August 2012), it was observed that both women's and children vitamins were stored in a locked cupboard in each of the four children centres visited within Liverpool (Speke, Everton, Wavertree, and Dingle Lane) and both children centres within Sefton (Seaforth and Linaker).

With the exception of Dingle Lane, the length of time it took to open a locked cupboard in the targeted area was over three minutes. There were several reasons for this:

- Staff were unable to identify the cupboard key-holder.
- The key-holder was on vacation and no interim plan had been put into place; the key-holder still had the key whilst on holiday.
- The receptionist at the centre was overwhelmed by the number of parents (three) requesting information at the front-desk. In this instance, after waiting fifteen minutes, the researcher left.
- At Dingle Lane, the receptionist knew who had the key and was able to show I the cupboard's contents within three minutes. This was the only centre visited in Liverpool that had a clear protocol of how to access the cupboard, including when the main key-holder was away.

Both children centres visited in the universal area (Sefton) had a clear protocol of how the receptionist should access the vitamin cupboard; it took less than two minutes for the researcher to view the vitamin bottles in both centres.

Adequacy of supply: Apart from Dingle Lane, there was a limited supply of vitamins for both women and preschool children (Table 3.5). There were no vitamins for either women or children at the Everton children centre; the centre had been waiting for the delivery of an order placed more than two months previously.

At the Wavertree centre, three bottles of women's vitamin tablets were available and due to expire within one year. Seven children vitamin bottles were available and going to expire the following month. At the Dingle Lane centre, the eight bottles of women's vitamin tablets available would expire in eighteen months and the twenty-four bottles of children vitamin drops available would expire in six months. The researcher had access to the vitamin cupboard at the two centres in the universal area, Seaforth and Linaker, but did not document the number of bottles present or their expiry date. The only filed-note made was that there were no children vitamins available at the Linaker Centre.

Table 3.7: Cross-sectional study of the number of Healthy Start vitamin bottles available in children centres on a single, unannounced visit by the researcher between May and August 2012 in North West England
Source: The researcher's observations

Children centre	Number of women's vitamin bottles available	Number of children vitamin bottles available
Dingle Lane	8	24
Wavertree	3	7
Everton	0	0
Linaker Lane	Not documented	0

Four of the children centres had a pharmacy located within a ten-minute walk. The pharmacies nearest to the Dingle Lane and Everton Centres were both 14 minutes' walk away.

Boots pharmacies had multi-vitamin syrup for children aged four months and above at a cost of £3.05 for a 200 ml bottle in 2012. Using the doses recommended and considering the different doses for each age category (Table 3.6), each bottle would last 30 days. Thus, the cost would be 10p per day for each preschool child. This contrasted with the cost of the Healthy Start children drops, which was £1.64 for a bottle that lasted for eight weeks, i.e. 3p per day per preschool child. In the Rowlands pharmacy, Abidec was available. Using Abidec would cost 13p per day per child.

For pregnant women, the Boots multi-vitamin was available at a cost of £12.99 (43p per day) compared with the £.0.01 per day using Healthy Start vitamins. The only women's vitamin available at the Rowlands pharmacy was a general multi-vitamin at the cost of £4.99 for 30 capsules (17p per daily capsule). Own-brand pregnancy multi-vitamins were available from nearby large-chain supermarkets; on average, this worked out at 10p per day (Table 13 and 14).

Table 3.8: Time-to-expiry date from time of manufacture for Boots multi-vitamin children syrup, by age category, based on a 200ml bottle available in the UK at a Boots pharmacy (North West England, 2012) in close proximity to one children centre where interviews were conducted

Source: The researcher's observations

Boots	Doses	Time to expiry date for Boots multi-vitamin children syrup
2.5ml for 4-6 months	80	2.7 months
5ml for 6-12 months	40	1.3 months
10ml for 1-3 years	20	20 days
15ml for 3-12 years	13	13 days

Calculations were based on Boots Pharmaceuticals Children Multivitamin Syrup 200ml usage instructions in 2012 for:

- Infants 4 to 6 months, half a 5ml spoonful daily
- Infants 6 months to 1 year, one 5ml spoonful daily
- Children 1-3 years, two 5ml spoonfuls daily

Source: https://www.boots.com/boots-multivitamin-syrup-6months-200ml-10192391 [Accessed 20.12.18]

Table 3.9: Cost of commercially available vitamins for preschool children and maternal and lactating women compared with Healthy Start vitamins (August 2012 prices) at pharmacies in close proximity to the children centres where interviews were conducted

Children vitamin brand	Cost per bottle	Cost per day
Healthy Start	£1.64	£0.27
Boots	£3.05	£0.10
Rowlands - Abidec	£3.93	£0.13
Women's vitamin brand		
Healthy Start	£0.83	£0.01
Boots	£12.99	£0.43
Rowlands - V Healthcare	£4.99	£0.16

3.2 Summary

This chapter identified differences in Healthy Start vitamin voucher take-up between a demographically similar targeted and universal area. The data collected revealed that:

- Take-up of vitamins was overall low.
- Take-up of vitamins was, however, significantly higher for both women's and children vitamins amongst the 'eligible' participants from the universal area compared with the targeted area.
- Food voucher take-up was consistently much higher in both targeted and universal areas.
- Food voucher take-up was slightly higher in the targeted area compared with the universal area.
- From the systematic observations, the availability of women's and children vitamins was ad hoc and the supply was limited. The following chapter explores possible explanations for the quantitative findings.

4 Chapter 4: Qualitative Results

To recap, the overarching aim of this study was to investigate the effect of a targeted versus universal implementation approach to the Healthy Start vitamin programme on the take-up of vitamins in the eligible population 'targeted' by the Department of Health, i.e. low-income families, and reasons for any observed differences. The eligible population was defined as a mother or preschool child from a family that met the following Department of Health Healthy Start eligibility criteria, i.e. the family received:

- Income Support, or
- Income-based Jobseeker's Allowance, or
- Income-related Employment and Support Allowance, or
- Child Tax Credit (but not Working Tax Credit unless the family is receiving Working Tax Credit run-on only) **and** has an annual family income of £16,190 or less (2014/15) (Healthy Start Unit, 2014)

Chapter 3 demonstrated that, within the Healthy Start programme, the take-up of food vouchers was consistently much higher than vitamin vouchers across and within all English regions. Overall, vitamin take-up was low in both universal and targeted areas.

Though the take-up of vitamins was higher amongst the eligible population in the area that used the universal implementation approach, food voucher take-up was slightly higher amongst the eligible population in the area that used the targeted implementation approach.

This chapter explores the second objective of the thesis using framework analysis of semi-structured interviews:

- To explore the explanatory factors as perceived by potentially eligible mothers, Healthy Start healthcare professionals, and commissioners for similarities and differences in vitamin take-up between the two areas and explore barriers at the point of supply to participants.

These qualitative findings from semi-structured interviews build on the quantitative findings, e.g. the notable finding of consistently high food voucher take-up compared with vitamin take-up. The explanatory factors are presented through answering three questions:

- Why was the take-up of food vouchers consistently much higher?
- Why was the take-up of vitamin vouchers consistently low?
- Why was the take-up of vitamin vouchers higher in the universal area?

There were five emergent themes from deductive analysis (and informed by the quantitative findings) (Table 4.1). These were:

- Acceptability
- Accessibility
- Awareness
- Adequacy of supply
- Accountability

Table 4.1: The five emergent themes from the deductive analysis of semi-structured interviews with mothers, providers, and commissioners about Healthy Start (May and August 2012, North West England)

Emergent theme – brief explanation	**Participant group**
Acceptability – this included the taste of the vitamins, the understanding that the food voucher had a financial value, and that the major supermarkets accepted the food vouchers	Mothers Providers
Accessibility – this included being able to obtain the Healthy Start vitamins tablets for mothers and vitamin drops for preschool children	Mothers Providers Commissioners
Awareness – this included awareness of the Healthy Start programme, about the health benefits of the vitamins, about where to obtain the vitamins, and the processes required to obtain the vitamins	Mothers Providers Commissioners
Adequacy of supply – it was not uncommon for the NHS central supply to have inadequate stock of Healthy Start vitamins, which had a 'ripple effect' in the stock held at local children centres	Mothers Providers Commissioners
Accountability – there was no process through which commissioners could be held accountable for delivering the Healthy Start statutory programme	Commissioners

4.1 Why was the take-up of food vouchers consistently much higher?

From the mothers' perspective, the emergent themes of acceptability, accessibility and awareness underpinned why the take-up of food vouchers was much higher compared with vitamin vouchers. Mothers reported that the food vouchers were easy to use as many food stores accepted the vouchers. It was also easier to remember to use food versus vitamin vouchers as grocery-shopping is part of daily life and the food vouchers had a monetary value. As an eligible mother from a universal area described:

P: … The vitamins are an additional thing [to remember]. Obviously, everyone carries on going shopping so any money that they can get off the shop is great…, but I think if people don't take vitamins anyway then they're not likely to go and pick them up at a children centre; it's another thing to remember to do as well isn't it, as well as being a busy mum, isn't it?

MD 40: Eligible mother from a universal area

Mothers reported that the use of the food vouchers was much more easily accessed as information was provided by the national Healthy Start Unit about where they could use the food vouchers. At the time of data collection, no information was given about where the vitamin vouchers could be used. As an eligible mother from a targeted area described:

P: … It [the letter from the Healthy Start Unit containing both food and vitamin vouchers] has it [information about where food vouchers can be used] all there on the bottom. It told you, you can go to any supermarket and stuff, and it's just general. I just take them to the shops and I go 'can I use these vouchers here?' and they say yes or no… if you go to your corner shop you can use them. If you go to Tesco's, Asda, Sainsbury's, you can use them anywhere.

MD 26: Eligible mother from a targeted area

Mothers also appeared to be more aware of the food vouchers compared with the vitamin vouchers when they arrived together by post from the national Healthy Start Unit. One mother found her experience of using the food vouchers "*brilliant*" whilst not being clear about whether she had received vitamin vouchers from the Healthy Start Unit:

R: Did you use any of the vitamin vouchers?

P: No, no, because they were at the top. I remember it saying that I would receive some and couldn't remember if I had received any, 'cause it doesn't look like a voucher at the top. I didn't ever use it and, by the time a friend told me about it, I was like 'oh gosh, I will have to use it', and then they stopped coming [because the mother returned to work] so I missed out.

MD 18: Eligible mother from a universal area

Though the take-up of food vouchers was consistently higher compared with vitamin vouchers, some mothers expressed challenges with their use. One challenge referred to the monetary value of the food vouchers being not sufficient to support a family with a low income. Mothers explained that they received four food vouchers, each at a value of £3.10, every four weeks and that milk formula costed on average £9.00. This left mothers in a position of having to *"pay up three of them to cover the cost of one powdered milk"*, which would supply enough milk for the child for about one week:

P: The thing is with the Healthy Start if you're getting your vegetables, your fruit and your milk, the powdered milk, I found that the vouchers weren't covering the amount of powdered milk I needed… because they're [milk formula] like £9.10, so with a £3.10 voucher you are having to pay up three of them together to cover the cost of one powdered milk, and like you only get one food voucher to use a week… So, it doesn't cover it.

R: So how long would one powder last you?

P: When, when they're unsettled you can go through one and a half but normally one a week.

MD 10: Eligible mother from a universal area

Though some mothers found it easy to use the food vouchers when doing their grocery shopping, others found that there was a limited range of local stores where they could use them:

P: …not many places take them do they? It's only like the Asda or… that's the only place I really know that takes them.

MD 27: Eligible mother from a targeted area

At the time of data collection, administrative issues were raised by mothers between themselves and the national Healthy Start Unit around the consistency of supply of the vouchers during the transition from being pregnant to giving birth. Mothers noted that they

were not aware that they had to call the Healthy Start Unit to tell them that they had given birth:

P: … Mine [food vouchers] were stopped for a few weeks because I didn't realise that you had to inform them [the Healthy Start Unit] that you had given birth because obviously when you have the baby there's other things to think of rather than sending off a form (pause)… So, it was about 6 weeks I hadn't had any and so I rang up and reorganized it.

MD 40: Eligible mother from a universal area

In summary, from the mothers' perspective, the higher take-up of food vouchers was attributable to its ease of use as "*everyone carries on going shopping*" and "*you can use them everywhere*", and not seen as an "*additional thing to remember*". Additionally, the food vouchers were clear to eligible mothers when they arrived monthly through the post along with the vitamin vouchers. The mothers were also aware of the monetary value attached to each food voucher and received information from the Healthy Start Unit about where they could be used. Despite some interviewees finding the ease of use of the food vouchers as only '*OK*' together with some administrative delays, the take-up of food vouchers remained consistently higher compared with vitamin vouchers.

From the providers' perspective, the emergent themes of awareness and acceptability underpinned why the take-up of food vouchers was much higher compared with vitamin vouchers. Similar to the mothers, providers reported that the food vouchers were more "*noticeable*" and that, because grocery shopping is part of day-to-day life, it was easier to remember to use the food vouchers, which gave financial support to families. A provider working in a universal area summarised the similarities between the perspectives of the mothers and providers:

P: the food vouchers are much more noticeable than the Healthy Start vitamin vouchers and the thing is that with the food vouchers it is a benefit for the mum isn't it because it means she's £3.10 better off a week… she can go to the shop and actually use it for you know fruit and veg and milk so there is a real benefit for using those whereas for the healthy start [vitamin] vouchers she has to go to a health centre, doesn't she, and pick them up, or a community place to pick them up that is not quite as easy as going to any shop

MD 04: Provider working in a universal area

Providers also believed that mothers were not aware of the health benefits of the Healthy Start vitamins to themselves or their child/ren. From their experience, even when providers pointed out the Healthy Start vitamin vouchers received from the national Healthy Start Unit, mothers "sometimes still don't come and get them":

P: When you say have you noticed the other little part of the ticket where it says free vitamins, and I actually show them one, they say "oh yeah I get that all the time" and when you explain to them that the take-up of the vitamins is really low and that you can get them from here they are shocked and they go "OK" but they sometimes still don't come and get them. I don't think they understand the relevance or the importance of why they need the vitamins.

MD 14: Provider working in a targeted area

From the commissioners' perspective, when they were asked about their views as to why the take-up of food vouchers was consistently much higher, both answered by explaining why they thought the take-up of vitamins was consistently low.

4.2 Why was the take-up of vitamin vouchers consistently low?

Mothers, providers, and commissioners from both universal and targeted areas encountered several barriers inhibiting the use of Healthy Start vitamin vouchers.

From the mothers' perspective, the emergent themes of awareness, acceptability, accessibility and adequacy of supply of vitamins underpinned the low take-up of Healthy Start vitamin vouchers.

Awareness of eligibility: Mothers from both universal and targeted areas *"didn't realise"* that they were eligible for the Healthy Start vitamins and believed that this was due to a lack of communication between them and the health professionals:

P: I have seen all these pictures and I thought 'I wonder what that is?' and then, when they [health professionals] did actually make me aware, I didn't realise it is from when you are 12 weeks pregnant you can actually receive them. So, I had missed out on all that time, my whole pregnancy, because I think there is like a lack of communication.

MD 13: Eligible mother from a targeted area

Awareness of the vitamin voucher: Mothers from the universal area mentioned that the Healthy Start vitamin voucher was not easily visible on the letter received from the national Healthy Start Unit; some mothers were unaware of the vitamin voucher attached to their letter for over two years:

R: When you started on the Healthy Start programme, did you get both food vouchers and vitamin vouchers through the post?

P: I got the food ones, but I never got the vitamin vouchers, and this has been going on for two years! All I ever get is the food vouchers and a letter.

MD 10: Eligible mother from a universal area

Awareness of the health benefits of the vitamins: Mothers from both the universal and targeted area reported a lack of awareness of the health benefits of Healthy Start vitamins for both themselves and their young child/ren as a barrier to using the vitamins. This was attributed to a lack of information shared with them by healthcare professionals. One mother shared her frustration upon recalling a healthcare professional telling her, *"Alright, here, take these"*, with her wondering *"What was the point!"*, and never sought further vitamin supplies as she felt, "put-off by the whole thing". This lack of awareness and poor communication between mothers and healthcare professionals regarding the benefits of using vitamins during pregnancy were experienced by both eligible and non-eligible mothers in both targeted and universal areas. Mothers from both areas stated that they were not given any advice about Healthy Start vitamins. The following quotations illustrated this:

P: No, no one has spoken to me about vitamins.

R: OK.

P: …and I did actually go and ask my GP because there was a problem, saying I was slightly overweight, so… I went to see my GP and she basically just told me to join Weight Watchers, and I wasn't given any other advice at all

MD 16: Non-eligible mother from a targeted area

P: No, I only just started getting the vitamin tablets with my second child; I didn't know I could get the vitamins for the first one because no one told me.

MD 06: Eligible mother from a universal area

R: Which was the first health professional to discuss vitamins with you?

P: Nobody has discussed vitamins [with me]… she [her daughter] will be [2 years old] next month.

MD 11: Non-eligible mother from a universal area

Geographical accessibility: Many mothers were unsure of where to obtain Healthy Start vitamins, either because the letter from the Healthy Start Unit did not mention where to use the vitamin vouchers or because their health professionals did not know. This issue was raised more often by mothers from targeted areas. Notably, all eligible mothers interviewed from the targeted area were aware of the vitamin vouchers attached to the

national Healthy Start letter from the Department of Health but "*never actually followed through*":

P: To be honest. I've seen, I've always seen the vouchers and thought to myself, 'oh I will have to find out where you go, where you get them from', but I've never actually followed it through.

MD 30: Eligible mother from a targeted area

R: Did you notice the vitamin vouchers in it?

P: …Yeah… I just read what it said but it didn't say where you get them from or how you can get them?

MD 25: Eligible mother from a targeted area

P: I just read what it [letter from Healthy Start Unit containing the food and vitamin vouchers] said, but it didn't say how you can get them. I now know it was my midwife who should have told me from day one!

MD 13: Eligible mother from a targeted area

Accessibility due to bureaucratic processes: Mothers shared experiences of delays in accessing the Healthy Start vitamin vouchers due to administrative complexities of which they were either unaware or felt unable to tackle. This is illustrated by an example given by an eligible mother:

P: … I have a friend who has just turned 18 and she's pregnant. She can't get her vouchers until she claims child tax credits. She can't claim child tax credits because they've just changed the rules and her mum has to claim child benefit for her until September of this year. So, the government is expecting her to live, and her baby, to live off £20! I know they can get them under 18 without tax credits but if you turn 18 in January, and your mum can't stop claiming child benefit for you until the September (pause and sigh), so now she is having a baby with no money, and she can't get anything for her or her baby until September.

MD 38: Eligible mother from a universal area

Adequacy of supply: Some mothers who were initially able to obtain vitamins were discouraged when trying to get further supplies because, *"they [children centres and general practice surgeries] never have them!"*. This appeared to occur more often to eligible mothers from the targeted area. Mothers also found that the lack of supply occurred more often for the children vitamin drops:

P: … there was nowhere really to get them and every time I'd ask in the doctors', they said 'see your midwife'… and everywhere I ask they go 'we haven't got them in', like in the children centre; they are meant to have them!

MD 27: Eligible mother from a targeted area

Acceptability: Mothers highlighted that another barrier to the take-up of vitamin vouchers was the taste or that the vitamins made them "*just throw up*":

P: To tell the truth, I got one bottle of vitamins and I tried one night. Personally, didn't like them so I have not had them since. They taste too chalky.

MD 38: Eligible mother from a universal area

P: … but every time I have them I just throw up.

R: Oh, it makes you sick?

P: They do yeah, they don't agree with me… we haven't took them since

R: … so you just gave it one try?

P: Yeah,

MD 06: Eligible mother from a universal area

In summary, from the mothers' perspective, the low take-up of Healthy Start vitamins was attributed to the emergent themes of awareness, acceptability, accessibility, and adequacy of vitamin supply.

From the healthcare providers' perspective, from both the universal and targeted area, themes were similar to those emerging from the mothers. This included awareness, adequacy of supply, and challenges to accessibility due to bureaucratic processes.

Awareness: A common theme arose during interviews with healthcare providers from both the universal and targeted areas, i.e. a lack of knowledge about Healthy Start vitamins. This appeared to be more of an issue for the providers working in the targeted area. The lack of knowledge related to several aspects of the Healthy Start vitamins: the vitamins included in the women's and children Healthy Start vitamin tablets and drops, respectively; whether the vitamins were suitable for vegetarians or mothers with gluten allergies; where

to obtain the vitamins; and awareness of the voucher. Healthcare providers also noted that they did not think mothers, in general, were aware of the health benefits of the Healthy Start vitamins.

Awareness of the vitamins included in the women's and children Healthy Start vitamins: Some health professionals interviewed noted that their colleagues had misconceptions about the active ingredients in the Healthy Start vitamins and therefore did not offer them. This issue was illustrated by a provider working in the targeted area:

P: …some health professionals thought vitamin A was in the pregnant woman's own [vitamin tablets], and therefore they didn't offer it, because they wrongly thought it was there!

MD 02: Provider working in a targeted area

Healthcare providers attributed this lack of knowledge to a lack of training by those responsible for local maternal and child health teams. One midwife implied that Healthy Start vitamins may have been an insufficient priority and not perceived as sufficiently important to use up midwives' "*precious*" time:

P: I don't think I have had any training around Healthy Start vitamins… but we midwives can be quite precious about our time.

MD 05: Provider working in a universal area

P: We probably had an introduction I think, but that's all. They probably said 'oh here you are, you can give these healthy vitamins'.

MD 36: Provider working in a targeted area

Awareness of where to obtain the vitamins: Healthcare providers, mainly from the targeted area, were not aware about where mothers could exchange the Healthy Start vitamin vouchers for vitamin tablets and/or drops. Some healthcare providers thought that one solution to this was for the national Healthy Start Unit to give the mothers a list of places where she could access the Healthy Start vitamins near to where she lived so "*people know where they can get them from*":

P: … do people know where they can get them from because maybe… [since the vitamin vouchers are] sent in the post, when they get [the] first lot of Healthy Start [food] vouchers with the vitamin [vouchers] there should be a list of addresses where they can get the actual things from… because if they get that initially they will make their move which is the nearest to them, and then they will know that they can always access them there.

MD 24: Provider working in a targeted area

Awareness of the voucher: As with mothers, providers also believed that the poor visibility of the Healthy Start vitamin voucher on the letters sent by the Department of Health Healthy Start Unit was a notable barrier, commenting that the vitamin vouchers were "*just an add-on on the form*":

P: The Healthy Start vitamin vouchers can get lost on the form because it is just an add-on on the form isn't it? … I wonder how much notice people take of it because it is just an add-on on the form really,

MD 04: Provider working in a universal area

Awareness of health benefits of vitamins: Healthcare providers, as well as commissioners, thought that some mothers were not aware of the health benefits to themselves and their child/ren and did not "*believe in the need for the vitamins*". This related to mothers' misunderstanding of what constituted a "good meal". One healthcare provider related the understanding of the benefits of vitamins to the socio-economic background of the health administrative area:

P: … I suppose it's an educational thing isn't it? It's like you know some girls think that a good meal is you know sausage and gravy and they would think that that was quite a decent meal whereas if you get some of the educated people you know… You know, there is a huge difference, because I worked down in [place name] for about four years and what they eat down there you know was so different to the diet of you know three miles up the road… I had one girl say to me… she said "I did I had a proper Sunday dinner" so I said what did you have? And she told me that she had chippy chips, gravy and mushy peas and a sausage

R: Oh my goodness

P: now she was telling me that was a proper Sunday dinner, so you can imagine what she eats on another day.

MD 37: Provider working in a universal area

P: I think generally there's a lot of women that don't particularly believe in the need for the vitamins

MD 03: Commissioner working in a universal area

Adequacy of supply: A key issue mentioned by healthcare providers was that they did not believe that there was an adequate supply of staff for the perinatal support required by mothers and their young children. This lack of sufficient staff, and therefore time, had the consequence of healthcare providers sometimes forgetting to discuss Healthy Start vitamins with mothers. The healthcare providers had several competing topics of importance to cover:

P: We definitely need to cover reducing the risk of cot death… We then talk about immunisations, ask them to sign an intent form for the Child Health department for when the immunisations are due. We talk to them about development checks, their own health, any family history of anything, and we also talk about smoking, alcohol, diet, and smoke alarms, child benefits, and somewhere in there we have to fit in the vitamins! And that's for a straightforward mum; some of the cases I come across in the community have safeguarding issues and the like.

MD 05: Provider working in a universal area

It was notable that none of the providers offered possible solutions to overcome inadequate staff resources, such as collaborating to pool resources to overcome the lack of staff capacity within each 'silo' of care, e.g. midwives versus health visitors versus social workers. An absence of collaborative working was noted even within the same healthcare provider-group, with a provider stating that:

"Even within your own team, one of us will be doing something, and somebody might be doing something related to what I'm doing… so even when you're all working towards the same goal, you are working in silos to a degree, which can be difficult."

MD 08: Provider working in a targeted area

Accessibility due to bureaucratic administrative processes: The users of the national Healthy Start vitamin programme were not just the mothers and/or their children but also the healthcare providers as they had to support the processing of the forms, vitamin

vouchers, and supply of vitamins. Healthcare providers were frustrated by the bureaucracy of the Healthy Start vitamin programme, from the form-filling *"for a 97p bottle of vitamins"* to chasing Healthy Start applications on behalf of mothers. Some healthcare providers thought that the administrative processes "*put people off*" and that it would be a more efficient use of their time if they could give the vitamins to the mothers "*instead of the mothers having to go somewhere else to get them*":

P: …then they have to re-register once the baby is born so it's sort of a lot of red tape and forms to fill out and I think that can put people off.

R: Right, is that something mums or dads have fed back to you?

P: Definitely.

MD 15: Provider working in a targeted area

P: Sometimes you've got families who are going through complex situations that vitamins and the application procedure is completely off-putting and I know… I am working with [a family] and she has had difficulties of obtaining the vitamins due to the movement of addresses a few times and she'll have been backwards and forwards with, you know in care, and the child is nearly 3 and could have really done with them and all of the red tape has completely put her off… I have even rang the Department of Health and they can't speak to me about it, because it's her you know, so there is a lot of little complicated things [that] come round with just the whole application process.

MD 14: Provider working in a targeted area

P: What might help is if midwives could give them [vitamins] out instead of the mothers having to go somewhere else to get them. If midwives actually had them with them, the woman wouldn't have to go anywhere; she can just be given them! …quite frequently I get people ringing me asking me for the Healthy Start number, because they haven't heard anything back from the Healthy Start Unit!

MD 04: Provider working in a universal area

Some healthcare providers working in the targeted area felt frustrated that they were unable to give Healthy Start vitamins to families who understood the need for and benefit of the vitamins but did not meet the Department of Health eligibility criteria.

P: … we had a family recently who was really keen on obtaining them [Healthy Start vitamins]. She was from an ethnic minority and there were definitely some signs [of vitamin D deficiency], and I did recommend

that she go to a doctor… she didn't do that but she wanted, she wanted to buy them. She goes, 'please just let me buy them', and I was like, 'I can't because there is a lot of red tape again surrounding the purchase of them'. She understood the need for the vitamins… She just wanted to purchase them and all I could do was recommend, you know, her to go to, you know, her local pharmaceutical place and try and find something similar which was a big, big deal for her.

MD 15: Provider working in a targeted area

There were also some healthcare providers were not clear of the administrative processes relating to the national Healthy Start programme.

P…I had absolutely no idea until last Thursday, that, when you've had your baby, in order to get the vitamin drops, you have to let the Healthy Start Unit know that you've had the baby; that's a major gap in knowledge

MD 02: Provider working in a targeted area

From the commissioners' perspective, from both targeted and universal areas, the themes of awareness, accessibility, and adequacy of supply emerged. A new theme relating to accountability also emerged.

Awareness of the vitamins: Commissioners appeared surprised and disappointed at the healthcare providers' lack of knowledge about the Healthy Start vitamin programme. This appeared to be more of an issue in the targeted area. Commissioners commented that the lack of awareness of how and when to offer the Healthy Start vitamins led some healthcare providers to believe that: 1) they had to judge a mother's socio-economic status and thus preferred not to offer the vitamins at all; 2) the vitamins for pregnant women inappropriately contained vitamin A, which was *not* present, and thus did not offer the vitamins to pregnant women; 3) the vitamins were not suitable for vegans or those with gluten allergies. As one commissioner stated:

P: I was concerned when I met with health professionals at the hospital, who thought that they had to judge whether women were eligible; that was a real barrier. So instead of… having the discussions about Healthy Start and the vitamins, and getting them signed up, they just said, well, we're not doing this, because

we'll be making a judgement about the women. They missed the point completely!... The Healthy Start Unit has the information and will make the decision about eligibility'.

MD 01: Commissioner working in a targeted area

Commissioners also shared the views of mothers and healthcare providers that the visibility of the vitamin vouchers was poor compared with the food vouchers. One commissioner who had been working in the universal area since the inception of the national Healthy Start programme commented that because of the volume of information sent by the national Healthy Start Unit, and the relative size of the vitamin voucher, the vitamin voucher was not easily visible. This was illustrated thus:

P: Healthy Start put a lot of things in those letter packages to people. And originally the information about vitamins was, I couldn't even begin to describe to you… it was one line on the letter and the writing was very small, but Healthy Start improved the look of the voucher; I still didn't think it was wonderful but it was bigger, but it still wasn't as big as the food voucher. It still wasn't I don't think quite as noticeable as it should have been.

MD 03: Commissioner working in a universal area

Accessibility relating to the lack of financial resources to support the local Healthy Start vitamin programme was highlighted as a key challenge to the effective implementation of the Healthy Start vitamin programme at a local level. Commissioners described the process that after the central Healthy Start Unit received a vitamin order from a local health administrative area, the vitamins would be supplied via the NHS 'supply chain' (the NHS distribution service) to the primary care trust. The primary care trust (PCT) then had the responsibility of delivering the vitamins to local distributors, which included general practice surgeries, children centres, and pharmacies. The NHS 'supply chain' was contracted to deliver NHS supplies only to NHS estates, e.g. general practice surgeries. Local primary care trusts had to arrange the transport of vitamins to other distributors with no extra funding. Commissioners commented that it was during this time that vitamins would go out-of-date. Commissioners eventually appealed to the goodwill of other local distributors. Even when innovative solutions were found, the Department of Health acted as a barrier:

P: Through seeking the help of Estates, we identified a local mailing van, like the NHS mail-van that goes from clinic to clinic. We identified one that goes from children centre to children centre. This really made distribution of the vitamins simple. They now have a contract to deliver the vitamins on a monthly basis, and it has helped our overall working relationship with them.

MD 03: Commissioner working in a universal area

P: Estates were involved in distribution of the vitamins 'cause there was a lot of governance issues because we had NHS providing to the local authority 'cause children centres are local authority-led. …but the way that we worked, it worked absolutely fabulously because that was one of the barriers that Department of Health kept on saying to us – no you can't do this because governance issues, whilst it worked for us.

MD 22: Commissioner working in a universal area

Commissioners asserted that the lack of accessibility related to a lack of financial resources was also a key barrier when trying to engage hospital-based services and general practice surgeries to distribute Healthy Start vitamins, a new service. General practice surgeries were particularly resistant to distributing vitamins, asking *"how much are you going to give me for doing this?"*:

P: It wasn't simple, and you even get to the point within the NHS where people start looking at their job description and say, 'hang on a minute, you are asking me to do something that's out of my job description!' And the other thing is, the Department of Health had never thought this through properly, because commissioners can only do so much. We have to then negotiate with the providers for them to actually provide the service. However, normally you have to pay them to provide the service, and there was no incentive or payment! This was all supposed to be done out of goodwill! Providers today will tell you clearly, it's harder and harder to actually fulfil the requirements that are put on them by commissioners, so some things have to go.

MD 01: Commissioner working in a targeted area

Another key challenge faced by commissioners, within the emergent theme of accessibility, was in estimating how many bottles of vitamins to request from the national Healthy Start Unit, as this depended on timely and effective communication between all the local distributors and the PCT (local health administrative area). One additional barrier

affected this flow of communication; because children drops were considered a medicine (and not a supplement), local pharmaceutical approval was required before ordering. One commissioner was able to overcome this challenge by working closely with a local medicines management team-member:

P: We invited in Medicines Management and we had one of their managers, who very kindly arranged for us to have approval for us to order through her, so everything was purchased up front, everything was distributed from medicines management, and then the accountant, used what we actually put on the system, as purchased, and then put in as a return.

MD 01: Commissioner working in a targeted area

The ad hoc adequacy of supply of Healthy Start vitamins from the national Healthy Start frustrated commissioners from both the targeted and universal areas, as this affected the take-up of vitamins "*creating a cycle of failure*" with vitamins "*end[ing] up in the bin*":

P: The availability of the vitamins was very patchy and very difficult to access, which made it difficult for health visitors to be able to recommend them because they weren't available regularly.... there were central [Department of Health] supply problems, creating a cycle of failure… health visitors were reluctant to tell somebody to go and get something that they thought was highly likely not to be there for them. So, even when you had them stocked, they'd end up in the bin, because no one claimed them; we were paying to throw vitamins in the bin, because that's what happened!

MD 03: Commissioner working in a universal area

Another barrier to accessibility created by the Department of Health itself was the process, and expense to mothers, of updating the national Healthy Start Unit when they gave birth to their babies or calling the unit if they were having any challenges with the Healthy Start programme. The following quotation illustrated these issues:

P: And previously, way back then [the start of the national Healthy Start programme], when women actually had their babies, they then had to start the process again, to try and get it, the vitamins, for their children. It's changed now, where women can just make a phone call and say, 'I've had my baby' and the actual records will come through [to say] that they have, so then that's simplified it, but it's complicated… if I just come back to the telephone, the telephone again was a problem, because if there were any difficulties with the programme and the women were trying to contact the actual Healthy Start team, they… often,

women who are in low income households do not have a landline within their house, and they were using mobiles, and these calls were all on premium rate numbers, and that was very expensive, so that again was another barrier. Now, I, I had this problem and identified it with the DH, and I identified it at least three times to say to them, you know, you need to look into this, this is not helpful, it's another barrier.

MD 01: Commissioner working in a targeted area

Commissioners believed that having to be accountable for their Healthy Start vitamin service would encourage better take-up of vitamins. One commissioner was astonished that the national Healthy Start Unit did not "*want to know if the vitamins actually got to mothers; all they want is purchase data*." Having regular steering-group meetings acted as a form of local accountability and was thought to be key in encouraging the distribution and take-up of Healthy Start vitamins. In the targeted area, it was perceived that local authority staff in children centres were more engaged compared with NHS staff in hospitals and general practice surgeries. The commissioner believed this was because children centres had local authority-driven targets and inspections aligned to their Healthy Start vitamin performance:

P: Children centres are expected to actually deliver results and that's what they do! They also have 'OFSTED' inspections, which is something else that they work towards. Distributing Healthy Start vitamins is another way that they can show that they're being beneficial to the community, so it ticks lots of boxes for them, not to undermine the fact that they love what they do and do it wonderfully.

MD 01: Commissioner working in a targeted area

The belief that accountability structures both locally and nationally would encourage the distribution and take-up of Healthy Start vitamins was challenging to the Department of Health Healthy Start Unit. As an interviewee from the unit said, "*I think it would be unheard of for a government department to legally challenge another bit of the same public sector*."

R: … from your point of view those PCTs who have had nought for some vitamins for quite a few quarters, whose responsibility do you think it is to pull that PCT or that group of people within the PCT up about that?

P: I think that's 100 million dollar question. The simpler question to ask would be if they are not doing it, who would legally challenge them? I think it would be unheard of for a government department to legally challenge another bit of the same public sector. I suppose people who couldn't get their vitamins could challenge the PCT on it?

MD 44: Interviewee from DH Healthy Start Unit

The commissioner from the universal area believed that one of the main reasons why some local health administration areas did not provide returns was because the process of filing the returns did not justify the value of the financial return itself.

P: And I think that's shown by the fact that a lot of areas don't even provide returns, although there's other issues, … to [the] Healthy Start [unit] around vitamins; mostly because of the way finance systems are set up that means that it is too costly for them to do that.

MD 03: Commissioner from a universal area

4.3 Why was the take-up of vitamin vouchers higher in the universal area?

Though still low, the take-up of Healthy Start vitamin vouchers was higher in the universal area compared with the targeted area. Reasons given by the interviewees fell within the themes of accessibility and adequacy of supply.

From the mothers' perspective, mothers from the universal area reported that there were several places where they could exchange their vitamin vouchers for vitamin tablets or drops and that the administrative process used in the universal area appeared to make the use of vitamin vouchers less cumbersome. These points were explained thus:

P: [It is] very easy [to obtain Healthy Start vitamins] yeah coz there are quite a lot of key places around here that I can get them. Like I can get them here [a children centre]; there's lot of places I could get them.

MD 09: Eligible mother from a universal area

P: …I just have to take my card there every three months and they just give me the vitamins and they just sign it to say they have given me them.

MD 06: Eligible mother from a universal area

P: … they just gave me this, you get the yellow card, and each time you come you have to have it signed telling them that you have received them, the next one, and then that is it.

MD 19: Non-Eligible mother from a universal area

In the universal area there also appeared to be, from the mothers' perspective, a greater supply of the vitamins. Some mothers had the experience of being given Healthy Start vitamins at the same time as the vitamins were initially discussed, as noted here:

P: … we went to a weaning group and they told us about, about them [the vitamins], then so that was when we got them.

R: … you were given a bottle were you?

P: Yeah.

MD 12: Non-Eligible mother from a universal area

The ease of accessibility and adequacy of supply of vitamins for some mothers from the universal area contrasted with mothers from the targeted area. Many of the mothers from the targeted area reported that they did not know where to get the vitamins and that *"there was nowhere really to get them", "they just never have them"*:

P: There was nowhere really to get them. Every time I'd ask in the doctors' they said, 'see your midwife', and the midwife told me to look on the internet, but I haven't got any internet at home… I have never ever got the vitamins because I don't know where to get them from or anything. That's what, that's what my problem is – I want to get them but I can't.

MD 32: Eligible mother from a targeted area

P: I try you know [to use the vitamin vouchers], if you can get them for free, you've seen I've got the voucher right here… but the thing is I don't know whether it's because of the cutbacks or whether they've just stopped sending them but the (children) centres where I go ask for them, they just never have them.

MD 26: Eligible mother from a targeted area

From the providers' perspective in the universal area, a key reason why the take-up of vitamins was higher was because every mother was given a vitamin voucher. Whilst only the vitamins given to mothers defined as eligible according to Department of Health criteria were claimed from the Healthy Start Unit by the universal area, it meant that both eligible and non-eligible mothers could obtain the vitamins "*straight away*" making the vitamins more easily accessible:

P: Now locally we do have a programme where every lady will, can be given a form to come and get vitamins… from the children centre… we just have to put the house number and postcode on the top, the lady's name and then they just bring it along to one of the children centres or… one of the local places and they can pick up vitamin… often I will give one of those forms to everybody because it means they can go and get them straight away because Healthy Start, when you apply, those people can be waiting a little while for those to come through

MD 04: Provider from a universal area

Providers from the universal area thought that the take-up of vitamins could be further increased if health professionals were able to give mothers vitamins at the point of contact:

P: … what might help is if midwives could give them out wouldn't it? Instead of them [mothers] having to go somewhere, if midwives actually had them with them… the woman wouldn't have to go anywhere.

MD 04: Provider from a universal area

Providers from the universal area also appeared to know from where Healthy Start vitamins could be accessed compared with providers from the targeted area. One provider explained that the vitamins were accessible from "six children centres within a radius of about ten miles":

P: … they are available in every children centre so that's… six children centres within a radius of about ten miles? So they're quite freely available… They're available from the receptionist, so that makes things easier.

MD 05: Provider from a universal area

From the commissioners' perspective, in the universal area, the process of offering Healthy Start vitamins to all women encouraged staff to be more aware of and remember to offer the vitamins. At the inception of the Healthy Start programme, the universal area initially followed the Department of Health guideline to offer the vitamins only to eligible women. The commissioner from the universal area recalled that when the targeted implementation approach was used, staff "*were very rarely asked for [the vitamins] or would forget [to ask mothers] and they [the vitamins] would go out of date"*. Therefore, through using the universal implementation approach, staff were more likely to remember to discuss Healthy Start vitamins with mothers:

P: The clinic staff, if you speak to receptionists and people outside here, because they were very rarely asked for [the vitamins], or would forget [to ask mothers], and they [the vitamins] would go out of date… And managers would just stop stocking them and if nobody was telling them you have to stock them, they'd just fall off the agenda.

MD 03: Commissioner from a universal area

The commissioner from the targeted area implied that a lack of engagement from key health professionals contributed to the lower take-up of Healthy Start vitamins in the targeted area. In attempting to improve the take-up of vitamins, a small working group was formed, however there was a lack of engagement from midwives, GPs, and an accountant to support filing the returns to the Healthy Start Unit:

P: One of the Heads of the health visiting service, I spoke with her, and she pulled together a small group of people, … There was a pharmacist involved. We tried to get an accountant there, but we failed miserably…

R: Any midwives?

P: No

R: GPs?

P: No

R: Okay

P: None at all, and it was really that,

MD 01: Commissioner from a targeted area

The commissioner from the targeted area wished that the Department of Health would "sit down and speak to the people who have tried to implement this… And then see how we actually move forward altogether":

P: my recommendation would be to sit down and speak to the people who have tried to implement this. The DH have got to listen to people who have been doing this, sit down, talk, get people from different parts of the country, sit down and talk to them and say, OK, what, what are our barriers? Why has this actual take-up been so poor? And then see how we actually move forward altogether

MD 01: Commissioner from a targeted area

At the time of conducting the interviews, the researcher was concerned about whether the take-up of Healthy Start vitamins was higher in the universal area compared with the targeted area due to the universal area claiming for vitamins for both eligible and non-eligible women. The commissioner from the universal area made it clear that only vitamins distributed to eligible mothers were claimed for reimbursement as illustrated by the following quote:

R: How do you keep track [of which vitamins to claim]? Do you keep postcode records?

P: We keep a spreadsheet on a month by month basis from each children centre… and they would mark E for eligible or L for local…

R: Ah, and then that will allow you to know how much to ask for reimbursement as well?

P: Yes, that's done by Health Improvement group at the PCT.

MD 03: Commissioner from a universal area

4.4 Summary of the chapter

This chapter addressed the second research question of this study and explored the potential reasons why the take-up of Healthy Start:

- food vouchers were consistently much higher?
- vitamin vouchers were consistently low?
- vitamin vouchers were higher in the universal area?

From the three groups of participants interviewed:

- mothers
- healthcare providers
- commissioners

Five themes emerged from deductive analysis of the semi-structured interviews emerged. Mothers, providers, and commissioners reported issues under the emergent themes of accessibility, awareness, and adequacy of supply. Only commissioners discussed the themes of accountability; commissioners did not mention the theme of acceptability.

Key findings were:

- Mothers in the universal and targeted area found it easier to identify and use food vouchers compared with vitamin vouchers
- The overall low take-up of Healthy Start vitamins was attributable to:
    - bureaucratic processes between mothers, providers and commissioners, and the national Healthy Start Unit
    - mothers and healthcare providers not being aware of the health benefits of the vitamins
    - the Department of Health not providing a guide to local implementation of the Healthy Start vitamin programme or any additional financial resources
- Greater accessibility to vitamins and increased awareness of Healthy Start vitamins by mothers and healthcare professionals were attributable to the higher take-up of the vitamins in the universal compared with targeted area

In summary, the quantitative data showed that:

- Food voucher uptake was consistently much higher compared with vitamin voucher take-up,
- Overall, vitamin voucher take-up was low,

- The take-up of women's vitamin vouchers was higher compared with children's vitamin vouchers in both universal and targeted areas,
- There was a significantly higher take-up of vitamin vouchers in the universal area compared with the targeted area

From these quantitative findings, the researcher sought to understand the potential reasons for these observations and therefore specifically sought to explore from the perspective of mothers, healthcare providers, and commissioners their views about the quantitative findings. This also included understanding any possible barriers or facilitators to food and vitamin voucher take-up between the targeted and universal area.

The following chapter synthesises the quantitative and qualitative findings, discussing their potential implications for the Healthy Start vitamin programme.

5 Chapter 5: Discussion

The main findings that will be discussed in this chapter are:

I. Food voucher take-up was much higher compared with vitamin take-up
II. Overall, vitamin voucher take-up was low
III. Vitamin voucher take-up was higher in the universal area compared with the targeted area
IV. Women's vitamin voucher take-up was higher compared with children vitamin voucher take-up in both universal and targeted areas

These findings related to the overarching aim of this study (p.54), i.e. to investigate the effect of a targeted versus universal implementation approach to the Healthy Start vitamin programme on the take-up of vitamins in the eligible population 'targeted' by the Department of Health, i.e. low-income families, and reasons for any observed differences. The two objectives indicated the main comparisons:

1) Identify differences in Healthy Start vitamin voucher take-up between a demographically similar universal and targeted area
2) Explore the explanatory factors as perceived by potentially eligible mothers, healthcare professionals, and commissioners for similarities and differences in vitamin take-up between these two areas and explore barriers at the point of supply to participants

The chapter ends with a critique of the methods used, policy implications from the study findings, and recommendations for future research.

5.1 Food voucher take-up was much higher compared with vitamin take-up

From this analysis of national data, the take-up of food vouchers was consistently much higher compared with vitamin vouchers. The highest food voucher take-up recorded during the time of data collection in 2012 was 80.3%, whilst the highest vitamin voucher take-up was 7.3% and 3.6% for women and children, respectively. The eligible mothers proposed several reasons to explain the high take-up of food vouchers. Mothers reported that the food vouchers were easy to use. Many major supermarkets accepted them, and they found it easy to remember to use the food vouchers as food is a fundamental human need and grocery shopping part of everyday life. Though food vouchers and vitamin vouchers were simultaneously sent in the form of a letter from the Healthy Start Unit, the food vouchers were more visible, being larger than the vitamin vouchers and having a clear monetary value. The letter from the Healthy Start Unit also gave guidance as to where and how mothers could use the food vouchers, unlike the vitamin vouchers, which were not accompanied with similar guidance. My findings also suggest that mothers may have found it easier to understand the benefit they would receive through using food rather than vitamin vouchers, i.e. £3.10 off their grocery shopping per voucher.

In this work, none of the mothers interviewed mentioned that they felt any shame or stigma in using the food vouchers. This was surprising, as previous studies reported that parents felt a sense of shame or being judged when using Healthy Start food vouchers (Lucas et al., 2015, McFadden et al., 2014). In this study, this may reflect the normalisation of welfare support programmes in socio-economically disadvantaged areas or reluctance on the part of mothers to reveal to the researcher feelings related to disapproval.

Mothers in this study reported that many major supermarkets accepted the food vouchers, but some mothers expressed frustration and dissatisfaction that smaller shops closer to their homes did not accept them. McFadden et al. (2014), in their study of mothers' experiences of the Healthy Start programme in Yorkshire and the Humber and

London in 2011/12, also found that mothers preferred to use the vouchers in small shops but most of such shops were not registered to redeem the vouchers (McFadden et al., 2014).

The national Healthy Start Unit started reporting the take-up of Healthy Start food and vitamin vouchers in 2009, by when England was subject to a government austerity policy, with the welfare system undergoing radical changes (Stuckler et al., 2017). In this study, mothers from both universal and targeted areas reported that, though the food vouchers offered welcomed financial assistance, the assistance was limited. Mothers were, and are still, able to purchase fresh and frozen fruits and vegetables, cow's milk, and infant formula. Mothers who used the food vouchers to purchase infant formula expressed views that it would have been more helpful for them if an infant formula voucher was given, so that it could be exchanged for a standard tin of formula. This is because the average cost of a unit of infant formula was £8.00 at the time of data collection with a standard tin, on average, being enough to feed an infant for one week. Therefore, from the four food vouchers mothers received monthly from the Healthy Start Unit, mothers feeding their babies with milk formula used three vouchers in one week to purchase one tin of formula. This finding corresponds with a study conducted by Lucas et al. (2015), who reported that mothers feeding their babies with infant formula viewed Healthy Start food vouchers as scant financial assistance (Lucas et al., 2015).

Related to why the take-up of food vouchers was so much higher, providers had many views similar to the mothers. This included their ease of use, greater visibility, the financial support given through the vouchers, and that food shopping was a normal part of everyday life and therefore easy to remember to use. It is worth noting that as of December 2018, the value of the Healthy Start food voucher has remained the same; £3.10 since at least 2012. Though the cost of infant formula has not increased, the cost of fruits and vegetables has risen since summer 2018 (BBC News, 2018). It is hoped that any further increases to fruit and vegetable prices will be reflected in the value of the Healthy Start food voucher.

Commissioners, as well as some providers, did not specifically say why they thought food voucher take-up was high but did explain why they thought vitamin voucher take-up was low. One possibility is that this reflects the outcome-focused mindset of commissioners, which for Healthy Start is the take-up of Healthy Start vitamins, with little or no consideration given to the take-up of food vouchers and the discrepancy between the two.

5.2 Vitamin voucher take-up was low

Overall, vitamin voucher take-up was low. In the national dataset analysed here, the highest recorded vitamin voucher take-up amongst the local health administration areas in North West England between July 2009 and December 2012 was 7.3% and 3.6% for women and children, respectively, in 2012. This finding is consistent with McFadden et al.'s study (2015) showing a less than 10% take-up of Healthy Start vitamins by local health administration areas (primary care trusts (PCTs) at the time of their study) across England (McFadden et al., 2015).

Eligible mothers described the experience that, unlike the food vouchers, the vitamin vouchers were less visible as they were smaller compared with the food vouchers and that no guidance was given about how and where to exchange the vitamin vouchers for Healthy Start vitamins, at the time of data collection. These two experiences acted as barriers to the take-up of Healthy Start vitamins from the mothers' perspective.

The evidence about vitamin D deficiency in the UK population and the importance of vitamin D supplementation had been well established (Hyppönen and Power, 2007, Leaf, 2007) before the vitamin voucher data used in this study had been collected. With the aim of the Healthy Start programme being "to improve the health of low-income pregnant women and families on benefits and tax credits", equal emphasis on both food and vitamin vouchers received from the Healthy Start Unit could have been expected. Since the end of data collection, the Healthy Start website has been updated. The webpage now signposts mothers to ask particular healthcare professionals about the vitamin vouchers; "Your

midwife or health visitor will be able to tell you where you can swap your coupon for vitamins in your area" (Healthy Start Unit, 2018). This advice may be problematic as this research has found that there were healthcare professionals who were not aware from where to obtain the vitamins locally. The Healthy Start website has also been updated to state that the vitamins are approved by the Vegetarian Society and Halal Monitoring Committee UK. The website additionally states that the vitamin voucher is green. The website-updates are dependent on; 1) access to the internet and 2) English literacy.

Mothers who noticed the vouchers and asked their local healthcare professional for the Healthy Start vitamins were frequently unable to obtain them, either because the healthcare professional was not aware about where to obtain them or they were out-of-stock or out-of-date. The latter finding from this research is consistent with research conducted by Jessiman et al. (2013), who reported that poor accessibility to vitamins contributed to their low take-up (Jessiman et al., 2013). Some mothers who were able to obtain in-date vitamins noted that a lack of information from the healthcare professional about the health benefits of the vitamins did not encourage their use. Though not common, some mothers commented negatively about the palatability of the vitamins.

In summary, whether related to understanding the health benefits of the vitamins, to noticing the vitamin vouchers received from the national Healthy Start Unit, to knowing where to exchange the vitamin vouchers for Healthy Start vitamins, to obtaining in-date vitamins, or to the palatability of the vitamins, mothers faced barriers at every step in the process of obtaining the Healthy Start vitamins. These barriers occurred for mothers both in the universal and targeted area.

From the data analysed here for the 24 local health administrative areas in North West England, some areas had no recorded take-up for vitamins for several quarters of the year. One area had no recorded take-up for women's vitamins for the entire period of data collection between July 2009 and December 2012. These findings are of concern as the Healthy Start programme is a statutory provision with the Department of Health being legally responsible at the time of data collection (Healthy Start). One hypothesis is that

these findings reflect a lack of an accountability structure or feedback-loop built into the programme to ensure eligible mothers were receiving the vitamins as required by statute. At the time of writing, a 'target' for vitamin take-up to achieve amongst the eligible population could not be found. From the researcher's experience of working as a manager in an NHS acute trust, 'targets' can sometimes prompt healthcare professionals to focus on what is deemed important for patients and what outcomes should be achieved. One example of this is the 'breast cancer referral to treatment' target, i.e. 95% of patients begin their first treatment for cancer within 62 days following an urgent GP referral for suspected cancer. Setting a target for vitamin voucher take-up to be achieved by healthcare professionals might facilitate an increased Healthy Start vitamin take-up. The potential benefit of setting such a target needs, however, to be balanced by any potential unintended consequences. One such unintended consequence could be a higher distribution of vitamins, recorded as higher percentage take-up, without the women and children taking the vitamins on a regular basis and the health benefits of the vitamins therefore never realised.

Providers and commissioners viewed the process of obtaining Healthy Start vitamins from the Healthy Start Unit as complex and bureaucratic and even more cumbersome for the reimbursement of vitamins distributed by the local health administration area. McFadden at al. (2015) reported similar experiences amongst healthcare professionals in Yorkshire and the Humber and London (McFadden et al., 2015). To recap, percentage take-up of vitamins is calculated by the Healthy Start Unit as the number of vitamin coupons returned to the Healthy Start Unit (numerator) divided by the number of women or children eligible for the vitamins (denominator). With a cumbersome reimbursement process, local administrative areas may have considered the administrative cost of reimbursement to be much greater than the financial value of reimbursement itself, thereby foregoing the reimbursement. This would result in no or low recordings of vitamin take-up by the Healthy Start Unit and may explain in part the overall low take-up of Healthy Start vitamins.

Take-up of vitamin vouchers for both mothers and preschool children increased between February 2012 and December 2012 (see Figure 3.1, p.86). This increase coincided with the Chief Medical Officer for England, Dame Sally Davies, expressing concerns in January 2012 that some children and adults were not getting sufficient vitamin D (BBC News, 2012). In February 2012 the four Chief Medical Officers of the UK wrote to healthcare professionals about the importance of vitamin D supplementation (Appendix 1). The influence of the media and the role of power and authority in influencing the take-up of Healthy Start vitamins is an area for further research.

5.3 Take-up of vitamin vouchers was higher in the universal compared with targeted area

The take-up of both women's and children vitamin vouchers was significantly higher in the universal compared with the targeted area: 6.3% versus 1.6%, $p < 0.001$ and 3.2% versus 1.2%, $p < 0.001$, respectively. Though take-up of vitamin vouchers was still much lower than for food vouchers, potential explanatory factors for this significant difference in take-up (universal versus targeted) need consideration.

To recap, in the universal area, all pregnant women (whether eligible or not eligible for the Healthy Start programme) received the locally developed Healthy Start vitamin voucher at the start of their pregnancy. This meant that mothers who were eligible for the Healthy Start programme had two options for obtaining Healthy Start vitamins: the national Healthy Start vitamin voucher or the locally developed Healthy Start vitamin voucher. Whichever voucher the eligible mother chose to use, postcode data were recorded on a local database so that the local commissioner knew how many vitamins would be claimed for reimbursement from the national Healthy Start Unit. Therefore, the likelihood of an eligible mother using both vitamin vouchers simultaneously was low as the midwife, health visitor, or children centre receptionist would be able to see how recently she last collected Healthy Start vitamins. A code of "E" was placed next to all eligible mothers who collected vitamins;

these were the vitamins claimed for reimbursement. A code of "L" was used against all non-eligible mothers who claimed Healthy Start vitamins; reimbursement was not sought for any of these vitamins. Therefore, the likelihood of the higher vitamin take-up in the universal area being because non-eligible mothers also claimed vitamins locally was negligible. The local commissioner checked the reimbursement data before these were sent to the Healthy Start Unit.

The local voucher was an *aide-memoire*. Kessels (2003) found 40–80% of medical information provided by healthcare professionals was forgotten immediately. Two factors are considered important in affecting recall: the perceived importance of the information and the mechanism of information-sharing, be it written or spoken. Pictographs have been shown to have a statistically significant effect on improving patient recall, with correct recall being 85% with pictographs compared with 14% without pictographs in one study ($p < 0.0001$ (Houts et al., 1998). As eligible and non-eligible mothers were usually given the locally developed Healthy Start vitamin vouchers during their first contact with a healthcare professional, the local Healthy Start vitamin voucher may have acted as a pictograph facilitating better recall. Eligible mothers from the universal area would have had an *aide-memoire* to seek the vitamins during their pregnancy and after the baby was born. The prior knowledge of how and where to exchange the local vitamin voucher may have made it easier for mothers from the universal area to use the vitamin voucher received from the national Heathy Start unit.

The environment had a potential role. Mothers living in the universal area reported that they were aware of Healthy Start vitamins and that there were many places from which they could obtain the vitamins, with healthcare professionals or receptionists at children centres knowing where to direct them. From the perspective of mothers, healthcare professionals from the universal area appeared to remember to discuss Healthy Start vitamins with them. Healthcare providers from the universal area reported that it was easier to remember to discuss Healthy Start vitamins with pregnant women and mothers of young children as it was an integral part of their consultation, with every mother being offered a

vitamin voucher. This contrasted with the targeted area where several mothers mentioned that their healthcare professional did not discuss or know where mothers could obtain Healthy Start vitamins. Healthcare providers working in the targeted area also wrongly believed that they had to make a socio-economic judgement about the mother before offering the Healthy Start programme, which many of them refused to do, resulting in Healthy Start vitamins not being discussed at all.

Two studies from recent nutritional supplementation literature for children highlighted the potential importance of the environment in which nutritional supplementation is offered. Moore et al. (2014) and Keyte at al. (2012) examined the dietary behaviours of children in schools that participated in a universal food supplementation programme versus no supplementation. Moore et al. (2014) conducted a cluster-randomised controlled trial where 55 schools offered free school breakfasts to all Year 5 and 6 pupils (i.e. aged 9-11 years); 56 primary schools were in the control group where free school breakfasts were not offered. At the school-level, the study showed that children in the intervention schools ate a greater number of healthy items ($p < 0.01$; 95% CI 0.07 to 0.44) and had more positive attitudes towards breakfast ($p < 0.05$; 95% CI 0.20 to 1.50) compared with children in control schools. Breakfast-skipping was also reduced among children from more deprived schools and households ($p < 0.05$: 95% CI -0.15 to 0) (Moore et al., 2014). Keyte et al. (2012) showed that children aged 7-9 years attending schools in the National Healthy Schools Programme ate a median of two portions of fruit and vegetables compared with one portion amongst children in schools not engaged in the Programme ($p = 0.001$) (Keyte et al., 2012). The National Healthy Schools Programme aims to improve children eating patterns through the education curriculum, the school environment, and engagement with parents and carers; healthy and nutritious foods were made in school canteens and available in schools. Though Moore et al. (2014) and Keyte at al. (2012) did not compare the take-up of food supplementation using a universal versus targeted implementation approach, the potential importance of the environment on influencing take-up of nutritional-supplementation was considered.

Moy et al. (2012) examined whether the universal provision of vitamin D supplements to all children under the age of five years and all pregnant and lactating women resident in the inner-city health area of Birmingham would reduce the number of cases of vitamin D deficiency in those under 5 years. A public awareness campaign accompanied the start of universal vitamin D supplementation. A 59% decrease in the absolute numbers of symptomatic vitamin D deficiency was observed: 29 cases in 2005 versus 12 cases in 2010, with the incidence rate reducing from 120/100,000 children under the age of five years to 49/100,000. Notably, the highest vitamin take-up recorded during the Moy et al. (2012) study was 17% whilst public awareness about the importance of vitamin D for bone health rose from 21% in 2007 to 79% in 2011. The national Healthy Start programme was launched in 2006; the healthcare professionals and residents in inner-city Birmingham may have benefited from a longer period of public awareness campaigning than initially intended by Moy et al. (2012). Nevertheless, though not examined by Moy et al., the environmental factors contributing to the reduction in symptomatic vitamin D deficiency, despite a maximum recorded take-up of vitamin take-up of 17%, should be considered.

In relation to the study for this thesis, the environment may have played an important role in both the higher take-up of Healthy Start vitamins in the universal area and the lower take-up in the targeted area. The environmental factors, facilitators, and barriers that potentially influence Healthy Start vitamin take-up need further exploration.

Engaging key stakeholders is important. It can be speculated that the absence of two key stakeholders - GPs and midwives - in the local Healthy Start steering group may also have contributed to the lower take-up of Healthy Start vitamins in the targeted area. The contrasting sense of teamwork and collective ambition amongst the key stakeholders within the universal area was notable; this may have contributed to the higher take-up of Healthy Start vitamins. The importance of a group of key stakeholders having a collective ambition in achieving a result has been highlighted in the management literature (Ready and Truelove, 2011).

During the research process the researcher presented the quantitative findings at the European Public Health Conference, 2012 (Moonan et al., 2012) (Appendix 13). Subsequent to this, the chief medical officer for England asked the National Institute for Health and Care Excellence to provide an economic analysis of the Healthy Start vitamin programme to determine whether it would be cost-effective to move from the current targeted approach to a universal offering (National Institute for Health and Care Excellence, 2015). Though no association could be made about the universal provision of Healthy Start vitamins to mothers and preschool children and a reduction in vitamin D deficiency, it must be remembered that the cost-effectiveness analysis was undertaken in the context of cumbersome and bureaucratic processes in accessing Healthy Start vitamins (discussed further in section 5.5).

5.4 Take-up of women's vitamins was higher compared with children vitamins

In both the universal and targeted areas, the take-up of women's vitamins was higher compared with children vitamins. One of the main reasons for this given by commissioners was that children vitamin drops were considered medicines and therefore any ordering of children vitamins had to firstly go through the relevant local medicines management governance processes before an order from the national Healthy Start Unit could be placed. This process was a considerable barrier to the availability of children vitamin drops as medicines management teams, from the researcher's experience, usually meet monthly to approve drug requests.

Another reason for the lower take-up of children vitamins was due to the ad hoc availability of the vitamins drops from the Healthy Start Unit. The latter was due to unanticipated supplier production issues resulting in the NHS Supply Chain unable to deliver vitamin drops to local health administration areas. The unanticipated supplier production issues occurred twice during the time of data collection for this thesis. The most recent

occurrence was in October 2017 resulting in a temporary limit on order quantities of 15 units per week, with an alternative ordering process put into place (NHS Supply Chain, 2017). The introduction of an alternative ordering process on top of an already complex ordering process, as described by providers and commissioners, may act as a barrier to obtaining children vitamin drops. An ad hoc supply of vitamin drops may also act as a barrier from the perspective of mothers as she would not be able to obtain Healthy Start vitamins for children from the venue the healthcare professional indicated. Though not a failing of the healthcare professionals, trust could then be broken between mothers and healthcare professionals, resulting in mothers no longer seeking to obtain Healthy Start vitamins.

The shorter half-life of children vitamin drops was also highlighted as a potential reason contributing to the lower take-up of vitamin drops. An irregular supply of vitamin drops via the NHS Supply Chain could have led to an infrequent request for the children vitamins from the mothers in both universal and targeted areas. Therefore, by the time a mother wanted to exchange her vitamin voucher for vitamin drops, the expiry date on the drops could have passed.

5.5 Administrative process from a quality improvement perspective

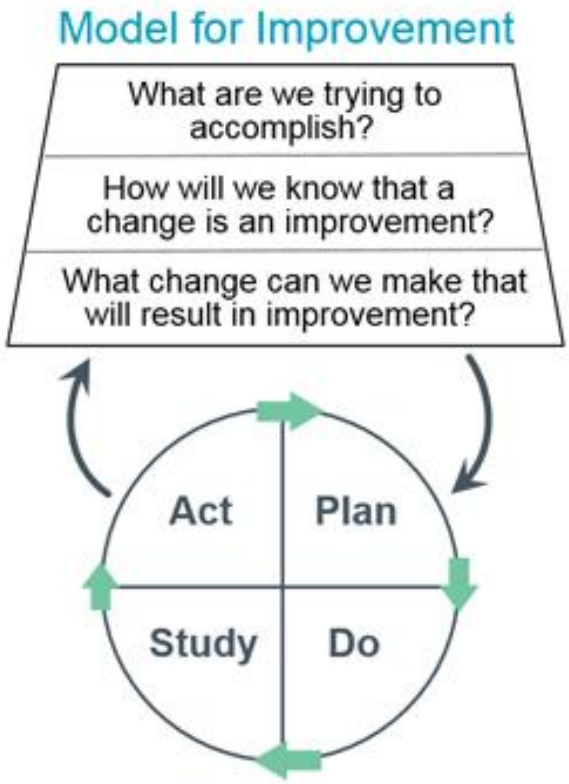
The purpose of this section is not to detail quality improvement method in healthcare but to consider how some of its guiding principles could have potentially supported a higher take-up of Healthy Start vitamins from the inception of the Healthy Start programme.

The Model for Improvement (Langley GL, et al., 2009) is used nationally and internationally as a framework to guide improvement work. The model asks three questions (Figure 5.1):

- What are we trying to accomplish?
- How will we know that a change is an improvement?

- What change can we make that will result in an improvement?

Figure 5.1 – A model for improvement
This framework can guide specific improvement activates in many settings, including healthcare (Langley GL, et al.,2009).



The Healthy Start programme can be considered an improvement project with the aim to "improve the health of low-income pregnant women and families on benefits and tax credits" (Healthy Start Unit, 2018). From a quality improvement perspective, this aim is not

narrow enough to drive forward an improvement as 'health' is non-specific and therefore difficult to measure. Establishing measures *before* the start of any improvement project is critical to the success of any improvement project as the measures instruct the project team in knowing whether the intervention or change is leading to the desired improvement soon after the intervention has been implemented. It was not possible to establish any measures before the start of the Healthy Start programme because the Government implemented the programme before requesting support for its evaluation. Dyson et al. (2007), on behalf of the Public Health Research Consortium, noted in their report that considering evaluation options after the implementation of the programme in 2006 was difficult and not robust. The establishment of process measures such as systematically measuring the take-up of Healthy Start vitamins could have facilitated a refinement of the Healthy Start programme implementation processes soon after its initial implementation in 2006. The latter is debatable, as a paper published in 2009 reported that none of the Healthy Start recipients were receiving the vitamin supplements (Ford et al. 2009). Subsequent papers also reported vitamin take-up of less than 10% (Jessiman et al. 2013, McFadden et al., 2015). To the researcher's knowledge, no implementation process changes have occurred after the publication of these papers, despite the Chief Medical Officer's enthusiasm for the vitamin programme (Davies, 2013).

The Healthy Start vitamin programme is intended to improve the health of mothers and young children from low-income families. The results from this research have illustrated that at every step in the process of trying to get vitamins to mothers, barriers were faced by mothers, healthcare providers, commissioners, and the Healthy Start Unit.

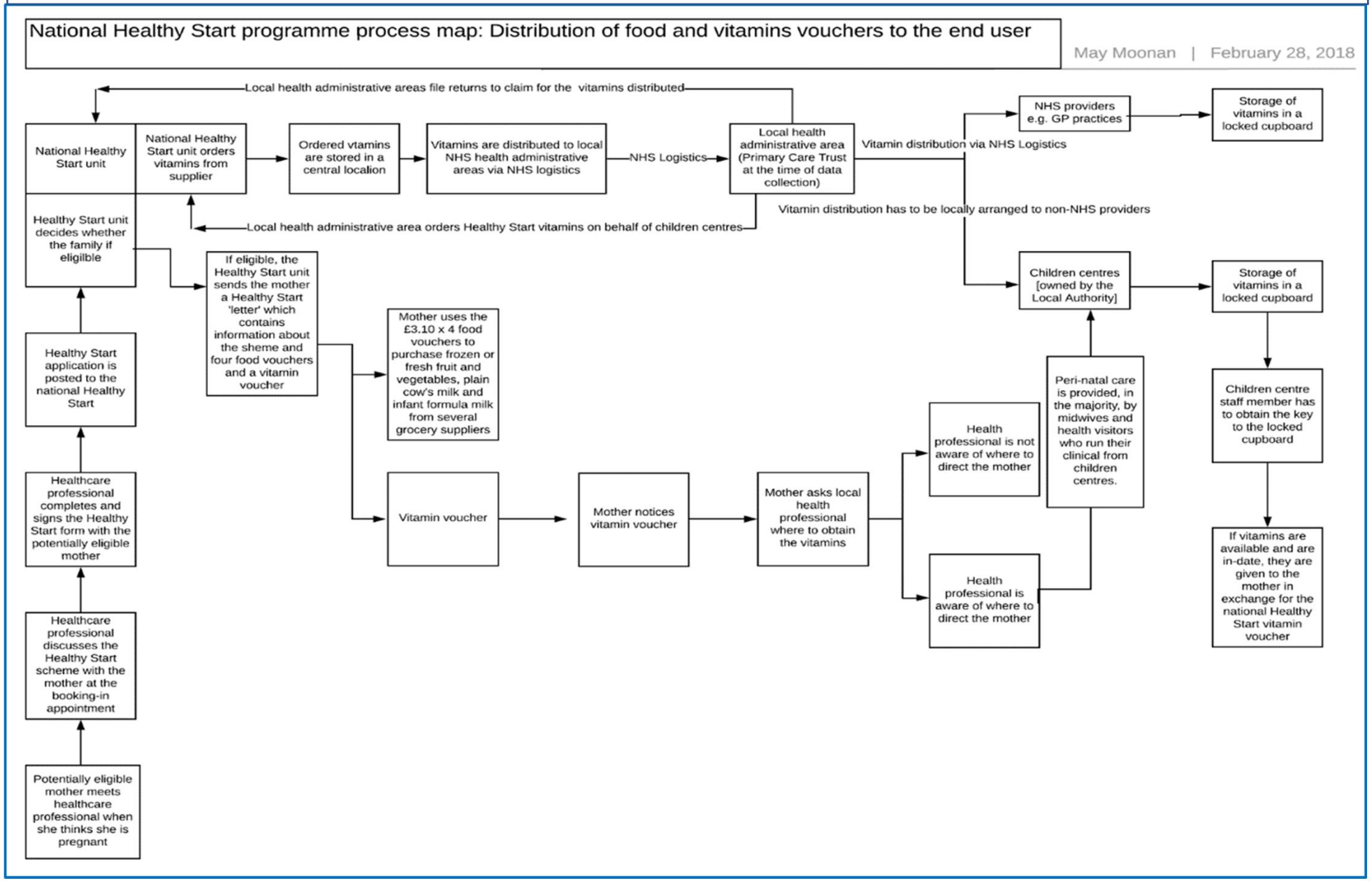
The process-steps could be summarised as (Figure 5.2):

- The mother must complete the Healthy Start form and have it signed by a healthcare professional
- On receipt of the Healthy Start letter, the mother must notice the vitamin voucher
- If she notices the vitamin voucher, she must interpret where and how to use the voucher

- Should the mother progress to asking a healthcare professional about the Healthy Start vitamins, the healthcare professional must be aware of where the mother can obtain the vitamins locally; from this study, this was a local children centre
- The children centre must have a supply of in-date vitamins to give to the mother in exchange for the vitamin voucher
- The mother has to remember to take her vitamins and give her children their vitamins every day; this is less likely if the mother does not understand how she and her children will benefit from the vitamins
- The local commissioner then liaises with the children centres to ascertain the number of vitamins given to eligible mothers
- The local commissioner then sends these figures to the national Healthy Start Unit for reimbursement

Figure 5.2 National Healthy Start programme process map as observed by the author of this research

A process map in quality improvement is a workflow diagram that gives a clearer understanding of the processes involved in achieving an outcome. This process map highlights the steps, or processes, involved in an eligible mother obtaining Healthy Start food vouchers and Healthy Start vitamins



Reducing the barriers to the take-up of Healthy Start vitamins can potentially facilitate a meaningful increase in vitamin take-up. The emergence of local integrated care organisations in the English healthcare system could offer an opportunity to revitalise the Healthy Start vitamin programme with sustainable improvements.

The researcher's findings here suggest that offering the Healthy Start vitamin programme universally would be more effective, as measured by percentage take-up of the vitamins, compared with offering the vitamins to only a targeted population. The Department of Health has used strict eligibility criteria to determine which mothers and children in the UK population are eligible for the Healthy Start programme, which encompasses both Healthy Start food vouchers and Healthy Start women's and children vitamins.

One recommendation would be to separate the food voucher versus vitamin voucher programme. This would allow Department of Health eligibility criteria to continue to be applied to the provision of food vouchers whilst allowing the vitamin vouchers to be offered universally to the UK population. Insanity has been defined as "*doing the same thing over and over again, but expecting different results*", a famous quotation attributed to Albert Einstein. The Healthy Start programme was launched in 2006 and since the start of national data collection food voucher take-up has been high and vitamin voucher take-up has been very low; this is despite media campaigns, calls from the chief medical officers to encourage Healthy Start vitamin use, and a substantial body of evidence that vitamin D levels in the UK population are low. It would therefore suggest that continuing the Healthy Start vitamin programme in its current form is not going to increase the take-up of Healthy Start vitamins amongst the eligible population. It is also illogical that the population fulfilling the eligibility requirements for the food vouchers should be the same population targeted for the vitamin vouchers as most of the UK population have low levels of vitamin D; most of the UK population are not in need of the financial assistance provided through the food vouchers.

Taking into consideration that this study shows a higher take-up of Healthy Start vitamins in the universal area and that vitamin D deficiency is almost a universal problem for

the UK population, the universal provision of Healthy Start vitamins for pregnant women and preschool children is recommended.

Using the researcher's recent experience of childbirth, it is suggested that Healthy Start vitamin take-up could potentially be increased if midwives distributed vitamins to pregnant women during antenatal care and recorded this in the woman's 'green book' and health visitors distributed children vitamins during a woman's postnatal care and recorded this in the child's 'red book'. This approach would contribute to a reduction in the incidence of vitamin D deficiency and therefore reduce its prevalence. How to reduce the prevalence of vitamin D deficiency in the UK population was not a research question in this study though.

The most recent version of Healthy Start vitamin information online states that "Healthy Start vitamin distribution arrangements are the responsibility of the commissioning organisation for 0-5 services in the local area. Usually this sits within the Public Health Department at the Local Authority" (Appendix 12). This statement does not overcome the ad hoc supply of the vitamins from the Department of Health. The latter in turn does not overcome many of the barriers to take-up observed during this study.

5.6 Strengths and limitations of the mixed-methods study

The strengths and limitations of this mixed-method study should be considered from three key aspects: the quantitative component, the predominant qualitative component, and the nature of the 'mixing'.

5.6.1 Quantitative component

A major strength of the quantitative component of this mixed method study was the use of the national dataset that monitors Healthy Start vitamin voucher take-up. From the first five Healthy Start Unit quarterly reports, the reporting of the number of eligible participants (beneficiaries) and the number of eligible participants who exchanged their vitamin claim-

forms for vitamins allowed comparison of the vitamin take-up for women and preschool children between universal and targeted implementation areas.

There were, however, several limitations to using this dataset. Firstly, the data in each quarterly report were cross-sectional, giving only a 'snapshot' of vitamin take-up over three months. Secondly, as happens frequently with secondary analysis of a dataset, the data available were not aligned to the priorities of the research project. This study was limited to reporting the number of vitamin claim-forms sent to the Healthy Start Unit by a PCT as a proxy for vitamin take-up. The number of claim-forms reported per quarter could have been from either: 1) a minor proportion of the eligible participants who claimed their total vitamin allowance, e.g. a pregnant mother with a three-year-old and 18 month-old child could submit a maximum of two vitamin claim-forms for herself and four vitamin claim-forms for her two children, in one quarter, or 2) a larger proportion of the eligible population where individuals exchanged only one vitamin-voucher for vitamins per yearly quarter. From the interviews conducted with mothers, healthcare professionals, and commissioners, the latter seems more likely.

As the only information available was the number of vitamin-vouchers claimed by a PCT, no estimates of compliance with Healthy Start vitamins could have been ascertained. From the qualitative data, mothers varied from taking 'most of the vitamins' to 'threw them out after the first one'. Therefore, the percentage take-up of Healthy Start vitamins could be an overestimate of how many mothers and children took the vitamins.

In the UK, over 90% of the Healthy Start food vouchers issued by the national Healthy Start Unit to beneficiaries are claimed by a registered retailer (a retailer authorised to accept Healthy Start food vouchers in exchange for the purchase of fruits and vegetables, milk, and infant formula), but there are no requirements for retailers to record the products that are purchased. Therefore, no data on what foods were available and who consumed the food purchased were available; it was assumed that it was the eligible mothers and children. From the qualitative interviews, eligible mothers reported using the food vouchers

to purchase the recommended products unlike that found by Lucas et al. (2015), where food vouchers were sometimes used to purchase heating.

5.6.2 Qualitative component

A key strength of the qualitative component was the high recruitment of interviewees to each of the three sub-studies (mothers, healthcare professionals providing the relevant service, and commissioners of that service), with no-one approached refusing interview. This may have reflected a keen interest in the topic, with many mothers expressing frustration at their inability to access Healthy Start vitamins. It may have also reflected the power of networks, i.e. asking the Healthy Start leads from the universal and targeted areas to suggest healthcare professionals for interview. Though this purposive sampling strategy was successful, the people recommended for interview may have been more informed about the Healthy Start vitamin programme. The interviews with healthcare professionals suggested, however, that this was not the case. Furthermore, to overcome sampling challenges, the recruitment strategy involved my attending preschool playgroups to invite parents attending that day to interview. The researcher was able to interview two or more mothers at each playgroup attended; each playgroup usually had about eight carers, which typically comprised mothers, fathers, and grandparents.

Lincoln and Guba (1985) theorized that trustworthiness of a research study is important to evaluating its worth. In establishing trustworthiness, four criteria need to be addressed: credibility, transferability, dependability, and confirmability.

Credibility (the confidence in the 'truth' of the findings from the perspective of the participants): Before reaching the interview-stage of the research, the researcher was asked to support the commissioner who worked in the targeted area in her public health capacity. At the time, the researcher was also a clinical lecturer at the University of Liverpool with time allocated to the local health administrative area as an honorary NHS public health specialty registrar. It was through the interaction with the commissioner that the poor take-up of Healthy Start vitamins emerged. Before deciding on the research study, the

researcher was exposed to the environment in which the commissioner was working; the latter could be considered as time in the field. On starting this research study, the researcher accessed the Healthy Start Unit national datasets on food and vitamin voucher take-up, analysed these data, and conducted the qualitative interviews over a period of eighteen months. This allowed enough time to understand the context in which the healthcare professionals and commissioners were working. The researcher only met mothers who were potential participants once, in the children centres. Though a constructive rapport was established swiftly at the start of the interview with mothers, this relatively brief interaction may have been insufficient time to establish the level of trust needed for a mother to share issues such as stigma or shame. From the research perspective, the latter is not likely, as the researcher was intentionally observing the mother's body language during the interview. At no point did a sense of shame or belief of stigma come across from the mothers when describing how food and vitamin vouchers were used. Each interview was approached without a presupposition of the findings.

Triangulation was used to ensure the credibility of the research findings. Three types of triangulation were used: methods, sources, and analyst (Patton, 1999).

- Methods: Systematic quantitative observations were used to understand what was going on whilst semi-structured interviews were used to understand why the phenomena were occurring.
- Sources: Perspectives from four different sources were sought: mothers, healthcare providers, commissioners, and Healthy Start Unit staff. All interviewees, except for one healthcare provider, appeared to be White British. Though a comparison by ethnicity was not one of the objectives of my study, it would be interesting for future research to look at ethnic differences in vitamin voucher take-up.
- Analysts: The researcher was aware that coding was not an analytically neutral activity. By choosing certain pieces of data and applying codes, assumptions were made about the kinds of phenomena emerging, while also simultaneously disregarding other pieces of data. That participants repeated several phenomena

(overlapping with findings from established literature) suggested robustness, including external reliability, i.e. *"the level of replication that can be expected if similar studies are undertaken"* (Ritchie and Lewis, 2003), which here would be better termed transferability. The latter also relates to the dependability of the research findings (akin to internal reliability or inter-rater reliability in quantitative research), where other researchers are used to confirm the consistency of the analytical procedure. Here, two of the researcher's supervisors independently coded transcripts and the coding was compared for agreements whilst also looking for any blind-spots from I's perspective. Further to that, numerous supervisory discussions and correspondence with the three supervisors highlighted and reinforced emerging themes, comparisons to be pursued, and exceptions to note.

Confirmability: As the interviewer, the researcher was aware of possibly being perceived by interviewees as being at either a higher, equal, or lower position of power. This power dynamic could have affected the information shared by the interviewees. Perceptions about the interviewer's power may have arisen due to interviewees' assumptions about the interviewer's educational background, title as a doctor, ethnicity, and socio-economic status. The interviewer tried to overcome any perceived imbalances in power by building a constructive rapport with each interviewee before the start of the interview; when interviewing potentially eligible participants, the researcher sought to emphasise that she was there in her capacity as a research student and not as an NHS employee or doctor, to reduce perceived imbalances in power dynamics. The triangulation of methods, sources, and analysts also encouraged the neutrality.

Validity: In qualitative research, validity has been described as *"truth: interpreted as the extent to which an account accurately represents the social phenomena to which it refers"* (Hammersley, 1991, p.57) or the 'precision' of the research findings (Ritchie and Lewis, 2003). External validity asks how applicable the findings are to other populations versus internal validity, which considers whether the study explored its aim and objectives. This study shows robustness in credibility ('internal validity') as the themes generated are linked

to the study objectives. As for transferability ('external validity'), the researcher cannot declare how the research findings have applicability in other contexts from the perspective of the reader, but details of the following issues were given at the outset to support readers to decide for themselves how findings may be transferred to other contexts: a) the number of participants in the fieldwork, where they were based, and whether they were from a universal or targeted area; b) openness about the individuals who contributed and did not contribute data; c) the data collection methods that were employed; d) the number and length of the data collection sessions; and e) the time-period over which the data were collected (Shenton, 2004).

5.6.3 Mixed methods design

Using an element of 'mixing' justified the label of mixed-method research design (integrating both quantitative and qualitative methods), even though the qualitative component was predominant. Such mixing was a key strength of this study, enabling a more complete understanding of the take-up of Healthy Start vitamins than if either approach was used alone. To meet the two research objectives, a sequential explanatory design was used, with the second (qualitative) component facilitating rich insights into the explanatory and contextual factors surrounding the first component, the quantitative findings.

One key limitation in this mixed method design was, however, that the researcher was unable to link the potentially eligible interview participants to the quantitative data. The use of different samples, according to Creswell and Plano-Clark (2011), can be a risk to the validity of the study if the participants recruited in the qualitative research are unlikely to be able to explain the significant results identified in the quantitative research. Most of the population in both the universal and targeted areas were White British; therefore, the quantitative data would reflect this ethnic group. As the potentially eligible mothers interviewed in both the universal and targeted populations were White British, the samples in the quantitative and qualitative components were comparable.

5.6.4 From a personal perspective : Positionality and reflexivity

Positionality: I am a consultant in public health medicine and director of service improvement working in an acute NHS trust. The latter job role gives me the opportunity to understand the challenges facing NHS staff from both a 'shop floor' perspective where quality improvement projects are conducted as well as from a management perspective where strategic decisions are made. Due to the public health nature of the role, I have the opportunity to appreciate health and social care challenges from the perspective of NHS acute and community care services as well as from the local authority perspective. During the design and analysis of my study's findings I was able to flex between various perspectives to understand how the Healthy Start vitamin programme affected the various stakeholders.

I introduced myself to the participants as a researcher noting that my research contributed to a doctoral degree. The participants also knew I was a medical doctor who had worked in the area of public health with a keen interest in how welfare programmes for mothers and young children could be improved. This explicit clarification of my positionality appeared to provoke open and frank discussions. This may have been because the participants believed I had a vested interest in improving the welfare or health services they received.

Reflexive deliberations: Reflexivity has been described as "the recognition that I is part of the process of producing the data and their meanings, and a conscious reflection on that process." (Green and Thorogood, 2004, p.184). I was aware that my background and position (see p.58-59) affected what I "choose to investigate, the angle of investigation, the methods judged most adequate for this purpose, the findings considered most appropriate, and the framing and communication of conclusions" (Malterud, 2001 p.483). The following specific areas of prior knowledge and experiences influenced the research process:

- I am a Public Health consultant with a medical background, originally in general medicine working in an acute hospital setting for four years before Public Health.

- I am now a NHS senior manager with expertise in quality improvement methods and am aware of the considerable pressures under which NHS organizations have been operating, e.g. severe budget cuts, staff shortages, and the mandate to improve the quality of health and social care from NHS England without additional resources. The Department of Health required local health administration areas, primary care organisations at the time, to implement the Healthy Start programme without additional resources to incentivise key stakeholders such as GP surgeries.
- I am now a mother of two young children who has recently experienced the NHS healthcare system from pregnancy to postnatal care; I was aware that this experience in particular affected my analysis of the data and the angle from which conclusions were drawn. As a mother, I was disheartened by the ineffectiveness of a welfare programme designed to help mothers and children from low socio-economic backgrounds. I had to regularly detach myself emotionally from the research findings.

Over the study-period and write-up, I progressed from clinical lectureship (academic) to working in the Ontario public health system whilst completing a MSc in quality improvement and patient safety in Toronto, Canada, to NHS senior management (service-based in an acute trust) and my insight about the Healthy Start programme and about my own research approach developed. I became more aware of the challenges faced by the health and social care system, the differences between academic health services research and the implementation of health and social care services in the NHS setting, and the process issues related to quality that were impeding the delivery of high quality health and social care.

In turn, the research process changed my outlook in several ways. I learnt:

- the power of the supervisory conversation, responding to challenges about logic and justification, clarifying what I thought was obvious or had not yet considered. The power of supervisory conversations and their positive influence cannot be emphasised enough for my study

- how to keep focused on my research questions whilst reading relevant research about the Healthy Start programme and food supplementation programmes
- that for my study's findings to have any traction in terms of potentially influencing policy, the findings must be of interest to, at the minimum, local health and social care system leaders, as they are the individuals who decide on where financial resources are spent in the newly devolved health and social care system
- that health services research and the delivery of health and social care services can have a synergistic relationship, but frequently: 1) health and social care leaders do not have access to health services research, whether that be due to a lack of resources, including time, or other reasons and 2) the academic findings have to be translated into a format that is easily understood by those without an academic background
- that even though there may be a low take-up of a welfare programme, the individuals directly working to deliver the programme are working relentlessly to try to make the programme a success, despite knowing there are inefficient processes that they believe they cannot influence
- that quality improvement methods can add value in planning and evaluating public health programmes, as quality improvement practitioners have to describe what short-term measures will be used to determine whether the intervention is a success before the commencement of any initiative

Consequently, I have added a brief section to the Discussion chapter about the fundamentals of quality improvement methods and I understand that my study can add to the literature around how to improve the take-up of Healthy Start vitamins.

5.7 Conclusion and recommendations for further research

Drawing on the key findings and strengths and limitations of my study, the following section proposes implications for policy implementation and recommendations for future research.

1. The universal programmes achieved higher take-up than the targeted programmes, but the take-up was still very poor in both areas, not achieving levels anywhere near the take-up of the food vouchers. The universal programme: 1) in the Heart of Birmingham resulted in a 59% reduction in the number of cases of vitamin D deficiency between 2005 and 2010 (Moy et al., 2012) and 2) increased the vitamin voucher take-up in Blackburn and Darwen up to 67.5% (Collaborative Change Ltd, 2012). The ongoing high vitamin take-up in these areas was severely truncated by the ad hoc availability of vitamins from Department of Health-commissioned vitamin manufacturers, which not even the most thoroughly tested local implementation process could overcome. The universal programmes have demonstrated that, where implementation processes are functioning, there is the potential for higher vitamin take-up compared with targeted areas, followed by improved health outcomes for the population (Moy et al., 2012). Given this, together with the high prevalence of vitamin D deficiency in the UK, across several age-groups and ethnicities, there could be a strong ethical and economic case for implementing the Healthy Start vitamin programme universally. This study has demonstrated, however, that implementing the Healthy Start vitamin programme universally, in its current guise, may not lead to meaningful take-up of Healthy Start vitamins.

   Policy implication: Separate the two provisions encompassed within the Healthy Start programme and offer them as two independent programmes aiming to achieve two different outcomes: 1) the Healthy Start food voucher programme, with eligibility criteria, aiming to offer financial assistance to mothers and preschool children from lower socio-economic backgrounds encouraging the intake of fruits

and vegetables. 2) A vitamin supplementation programme for all pregnant women and preschool children with the aim of reducing the prevalence and incidence of vitamin D deficiency in the UK population. A potentially appropriate name for this vitamin programme could be a Strong Start.

2. Offering the vitamin programme universally to all pregnant women and preschool children may not lead to a higher percentage take-up or intake of vitamins. Building on offering the vitamins to all pregnant and lactating women and preschool children, from this study's findings, offering vitamins universally without changing any of the processes involved in vitamin distribution may not lead to a higher percentage take-up.

   Policy implication: Simplify the vitamin distribution and purchasing processes between the NHS Supply Chain and local vitamin distributors, making contingencies for when there is a low supply from the NHS Supply Chain vitamin supplier.

3. Distributing the vitamins universally, but only via children centres and NHS providers, may limit their accessibility and therefore take-up. This study has shown that mothers having to go to venues that were not part of their daily routine in order to exchange their Healthy Start vitamin vouchers for vitamins acts as a barrier to the take-up of the vitamins.

   Policy implication: Make Healthy Start vitamins available at local pharmacies and the major supermarkets, with the vitamin voucher used as the unit of exchange.

4. A pregnant woman is given information about the importance of vitamin D supplementation and Healthy Start vitamins at her booking-in clinic. The booking-in clinic takes about an hour and covers a myriad of issues including safeguarding issues, whether the mother currently receives welfare benefits, and whether the mother currently smokes, consumes alcohol or uses recreational drugs. As such, during the booking-in clinic, a mother may not recall the importance of vitamin D supplementation for her baby and the possible provision of Healthy Start vitamins. Additionally, babies who are drinking at least 500ml of formula per day do not need

Healthy Start vitamin supplementation (NHS. 2018); bottle feeding is high in the targeted population (Leeming, 2016).

Policy Implication: Give information universally about the importance of vitamin D supplementation for both mothers and preschool children at the booking-in clinic and remind all mothers of vitamin D supplementation at the 16-week and 12 month childhood vaccinations. Mothers who meet the eligibility criteria for Healthy Start vitamins can then request them and ideally the vitamins can be available from the health practitioner providing the vaccinations.

5. Looking at Figure 3.1, there was a steady increase in vitamin voucher take-up between October 2011 and December 2012, with the highest national take-up between October and December 2012. This increase in vitamin voucher take-up took place during the period of promotion of Healthy Start vitamins by the Chief Medical Offices of England (Davies, 2013) and increased debate via the national media about vitamin D deficiency (BBC News, 2011, 2012).

   Policy implication: The national Healthy Start programme should be accompanied by timely media campaigns, particularly in the period preceding autumn and winter.

Given the findings of this study (interpreted against the caveats that have been highlighted), the priorities for further research on this topic are:

1) Secondary analysis of the whole Healthy Start Unit vitamin take-up dataset could be undertaken to identify whether the areas in England that implemented the Healthy Start vitamin programme universally had a significantly higher vitamin take-up amongst women and preschool children from low-income families compared with areas that used the targeted implementation approach
2) If the finding from 1) above is consistent with this study, the ability to distinguish whether ethnicity contributed as a factor should be explored.

3) As this study and previous studies have explored the explanations for low vitamin take-up from potentially eligible participants, healthcare professionals, and commissioners, a study identifying the key process differences that facilitated high vitamin take-up would be informative. This could include only offering bottle-fed babies Healthy Start vitamins once the weaning process has commenced.
4) Considering that the explanatory factors behind the statistically significant difference in take-up of Healthy Start vouchers between the universal versus targeted area align with what is known about the importance of the environment when trying to encourage healthier behaviours (Moy et al, 2012), the role of the environment in facilitating higher take-up in Healthy Start vitamins should be explored.

5.8 Conclusion: How does this thesis add to the evidence?

The key finding that stands out from this study is that Healthy Start vitamin take-up throughout England is low and, based on the available evidence, has been consistently low since the launch and implementation of the Healthy Start programme in 2006. Several explanations emerged out of the qualitative interviews with mothers, providers, and commissioners, which can be summarised in one unifying factor, i.e. ineffective implementation.

This is the first study known to the researcher to describe systematically the process-steps a potentially eligible mother has to overcome in order to obtain Healthy Start vitamins. When comparing the two process-steps a pregnant mother from a higher income background must execute in order to obtain vitamins for herself and/or her preschool children, i.e. purchase vitamins and take the vitamins, with the over 14 process-steps that a low-income, potentially eligible mother has to overcome, one can hypothesise that if the implementation of the Healthy Start vitamins programme continues in its current form, any existing inequality in vitamin D deficiency will widen. It is worth noting that the process-steps described in Figure 5.2 are for English-speaking women. Additional processes, such as a translator, would have to be added for non-English speaking women.

This is also the first study known to the researcher that evaluates the take-up of Healthy Start vitamins, comparing a universal versus targeted approach to implementation. Though other studies have suggested that using a universal versus targeted implementation approach would increase the take-up of Healthy Start vitamins (Moy et al., 2012, McFadden et al., 2015), this is the first study to demonstrate that the solution to increasing Healthy Start vitamin take-up is not as simple as offering the vitamins universally.

This is also the first study known to the researcher that challenges the implementation processes of the Healthy Start vitamin programme from a quality improvement perspective. Before the programme's implementation, the Healthy Start Unit should have published: 1) what they were trying to achieve, 2) how this was going to be measured, then 3) using feedback from mothers, healthcare professionals, and commissioners, amended the implementation process so that 12 years after the Healthy Start programme was launched, vitamin take-up would not be so low.

This is also the first study to bring out the issue of poor monitoring of the Healthy Start vitamin programme with insufficient accountability structures in place. If effective accountability structures were in place, having local administration areas with no recorded take-up of Healthy Start vitamins for over three years would be unlikely.

In summary, the solution to increasing the take-up of Healthy Start vitamins is not as simple as offering the vitamins universally. The process-steps involved in Healthy Start vitamin programme implementation need to be reviewed, starting at the national level and with lessons learnt thus far. These lessons will be valuable in redesigning how the Healthy Start vitamin programme is implemented nationally. As described by some of the interviewees in this study, unless the delivery of the Healthy Start vitamin programme changes, a vast amount of hard work at a local level can still result in the low take-up of vitamins.

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Appendices

Appendix 1: Letter from the four chief medical officers, UK, to healthcare professionals about the importance of vitamin D supplementation, 2012

Vitamin D - advice on supplements for at risk groups

Llywodraeth Cymru
Welsh Government

Department of Health, Social Services and Public Safety

The Scottish Government

DH Department of Health

Our reference: CEM/CMO/2012/04
Gateway reference: 17193

To:
General Practitioners
Practice Nurses
Health Visitors
Community Pharmacists

2 February 2012

Dear Colleague

VITAMIN D - ADVICE ON SUPPLEMENTS FOR AT RISK GROUPS

We are aware that some of the UK population may be at risk of vitamin D deficiency. This is a concern, particularly for at-risk groups such as pregnant women and infants and young children, which is why we, the Chief Medical Officers for the United Kingdom, are writing to health professionals to increase awareness of this important issue.

Last year the Chief Medical Officer for Scotland, Sir Harry Burns, wrote to health professionals in Scotland on this topic.
http://www.scotland.gov.uk/Topics/Health/health/Health/EatingHealth/vitamind/CMOletter

This letter is a restatement of this advice and contains important information about prescribing and recommending vitamin D supplements to those groups of the population at risk of vitamin D deficiency.

The National Diet and Nutrition Survey, demonstrates that up to a quarter of people in the UK have low levels of vitamin D in their blood, which means they are at risk of the clinical consequences of vitamin D deficiency[1]. Although we do not have clear data on the implementation of the current advice on the use of dietary supplements containing vitamin D by

[1] Data from years 1 & 2 of the National Diet and Nutrition Survey (NDNS) rolling programme. Low status is defined by the Department of Health as a plasma concentration of 25-hydroxyvitamin D (25(OH)D, the main circulating form of the vitamin) of below 25nmol/l (equal to 10 ng/ml).

the at-risk groups listed below, information from the 2005 Infant Feeding Survey[2] suggests that the majority of women do not take vitamin D supplements during pregnancy.

Vitamin D deficiency impairs the absorption of dietary calcium and phosphorus, which can give rise to bone problems such as rickets in children, and bone pain and tenderness as a result of osteomalacia in adults.

The following groups of people are at risk of vitamin D deficiency:

- All pregnant and breastfeeding women, especially teenagers and young women.
- Infants and young children under 5 years of age.
- Older people aged 65 years and over.
- People who have low or no exposure to the sun, for example those who cover their skin for cultural reasons, who are housebound or confined indoors for long periods.
- People who have darker skin, for example people of African, African-Caribbean and South Asian origin, because their bodies are not able to make as much vitamin D.

Recommendations

All UK Health Departments recommend:

- **All** pregnant and breastfeeding women should take a daily supplement containing 10 micrograms of vitamin D, to ensure the mother's requirements for vitamin D are met and to build adequate fetal stores for early infancy.

- **All** infants and young children aged 6 months to 5 years should take a daily supplement containing vitamin D in the form of vitamin drops, to help them meet the requirement set for this age group of 7-8.5 micrograms of vitamin D per day. However, those infants who are fed infant formula will not need vitamin drops until they are receiving less than 500ml of infant formula a day, as these products are fortified with vitamin D. Breastfed infants may need to receive drops containing vitamin D from one month of age if their mother has not taken vitamin D supplements throughout pregnancy.

- People aged 65 years and over and people who are not exposed to much sun should also take a daily supplement containing 10 micrograms of vitamin D.

Are free vitamin D supplements available?

Women and children from families who are eligible for the Government's Healthy Start scheme[3] can get free vitamin supplements which include vitamin D, in the form of tablets for women and drops for children.

It is the statutory responsibility of PCTs, the local trust or Health Board[4] to make Healthy Start vitamins available locally to women and children on the scheme. Health

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[2] Bolling K, Grant C, Hamlyn B, Thornton A (2007). Infant Feeding Survey 2005. The Information Centre

[3] Healthy Start is a UK-wide statutory scheme providing a means-tested nutritional safety net to pregnant women and families with children under four years old in very low income and disadvantaged families. It provides vouchers for basic healthy foods and coupons for Healthy Start vitamin supplements to women and children in around 460,000 UK families.

professionals should familiarise themselves with local distribution arrangements for Healthy Start vitamins.

Uptake of the Healthy Start vitamins among families qualifying for the scheme is currently low. However, the UK Health Departments are committed to continuing to support NHS staff involved in maintaining local distribution arrangements, and those in a position to champion Healthy Start, to share and encourage good practice.

It is important that women and families who may be eligible for Healthy Start know how they can apply for the scheme, and are made aware of how they can obtain vitamins locally.

Women qualify for Healthy Start from the 10th week of pregnancy or if they have a child under four years old, **and** if she or her family receive:

- Income Support, or
- Income-based Jobseeker's Allowance, or
- Income-related Employment and Support Allowance, or
- Child Tax Credit (but not Working Tax Credit unless the family is receiving Working Tax Credit run-on only) **and** has an annual family income of £16,190 or less.

Women who are under 18 and pregnant also qualify, even if they do not get any of the above benefits or tax credits. Further information can be found on the Healthy Start website at www.healthystart.nhs.uk

NHS organisations can choose to sell the vitamins or supply them free of charge to those who are not eligible for Healthy Start, and we encourage this[5]. Alternatively, vitamin D supplements are available for purchase or can be prescribed for those who are not eligible for the scheme.

The National Institute for Health and Clinical Excellence (NICE) public health guidance on maternal and child nutrition[6] (published in 2008 and updated in 2011), supports the UK Health Departments' recommendations on vitamin D supplements. NICE recommend that during the booking appointment at the beginning of pregnancy, midwives should offer every woman information and advice on the benefits of taking a vitamin D supplement during pregnancy and while breastfeeding. NICE also recommend health professionals take particular care to check that women at greatest risk of deficiency are following the advice during pregnancy and while breastfeeding. This includes women from ethnic minority groups (particularly of African, South Asian or African-Caribbean origin) and women who do not get much sun (for example, women who cover their skin when outside or who spend large amounts of time indoors).

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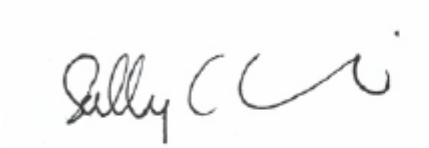
[4] The Healthy Start Scheme and Welfare Food (amendment No.2) Regulations 2006 (2818). Section 7 and The Healthy Start Scheme and Day Care Food Scheme Regulations (Northern Ireland) 2006 (S.R. 2006 No. 478) Regulation 11 *'Provision of Healthy Start vitamins'*

[5] For more information about Healthy Start vitamins including distribution case studies visit www.healthystart.nhs.uk/for-health-professionals/vitamins

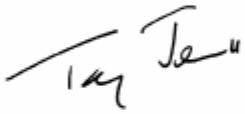
[6] NICE public health guidance (2008). PH11 *Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households.*

It is important for public health that low levels of vitamin D are avoided. As health professionals, you can make a significant difference to people's health by making those at risk aware of how important it is to make sure they get enough vitamin D, and how they can get access to these important daily supplements.

We, the Chief Medical Officers, thank you for your continued help and support with raising awareness of this issue, which in turn should raise the levels of vitamin D in those at risk, and vulnerable groups.



PROFESSOR DAME SALLY C DAVIES
CHIEF MEDICAL OFFICER ENGLAND
CHIEF SCIENTIFIC ADVISER



DR TONY JEWELL
CHIEF MEDICAL OFFICER WALES

DR MICHAEL McBRIDE
CHIEF MEDICAL OFFICER NORTHERN IRELAND

Sir HARRY BURNS
CHIEF MEDICAL OFFICER SCOTLAND

Appendix 2: Letter of sponsorship from the University of Liverpool for the research study "Exploring the implementation of the Healthy Start vitamin supplementation programme"

Faculty Support Office
University of Liverpool
1st Floor Duncan
Building
Daulby Street
Liverpool
L69 3GA

Tel 0151 706 4523
Fax 0151 706 5668
Lindsay.Carter@liv.ac.uk

Faculty of Health and Life Sciences Ref: UoL000752

Dr Barbara Hanratty (May Moonan)
Institute of Psychology, Health & Society

Thursday, 09 June 2011

Dear Dr Hanratty

I am pleased to confirm that the University is prepared to act as Sponsor under the Department of Health's Research Governance Framework for Health and Social Care 2nd Edition (2005) for your study entitled "Exploring the implementation of the Healthy Start vitamin supplement programme". This approval for sponsorship is subject to the following.

1. The University expects you, as Chief Investigator, to conduct the study in full compliance with the requirements of the Framework so that it is able to meet its obligations as Sponsor.

2. In addition to sponsorship, your study will require NHS ethical approval through the National Research Ethics Service (NRES). If you have not already done so, in order to apply for this please use the Integrated Research Application System (IRAS) at https://www.myresearchproject.org.uk/Home.aspx. Please contact me on 0151 706 4523 or at sponsor@liv.ac.uk for further advice.

3. As the Chief Investigator, the University expects you to comply, where appropriate, with the University's policy on the use and / or storage of human tissues, details of which may be found at www.liverpool.ac.uk/humantissues.

4. If you wish to conduct any part of the study in a site outside the UK or you wish to sub-contract any part of the study to a third party please contact me to ensure that appropriate contractual arrangements are in place.

5. University professional indemnity and clinical trials insurances will apply to the study as appropriate. This is on the assumption that no part of the clinical trial will take place outside of the UK. Such cover will extend to cover for non-negligent harm.

I trust that this statement will enable you to proceed with your research but if you have any queries please contact me on 0151 706 4523 (email sponsor@liverpool.ac.uk).

Yours sincerely

L. Carter

Mrs Lindsay Carter
Research Coordinator, Faculty of Health & Life Sciences

Cc Head of Institute, *Insert Name of Institute*

Appendix 3: Local research governance approval from Liverpool Primary Care Trust to conduct interviews with staff and potentially eligible mothers

Liverpool NHS
Primary Care Trust

Research Governance
Liverpool & Sefton PCTs
Liverpool PCT
1 Art House Square
2nd Floor
61-69 Seel Street
Liverpool
L1 4AZ
Tel: 0151 296 7726
Fax: 0151 296 7676
Email: gabrielle.marr@liverpoolpct.nhs.uk
Main Switchboard: 0151 296 7000

1st November 2011

Dear Dr Moonan

Re: Exploring the implementation of the health schools programme

I am pleased to inform you that your request to carry out the above research has been given approval by the Liverpool & Sefton PCTs Research Management and Governance Collaborative Chair.

As discussed we will issue you with an NHS to NHS letter of access. I will therefore require a completed copy of the pre-engagement check form, an up to date CV and a copy of the confirmation of details form which I will email to you.

As discussed and agreed the Research Sponsor for the project is the University of Liverpool.

In line with national policy, the Organisation will not give approval for any NHS research work which does not comply with Research Governance guidelines. (The Research Governance Framework for Health and Social Care is available from the DH website).

The Principle investigator is required to send a final report and a lay summary to the Organisation within 3 months of the completion date of the research project.

In particular, it is a condition of our approval that the PCT Research Department must be notified of:

- Commencement and completion of the study;
- Provide accrual numbers every 3 months to R&D office;
- Any significant changes to the study design;
- Any further decisions made by a Research Ethics Committee regarding this study, and copies of the relevant correspondence;
- Any serious adverse events on participants or staff;
- Any suspension or abandonment of the study.

Please sign and return the enclosed investigators agreement prior to starting your research.

I look forward to receiving a copy of your final report.

Yours sincerely

Gabrielle Marr
On behalf of
Liverpool & Sefton PCTs
Research Management &
Governance Collaborative

Encl. (1)

Appendix 4: Local research governance approval from Blackburn with Darwen Primary Care Trust to conduct interviews with staff and potentially eligible mothers

Blackburn with Darwen NHS
Teaching Care Trust Plus

Guide Business Centre
School Lane
Guide
Blackburn
BB1 2QH

Dr Helen Lowey
Associate Director of Public Health
Tel: (01254) 282 056
Fax: (01254) 282 002

RM&G Contact
CLRN RM&G Coordinator: Nicky Dooley
Nicola.Dooley@lthtr.nhs.uk
Tel: 01772 524946

Ref: HL/NJD/62940

2nd June 2011

Dr Patricia Lucas
Chief Investigator
School for Policy Studies
University of Bristol
8 Priory Road
Bristol, BS8 1TZ

Dear Dr Lucas

Research Protocol: **The Healthy Start Voucher Study**
REC Reference: **10/IEC08/36**
CSP ID Number: **62940/CL**
Protocol: **V3**

NHS Permission includes review of Amendment 1 - dated 09/03/2011

We are pleased to inform the Research Management and Governance (RM&G) process for your project has been completed successfully and **NHS Blackburn with Darwen Teaching Care Trust Plus** (NHS BwD TCT+) has granted NHS Permission for your project.

All research carried out within NHS BwD TCT+ must be in accordance with the principles set out in the Research Governance Framework for Health and Social Care (Second Edition, DH 2005).

Please ensure that all amendments are sent to the Lead CLRN Western for uploading on to CSP. Protocol amendments may require further review by the Social Care REC before they are implemented; further information is available via the NIHR or REC webpages.

As previously discussed should any members of the Research Team require letter of access or research passports please contact **Nicky Dooley, RM&G Coordinator** details at top of this letter.

NHS BwD TCT+ should be informed of the outcome of the research, in particular any presentation of the results at scientific or professional meetings, papers published or direct and indirect impacts on patient care.

May I also draw your attention to the need to comply with the Health & Safety at Work Act, the Data Protection Act and the Human Tissue Act 2004.

As your study has been included on the UKCRN Clinical Research Portfolio it is important that you send your accrual information on a monthly basis to the specified network. This will ensure that the Trust will be allocated the necessary funding from the Cumbria and Lancashire CLRN.

Please contact us if you require any further guidance or information on any matter mentioned above.

We wish you every success in your research.

Yours sincerely

Dr Helen Lowey
Associate Director of Public Health

Copy to:

Tricia Jessiman
School for Policy Studies
University of Bristol
8 Priory Road
Bristol, BS8 1TZ

Appendix 5: Local research governance approval from Liverpool Women's NHS Foundation Trust to conduct interviews with staff and potentially eligible mothers

Liverpool Women's NHS
NHS Foundation Trust

Crown Street
Liverpool
L8 7SS

Tel: 0151 708 9988
www.lwh.nhs.uk

27th July 2012

Dr May Moonan
Clinical Lecturer in Public Health Medicine
NICE Scholar/Specialty Registrar in Public Health
Department of Public Health and Policy
Institute of Psychology, Health and Society
University of Liverpool
3rd Floor, Whelan Building
The Quadrangle
Liverpool L69 3GB

Direct dial: 0151 702 4346
Email: gillian.vernon@lwh.nhs.uk

Dear Dr Moonan

LWH0941: Exploring the implementation of the Healthy Start vitamin supplement programme

Following submission of project documents and associated paperwork to the Trust's R&D Department, I am pleased to inform you that your research project has been approved.

This project involves NHS staff only and in-line with the current guidance does not require a favourable approval from an independent Research Ethics Committee.

The research is registered on the Trust's R&D database under the reference LWH0941, which I would be grateful if you could quote in all future correspondence regarding the project.

The Sponsor(s) of this research project under the Research Governance Framework for Health and Social Care (RGF) is the University of Liverpool.

Having gained approval to conduct this research under the auspices of Liverpool Women's NHS Foundation Trust, you will be expected to comply with the principles and guidelines set out in ICH Good Clinical Practice and the Department of Health RGF. Our Trust R&D Department must be kept informed of regulatory amendments, updates and approvals.

I would like to take this opportunity to wish you the best of luck with this research and to request a copy of the final report and any subsequent publications.

Regards,

Gillian Vernon
Research & Development Manager

Appendix 6: Participant consent form for mothers, healthcare providers and commissioners to conduct a semi-structured interview concerning Healthy Start vitamin supplementation

IN CONFIDENCE

Participant Consent form

Exploring the implementation of the Healthy Start vitamin supplement

You do not have to print your name.

You, the participant should complete the whole of this sheet by yourself.

(Please tick the box if you agree)

I have read the information-sheet and had an opportunity to ask questions and ☐

I understand that I am free to withdraw from the study at any time without it affecting my future care

I wish to take part in the study ☐

Signature of participant: .....

Date:

Code number of participant:

Signature of person obtaining consent i.e. the researcher: .....

Date: Dr May Moonan

Appendix 7: Participant information-sheet for mothers, healthcare providers and commissioners explaining the purpose of the Healthy Start vitamin supplementation study

UNIVERSITY OF LIVERPOOL

Exploring the implementation of the

Healthy Start vitamin supplement programme

PARTICIPANT INFORMATION SHEET

Dear Participant,

You are being asked to take part in a research project. Before you make a decision, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is unclear, or if you would like more information, please do not hesitate to contact the researcher. Contact details are available at the end of this sheet, with an accompanying tear off slip. Take time to decide whether or not you wish to take part.

Thank you for reading this letter.

1. What is the purpose of the study?

The purpose of this study is to gather views on the delivery of a public health vitamin programme, Healthy Start, from professionals and potential recipients of the programme. Different ways of making the vitamins have been tried. Some areas, such as Liverpool, offer the vitamins to families with low incomes. Other areas, such as Sefton, offer the vitamins to all families. This study will help to answer the question of whether it would be better for the recipients and the NHS to offer vitamins to all pregnant women and children less than 4 years of age, or to offer the vitamins only to pregnant women and children who are less financially well-off.

2. Why have I been invited?

You have been invited because you could be taking part in the Healthy Start programme in Liverpool or Sefton.

3. Do I have to take part?

No, you do not have to take part. You will be given this information sheet to keep if you decide to take part and will be asked to sign a consent form. You are free to stop taking part at any time without giving a reason, even after signing the consent form.

4. What will happen to me if I would like to take part?

We will ask for your permission to allow the researcher the contact you via telephone to discuss the study with you and answer any questions you may have about the study. If you are happy to be interviewed after this discussion, the researcher will arrange a convenient time and place with you for the interview. The interview can either be face to face or over the telephone, whichever you prefer.

5. What will happen during the interview?

You will be asked some questions about the Healthy Start programme and Healthy Start vitamins. There are no right and wrong answers; we would like to hear about your experiences and your views. The interview will be audio-recorded with your permission. All material will be confidential. No one will know that you have taken part if you do not tell them and every effort will be made to ensure that you are not identifiable from any reports written about the Healthy Start programme.

6. How long with the interview last?

This interview should take no longer than 45 minutes (but can take longer if you wish).

7. What are the possible disadvantages and risks of taking part?

We do not think there are any risks to taking part in this study. You may stop the interview at any point if you are uncomfortable with any of the questions.

8. What are the possible benefits of taking part?

There are no direct benefits to you from taking part. We hope that you will find the interview interesting. We also hope that the information we get from this study can be used to help improve public health services.

9. What if something goes wrong?

If you wish to make a complaint about this study you may contact Rob Turner, Research Officer, Faculty Support Office, Faculty of Health and Life Sciences, University of Liverpool, 0151 706 4278. Email: sponsor@liverpool.ac.uk

10. Will my taking part in the study be kept confidential?

Yes. All information about you will be kept strictly confidential. Before you begin the interview you will be given a 'code number' which will be used throughout the interview. Only the researcher will know the names for each 'code number'.

11. What will happen to the results of the research study?

The results of this study will be published in print and online journals. A brief report, highlighting the key findings from the research, will also be written the Primary Care Trust, Local Authority and National Institute of Clinical Excellence. Your name and any other personal details will not be linked with the information you provide. All information you provide will be seen only by the researcher and will be kept securely so no-one else can access it.

12. Who is organising and funding the research?

This research is being funded by the University of Liverpool, with the National Institute of Health and Clinical Excellence (NICE) supporting some aspects about the way the research is done.

13. Who has reviewed the ethical issues around this study?

The study has been considered and approved by NRES Committee East Midlands – Derby 1

14. Contact for further information

You can contact May Moonan on 0151 794 5568 or at may.moonan@liv.ac.uk should you wish to ask more questions.

Thank you very much for spending time to read this information sheet.

Dr May Moonan, University of Liverpool, School of Population, Community and Behavioural Sciences, Division of Public Health, Whelan Building, Brownlow Hill, Liverpool L69 3GB.

.....

Please contact for further information:

May Moonan

Telephone: 0151 794 5568

Email: may.moonan@liv.ac.uk

V2 Page | 2 18.10.11

If you'd like to contribute to this project please provide further contact information:

Name:

Job role:

Best contact number:

Email:

Appendix 8: Healthy Start food and vitamin voucher uptake for July to September 2009 for primary care trusts in North West England

Vitimin uptake by PCT in England

Quarter ending September 2009/10

Code	Region	Code	PCT	1.) Estimated number of beneficiaries in cycle 84	2.) Children's drops claimed for	3.) Cost of drops claimed for	2.) Children's drops claimed for / 4.) Potential number of drops if 100% uptake	4.) Potential number of drops if 100% uptake	5.) Potential claim for drops if 100% uptake	6.) Women's tablets claimed for	7.) Cost of women's tablets claimed for	6.) Women's tablets claimed for / 10.) Total potential number of tablets if 100% uptake for all women	8.) Potential number of tablets if 100% uptake for pregnant women	9.) Potential number of tablets if 100% uptake for women with children under one	10.) Total potential number of tablets if 100% uptake for all women	11.) Potential claim for tablets if 100% uptake for all women	12.) When invoice last received...
B	North West	5HG	Ashton, Leigh and Wigan PCT	2818	59	£94.99	1.5%	3889	£6,261.03	35	£24.50	3.4%	338	705	1043	£729.86	Sep-09
B	North West	5CC	Blackburn with Darwen PCT	2075	81	£130.41	2.8%	2864	£4,610.24	22	£15.40	2.9%	249	519	768	£537.43	Sep-09
B	North West	5HP	Blackpool PCT - NIL RETURN	2064		£0.00	0.0%	2848	£4,585.80		£0.00	0.0%	248	516	764	£534.58	Sep-09
B	North West	5HQ	Bolton PCT	3047		£0.00	0.0%	4205	£6,769.82		£0.00	0.0%	366	762	1127	£789.17	Pre March 08 or never
B	North West	5JX	Bury PCT	1545	25	£40.25	1.2%	2132	£3,432.68	5	£3.50	0.9%	185	386	572	£400.16	Sep-09
B	North West	5NP	Central and Eastern Cheshire PCT	2725		£0.00	0.0%	3761	£6,054.41		£0.00	0.0%	327	681	1008	£705.78	Pre March 08 or never
B	North West	5NG	Central Lancashire PCT	3474	30	£48.30	0.6%	4794	£7,718.53	1	£0.70	0.1%	417	869	1285	£899.77	Sep-09
B	North West	5NE	Cumbria PCT	3098		£0.00	0.0%	4275	£6,883.14		£0.00	0.0%	372	775	1146	£802.38	Mar-09
B	North West	5NH	East Lancashire PCT	3709	193	£310.73	3.8%	5118	£8,240.66	174	£121.80	12.7%	445	927	1372	£960.63	Sep-09
B	North West	5NM	Halton and St Helens PCT	3868	26	£41.86	0.5%	5338	£8,593.92	9	£6.30	0.6%	464	967	1431	£1,001.81	Sep-09
B	North West	5NQ	Heywood, Middleton and Rochdale PCT	2873		£0.00	0.0%	3965	£6,383.23		£0.00	0.0%	345	718	1063	£744.11	Jun-09
B	North West	5J4	Knowsley PCT	2441		£0.00	0.0%	3369	£5,423.41		£0.00	0.0%	293	610	903	£632.22	Pre March 08 or never
B	North West	5NL	Liverpool PCT	6124	132	£212.52	1.6%	8451	£13,606.30	134	£93.80	5.9%	735	1531	2266	£1,586.12	Dec-08
B	North West	5NT	Manchester PCT	8521		£0.00	0.0%	11759	£18,931.96		£0.00	0.0%	1023	2130	3153	£2,206.94	Pre March 08 or never
B	North West	5NF	North Lancashire PCT	1914		£0.00	0.0%	2641	£4,252.53		£0.00	0.0%	230	479	708	£495.73	Pre March 08 or never
B	North West	5J5	Oldham PCT	3037	78	£125.58	1.9%	4191	£6,747.61	18	£12.60	1.6%	364	759	1124	£786.58	Sep-09
B	North West	5F5	Salford PCT	3253		£0.00	0.0%	4489	£7,227.52		£0.00	0.0%	390	813	1204	£842.53	Jun-09
B	North West	5NJ	Sefton PCT	2134		£0.00	0.0%	2945	£4,741.32		£0.00	0.0%	256	534	790	£552.71	Pre March 08 or never
B	North West	5F7	Stockport PCT	2012		£0.00	0.0%	2777	£4,470.26		£0.00	0.0%	241	503	744	£521.11	Pre March 08 or never
B	North West	5LH	Tameside and Glossop PCT	2720	9	£14.49	0.2%	3754	£6,043.30	4	£2.80	0.4%	326	680	1006	£704.48	Sep-09
B	North West	5NR	Trafford PCT	1378		£0.00	0.0%	1902	£3,061.64		£0.00	0.0%	165	345	510	£356.90	Jun-09
B	North West	5J2	Warrington PCT	1302		£0.00	0.0%	1797	£2,892.78		£0.00	0.0%	156	326	482	£337.22	Sep-08
B	North West	5NN	Western Cheshire PCT	1405		£0.00	0.0%	1939	£3,121.63		£0.00	0.0%	169	351	520	£363.90	Pre March 08 or never
B	North West	5NK	Wirral PCT	3729	23	£37.03	0.4%	5146	£8,285.09	1	£0.70	0.1%	447	932	1380	£965.81	Sep-09

1.) This is the total number of beneficiaries on the scheme within the 4 week period, including those who began and finished during this time.
2.) This is the number of children's drops that we have received a claim for, for this quarter. If blank, that means no invoice has been received to date.
3.) This is the total cost for the amount claimed for. (Children's drops cost £1.61)
4 & 5.) This is an estimate amount of the number and cost of children's drops which could have been given out if there was 100% uptake.
6.) This is the number of women's tablets that we have received a claim for, for this quarter. If blank, that means no invoice has been received to date.
7.) This is the total cost for the amount claimed for. (Women's tablets cost 70p)
8.) This is the estimate number of women's tablets which could have been given out to pregnant women if there was 100% uptake.
9.) This is the estimate number of women's tablets which could have been given out women who have a child under one year old if there was 100% uptake.
10 & 11.)This is an estimate amount total number and cost of women's tablets which could have been given out if there was 100% uptake.

Appendix 9: Semi-structured interview-schedule for potentially eligible mothers for Healthy Start vitamins

Interview Schedule for potentially eligible recipients of Healthy Start vitamins

Box 5.1

Exploring the implementation of the Healthy Start vitamin supplement programme

Interviewee details: sex, ethnicity, rough age, number of children, employment status

1. **Awareness of the Healthy Start programme**

- What sort of support or advice did you receive during your pregnancy about healthy eating and helping your child grow up strong and healthy?
- Do you think your midwife or health visitor was particularly helpful in giving you advice about this?
- How was giving your child a healthy start in life discussed? How did this make you feel?
- Tell me a bit about the Healthy Start programme if this was discussed during or after your pregnancy.

2. **Awareness of Healthy Start vitamin supplements**

- What do you think about using vitamin supplements during pregnancy?
- What do you think about young children using vitamin supplements?
- Was the use of vitamin supplements either during your pregnancy or whilst your child was under the age of four years ever discussed with you by a health professional?
- What do you know about Healthy Start vitamin supplements?

3. **Uptake of the Healthy Start vitamins**

The uptake of Healthy Start vitamins has been low within this area and across the country.

- As a mother, do you have any thoughts about why this may be the case?
- What do you think about offering Healthy Start vitamins to all pregnant women and children under the age of four years at no cost to the parent?
- What are your views about only offering the Healthy Start vitamins to pregnant women and young children of parents who are on income support or another form of benefit, including child tax credits?

4. **Access to Healthy Start vitamins**

- If applicable, tell me about how you found out where to go to get the vitamins?

Interview Schedule for potentially eligible recipients of Healthy Start vitamins

- Did you ever have any problems getting the vitamins or the vitamin vouchers?

5. If you had the opportunity and knowing a bit more about the Healthy Start vitamin programme now, how would you run the Healthy Start programme?

- Would you offer the vitamins to all pregnant women and children?
- Would you offer the vitamins to only families with low incomes?

6. Concluding remarks and questions

- Is there anything else that you want to add about the Healthy Start programme?
- Thank you for taking part in an interview today.
- Could you suggest anyone else who I should talk to?

A Healthy Start booklet will be available should the interviewee want any further information about the programme.

Appendix 10: Interview-schedule that was used to guide the interviews with healthcare providers and commissioners concerning the Healthy Start vitamin supplementation programme

Exploring the implementation of the Healthy Start vitamin supplement programme:
Interview schedule for providers

Interviewee details:

Sex	Ethnicity	Age	Organisation	Profession	Area

Targeted area (Liverpool) **Universal area (Sefton)**

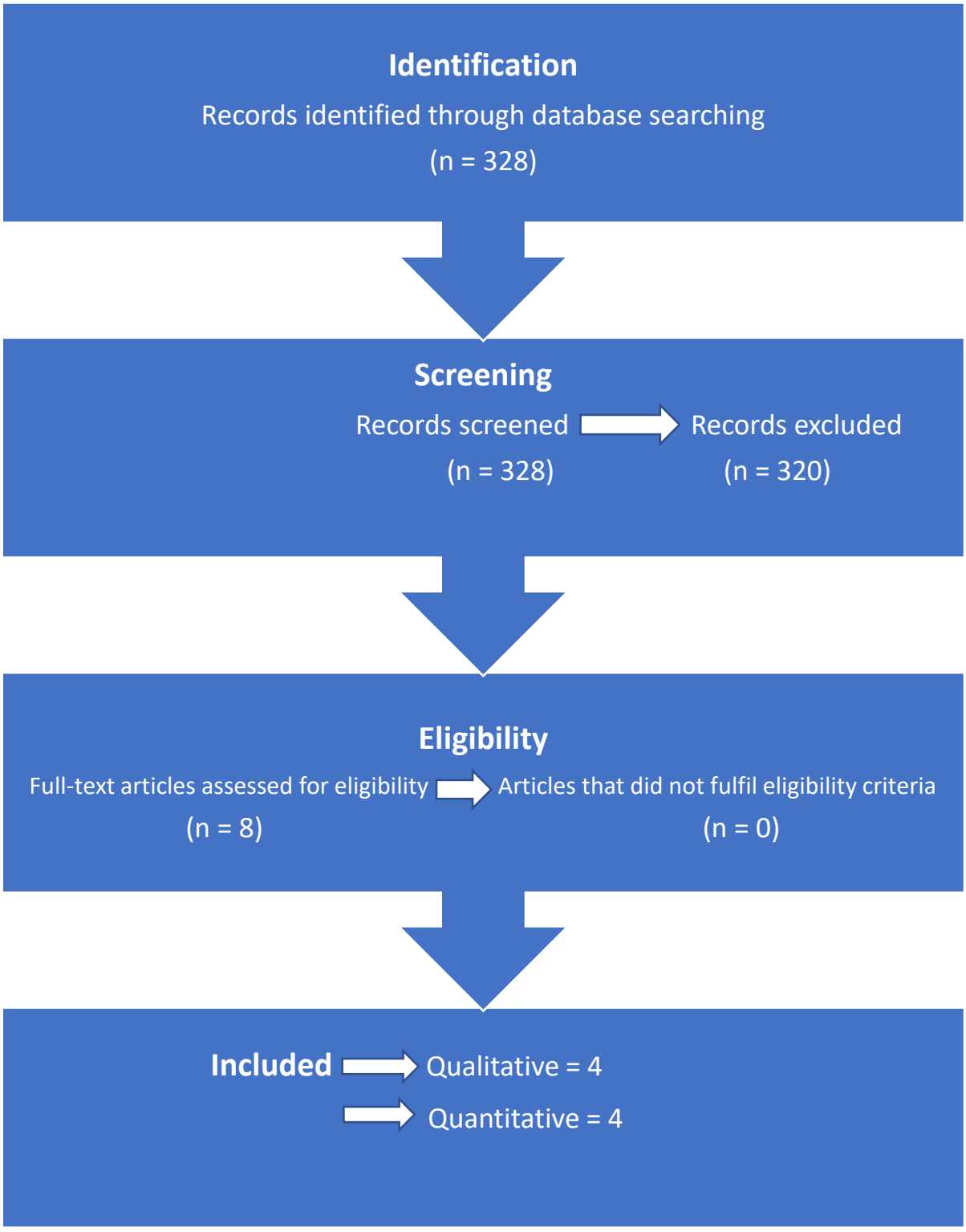
****

1. **Could you tell me a little bit about your role as a midwife/HV/GP/LA employee**
2. **How long have you been in this role?**
3. **What sort of things are you aware of about Healthy Start?**
4. **Could you tell me about how the Healthy Start scheme is offered to mothers?**
5. **What sort of training is offered to you about Healthy Start?**
6. **Healthy Start vitamin uptake is relatively low compared to food vouchers across the country. From you experience, have mothers mentioned any barriers to accessing or using Healthy Start vitamins?**
7. **Is there anything that sticks in your mind about the vitamin vouchers, maybe through a conversation with a mother or colleague?**
8. **From your experience, have mothers mentioned anything which would facilitate the uptake of Healthy Start vitamins?**
9. **From your conversations with mothers, what are your thoughts about their level of awareness of the potential benefits of the Healthy Start vitamins?**
10. **As a provider, do you think there is anything that can be done differently to increase the uptake of Healthy Start vitamins?**
11. **Are you aware of any evidence supporting the use of Healthy Start vitamins?**
    (If the interviewee does not mention NICE I will briefly introduce the guidance here)
12. **Is there anything NICE can do differently to make health professionals aware of relevant guidance supporting your professional practice?**
13. **If you know NICE supports your area of professional practice, how would this affect your day to day practice?**
14. **Is there anything else you think I should be aware of concerning the Healthy Start scheme**

Thank you: Is there anyone else who would recommend I speak to?

Appendix 11

PRISMA (Liberati et al., 2009) flow-chart of the structured literature review: **"What is known about the implementation of the UK Healthy Start vitamin programme?" (January 1990 – March 2018)**



Criteria used to select studies for data collection of the structured literature review: “What is known about the implementation of the UK Healthy Start vitamin programme?” (January 1990 – March 2018)

Study design: Primary and secondary empirical studies

Participants/population: Mothers and preschool children in the UK from January 1990 to March 2018

Intervention: Universal and/or targeted (means-tested) implementation of the Healthy Start programme

Outcome measures: Take-up or participation

Publication characteristics: English language, UK, humans

Appendix 12: Information about Healthy Start vitamins for Health Professionals available (2018) https://www.healthystart.nhs.uk/for-health-professionals/vitamins/

Vitamins

How Healthy Start vitamins are made available across the UK varies from country to country. To find out more select a country:

England

Northern Ireland

Scotland

Wales

About Healthy Start vitamins

Pregnant women, women with a child under 12 months and children aged from six months to four years who are receiving Healthy Start vouchers are entitled to free Healthy Start vitamins.

Healthy Start vitamins contain vitamins A, C and D for children aged from six months to four years, and folic acid and vitamins C and D for pregnant and breastfeeding women.

Healthy Start vitamins are important because:

- 8% of children under five in the UK don't have enough vitamin A in their diet[1]
- families in lower-income groups tend to have less vitamin C in their diet[1]
- all pregnant and breastfeeding women and young children are at risk of vitamin D deficiency[2] (teenagers, younger women and those from ethnic minorities are particularly at risk).

Two bespoke Healthy Start branded products are available:

- Healthy Start children's vitamin drops (containing vitamins A, C and D)
- Healthy Start vitamins for women (containing folic acid and vitamins C and D).

Every eight weeks beneficiaries are sent a green vitamin voucher, which they can swap for either Healthy Start women's vitamin tablets or Healthy Start children's drops locally.

Healthcare professionals should discuss the importance of vitamin supplements with beneficiaries and advise them where they can swap their green vitamin coupons locally.

To find out how we advise beneficiaries to get vitamins locally **click here**.

Healthy Start children's vitamin drops
Children receiving Healthy Start vouchers qualify for free vitamin supplements from six months old until their fourth birthday. The daily dose of five drops contains:

- 233 micrograms of vitamin A
- 20 milligrams of vitamin C
- 7.5 micrograms of vitamin D3

Children who are having 500ml or more of formula a day do not need Healthy Start vitamins.

The vitamins are suitable for vegetarians and free from milk, egg, gluten, soya and peanut residues, and have a shelf life of 10 months from manufacture. They come in 10ml bottles, each of which contains just over 56 daily doses. Beneficiaries are entitled to one bottle every eight weeks.

Healthy Start women's vitamin tablets
The daily dose is one tablet, which contains:

- 70 milligrams of vitamin C
- 10 micrograms of vitamin D
- 400 micrograms of folic acid.

They are suitable for vegetarians and free from wheat, fish, egg, salt. No colours, flavours or preservatives. No gluten containing ingredients.

The shelf life is two years from manufacture. Beneficiaries are entitled to one bottle of 56 tablets every eight weeks.

[1]Scientific Advisory Committee on Nutrition (2008) *The Nutritional Wellbeing of the British Population*. London: TSO.
[2]Scientific Advisory Committee on Nutrition (2007) *Update on Vitamin D*. London: TSO.

Appendix 13: Which is more Effective, A Universal or Targeted Approach, to Implementing the National Healthy Start Programme? A Mixed Methods Study

M Moonan, B Hanratty, M Whitehead

Background Healthy Start is a statutory scheme in the UK, aiming to improve the health of children and pregnant or lactating women by providing food vouchers and vitamins. The Department of Health intended the intervention to be targeted to low incomes families (a targeted approach), but in some areas Healthy Start vitamins are available to eligible mothers and children independent of income (a universal approach). The aim of this study is to investigate which approach is more effective and to identify barriers to implementation.

Methods 1) Systematic review of the literature to identify which approach, universal vs. targeted, achieves the highest coverage of vitamin use in preschool children and pregnant women.; 2) Using national data, a comparison of vitamin uptake rates in targeted and universal areas.; 3) In depth qualitative interviews with 30 commissioners, providers and service users from a targeted and universal area. Data were thematically analysed.

Results 1) Initial findings from the systematic literature review reveals that universal supplementation of vitamins such as folic acid significantly reduces the incidence of preventable ill health due to vitamin deficiencies such as neural tube defects compared to a targeted approach.; 2) In areas using the targeted approach, the uptake of children's drops and women's tablets was 1.46% and 2.56% respectively. In the area that adopted a universal approach, the uptake of children's drops and women's tablets was 3.97% and 7.72% respectively. ; 3) Barriers shared by both approaches include a lack of awareness of the scheme amongst health professionals, onerous administrative processes and the availability of vitamins. The universal approach is supported by health professionals because it does not stigmatise recipients.

Conclusion 1) From the systematic review, mandatory universal fortification of foods, e.g. flour is a major public health opportunity for the UK.; 2) Uptake of Healthy Start food vouchers and vitamins is low whatever the implementation strategy. However, uptake of Healthy Start vitamins is significantly higher in areas adopting a universal approach to implementation. A universal approach to implementation is supported by the literature and this study suggests that it may overcome some barriers to the implementation of the Healthy Start scheme nationally.; 3) In particular, a universal approach may reduce some of the administrative hurdles confronted by a targeted approach and will also address the stigma associated with the use of Healthy Start vitamins.