THE MANAGEMENT OF PAEDIATRIC GASTROENTERITIS

At home and within UK primary care.

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We are made to persist.
That's how we find out who we are.

Tobias Wolff

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Summary

Paediatric gastroenteritis [GE] is a common and important condition that causes a considerable burden on the NHS, the families and the patient. Despite this, the evidence for effective management is limited. Only a proportion of patients (and parents) consult, but we know little about their reasons for consulting and how they manage the illness at home.

Using a mix of methods this project aimed to explore the current management of paediatric gastroenteritis in the United Kingdom, focussing specifically on home management and primary care consultations.

A prospective case series was designed in which primary care clinicians within Wales identified and invited paediatric patients (and their parent) to take part in the study. Baseline information was recorded for all eligible patients. Parents of eligible patients were invited to take part in a qualitative telephone interview as well as being identified through social media. Clinicians were approached to take part in a separate qualitative study. Anonymous patient records of paediatric patients presenting to primary care between 2003 and 2012 were extracted from CPRD

Results show a decrease in consultation rates over 10 years however hospital referrals and stool sample requests have increased. Parents' attitudes toward GE management impacted on their actions around prevention of illness and transmission. The variety of beliefs around causes of and threats from GE also influenced their actions. Reported clinical decisions and advice to parents were often not in line with current guidance from expert bodies. Many clinicians were not aware of guidelines on managing paediatric GE which might account for some of the variability in their management.

Variation can ultimately result in inappropriate management and thus increase the burden of illness on both families and the NHS. Parent and clinician beliefs need to be addressed in order to ensure management of GE is appropriate and not detrimental to patients.

Abbreviations

AAP: American Academy of Paediatrics	**IID:** Infectious Intestinal Disease
AB: Aneurin Bevan Health Board	**IV:** Intravenous
ABM: Abertawe Bro Morgannwg University Health Board	**MRC:** Medical Research Council
ADVICE: Acute Diarrhoea and Vomiting in Children	**MeSH:** Medical Subject Headings
A&E: Accident and Emergency	**NHS:** National Health Service
BRAT: Banana, Rice, Apple Sauce and Toast diet	**NICE:** National Institute for Health and Care Excellence
BNF: British National Formulary	**NRES:** National Research Ethics Service
C&V: Cardiff and Vale University Health Board	**NISCHR:** National Institute for Social Care and Health Research
CAQDAS: Computer assisted qualitative analysis software	**ORS:** Oral Rehydration Solution
CI: Confidence Interval	**ORT:** Oral Rehydration Therapy
CPRD: Clinical Practice Research Datalink	**OSOP:** One Sheet of Paper
CRC: Clinical Research Centre	**OTC:** Over the counter
CRF: Case Report Form	**PCT:** Primary Care Trust
CT: Cwm Taf University Health Board	**PCU:** Permissions Co-ordinating Unit
CU: Cardiff University	**pi-IBS:** Post-infectious Irritable Bowel Syndrome
EMR: Electronic Medical Record	**QoL:** Quality of Life
GE: Gastroenteritis	**R&D:** Research and Development
GHQ: General Health Questionnaire	**RCT:** Randomised Control Trial
GI: Gastrointestinal	**RVGE:** Rotavirus Gastroenteritis
GP: General Practitioner	**SAP:** Statistical Analysis Plan
GPRD: General Practice Research Database	**SSI:** Site Specific Information
HBM: Health Belief Model	**UK:** United Kingdom
HD: Hywel Dda University Health Board	**US:** United States
HPA: Health Protection Agency	**UTS:** Up to standard
HUS: Haemolytic Uraemic Syndrome	**UTI:** Urinary Tract Infection
IBS: Irritable Bowel Syndrome	

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CHAPTER ONE: INTRODUCTION

1.1 Introduction

This thesis presents a descriptive study exploring current management of paediatric gastroenteritis [GE] in the United Kingdom [UK], focussing specifically on home management and primary care consultations. The views of both parents and primary care clinicians are explored to understand the factors impacting their management decisions and for parents, their reasons to seek further medical care. The use and consideration of published guidance on the management of this condition is also explored to identify inappropriate variation in practice that could impact the child, community or healthcare resources.

1.2 Gastroenteritis

1.2.1 Defining GE

Acute GE is an important condition that is associated with high morbidity and mortality across the world ((PHIL) 2005, Merrick et al. 1996, PHIL 2005). GE refers to the inflammation of the stomach and intestines and includes infectious and non-infectious causes. It most commonly presents as a sudden onset of diarrhoea, with or without vomiting.

There are a number of terms which are used interchangeably by researchers, academics and clinicians to describe the symptoms associated with acute GE in the paediatric population. Even within research papers, the terminology varies considerably (i.e. surveillance studies vs. clinical trials vs. review papers). Many define GE by the symptoms *"acute diarrhoea illness"* (Jones et al. 2007), *"paediatric acute diarrhoea"* (Johnston et al. 2010), *"diarrhoea and vomiting"* (Harris et al. 2008) or the cause *"acute bacterial gastroenteritis"* (Saps et al. 2008), *"acute infectious gastroenteritis"* (Halvorson et al. 2006), *"rotavirus gastroenteritis"* (Van der Wielen et al. 2010), *"infectious intestinal disease"* (O'Brien et al. 2010, Wheeler et al. 1999), *"highly credible gastrointestinal symptoms"* (Payment et al. 1997). In addition to the terminology used, the definitions also vary. A review of 138 randomised controlled trials investigating paediatric acute diarrhoea identified 64

unique definitions of diarrhoea and 69 unique definitions of diarrhoea resolution (Johnston et al. 2010). This variability impacts on how we can compare study findings using different terminology and definitions. For this project, we have attempted to be as inclusive as possible for both literature searches and study inclusion. We use the term GE in order to include the presence of symptoms of diarrhoea and/or vomiting as well as infectious and non-infectious causes (presumed and confirmed).

1.2.2 Worldwide perspective
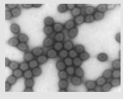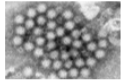
Approximately 10.6 million children die every year before reaching the age of five years, of which GE alone is responsible for almost 20% of these deaths (Kosek et al. 2003). There has been a significant reduction in childhood deaths since the 1970's owing to the use of oral rehydration therapy (ORT). However, in low-income countries, diarrhoeal diseases are still responsible (in/directly) for over 3million deaths each year [equating to 1 every 10 seconds] (Casburn-Jones and Farthing 2004). The average number of episodes of GE per year per child in low-income countries is 3 (Casburn-Jones and Farthing 2004).

1.2.3 GE in the UK

The transmission and presenting symptoms of GE largely depend on the cause of the illness. The most frequently identified pathogens of acute GE in the UK are norovirus, sapovirus, rotavirus and *Campylobacter* (Tam et al. 2012).

Symptoms can include mild to severe diarrhoea and / or vomiting, stomach pain, headache, fever and presence of blood/mucus in the stool. The illness can last anywhere from 12 hours to 10 days and this is commonly indicatory of different pathogens (Jones and Rubin 2009) [Table 1]. Around 50% of patients with

Table 1. Symptoms and Transmission of the four most common GE-associated pathogens, adapted from McClarren et al. (2011)

Pathogen	Transmission	Incubation	Typical Symptoms	Duration of illness
Rotavirus	faecal-oral	1 to 4 days	Nausea; Vomiting; Fever; Headache; Watery diarrhoea	4 to 5 days
Norovirus / Sapovirus *Calcivirus family*	faecal-oral aerosolisation	24 to 36 hours	Nausea; Vomiting; Abdominal cramps; watery diarrhoea	24 to 48 hours Shedding may be present for >2 weeks
Campylobacter	person-person; faecal-oral; improperly cooked meat; unpasteurised milk	1 to 10 days	abdominal pain; diarrhoea (watery to dysenteric); fever; nausea; vomiting; headache	2 to 7 days

infectious diarrhoea present with a high fever and headaches are most common in rotavirus infections (Jones and Rubin 2009).

Rotavirus infection is most common in children 6-24 months of age (Giaquinto et al. 2007b). It is responsible for a substantial number of medical consultations across Europe, although death due to rotavirus infection is rare (Giaquinto et al. 2007a). By the age of 5 years, almost every child will experience at least one rotavirus infection, one in seven will present to their general practitioner [GP] and one in 54 will need hospitalisation (Szajewska and Dziechciarz 2010). A rotavirus infection in children, is 3 times more likely to result in hospitalisation than from any other cause of infectious GE (Soriano-Gabarró et al. 2006). Rotavirus was reported to be responsible for 231 deaths annually in the European Union in 2007 (Giaquinto et al. 2007b).

Mortality rates due to GE in the UK has fallen over the last four decades (Pantenburg et al. 2007) from 164 in 1978 (Conway et al. 1990) to 33 in 1999 (Wheeler et al. 1999). 2012 mortality statistics reported 8 deaths caused by infectious intestinal disease for 0-14 years in England and Wales (ONS 2012).

In spite of the lowering mortality rates in industrialised countries, this common illness remains a significant cause of childhood morbidity, parental anxiety and cost to the economy. The illness severity is milder than 50 years ago (Conway et al. 1990) and yet the numbers of admission, without signs that might be expected to concern the primary care physician, has increased.

Hospital admission rates with a primary diagnosis of intestinal infectious disease indicate an increase from 37,560 in 2003 to 50,911 in 2012 for hospitals in England. Paediatric patients (ages 0 to 14) represent approximately 60% of these admissions [Figure 1] (HSCIC 2003-2012).

A recent study of infectious intestinal disease (IID2 Study) estimated that 25% of the UK population suffered from an episode of infectious GE in 2008-2009 resulting in 17.7 per 1000 person-years primary care consultations (Tam et al. 2012). This rate of consultation has decreased since the mid-1990's when Wheeler et al. (1999) reported a rate of 33.1 primary care consultations (per 1000 person-years).

ANNUAL ADMISSIONS RELATED TO A
PRIMARY DIAGNOSIS OF INTESTINAL
INFECTIOUS DISEASE.
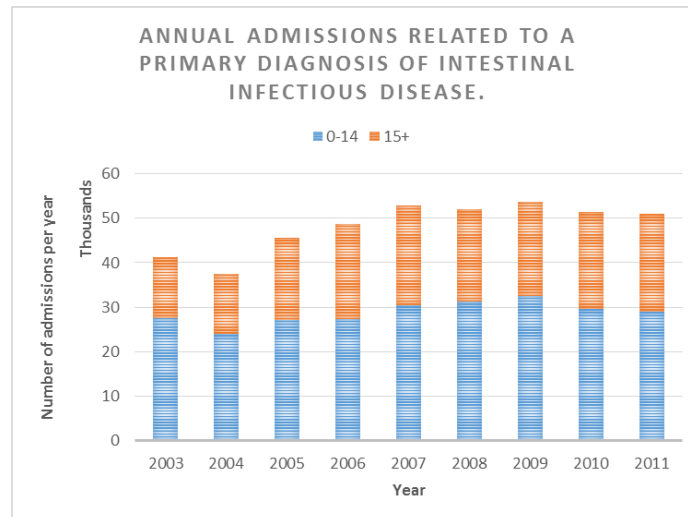
Figure 1. Annual admissions in Hospitals in England with a primary diagnosis of intestinal infectious disease. Separated into two age groups, Ages 0-14 years and Ages 15 upward. Data extracted from Statistics from Annual HES Publications

There has, however, been a considerable increase in incidence in the community from 194 cases (Wheeler et al. 1999) to 274 cases in 2009 (Tam et al. 2012). It is not clear whether the drop in primary care consultations and rise in secondary care admissions is related. It is clear, however, that the burden of GE is of significant importance both from the community perspective and in terms of use of healthcare resources.

Clinical management and home management of paediatric GE is reportedly variable resulting in inappropriate hospital admissions and ineffective treatment regimens. Increased hospital admissions for this condition, as well as high primary care consultation rates and wide variation in care, suggest that further research is required, focussing on management prior to hospital admission.

There is little high-quality evidence to guide the management of acute GE in the primary care setting or to guide self-care in the community. Most evidence in this field comes from other settings such as secondary care or the developing world.

There is therefore a pressing need for further research into the management of acute GE in the UK. This is especially true for children, who are the main sufferers of this condition. However, before conducting trials to evaluate interventions aimed at improving care (including interventions aimed at improving uptake of established evidence-based practice) we need to clearly define the problem.

1.3 Project Aims

To provide a description of the management of paediatric GE prior to and following a primary care consultation.

- ◆ *Range, duration and severity of symptoms prior to consultation*
- ◆ *Medication and nutritional management*

Describe the current clinical management of paediatric GE in primary care, including:

- ◆ *Prescription and advised medication*
- ◆ *Frequency of requesting stool specimen test*
- ◆ *Hospital referrals*

Describe parents' understanding, perceptions and health beliefs about paediatric GE.

- ◆ *Home management (diet, medication)*
- ◆ *Factors contributing to the decision to consult a GP*
- ◆ *Beliefs about hygiene and prevention of illness*
- ◆ *Impact of illness*

Describe the current attitudes and health beliefs of primary care clinicians towards the management and treatment of paediatric GE.

- ◆ *Usual management*
- ◆ *Factors taken into consideration in management decisions*
- ◆ *Guidelines consideration*

1.4   A Mix of Methods

"Mixed Methods - The class of research where the researcher mixes or combines quantitative and qualitative research techniques, methods, approaches, concepts or language into a single study" (Johnson 2004)

The concept of mixing different methods likely originated in 1959, when Campbell and Fiske used multiple methods to study the validity of psychological traits (Campbell 1959).

Recognising that all methods have their limitations and weaknesses, it is believed that the inherent biases of a single method can be resolved by combining other methods (Greene et al. 1989). As well as providing a more rigorous design method, mixed methods can also improve the quality of the results by answering a research question as comprehensively and completely as possible (Morse 2003).

This project has used complementary methods within a single research project. The project is separated into four studies, of which two use qualitative approaches and two use quantitative approaches. The four studies were conducted in parallel and aimed to address different but associated questions. The findings from each study have been synthesised together during the overall project discussion and conclusion.

1.5   Approval and Governance

1.5.1 Ethics approval

The study procedures were given full ethical approval by the Proportionate Review Sub-committee, North Wales Research Ethics Committee (Central & East) [Ref: 11/WA/0262].

[See Appendix 1.1 for ethical approval letter]

1.5.2 Sponsorship

The study was sponsored by Cardiff University

1.5.3 NHS Permissions

Approval was gained from National Institute Social Care and Health Research [NISCHR] Permissions Co-ordinating Unit (Global NHS Permissions) [Ref: 83175]

and all health boards in Wales - Aneurin Bevan, Abertawe Bro Morgannwg, Betsi Cadwaladr, Cwm Taf, Cardiff & Vale, Hywel Dda & Powys.

1.5.4 Independent Scientific Advisory Committee [ISAC]

ISAC approval was granted for the protocol to access and use patient level data for this research project [Ref:14_021R].

1.5.5 PhD Studentship

Funding was received for three year studentship, half funded by the Medical Research Council (MRC) and half by the Institute of Primary Care & Public Health.

1.5.6 Wales School of Primary Care Research

Additional funding of £24,000 was awarded from the Wales School of Primary Care Research.

1.5.7 NHS Service Support and excess treatment costs

Service support and excess treatment costs of £17,000 were provided by NISCHR - Welsh Assembly Government to cover costs associated with compensating clinician time during recruitment.

1.6 The ADVICE Study

The ADVICE Study [**A**cute **D**iarrhoea and **V**omiting **I**n Childr**E**n] was developed to address the project objectives. The study design was submitted for approvals and comprised of three sub-studies, referred to in the study protocol as phases. During the development of study documents for both clinicians and parents a study acronym and logo was designed and used throughout the study information leaflets, website and advertisement documents [Figure 2].

Figure 2. The ADVICE Study Logo used for all study documents.
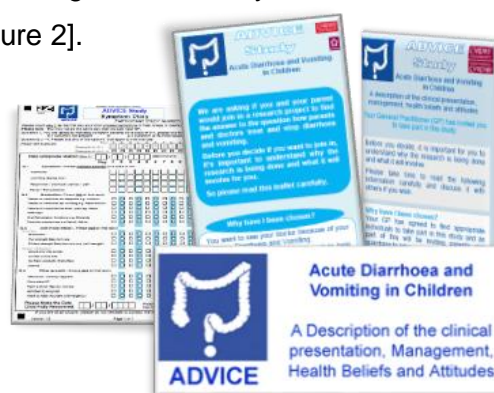
1.7   Thesis Synopsis

This chapter has outlined the background of the project.

Chapter two describes the current evidence base in relation to the impact and management of paediatric GE.

Chapter three describes the original study design and implementation of a prospective case series (Phase One), as well as presenting the results from this study it also reflects on the set-backs experienced during study set up and recruitment that resulted in premature study closure.

Chapter four presents the adapted retrospective observational study used to address the objectives outlined in chapter three using anonymous patient data. The data reported here is primarily descriptive, although sub-group analyses were conducted where appropriate.

Chapter five outlines the methods employed to conduct the two qualitative studies (Phase Two and Three) with parents and clinicians.

Chapters six and **seven** focus on the experience and beliefs of parents regarding the management of their child's episode of GE.

Chapter eight presents the findings from the primary care clinicians' interviews in relation to their clinical management of paediatric GE and the factors that impact on their management decisions.

The final chapter, **chapter nine**, provides a summary and evaluation of the research findings and their importance in the wider context. Limitations of the project as whole will be evaluated as well implications of this project for the future.

CHAPTER TWO: BACKGROUND

2.1 Introduction

This chapter outlines the current recommendations regarding paediatric GE, including both clinical management and home management, and the evidence base that informs the recommendations. The burden of current management for both the National Health Service [NHS] (primary care) and the community is reported as well as literature from outside of the UK where UK data was limited. Reported management and beliefs of management is summarised, again focussing on other countries where UK research is restricted. The chapter concludes by identifying the gaps in the research identified by this literature review.

2.2 The burden of GE in the UK Primary Care Setting

Despite a dramatic drop in mortality rates since the 1970's, the burden of the illness continues to be substantial. This section explores both the burden on clinicians and the NHS as well as the impact of illness on the patient, family and community.

The management and burden of illness will differ depending on the severity of illness and this has been extensively reported in secondary care settings. In addition, the presentation of symptoms is likely to be more severe in studies set in secondary care; therefore the main focus of this section of the literature is on the mild self-limiting episodes of GE seen in the community and primary care.

Many studies have focussed specifically on the burden of rotavirus GE due to the high incidence in the population. The introduction of a rotavirus vaccine has also spurred research into the burden of this pathogen, including cost of illness studies, in order to identify the positive impact a vaccine would have.

This project is specifically interested in the burden in the UK primary care setting and the community; however, limited research has been carried out solely in the UK in recent years.

Two cohort studies have significantly led the research in the burden of GE in the UK – specifically, confirmed infectious GE, the IID Study (1999) and the IID2 study (2012).

2.2.1 The IID Study

The study of infectious intestinal disease [IID] in England [IID1 Study] was conducted between 1993 and 1996 to establish the incidence and aetiology of IID in both the community and primary care settings (Wheeler et al. 1999).

A community cohort consisted of 9776 individuals (response rate of 40%), of which 781 cases of IID were identified during the study period, resulting in a rate of IID in the community of 19.4 per 100 person-years (95% CI 18.1 to 20.8). A primary care cohort of 8770 (patients presenting with IID) were included in one of the two arms of the study, half had stool samples sent as per study protocol, and half normal clinical practice was assumed. Consultation rates for IID were calculated to be 3.3 per 100 person-years (95% CI 2.94 to 3.75) (corrected for list inflation and under-ascertainment).

An assessment of the impact of IID on the community, primary and secondary care was conducted by Roberts et al. (2003) using data from IID1 study;

Primary care and community - In the primary care cohort, as per the study design, all cases consulted a GP. The average cost per visit was estimated at £20.45 per IID case (expressed in 1994/5 prices). 5% of children reported exclusion from school due to the risk of spreading infection and the average number of days lost from school was 4 days.

Primary care referral to secondary care - 3.5% of children aged 12months or younger were hospitalised and for all age groups an average of 1.8% patients resulted in hospitalisation and this was for an average of 4 days. The cost of hospitalisation was estimated at £5.66 per IID case (expressed in 1994/5 prices).

These two studies identify the rates of IID in both the community and within the NHS, as well the impact this has on the individuals, family and NHS. This population of participants included all ages and sub-group analyses were not reported.

This study in England was conducted almost 20 years ago; in 2008-09 a second study was conducted in order to update current knowledge of the incidence of IID in the community and primary care [The IID2 Study].

2.2.2 IID2 Study

IID2 was made up of three studies of which the population cohort and GP presentation mimic the earlier IID1 study and the additional national surveillance study aimed to identify how many IID episodes were reported to UK national surveillance centres. This study covered England, Northern Ireland, Scotland and Wales representing a population of 800,000 individuals [study protocol published in 2010 (O'Brien et al.)]. 6,836 participants were recruited and their data analysed in the cohort study and 991 participants in the GP presentation study (Tam et al. 2012).

The overall rate of confirmed IID was 274 cases per 1000 person-years (95% CI 254 to 296) [adjusted for age and sex] and the rate of both confirmed and possible cases of IID the rate was calculated as 523 cases per 1000 person-years.

Primary care consultation rates were estimated for the two cohorts, the GP presentation study estimated a consultation rate of 17.7 per 1000 person-years (95% CI 14.4 to 21.8) compared with the community cohort estimate of 25.3 per 1000 person-years.

The incidence of Norovirus was 47 per 1000 person years and accounted for 2.1 GP consultations per 1000 person years. *Campylobacter* was the most common bacterial organism isolated attributing to 9.3 cases per 1000 person-years and 1.3 GP consultations per 1000 person years.

This second IID study shows a decrease in GP consultation rates since the 1990's but an increase in the estimated rate of IID in the community.

These figures represent confirmed IID and not those who did not have a stool sample sent or it was a negative result. The inclusion criteria required patients to have a confirmed infectious case of IID and be symptom free for the preceding 3 weeks, therefore an under ascertainment of symptoms of IID/GE in the community is likely to be present. This study has not focussed on the management of IID in the community or in primary care.

2.2.3 Rotavirus specific

The burden of rotavirus GE [RVGE] in the UK and worldwide is substantial due to the high incidence of infection and morbidity associated with paediatric patients. Many studies across Europe have described primary care consultation and hospital admission rates - in Spain (Visser et al. 1999), in Denmark (Fischer 2001) and in

the Netherlands (De Wit et al. 2001), however few have been conducted in the UK primary care to a representative sample. Three studies are described below of which only one focusses specifically on UK primary care.

A prospective epidemiologic study of paediatric rotavirus GE was undertaken over 12months between October 2004 and September 2005 in 7 European countries (Giaquinto et al. 2007b). 76 patients were recruited into the UK study when presenting to primary and/or secondary care with confirmed RVGE. The percentage of patients in each setting were - 51.3% in hospital (paediatric ward), 28.9% in accident and emergency [A&E], and 19.7% in primary care. [Patients who visited more than one of these settings were defined at the highest level of care i.e. patients presenting to primary care and the hospital were defined in "hospital"]. Giaquinto et al. (2007b) concludes that rotavirus GE incurs considerable resource use and burden on both community, primary care and secondary care settings. Despite the low numbers of patients in the UK study, this study highlights the impact of rotavirus GE, a comparison of rotavirus GE management with GE (not diagnosed) management to determine how representative this study is to the rest of patients presenting with similar symptoms without a diagnosis.

Country specific estimates of rotavirus incidence and burden were calculated by Soriano-Gabarro et al. (2006) based on the assumption that for every hospitalisation, ~8 children present to their GP; every rotavirus infection results in a GP consultation and for every GP consultation 4 episodes occur in the community. Mortality rates were calculated based on the proportion of hospitalisations attributed by rotavirus multiplied by the diarrhoea-caused mortality rate of children for each country. Using the populations of individuals younger than 5 years for each country, it was calculated that the annual incidence of rotavirus disease in children for the UK is as follows; 409,173 episodes in the community of which 102,293 result in a GP consultation, of which 12,787 patients are hospitalised. The death rate calculated for the UK attributed by rotavirus was 14 per year. This study does not compare their estimates with actual incidence or mortality figures and there is no evidence that these assumptions are founded. Mortality rates in the UK due to GE are substantially lower than the figure reported here therefore these estimations should be used with caution.

A cost of illness study was conducted alongside a surveillance study during the winter season of 3 consecutive years (December 2000 and April 2003) in East

Anglia (Lorgelly et al. 2008). 136 patients aged 5 years or less presented with symptoms of GE and were recruited to one of twenty GP's taking part.

2.2.4 Family

There are many aspects to the burden of GE on the family. An un-well child results in time off work, transmission of illness, emotional and physical effort during the management of the illness, as well as the financial burden.

If a child is admitted to hospital with GE symptoms, 91% of these cases require at least one parent to be absent from work (Van der Wielen et al. 2010). 20% of children that present to primary care required one parent to be absent from work (Giaquinto et al. 2007b). On average, the number of workdays lost per episode of paediatric RVGE in the UK is 4 days (Giaquinto et al. 2007b).

In households where a child suffered from IID, 40% of the time another member of the household would also be ill (Roberts et al. 2003). The other member most likely to catch the infection was the mother (Roberts et al. 2003). This will result in further work days lost.

Exclusion from childcare during and following an episode of GE requires time off work and lost money from days paid to nursery (Van der Wielen et al. 2010). If the child then develops a chronic persistent condition followed on from the initial acute illness, this can become very difficult to manage. Although the child will not necessarily be infectious, their symptoms will present similarly to the original acute illness and mean further complications with childcare.

The illness brings with it an increase in excrement and thus increased nappies and the associated financial burden. One study has shown 2-fold increase in the use of nappies during rotavirus GE (Van der Wielen et al. 2010) – an average of 5-7 additional diapers per day (Giaquinto et al. 2007b).

Stress levels of parents during a child's illness are often high (Van der Wielen et al. 2010). It has been suggested that one of the reasons to admit a child suffering from D&V is based on the parent not coping to look after the child at home (Conway and Newport 1994). Parental concern and anxiety for their child may influence a clinician's decision to admit a child (Conway et al. 1990). Evidence suggests that a previous hospital admission increases the expectation of hospital admission during a subsequent illness involving similar symptoms. Parents may create a link

between GE and the need for hospitalisation, which may not be appropriate or necessary.

The quality of life [QoL] during an episode of paediatric GE was explored in a qualitative interview and focus group study by Johnston et al. (2013) in order to develop a conceptual framework specific to the QoL during GE. For the child, impacts such as lack of sleep and appetite negatively impacted on their QoL, as well as the reduction of daily activities (school, playgroup). Parents indicated emotional impacts (helplessness) as well as more physical symptoms (fatigue) from the constant care required. This study identified the considerable burden on both children and their parents during an episode of GE.

Even clinically mild diarrhoea can result in a significant parental perception of disease burden, for both parents and their child (Huppertz et al. 2008).

2.2.5 Patient

Development of persistent gastrointestinal symptoms

An important complication that has been shown to be associated with acute GE is post-infectious irritable bowel syndrome [pi-IBS] (Haagsma et al. 2010). IBS is characterised by abdominal discomfort and altered bowel habit with no abnormality on routine diagnostic tests (Thabane et al. 2009). With post-infectious IBS, the abdominal discomfort, bloating and diarrhoea will persist despite the clearance of the inciting pathogen which defines the condition as "post illness" as it has a defined moment of onset (Thabane et al. 2009). Although not a life-threatening condition, IBS varies between patients on the severity of the symptoms and it can have a severe effect on daily life. In children, it may affect their school life / early education, their social life / activities and can decrease their QoL over long periods (Haagsma et al. 2010). The burden of illness on the parents and family is the same as that of an acute episode with the extra burden of a longer recovery time. This aspect of acute GE disease burden has not currently been considered, and as prevalence of IBS in the Western population rises, there is a significant underestimation of the size of the burden of this GI disease (Haagsma et al. 2010). Acute GE episodes are brief and self-limiting, therefore the long term effects are rarely considered (Saps et al. 2008). Currently, there are not therapies that are proven to be effective specifically for the management of IBS (Thabane et al. 2009).

The computed risk estimate developed based on a meta-analysis literature review suggest that an individual suffering from infectious causing GE has a sevenfold increase in odds for developing IBS (Halvorson et al. 2006).

The risk is also dependent on the pathogen causing the acute episode, the most frequently isolated pathogens linked to pi-IBS include *Salmonella*, *Shigella*, *Campylobacter* and rotavirus, however this is not an exhaustive list (Barbara et al. 2009). Another study conducted in the United States [US] looked at patients aged 3-19 (n=88) who suffered from bacterial causing GE, after 6 months 87% (n=77) had irritable bowel syndrome and 24% (n=24) suffered from dyspepsia (Saps et al. 2008).

Other risk factors for pi-IBS have been investigated, however many studies have focussed on adults and factors such as smoking have been confounding factors. This is unlikely to affect children except in the passive risk smoking brings (Halder et al. 2010). The risk of pi-IBS increases 2-fold if the acute diarrhoeal illness lasts more than 7 days, and over 3-fold if the diarrhoea lasts more than 3 weeks (Thabane et al. 2009).

Parental treatments (including dietary management) of acute GE could potentially influence the risk of pi-IBS. However, to date, no study has described the parental treatments or dietary management of acute GE, let alone investigated the relationship between common treatment measures, and the development and severity of pi-IBS.

Establishing a relationship between acute GE and functional gastrointestinal [GI] disorders, of which both have a high prevalence and morbidity in children, may lead to modifications of the current approach to acute GI infections (Saps et al. 2008).

2.3   Clinical Management of GE - Available evidence and recommendations

Clinical practice continually changes as new therapies are introduced, research is updated and current practice is shown to be ineffective or harmful. Guidelines are the bridge between evidence-based knowledge and clinical practice (Rogers 2002) and aim to improve the quality of care, reduce inappropriate variation in practice, recommend novel treatments of proven efficacy (Rogers 2002), as well as increasing the efficiency in use of health care resources (Shaneyfelt et al. 1999).

The management of GE in the paediatric population is complex and continually changing (NICE 2009). Practice variation among clinicians is well documented across many conditions (Powell and Hampers 2003) including for GE in areas such as nutritional management during and following an acute episode. There is also reported variation in the approach to escalation of care - from the management of illness at home to a child requiring hospital admission, resulting in avoidable admissions.

To understand the management of paediatric GE and identify inappropriate variation, current recommendations on best clinical practice need to be identified.

2.3.1 Guidelines

There are a number of guidelines and recommendations for the management of paediatric GE published, however most have not been written for UK primary care setting (Bhatnagar et al. 2007, King et al. 2003) or are now out-dated for present day UK (Murphy 1998).

Most recently, the National Institute for Health and Clinical Excellence [NICE] guideline was developed and published in 2009 [CG84 – Diarrhoea and vomiting in children: Diarrhoea and vomiting caused by gastroenteritis: diagnosis, assessment and management in children younger than 5 years] (NICE 2009).

NICE guidelines are developed to inform both clinicians and the public in England and Wales. Topics are commissioned by the Department of Health based on many factors such as the burden of disease, impact of illness on resources, and when there is evidence of inappropriate variation. Once developed, NICE guidelines are used within the NHS as well by the Health Protection Agency [HPA] (Now part of Public Health England).

The clinical guideline for paediatric GE was developed by a team of 13 healthcare workers and 2 lay members. As a group, the current evidence was reviewed and where the literature remained unclear, the team came to a consensus decision based on their knowledge and experience. Health economics was considered when recommending treatments so as to ensure a cost-effective use of resources.

The current recommendations for the management of paediatric GE will now be summarised, focussing largely on the NHS recommended NICE guidance. The evidence base for the recommendations will be examined and where appropriate, additional literature will also be reviewed for management topics.

The clinical recommendation topics that the NICE guidance covers are:

→ *Diagnosing GE (including stool microbiology use)*
→ *Assessing dehydration and fluid management*
→ *Nutrition*
→ *Escalating care*
→ *Medication*

2.3.2 Diagnosing GE

This section outlines the current guidance for identifying GE illness based on presenting symptoms. In addition, circumstances where further diagnostic test are required are outlined.

Diarrhoea and Vomiting duration

> *Guidance -* *Be aware that in children with GE, diarrhoea usually lasts for 5-7 days, and in most it stops within 2 weeks; vomiting usually lasts for 1-2 days, and in most it stops within 3 days.*

The evidence NICE considered for symptom duration was based on 5 hospital setting cross sectional studies and one community setting cross sectional study; all were non-UK studies. Of a cumulative of sample size of ~850 patients the mean duration of diarrhoea was 4.1 days (range of 0.6 - 8.3 days). Three studies were identified that reported vomiting duration (range of 1.6 to 2.5days). No evidence was reported that indicated diarrhoeal symptoms lasting up to 14 days.

Using data from hospital settings studies infers a bias of the more severe cases of GE and does not represent illness in the community. Symptom duration is dependent on the microbiological cause of the illness therefore an average across all pathogens causes wide confidence intervals. In addition, different pathogens are endemic to different countries and thus comparisons between countries is difficult.

None of the studies reviewed had a primary objective of calculating symptom duration and thus information was limited on these reported outcomes. Symptom duration was recorded as of the first day of entering the study and no retrospective data was collected on patient symptoms prior to trial registration. Exclusion criteria did not indicate that symptoms were required to be present for less than 24 hours. It is therefore likely that the symptom duration reported is the minimum rather than the actual.

It is noted that following the review of these trials, the NICE team drew on their own knowledge and experience of managing GE in community settings to develop the above recommendation.

Natural history of GE

The causes of GE are considered here in 3 cross sectional studies (One UK based). A case control study in India identified 5 risk factors that independently increased the likelihood of persistent (beyond 14days) diarrhoea; these were found to be important in a UK setting due to the multi-ethnicity of the UK and the "increasing frequency of overseas travel".

It is arguable however, that other studies were excluded from the NICE review on the basis of "important difference in the baseline characteristics of a population" such as malnutrition in developing countries (NICE 2009, ©NICE 2009). A consistent inclusion or exclusion of trials based on location and population is needed here.

Stool sample requests

The document sets out to explain that more paediatric patients with GE do not require stool investigation as "a clinical assessment is all that is required". Therefore the guidelines cover circumstances that a stool investigation could aid in a diagnosis.

> *Guidance -* *For cases where the clinician is in doubt that the patient has GE, a stool investigation is required to provide reassurance around the diagnosis.*
>
> *If blood or mucus is present, a stool investigation can help to rule out other serious conditions such as ulcerative colitis.*
>
> *If the diarrhoea has persisted beyond 7 days, it could be due to a treatable enteric infection*
>
> *A patient presenting "very ill" and the clinician suspects septicaemia, a microbiological test would indicate the most appropriate antibiotic*
>
> *A patient is more likely to acquire a pathogen requiring antibiotic therapy (e.g. Giardia lamblia) if they have a recent history of foreign travel.*

Evidence was provided on rates of organisms detected in the UK which indicated rotavirus as the predominant pathogen responsible for childhood GE, this was largely from a cohort study in the 1990's that identified incidence rates of infectious intestinal disease (Wheeler et al. 1999). Other viral pathogens such as norovirus were recognised as causing significant burden on the paediatric population of the UK, however, as well as the bacterial pathogens salmonella and campylobacter.

Treatment for any of the above pathogens is supportive, therefore identification of the pathogen is unlikely to be required in non-outbreak cases.

A further study published in 2012 updated the work by Wheeler identifying norovirus and sapovirus as the most significant burdens of infectious intestinal disease (Tam et al. 2012). As neither of these viral pathogens require alternative treatment, it would not affect the diagnostic guidance for GE.

This evidence supports the overall statement that a stool investigation is unnecessary; however, the evidence is unclear for those circumstances where a stool investigation could be considered.

These circumstances were developed and decided as part of the NICE team, based on their collective knowledge and experience of stool investigations and complicated GE infections.

2.3.3 Dehydration and Fluid management

Assessing dehydration

Guidance - *During assessment, ask whether the child:*

Appears unwell; has altered responsiveness, for example is irritable or lethargic; has decreased urine output; has pale or mottled skin; has cold extremities.

[Use the table provided in the guideline to assess presence and severity of dehydration]

The table designed for the purpose of the NICE guidance identifies three classifications: The patient shows no clinical detectable dehydration; the patient shows clinical detectable dehydration; and patient shows clinical shock.

This table was developed so that clinicians could assess a patient remotely (over the phone) asking questions that a parent could answer (i.e. no clinical test needed). The symptoms listed in this reference table vary in significance in terms of the likelihood that a patient is dehydrated if showing just one symptom, however when multiple symptoms are present at once, this indicates an increased likelihood of dehydration.

Although there has been a lot of research in this area (mainly in secondary care), conclusions vary significantly, as well as the importance of specific symptoms determining the likelihood of dehydration. The guideline itself identifies that the methods deployed were not "gold standard" and all but two studies included as evidence were carried out in secondary care settings. Symptoms are likely to be more severe if the patient has already been hospitalised. There is a need for

research in assessing patients in the community with GE where dehydration is likely to be milder and symptoms less determinate.

Fluid Management

> **Guidance -** _In children with gastroenteritis but_ without _clinical dehydration:_
>
> _Continue breastfeeding and other milk feeds; Encourage fluid intake; Discourage the drinking of fruit juices and carbonated drinks [especially in those at increased risk of dehydration]; Offer oral rehydration salt (ORS) solution as supplemental fluid to those at increased risk of dehydration._
>
> _In children with gastroenteritis showing clinical dehydration:_
>
> _Use ORS solution to rehydrate children [unless intravenous fluid therapy is indicated]._

Only one study was identified as appropriate evidence related to preventing dehydration in a child suffering from GE. This case controlled study by Faruque et al. (1992) was carried out in Bangladesh and reported that the cessation of breast feeding during GE increased the likelihood of a child developing more severe dehydration by 5 times. The study also reported the increased risk of dehydration if children did not receive ORT. The study does not discuss if any other fluids were given to the patients therefore it is unclear whether any patient who received _no_ fluids was at risk of dehydration or if all fluid intake (other than breast milk and ORT) was controlled for.

What this study _did_ indicate was that fluid intake (in general) was beneficial for the child and therefore should not be discouraged.

With regards the recommendation for fluid therapy during dehydration, the evidence base is extensive and indicates it is as effective as IV therapy (Hartling et al. 2006, WHO 2006). The use of ORT to manage GE in the UK in the late 1970s led to a drop in mortality rates from 300 deaths per-year to 25 deaths per-year [in England and Wales] (Walker-Smith 1990).

Where it is unclear, however, is the evidence that fruit juices and carbonated drinks are _not_ effective in the prevention of dehydration. Reference to a study that compared salt and sugar compositions of products in Canada in 1979 (Wendland and Arbus) was the only evidence provided, which presented a range of osmolality's in clear fluid products. The study is likely to be out-dated for present day UK and as the objective was not to determine the effects of these osmolality's it would be inappropriate to draw conclusions from this.

2.3.4 Nutritional management

> **Guidance -** *During rehydration therapy:*
>
> *Continue breastfeeding; Do not give solid foods; for children without red flags symptoms or signs, do not routinely give oral fluids other than ORS solution; however, consider supplementing with usual fluids (including milk feeds or water, but not fruit juices or carbonated drinks) if they consistently refuse ORS solution; For children with red flag symptoms or signs, do not give oral fluids other than ORS solution.*
>
> *After rehydration:*
>
> *Give full-strength milk straight away; Reintroduce the child's usual solid food; Avoid giving fruit juices and carbonated drinks until the diarrhoea has stopped.*

Early versus late re-feeding

The evidence considered for the benefit of early feeding compared with late feeding consisted of five studies, of which three were based in developing countries [Peru, Pakistan & Israel]. The benefit identified by two of the studies was an increase in weight gain when early feeding was introduced, however the data from other trials indicated opposing evidence or no difference at all. Other than weight gain, no other patient outcome was measured such as duration of diarrhoea, stool output or treatment failure.

The translation from evidence to recommendation was made by the view that there was "no evidence of harm" and that a general trend towards increased weight gain meant the recommendation in the guidelines of early feeding being necessary was most appropriate.

A Cochrane review (Gregorio et al. 2011) of 12 randomised controlled trials [RCT] looking at early (within 12 hours of start of rehydration) versus late re-feeding (more than 12 hours after start of rehydration) among paediatric patients (<10years old) with acute GE concluded that early re-feeding did not increase vomiting, persistent diarrhoea or risk of unscheduled IV use. The effect on duration of diarrhoea was not clear from the varied results. In future this review can be used to support the NICE current recommendation.

Lactose versus Lactose free products

Observational studies in the UK in the mid-1970's to mid-1980's recognised the existence and rate of transient lactose intolerance following GE. (Gribbin et al. 1975, Szajewska et al. 1997, Trounce and Walker-Smith 1985). This phenomenon has since decreased in developed countries but a link between rotavirus GE and the increases risk transient lactose intolerance still exists (Szajewska et al. 1997).

The evidence considered six trials comparing full-strength feeding against graded feeding, of which five of the trials were of poor quality and had small sample sizes. Two of the trials produced evidence towards full-strength feeding being more beneficial with regards to weight gain but neither provided statistically significant results. Of the six trials included in the analysis, three were from Brazil or South Africa, which does *"not provide a realistic comparison to acute gastroenteritis in the UK"* (NICE 2009, ©NICE 2009). Therefore the conclusions reached were based on their own experience of transient lactose intolerance and without evidence to indicate a risk of lactose-containing products, it was considered appropriate to advise continuation of lactose products.

Evidence contradicting NICE recommendations has since been published by MacGillivray et al. (2013) in a Cochrane review comparing symptom duration against lactose free / lactose-containing products for paediatric patients with GE. From the 33 trials included in the review, it was concluded that patients on a lactose-free diet experience a reduction in diarrhoea duration by a mean of 18hours (95% CI 10.21-25.32) and that diluting lactose products had no effect on reducing this risk. This conclusion does not include children who are breastfed as many trials reviewed excluded this sub-population.

This is certainly an area of controversy and perhaps reflects the variability in the consumption of lactose during and shortly following GE.

2.3.5 Medication

Guidance - Recommendations on antibiotic therapy:

Do not routinely give antibiotics to children with gastroenteritis.

Give antibiotic treatment to all children:

With suspected or confirmed septicaemia; With extra-intestinal spread of bacterial infection; Younger than 6 months with salmonella gastroenteritis; Who are malnourished or immunocompromised with salmonella gastroenteritis; With Clostridium difficile-associated pseudomembranous enterocolitis, giardiasis, dysenteric shigellosis, dysenteric amoebiasis or cholera.

For children who have recently been abroad, seek specialist advice about antibiotic therapy.

Recommendations on Other therapies:

Do no use antidiarrhoeal medications

Antibiotics

For viral GE, antibiotics are not a recommended practice. The most common bacterial causes have also been shown to be un-affected by antibiotic therapy and are also not recommended. For some bacterial GE (i.e. E. coli O157:H7) there is

evidence to suggest antibiotic treatment increases the risk of haemolytic uraemic syndrome [HUS] (Wong et al. 2012).

Evidence suggests that antibiotic treatment for paediatric GE does not shorten symptom/illness duration for bacterial causes such as *Salmonella*, *Shigella*, *Escherichia coli* (de Olarte et al. 1974), *Campylobacter jejuni* (Robins-Browne et al. 1983) and Yersinia (Pai et al. 1984).

There was evidence to suggest that antibiotics reduced the time for patients to stop shedding bacteria via their faeces – *Salmonella* or *Shigella* with ampicillin (de Olarte et al. 1974) and *Yersinia* with erythromycin (Pai et al. 1984), which is an important public health consideration. Despite the evidence provided, the guidelines do not consider antibiotics for reducing bacterial shedding for patients, this may be due to side effects that antibiotics can have, such as diarrhoea as well as the risk of increasing the problem of antibiotic resistance.

Other therapies

The therapies considered encompassed anti-emetics, antidiarrhoeals and probiotics. Evidence from three RCTs undertaken in the US indicated oral ondansetron is effective in reducing vomiting and thus decreasing the risk of developing dehydration, the need for intravenous [IV] therapy and hospitalisation. A significant side effect to this medication was an increase in diarrhoea and it was for this reason that the antiemetic has not been included in the guideline as a recommended treatment.

Evidence of activated charcoal and smectite (adsorbent agents), and racecadotril (an antisecretory agent) indicate potential for the clinical treatment of diarrhoea however NICE indicated that further research would be required in the UK before including these in their recommendations.

The antimotility agent loperamide has shown to significantly reduce diarrhoea duration in children (Li et al. 2007). Meta-analysis conducted by Li et al (2007) summarised that the presence of symptoms such as malnourishment, moderately to severe dehydration, blood in stool or the child is 3years of age or less; loperamide treatment would not be advised as side effects would outweigh the benefits of the medication. For all other children, loperamide is "a useful part of treatment".

Despite this evidence, loperamide is currently not licensed for use in the UK for young children (for the therapy of acute GE).

Seven studies (three systematic reviews and four RCTs) were considered by the panel to determine any significant effect of probiotics to treat children with GE. Six out of the seven studies reported a statistically significant reduction in diarrhoea duration for patients receiving probiotic treatment; however, there was a huge range in probiotics investigated as well the treatment regimens employed. Further research was reported to be required before probiotics were considered as clinical treatment of childhood GE.

Since this guideline was published, a Cochrane review (Allen et al. 2010) evaluated 63 studies of which 56 included paediatric participants. Despite a range of organisms tested, treatment dosages, population settings and demographics, probiotics reduced diarrhoea duration and no adverse events were identified. Diarrhoea duration was reduced for a mean difference of 24.76 hours (95% CI 15.9-33.6) as a cumulative score of many probiotic ingredients. Recommendations from this review indicate probiotics are safe and have beneficial effects (reducing duration of diarrhoea) during an acute GE episode but due to the range in probiotics considered more research is required to explore just one particular probiotic ingredient.

2.3.6 NICE Summary

The clinical guidance indicates that for a non-complicated (i.e. endemic pathogen) episode of paediatric GE, supportive treatment of rehydration therapy only is required. Diagnostic tests are only to be used for uncertain diagnoses, medications / therapies are unnecessary, aside from rehydration therapy, and dehydration is the main concern during an episode.

Information on adherence to this guideline is so far limited (Noone 2012). However, if these recommendations were in current practice, it would be expected that a low burden on NHS resources (diagnostics and prescriptions) would be seen. Data suggests the burden of paediatric GE is significantly greater than anticipated.

2.4 Clinical Management of GE – What is known?

There are very few studies in the UK that have explored the primary care clinical management of paediatric GE beyond consultation rates and hospital rates.

2.4.1 Stool sample requests

During the primary care cohort in the IID study in the mid 1990's, 27% of patients were reportedly requested to provide a stool sample (Wheeler et al. 1999). The IID2 study requested a stool sample from all eligible participants, therefore normal management request rates were not collected.

A more recent European study reported a stool request rate of 0 (Giaquinto et al. 2007b), however this was only within a sample of 15 UK patients, and therefore unlikely to represent the UK as a whole.

No further work describing the stool request rates in UK primary care have been found.

2.4.2 Prescriptions

The IID Study also indicated that 41-44% of patients (all ages) received a prescription in the primary care cohort with an average (for those who received a prescription) of 1.4 prescriptions per episode of IID (Roberts et al. 2003).

The European study conducted by Giaquinto et al. (2007b) reported that 7 out of the 15 patients received a prescription for "drugs or dietary products" when presenting to primary care with rotavirus GE. No further information regarding the types of prescriptions or dietary products was provided.

A small scale study in East Anglia, UK reported that 37% of patients (all ages) presenting with GE received a prescription; of which the maximum number of prescriptions per patient was 3. Rehydration therapies represented 64.6% of the prescriptions reported and paracetamol containing products and antibiotics each represented 12.3% of the overall prescriptions. 31% of patients consulting to their GP received a prescription for rehydration therapy and 5.8% of patients received paracetamol containing product and/or an antibiotic. This is the only study within UK primary care to itemise the prescriptions for GE. This study has a small sample size (n=136) and does not represent the UK for practice demographics or patient demographics etc. therefore further work in this area would better describe the current management of GE in paediatric population.

2.4.3 Primary care consultations

Of the patients presenting during the IID study, 87% of cases were conducted in the surgery (as opposed to home visits or telephone consultations) and 24% of patients

made more than one visit per episode. Children under 12 months had the highest number of repeat visits with 35% attending 2 or more times.

Variability in age specific consultation rates were reported in the IID2 study in which children aged less than 5 years consulted at a rate of 133 (95% CI 92 to 199) and 85 (95% CI 59 to 122) per 1000 person-years for the cohort and GP presentation study respectively. This is in comparison with an approximate rate of 21.5 per 1000 person-years for an average across all ages.

2.4.4 Summary

There is limited research describing the current clinical management for paediatric GE within the UK primary care setting. Secondary care literature is heavily biased on the more severe cases of GE therefore the approach to management is clinically different and therefore not reflective of the mild self-limiting symptoms seen in the community and in primary care.

It is unclear how representative the few primary care studies discussed here are for the whole of the UK, and in order to identify the burden of GE with regards resource use it would be an important area for investigation.

2.5   Self-reported Management and beliefs

This section will describe the evidence base around the beliefs of parents, patients and clinicians in relation to the management of paediatric GE. Some studies did not clearly differentiate between the beliefs of clinicians, patients and parents, and therefore a section on general beliefs is also included. My search strategy is described below.

2.5.1 Search strategy

Objective: To determine the available literature regarding UK clinical and home management of paediatric GE.

Eligibility criteria: For this mini-literature review, only primary source studies investigating actual or reported management of paediatric GE in resource-rich countries were included.

Information sources: All searches were conducted in Medline (1950-present) using the database Ovid[SP]. Medical subject headings [MeSH] were used in conjunction with normal keywords and/or word truncations.

Search: A search strategy was devised to identify all papers relating to management of paediatric GE. This was then combined with clinical management search terms and parent management terms (separately) to result in two separate search results (Figure 3).
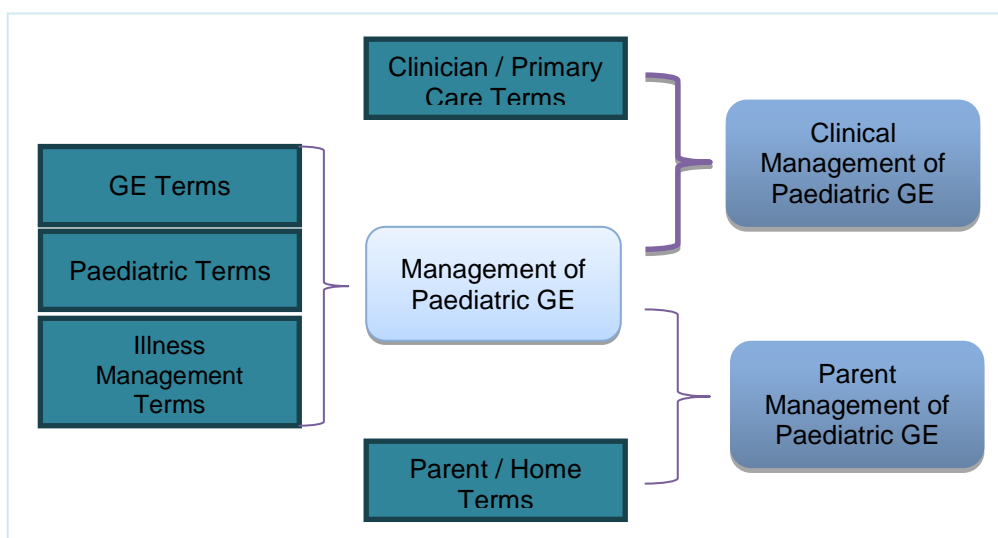
Figure 3. **Search terms and combining of terms to create two separate searches**

See <u>Appendix 2.1</u> **for the search strategy and search hits**

Summary of evidence retrieved: These searches ultimately identified literature regarding management and management beliefs, from the perspective of both clinicians and parents. There were limited studies undertaken in the UK in the last 20 years. Prior to 1990, mortality rates indicate that clinical management was not as effective as it could be, therefore, beliefs toward management would be inappropriate in present day. Research conducted in research poor countries were excluded after running the search - the papers not included at this stage are summarised in <u>section 2.5.4</u>.

2.5.2   Clinician management

Little is known about clinicians' attitudes toward the management of GE, the use of guidelines for this condition (Hoekstra et al. 2001) or the general management of GE in the UK.

Freedman et al. (2011) compared practice patterns of US and Canadian physicians working in emergency departments who provided care for paediatric patients presenting with acute GE. The survey was developed to ascertain management practices with regards antiemetics, probiotics and IV rehydration regimens. They

hypothesised that therapeutic regimens were highly variable between individual clinicians, institutions and internationally. Their sample counted for roughly 18% of the US physicians and an unknown proportion of Canadian physicians. Their results suggest that "*in keeping with available evidence*" use of anti-emetics has become routine practice, probiotic use was infrequent. The authors concluded that this was most likely because of a lack of high-quality evidence - despite recent guidelines supporting their use. They also reported that administration of IV rehydration approaches differed significantly between the two countries, perhaps because this was based mainly on training, experiences and the culture of the institution. These differences were considered to be largely due to the lack of specific instruction in guidelines for the volume or duration of administration. No evidence was provided that indicated the effects of this variation on the child's health or recovery rate, the study did not collect patient data to look at whether the variation reported was detrimental to child health. It is also difficult to ascertain the reasons why physicians carry out their management decisions, the authors suggested some reasons for the variation such as difference in the health care systems and other pressures such as inpatient bed shortages, therefore it is difficult to determine how practice can be improved if we don't fully understand the decisions involved. Social desirability bias is an important issue to consider in this study however, steps were taken to avoid this, such as self-completion and anonymity of responses. The survey was developed by the authors, which included members of the committees approached, and this may have biased the results.

The results discussed are difficult to generalise to the UK. The public health system is likely to ensure different pressures to those in the US or Canada. However, the variability in clinical management is unlikely to be solely attributed to variations in clinical presentation, and is therefore a cause for concern.

2.5.3 Parent beliefs

The management by UK parents has also been under-researched, especially regarding management prior to seeking medical care. I have only been able to identify three papers that describe parents' home management and their health seeking behaviours, and these were all in secondary care settings.

A prospective questionnaire administered at admission in five Yorkshire hospitals aimed to explore views on reasons for admission for a range of illnesses, including GE (MacFaul et al. 1998). Parents were asked to score the perceived severity of

illness, need for admission of their child, and following the child's discharge the consultant recorded their perception of appropriate admission. GE represented 10% of the 887 admissions recorded. Most admissions were felt to be necessary by both parents and consultants, and factors other than symptom severity were identified that influenced the need for admission.

Fitzgerald and McGee (1990) hypothesised that mothers of a child that was admitted to hospital would show significantly higher levels of psychological distress on the "General Health Questionnaire" [GHQ] than mothers managing at home. Other outcomes they were interested in were non-medical reasons for admission to hospital. The health questionnaire was administered as a structured interview, shortly after the child's symptoms had resolved. Overall results suggest mothers of hospitalised children were more depressed based on the GHQ.

Li et al. (2009) surveyed 623 parents of children with diarrhoea presenting to a tertiary paediatric emergency department in Washington to determine the therapies used and adherence to current guidelines. Recruitment started in November 2003 for 24 months. 53% of parents treated their child with appropriate fluids (in line with the American Academy of Paediatrics [AAP] guideline). 14% of parents used inappropriate treatments (discouraged by the guidelines) such as antidiarrhoeal medication and high sugar content fluids. An additional 17% reported using treatments neither encouraged nor discouraged by the guidelines for example, yoghurt, diet changes, and anti-emetics. Li et al. concluded that most parents treat their child's diarrhoeal illness with appropriate fluids, however other aspects such as medication and food intake are variably used by parents, many of which are not addressed in the guidelines. These therapies may be ineffective and thus potentially harmful to a child.

2.5.4 Culture-specific beliefs

The perceptions of mothers and/or caregivers about the causes and management of diarrhoea in children have been explored extensively in communities worldwide. Over 150 culture specific papers were identified that explored management beliefs in countries such as Kenya (Othero et al. 2009), India (Shah et al. 2012) Jamaica (Bachrach and Gardner 2002), Dominican Republic (Kirkpatrick et al. 1990) and Indonesia (Usfar et al. 2010). Many local beliefs about the management of diarrhoeal disease and GE symptoms were identified. However, these international studies have limited relevance to the UK setting as the cultures and causes of

diarrhoea are very different, and therefore results have not been included or appraised here.

2.6 Gap in research

Paediatric GE is a common and important condition that causes a considerable burden on the NHS, the families and the patient (short and long term effects). Despite this, the evidence for effective interventions in UK primary care is limited. Only a proportion of patients (and parents) consult, but we know little about their reasons for consulting and how they manage the illness at home. NICE have summarised the available evidence and made recommendations based on 'expert opinion'. We know little about current management by primary care clinicians, including how this relates to NICE guidance and how it is influenced by parental and clinician beliefs. There appears to be widespread variation in practice that is not evidence based, and this is therefore of concern.

"When variation is owing to external barriers, implementation strategies aimed at GPs will not be helpful." (Rogers 2002)

Research is needed to identify primary care clinicians' current practice and consideration of guidelines such as the NICE clinical guidance as well as understanding any barriers or factors that impact on their clinical management. Surveys have suggested that some clinicians question the intentions of guideline makers, believing that they are imposed on them in order to reduce costs rather than improve clinical care (Hoekstra et al. 2001).

It will also be important to identify current home management and treatment decisions faced by parents during their child's episode of GE. Understanding their experience of illness and decisions they are faced with would shed light on health-seeking behaviours.

As well as exploring management on an individual basis, primary care clinical management in the UK needs to be described. Prescriptions and stool investigations, despite recommendations that the majority of cases do not require these clinical outputs, appear to be high. Large-scale data needs to be collected to compare with smaller regional studies that have identified these high rates.

2.7 Chapter Summary

This chapter has provided a summary of the current literature on recommended clinical management of paediatric GE, the burden of management on both NHS resources and the community, as well as identifying research outside of the UK that indicates clinical and home variation of management for this condition.

The chapter concludes by identifying key areas for investigation based on the inconclusive literature or lack of literature found.

The following chapters aim to investigate and explore these gaps in the research, starting with describing current management in primary care.

CHAPTER THREE:
PROSPECTIVE CASE SERIES

This chapter describes phase one - a prospective case series of patients presenting to primary care with symptoms indicatory of acute GE. Due to a number of practical setbacks this study was unable to reach required recruitment and was closed early. The study rationale, methods and available data will be presented followed by a discussion of the sub-study that considers lessons learnt for future research.

3.1   Introduction

Phase one was designed as a case series of children presenting to primary care with acute diarrhoea and vomiting. The aim was to describe the clinical presentation, management and outcome of this condition by their parent and primary care clinician in addition to describing any longer term adverse outcomes.

This study focussed on the management actions taken by parents on behalf of their child; we therefore invited the parents of presenting children to participate. If the child was 11 years or older they were asked to help with the completion of data collection. As well as capturing the parents' decisions and perception of their consultation, we also asked the clinicians to record non-attributable baseline data. This was firstly to identify all eligible patients (recruited or not) that consulted with GE during the study period as well as capturing clinicians' reported management of paediatric GE.

The intention was to observe 385 patients over the initial 14 days of the illness and then follow up once after 6 months.

3.2   Aims of the Case Series

3.2.1   Primary aims

The primary aims were:

♦ To provide a description of the **presentation of acute GE i**n children consulting to primary care.

- To describe the **current management and recommendations for GE** in primary care including prescriptions, stool sample requests, advice offered to parents regarding home management such as nutritional intake.
- To describe the **management of paediatric GE by parents at home** prior to and following a primary care consultation.
- To describe the **short and medium term outcomes** of acute D&V in children presenting to primary care.

3.2.2 Secondary aims

The secondary aims were:

- To **compare** the recommendations and advice that general practitioners give to the reported management carried out by carers.

- To explore **associations** between possible chronic or persistent gastrointestinal related problems and management.

- To describe the degree of **clustering** at the GP and practice level in terms of the prescriptions and recommendation provided to patients.

3.3   Sample size calculation

The main aim of this study was to describe the presentation of GE symptoms and explore the variation in management. There was therefore no primary outcome or hypothesis for this observational exploratory study. I do provide an indicative power calculation demonstrating the precision achievable [Figure 4].

Sample Size Calculation

$$\text{Standard Error (SE)} = \frac{\text{Margin of error}}{1.96} \text{ (allows for 95\% level of significance)} = \frac{5}{1.96} = 2.55$$

$$N = \frac{P(100\% - P)}{(SE)^2}$$

Where:
SE= Standard Error = 2.55   P= Proportion = 0.5 or 50%

$$N = \frac{50\%(100\% - 50\%)}{(2.55)^2} = \frac{2500}{6.50} = 384.4675 = 385 \text{ (rounded)}$$

Figure 4. Sample Size Calculation, based on Fox et al. (2007)

A sample size of 385 provides us with the power to estimate any proportion to within five percentage points using a 95% confidence interval. This is based on estimating a proportion of 0.5, which is associated with the maximum variability

possible. The precision achievable for proportions not equal to 0.5 will be even greater.

The IID2 study reported incidence rates of confirmed infectious intestinal disease presenting to primary care. Using these figures, we estimated that, in a practice of around 6000 patients, approximately 50 under-16s would present with acute GE each year. Assuming a recruitment rate of 50% (of those eligible to participate, 50% expected to be invited to participate) and a response rate of 55% (of those invited, 55% expected to return the questionnaire) it was estimated that 14 participants per practice in a twelve month period would be recruited. In order to ensure recruitment of 385 participants within 12 months, 28 practices were required.

3.4   NHS Approvals

All health boards in Wales were approached for research and development [R&D] approval, using the new "streamline" National Institute for Social Care and Health Research Permissions Co-ordinating Unit [NISCHR PCU]. The approval process of gaining health board approval from all seven health boards took almost six months from submission to approval letter [Figure 5]. Whilst waiting for approvals, practices were approached and asked to consider taking part.

3.5   Recruitment of Primary Care Clinicians

In order to obtain a representative sample of GP practices across Wales, a randomised list of all practices was generated, practices were contacted consecutively and invited to participate in the study. However, after contacting 150 practices the response rate was 1.3% and therefore in conjunction with the phone calls, a letter raising awareness of the study was sent out to all practices. Practices were asked to get in touch if interested and a website was developed to provide extra information and a means for contacting the researcher. As numbers of interested practices were still low, we then approached practices that we knew had previously agreed to participate in other research. Help was also provided from NISCHR Clinical Research Centre [CRC] to contact and follow up interested practices [Figure 6].

Compensation

Funding enabled the study to compensate practices £400 PLUS £25 per participant recruited to the study.
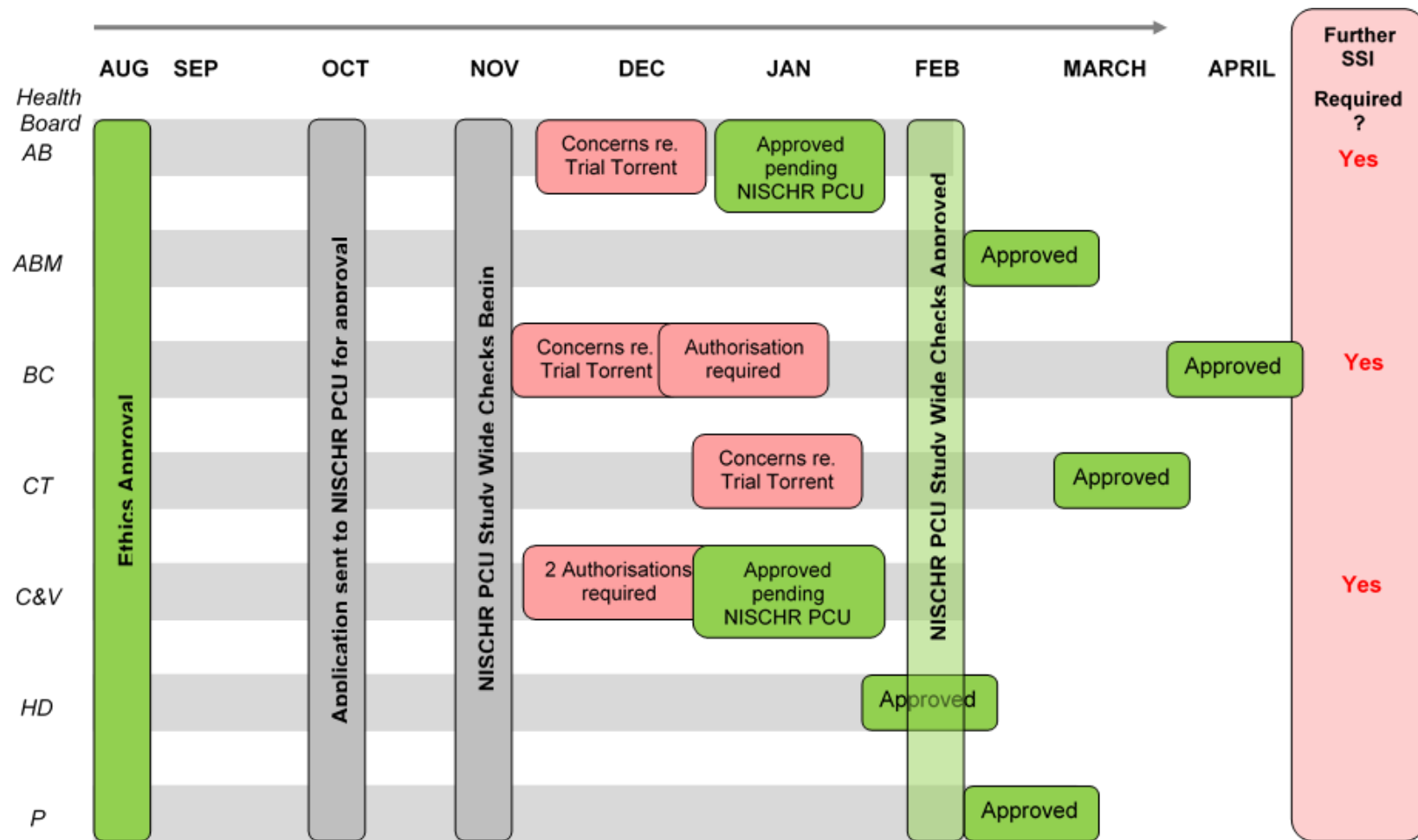
Figure 5. Time line of the approvals process from receiving Ethical approval August 2011 to receiving Health Board Level R&D Approval April 2012 – AB - Aneurin Bevan; ABM – Abertawe Bro Morgannwg; BC- Betsi Cadwaladr; CT – Cwm Taf; C&V – Cardiff & Vale; HD – Hywel Dda; P – Powys.

Figure 6. Approaches taken to recruit GP Practices from across Wales.
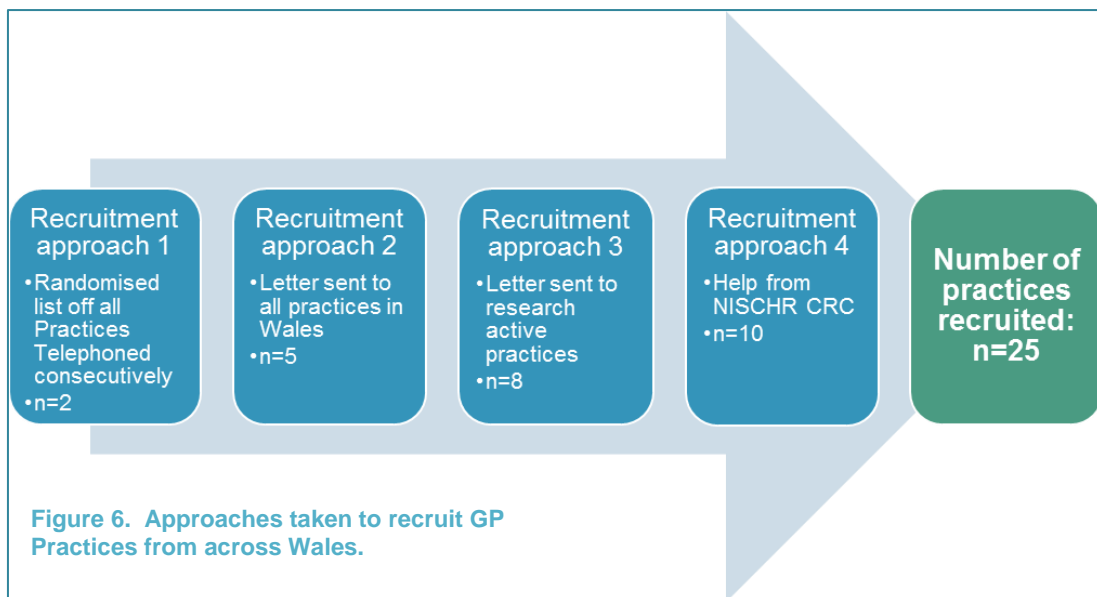
Practical setback: Recruiting GP Practices

Despite using four different approaches to identify and recruit general practices in Wales it took longer than anticipated to reach the target number of practices and we fell short of our target by two practices. The initial "health board level" R&D approval that was required before even approaching practices took three months for some health boards and some practices would not begin to consider the study until these approvals had been agreed.

Upon recruiting practices, the dropout rate was high due to the time it took to set up the study at the practice (see "Practical Setback 2: Trial Torrent" for details) and/or the time it took to obtain R&D approval for each site. Obtaining the Site Specific Information (SSI) for each practice took at least three weeks followed by a delay of one to four months per practice depending on the health board approving the site [Figure 7].

Following all these delays, the GPs were sent study packs with information on eligibility criteria for identifying patients and study recruitment began.

Practice recruitment began in February 2012. By September 2012, patient recruitment at the first practice had begun.

A

Health Board requiring SSI for each GP Practice

Health Board Level Approval

Approach GP Practice

If interested, complete SSI and send to Practice for Signatures

* Delays in returning SSI *

Receive Signed SSI from Practice and sent to NISCHR PCU

* Delays of up to 1 month in forwarding to Health Board *

Health Board receives SSI from NISCHR PCU

* Delays of up to 2 months for Health Board to Approve *

Health Board approves GP Practice

Proceed with Study

B

Health Board requiring only notification of GP Practices

Health Board Level Approval

Approach GP Practice

If interested, notify Health Board by email

Proceed with Study

Figure 7.   A - Demonstrating the areas of delay during Site Specific Information Approvals.   B - Demonstrating the ease of proceeding with the study within Health Boards that required no further information.

3.6   Trial Torrent

Practices were offered the option to use a piece of software, Trial Torrent, to aid with their recruitment of patients. This software was developed by Tay Dynamic© in conjunction with clinical practice and university medical schools with an overall aim to reduce the burden on GPs participating in research by providing an on-screen reminder when eligible patients consult in order to increase recruitment.

"A popup flags potential candidates, presents additional criteria and offers a 1-click signup process that seamlessly manages communication between patients, healthcare professionals and research staff." [Tay Dynamic©]

How Trial Torrent worked for the ADVICE Study

Trial Torrent was installed on the desktop computers of Primary Care clinicians participating in the ADVICE study. It was configured with the study inclusion criteria, which then communicated with the electronic medical record [EMR].

Once installed, this software reminded clinicians whenever an electronic record of potentially eligible patient was accessed and a relevant diagnostic code entered [i.e. a child aged 0-16years presenting with acute GE].   The software worked by recognising the Read Codes entered into the EMR and presented a pop-up window.

The case report form was then presented in a pop-up screen and the clinician completed the baseline data using drop down menus on all eligible patients.

Using the software, upon recruiting a parent, a secure email with the participants' contact information was sent to the researcher.

3.7   Baseline Data

3.7.1   Patients not recruited

In order to determine any potential selection bias, practices were asked to identify eligible participants and record non-identifiable information on the patient log even if the parent declined participation in the rest of the study or the parent was not approached about the study. If using the Trial Torrent software and after completion of the electronic patient log, the on-screen window would automatically close. If the parent declined participation and following completion of the patient log, the consultation would proceed as normal.

3.7.2 Case Report Form (Patient Log)

The case report form [CRF] (which was referred to as the "patient log" throughout the study) was used to collect data about recruited and non-recruited patients. The following data was collected on *all* potentially eligible participants:

- ◆ Age (in years)
- ◆ Gender
- ◆ Duration of diarrhoea (in days)
- ◆ Frequency of diarrhoea – at its worst (in 24h)
- ◆ Duration of vomiting (in days)
- ◆ Frequency of vomiting – at its worst (in 24h)
- ◆ GP to indicate if any of the following applied to the patient:
  - − Travelled abroad in the last 10days
  - − Blood in the stool
  - − Stomach cramps
  - − Antibiotics were prescribed
  - − Antidiarrhoeals were advised
  - − Antidiarrhoeals were prescribed
  - − ORS were advised
  - − ORS were prescribed
  - − Stool sample sent off for analysis
  - − Child was admitted to hospital

[See Appendix 3.1 for patient log]

3.8 Recruitment of Participants

3.8.1 Inclusion / Exclusion criteria

Eligible participants were the children who presented to primary care with acute GE and their parents. The GP practices involved in the recruitment of these parents included all seven local health boards in Wales.

The eligibility criteria for the children were as follows:

- ◆ Is 16years of age or younger
- ◆ Presents to the GP surgery
- ◆ Presents with acute GE
- ◆ Does not have a terminal illness
- ◆ Does not have a chronic condition causing diarrhoea/vomiting *e.g. Crohn's disease, ulcerative colitis, celiac, cystic fibrosis.*

Defining acute GE

Primary care clinicians were advised that the definition for acute GE for inclusion in this study was **the acute onset of diarrhoea, with or without vomiting, lasting less than 14 days**.

Justification for inclusion / exclusion criteria - Age

The National Research Ethics Service [NRES] guidance refers to a child as up to 16years of age; the same definition is being used in this study.

3.8.2   Recruitment process

Recruitment was planned for a period of twelve months.   Primary care clinicians were asked to identify suitable children during routine consultations.   The clinician provided parents (whose child met the eligibility criteria) with written information about the study from the study pack.   During recruitment, posters were placed in participating GP practices.   Practices were offered two methods of recruitment and recording of the anonymous baseline data – the use of a paper version of the patient log or Trial Torrent Software on their computer system [Figure 8].
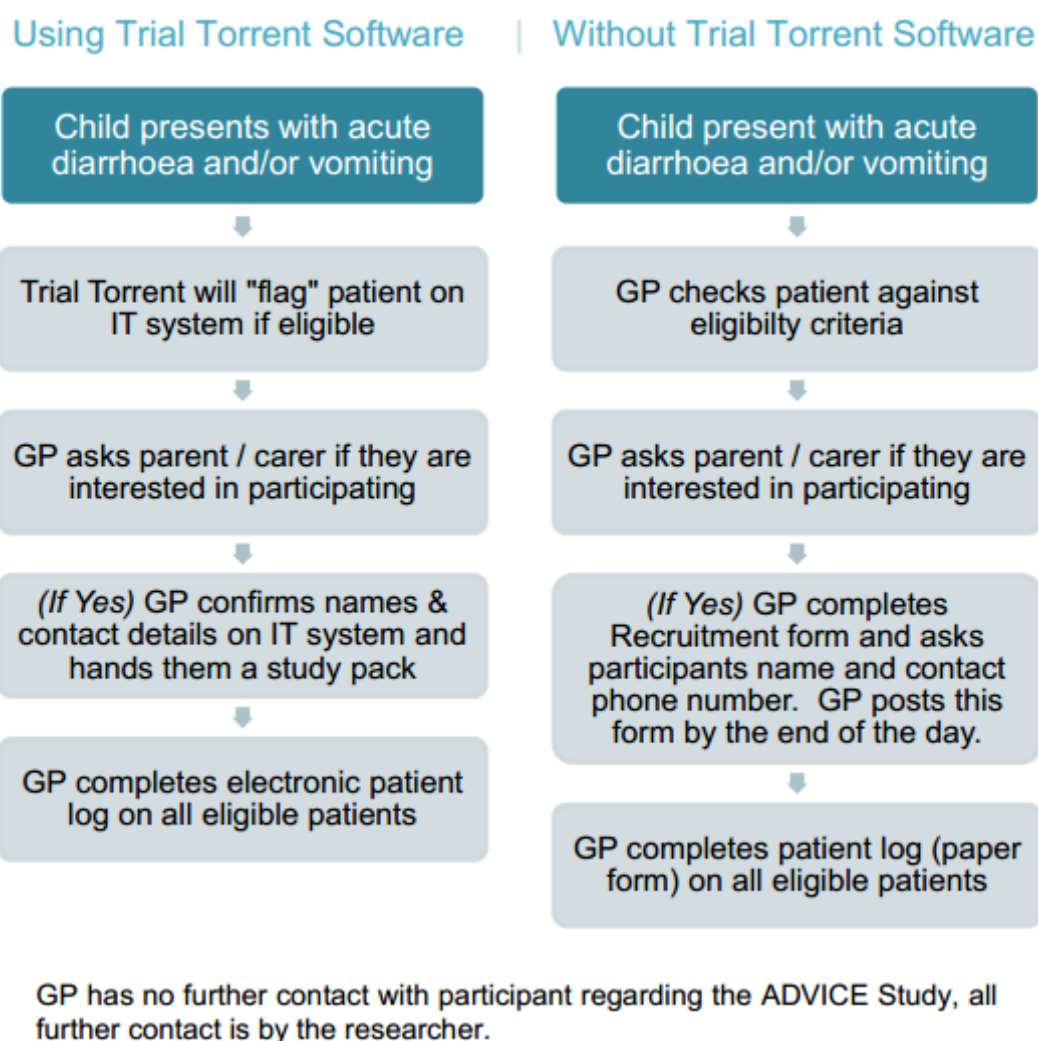
Figure 8.   **Study flowchart for both options of recruitment - Using Trial Torrent or Without Trial Torrent software**

3.8.3 Practices not using Trial Torrent

The option of a paper version patient log was provided to those practices who either did not wish to use the software or their IT system was not compatible with the software. The patient log was printed onto A4 paper and allowed input of 10 patients on one page. The other side of the sheet had a flowchart summarising what clinicians should do and in what order, with a reminder of the eligibility criteria.

Upon identifying an eligible patient, the clinician was asked to complete the baseline data on the patient log. The parent was then invited to take part in the study and provided with a study pack if they indicated interest in doing so. Parents were then asked to provide a contact name and number for the research team to contact them and GPs were asked to fax this information to the secure fax machine by the end of each working day.

3.8.4 Study Pack

The study pack (given to interested parents) contained:

- Study information for parent and child and contact information
- Consent and assent form for participation
- Three page questionnaire and one page symptom diary
- Return envelope

[See Appendix 3.2 for study pack materials]

Participants were asked to complete the questionnaire and consent form and complete a symptom diary over 14 days. If the child was 11 years or older they were asked to complete an assent Form and help their parent complete the questionnaire and diary. Participants were asked to post the completed documents back using a pre-paid envelope.

After six months, participating parents were contacted and asked about any persisting or recurrent symptoms subsequent to the consulted acute GE episode.

Practical setback: Trial Torrent Set-up

Trial Torrent is a novel piece of software and the ADVICE study was one of the first studies to use this software. As a result, we experienced considerable problems in getting the software approved for use as well as delays during study set-up and recruitment resulting in practices withdrawing use of the software or from the study entirely [Figure 9].

Trial Torrent added a delay of 3 months during the study set-up period due to the setback in implementing software in practices. There was also a lack of information regarding the IT systems that the software was compatible with, therefore upon recruiting practices keen to try the new software, were then told they could not use the integrated version and a web-based version then had to be developed. Further problems presented themselves once the practices were up and running and a further two practices reverted to the paper version of recruitment. *"We are finding the electronic ADVICE stuff very user unfriendly – there when we don't want it and not easy to access when we do."*

12 months on from the initial start date of practices to start using Trial Torrent, the final practice was set up.

There had been an expectation that this software would encourage practices to take part in the study because of the reduced burden on clinicians to remember to recruit participants. However, we were met with extreme caution and concerns by practice managers which reflected the concerns already raised by the health boards.

The idea of the software is a promising one, the reason it was not effective in this study is likely due to the fact that this study was a small scaled project run by one person. Communication regarding the steps of software installation and piloting were not apparent during the study set-up and therefore GP practices were ready to start before the software was ready to be used.
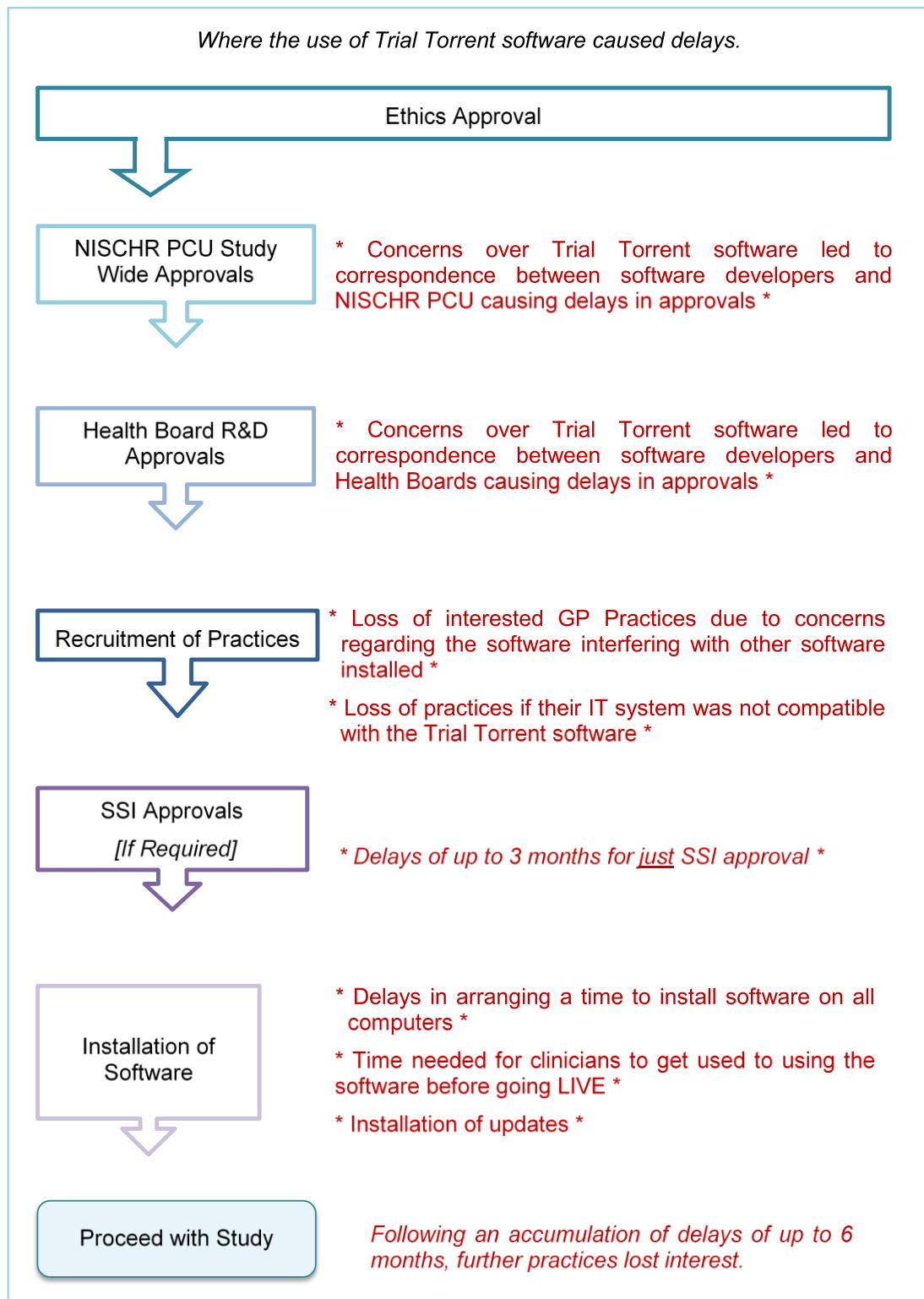
Figure 9. Delays caused by Trial Torrent.

The figure contains the following text:

Where the use of Trial Torrent software caused delays.

Ethics Approval

NISCHR PCU Study Wide Approvals
* Concerns over Trial Torrent software led to correspondence between software developers and NISCHR PCU causing delays in approvals *

Health Board R&D Approvals
* Concerns over Trial Torrent software led to correspondence between software developers and Health Boards causing delays in approvals *

Recruitment of Practices
* Loss of interested GP Practices due to concerns regarding the software interfering with other software installed *
* Loss of practices if their IT system was not compatible with the Trial Torrent software *

SSI Approvals [If Required]
* Delays of up to 3 months for just SSI approval *

Installation of Software
* Delays in arranging a time to install software on all computers *
* Time needed for clinicians to get used to using the software before going LIVE *
* Installation of updates *

Proceed with Study
Following an accumulation of delays of up to 6 months, further practices lost interest.

3.9   Data Collection

3.9.1   Parent Questionnaire

The questionnaire covered information on their child, the parents own experience during their child's consultation and their health beliefs on acute GE. Information recorded on the questionnaire included:

- Patient Information
- Patient Symptoms
- GP recommendations
- Parents health beliefs towards GE

3.9.2   Symptom Diary

Parents were asked to complete the symptom diary each day for the first 14 days of the child's illness. Participants indicated presence and absence of a set of symptoms by filling in the relevant boxes either by numbering the symptoms or ticking the relevant treatment aspects. Aspects that were recorded in the diary included:

- Child's symptoms
- Medication
- Diet
- Other Aspects

3.9.3   Six month follow up

A six month follow up was sent to all participants, after they had completed the initial questionnaire and symptom diary. Three questions were asked on a paper slip:

- Any persistence of acute diarrhoea and/or vomiting in their child
- Visited the GP with gastrointestinal problems
- Child been subsequently diagnosed with a chronic gastrointestinal condition or other illness

[See Appendix 3.3 for a copy of these data collection forms]

3.10 Data Management

3.10.1 Data Handling

A Microsoft Access database was developed to store all study data. This database was stored on a shared server owned by Cardiff University [CU] that was backed-up daily by CU Information Services.

Posted questionnaires / symptom diaries were sent to the research contact, entered into the study database and then stored in a locked cabinet.

3.10.2 Data Cleaning

The use of TeleForm[1] software enabled all CRFs that were designed and scanned into this software (Questionnaires, Symptom diary and Six month follow up) to be checked for missing data and range queries as soon as they were scanned in.

The correct range of values was decided in the design stage therefore any queries were identified during the TeleForm verifier stage. Missing data and range queries were identified by TeleForm verifier and checked against the original CRF. When exported, missing data was classed as 9 or 99 (depending on the variable).

3.11 Analysis

A statistical analysis plan (SAP) was developed for the Phase One data alongside the development of the primary outcomes of the study.

3.11.1 Primary analysis

We aimed to:

- Describe the symptoms patients most commonly suffered from during an episode of GE.
- Report the duration of diarrhoea, vomiting, fever and stomach pain during an episode of GE.
- Estimate the average duration of illness.
- Report the use of prescription and over the counter (OTC) medication.
- Report the dietary advice provided to parents during consultation.

---

[1] TeleForm is a forms processing application originally developed by Cardiff Software, but now owned by the company Hewlett Packard.

- ♦ Report the dietary management of parents (prior to and following consultation).
- ♦ Explore the duration of altered diet during and following an episode of GE.
- ♦ Report the frequency of stool sample requests.
- ♦ Explore the hygiene advice offered to parents during consultation.
- ♦ Describe any short term outcomes following an episode of GE (i.e. time off work, school).
- ♦ Describe any medium term outcomes following an episode of GE (i.e. persistence or recurrence of symptoms).

3.11.2 Exploratory analysis

We aimed to:

- ♦ Explore associations between reported chronic or persistent gastrointestinal symptoms and:
  - o Initial dietary | Medication management
  - o Presenting symptoms
  - o Parents attitudes/health beliefs of treatment and management

Practical setback: Recruitment of participants

By January 2013, with 12 practices up and running, only 21 parents had been identified and only 6 of these had returned their questionnaire/symptom diary.

Efforts to improve recruitment were put in place to keep practices engaged with the study. Emails and Newsletters were sent to the practice managers and forwarded to participating GPs. Payments were transferred to enable continued engagement with the study. NISCHR CRC (West Wales and South West) attempted to recruit more practices but no more were identified.

Unfortunately, it was not possible to visit individual practices as they were distributed all across Wales.

In order to further enhance recruitment potential primary care trusts [PCTs] and local research networks in England were approached. Local research networks/PCTs were interested in helping from:

Worcestershire – Dr David Aldulaimi; North Cumbria – Leon Jonker; Cumbria – Lesley Miller; PCRN South East [Surrey, West Sussex, East Sussex Downs & Weald and Medway] – Alana Morris; Peninsular CLRN – Jennie King; Western CLRN – Dr. Donna Ghezzi

Before any practices were recruited from England however, ethical approval to move the study across to England was required, followed by R&D approval.

3.12 Impact of setbacks - "Crunch time"

Due to the cumulative problems and setbacks, in consultation with my supervisory team, I made a pragmatic decision in January 2013 to change the plan for my PhD studies.

With the rate of recruitment and response achieved (5 recruited per month of which one participant responds) the target of 400 participants would be unattainable within the time limits of the PhD.

The following decisions were made with regards the change of direction:

➢ Discontinue the current data collection methods of the Case Series Study (excluding the patient log).

➢ Continue recording eligible patients using the patient log and ask clinicians to recruit parents to take part in a qualitative interview [Phase Three].

➢ Use the Clinical Practice Research Datalink (CPRD) retrospective observational data on children presenting with GE to describe:
   o Consultation rates
   o Prescriptions rates
   o Stool sample request rates
   o Referral rates
   [**Chapter Four**]

Qualitative interviews were already planned with Parents and clinicians therefore the recruitment for these phases were brought forward and clinicians proceeded to recruit parents to Phase Three **[Chapters Five to Eight]**.

3.13 Results

This section will summarise the main results of the original study design and will be presented in the following sections as planned in the original SAP:

- ♦ Response & Recruitment Rates
- ♦ Characteristics of Respondent and Child
- ♦ Range, duration and severity of symptoms
- ♦ Current management of acute diarrhoea
- ♦ Short and medium term outcomes of acute diarrhoea and vomiting
- ♦ Parents Lay Beliefs

3.13.1 Response & Recruitment Rates

Practice packs were sent to 15 GP Practices, 9 Practices identified 1 or more participants. The total number of participants identified was 42 of which 39 were handed study packs. At the point at which recruitment ceased in March, 11 participants had completed and returned their study packs giving a response rate of 28% [Figure 10]. With the assumption that all eligible patients were approached and recorded on the patient log the overall recruitment rate can be calculated as 92.9%.

Of the 42 participants identified, 50% were identified through Trial Torrent and 50% through the paper-based method.
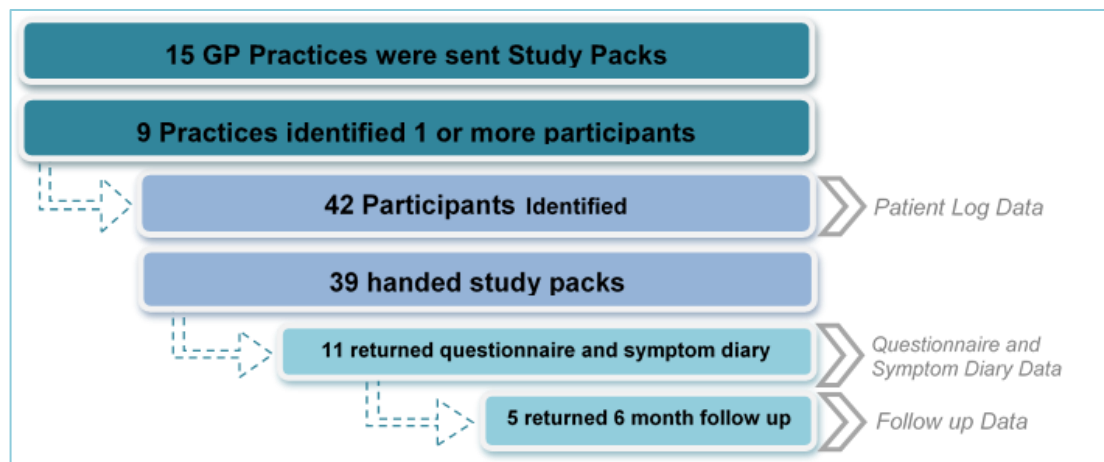
Figure 10. Recruitment numbers at each stage of the Case Series

3.13.2 Characteristics of Respondents and Child
Age of Patients

The median age for both sets of data (patient log and questionnaire) was one year old. The age of patients recorded on the Patient Log had a larger range of ages presenting (inter quartile range: 8 months to 3 years old; range: 1 month to 14 years old; mean: 2.56 years) as opposed to the patients captured in the questionnaire (inter quartile range: 8 months to 2 years 2 months old; range: 6 months to 10 years 11months old; mean: 2.81 years) [Figure 11].
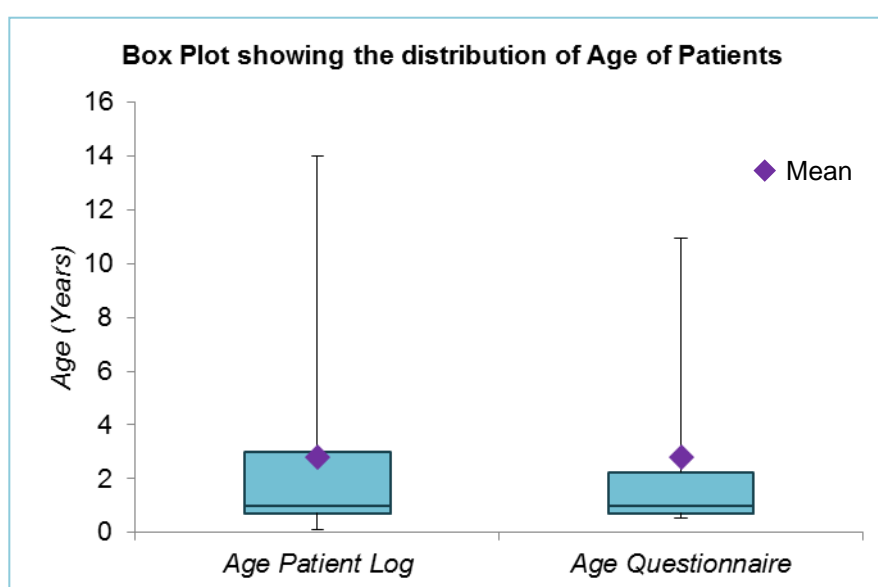
Figure 11. Box plot of the age distribution of children presenting with acute GE as recorded on the patient log and parent questionnaire.

Gender

More males presented to primary care than females, however, the parents of daughters represented a higher proportion of the returned questionnaires [Table 2].

Table 2. Gender of Patients presenting to primary care with acute GE

	Patient Log Count (%)	Questionnaire Count (%)
Male	25 (59.5)	5 (45.5)
Female	17 (40.5)	6 (54.5)
Total	42 (100)	11 (100)

Number of Adults and Children in the household

The following demographic characteristics were collected only in the questionnaire therefore n=11. 9 of the 11 of the participants (81.8%) came from a 2 adult household with the remaining 2 from a single parent household (18.2%). 6 of the

11 children were reported as an only child (54.5%) and the remaining 5 had one other sibling.

Illness in household

Parents were asked to document if any other member of the household had fallen ill with diarrhoea and vomiting as well, and if so, how many. The majority (n= 7, 63.6%) did not have any other members ill, however 3 reported that one other individual was ill and one participant reported that 2 other individuals were ill.

3.13.3 Range, duration and severity of symptoms

The following data is presented from the patient log, questionnaire and symptom diary.

Symptoms were reported upon presentation to the GP, over 14 days and on the day the parent completed the questionnaire. Diarrhoea was the most common symptom present upon consulting the GP, followed closely by Vomiting [Table 3].

Table 3. Symptoms present as recorded by clinician during consultation

Symptoms present	Count (%)
Diarrhoea	37 (88.1)
Vomiting	34 (81.0)
Stomach Cramps	6 (14.3)
Blood in Stool	0 (0.0)

None of the patients were recorded as have travelled abroad in the last 10 days before presentation to the GP, however, one carer reported in the questionnaire that their child *had* been abroad but did not specify where.

The duration and frequency of diarrhoea and vomiting were recorded by the GP to indicate the point at which the parent consulted the GP. The results indicate that after 4 days of diarrhoea and/or 2 days of vomiting they were likely to consult however the frequency and duration of both symptoms had a variable range [Figure 12].
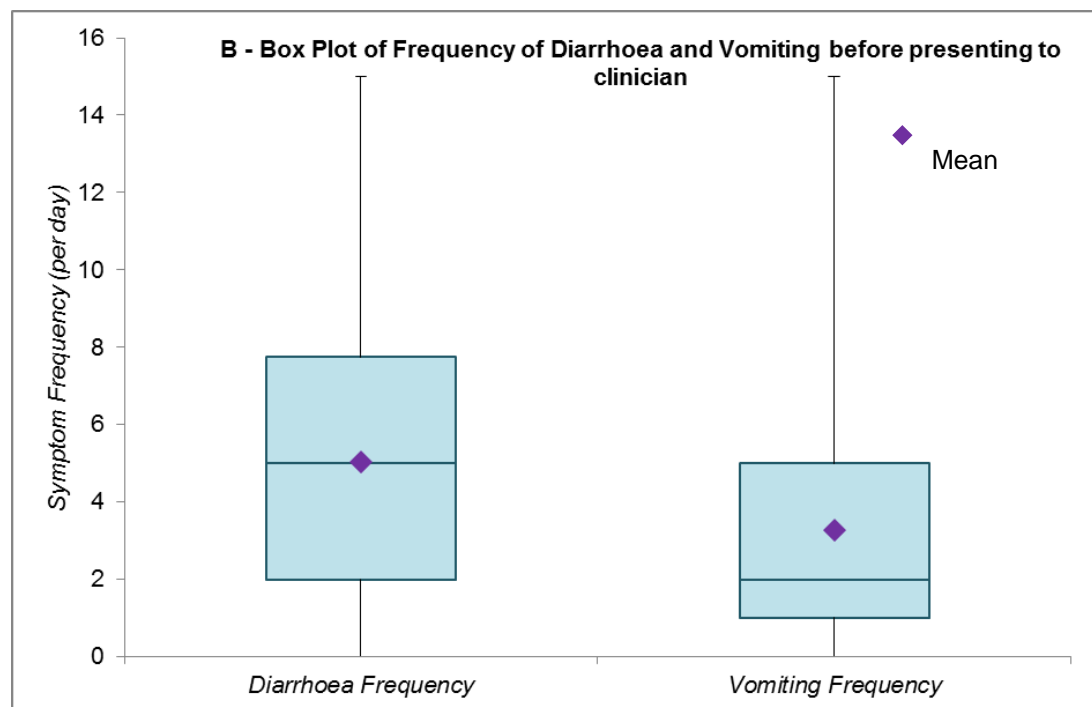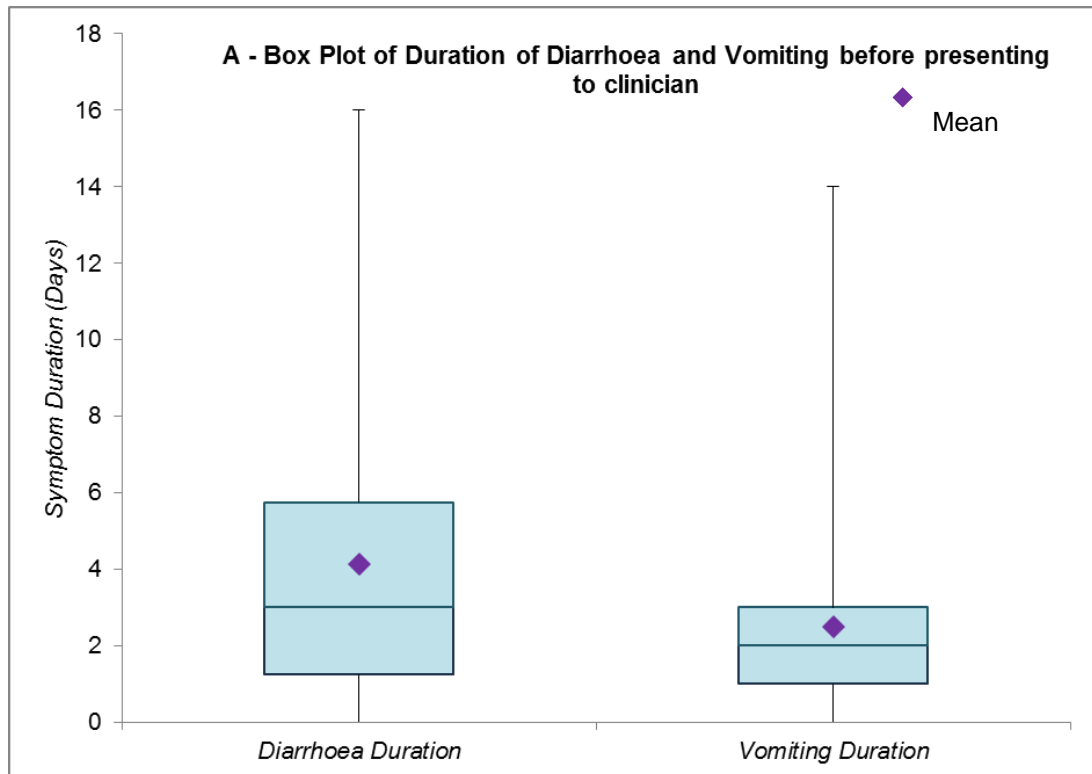
Figure 12. Box plots for the average A - Duration B- Frequency of GE prior to presenting to a primary care clinician.

A wide range of symptoms were present alongside diarrhoea and vomiting [Table 4], stomach pain, lethargy and loss of appetite were the most common symptoms additional to the diarrhoea and vomiting. Patients were reported having up to 8 symptoms additional to the diarrhoea/vomiting with only blood in stool as absent for all patients.

Table 4 Symptoms present, as recorded by the carer

Symptoms present	Count (%)
Diarrhoea	11 (100)
Vomiting	10 (90.0)
Nausea	4 (36.4)
Blood in stool	0 (0)
Stomach pain	8 (72.7)
Fever	4 (36.4)
Headache	2 (18.2)
Lethargy	7 (63.6)
Cough / sore throat	4 (36.4)
Blocked / runny nose	5 (45.5)
No appetite	8 (72.7)

Severity of four symptoms (Diarrhoea, vomiting, stomach cramp and temperature) was recorded by 11 parents over 14 days. The mean severities of each symptom are presented in a single figure [Figure 13] to enable comparison of all four symptoms.
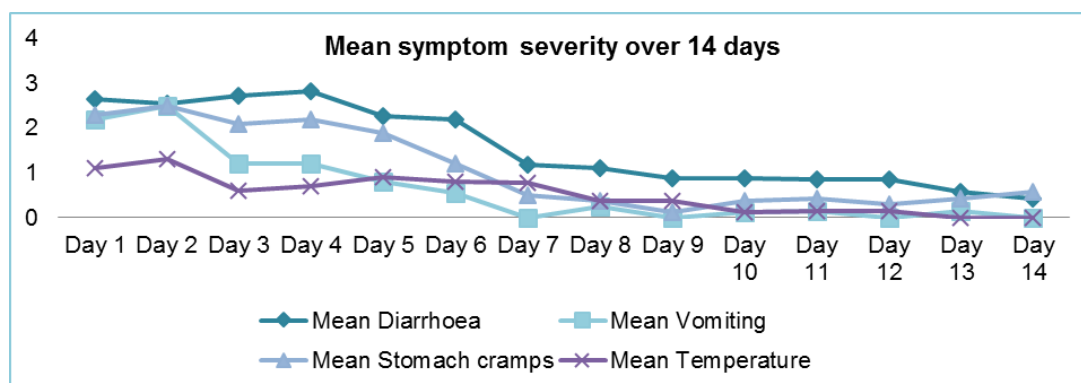
Figure 13. Average severity of symptoms during an episode of GE.

The individual symptoms are presented for all 11 participants [Figure 14]. In our population of patients, over the 14 days reported, most patients vomiting and stomach cramps had ceased by day 7, and by day 8, most patients' diarrhoea had also ceased.
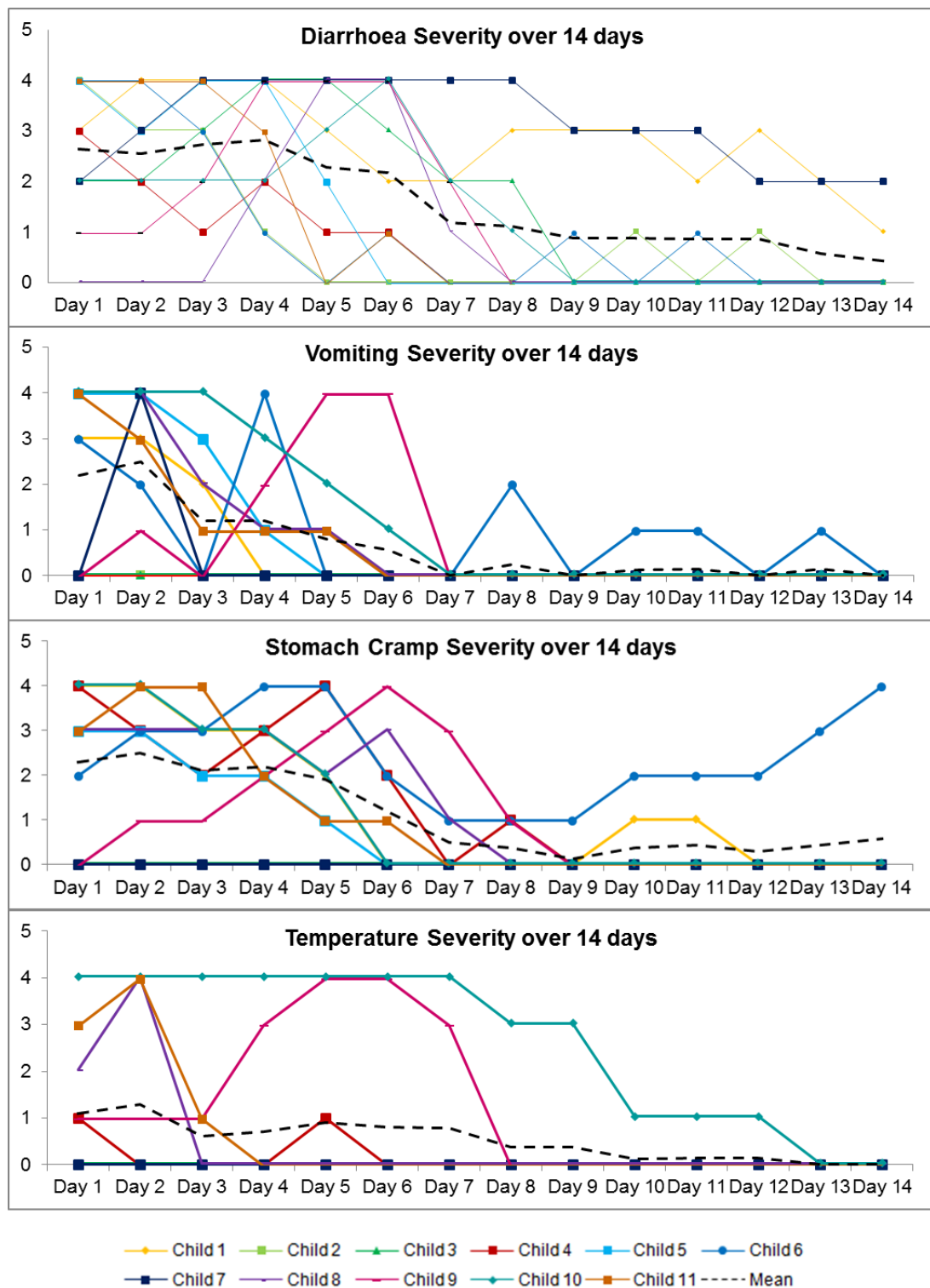
Figure 14. Symptom duration and severity for the 11 participants reported.

3.13.4 Medicinal management of GE

GP's recorded prescriptions for certain medications on the patient log, Table 5 shows the number of medications advised or prescribed for the 42 patients recorded.

Table 5. Management as recorded by the GP during consultation

	Count (%)
Antidiarrhoeals were advised	0 (0.0)
Antidiarrhoeals were prescribed	0 (0.0)
ORS were advised	12 (28.6)
ORS were prescribed	10 (23.8)
Antibiotics were prescribed	2 (4.8)

During completion of the questionnaire following the GP consultation, parents also recorded if they had been advised / prescribed certain medication. Of the eleven that returned their questionnaire, six parents (54.5%) report having been recommended ORT and subsequently recorded over the 14 days as having given their child an ORT with the average duration of one day.

Of the two patients prescribed antibiotics – as recorded in the patient log, one of these patients recorded their medication use over 14 days, and described taking antibiotics every day for 14 days.

Over the 14 days, no parents report giving their child any other medication specifically targeted to reduce their diarrhoea or vomiting. However, nine children (81.8%) were given medication for their fever, with a mean duration of 4 days.

No clinician reported recommending probiotics and no parents reported giving their child any probiotic during their child's illness.

3.13.5 Dietary Management

Dietary recommendations from the clinician were recorded by parents, with seven parents reporting being offered some form of dietary advice.

Three parents consulting at different practices reported being told to continue a normal solids diet.

Two parents were advised to avoid solids – this advice was offered to both parents by the same clinician and this was implemented by both parents (as recorded in the symptom diary).

Five parents report being advised to exclude dairy products from their child's diet. Two clinicians made these recommendations. The reported dietary management of

four out of the five carers over 14 days adhered to the clinician's recommendations. However, one parent did not indicate that a dairy free diet had been applied.

Diet was recorded over 14 days [Table 6]. An alteration in the diet appeared to be popular, even without any recommendations from the GP.

Table 6 Diet followed over 14days

	Count (%)	Mean duration Days
Breast-fed	-	-
Full strength Formula Milk	4 (36.4)	4
Diluted Formula Milk	2 (18.2)	1
Liquid only diet	7 (63.6)	2
Limited solids diet	7 (63.6)	3
Dairy free	5 (45.5)	1
Normal diet	5 (45.5)	3

Some parents reported altering the diet in multiple ways. The most frequently reported combination was a liquid diet and a limited solid diet over the 14 days followed by a combination of a limited solids and a dairy free diet – of which four of the 11 parents combined these three diet alterations during the 14 days.

3.13.6 Advice sought before consulting GP

Parents were asked to record on the questionnaire what, if any, advice they sought before presenting to the GP that day, seven participants indicated that they had not sought any advice. Two participants reported they had consulted the out of hours GP service, one had consulted a pharmacist and two indicated they had sought advice from the Internet.

3.13.7 Other recommendations during GP consultation

Data from the patient log reported that none of the 42 patients that presented to primary care were admitted to hospital as a result of the consultation and nine patients were reported as having been requested to provide a stool sample.

Parents reported consulting a GP up to 3 times for the index illness over the 14-day diary period in some cases. However, the average number of consultations over the 14-day period was 1.7. A stool sample was requested in four cases. One child was admitted to hospital. No parents reported presenting to A&E during the 14 days.

Other advice/recommendations provided by the GP, as reported by parents in the questionnaire were:

♦ *"Keep checking temperature and look out for rashes"*

- *"No food for 12 hours"*
- *"Stool and urine sample to be taken"*

3.13.8 Short term outcomes of acute diarrhoea and vomiting

Five parents reported that they had been off work due to their child's illness and five children were reported to have been off from school. Over the 14 days, the average duration of time off school / nursery was 3 days.

3.13.9 Medium term outcomes of acute diarrhoea and vomiting

Of the 11 parents who returned their questionnaire and symptom diary, 5 also responded to the six month follow up. No parents reported that their child had experienced a recurrence of GE, had consulted their GP regarding GE symptoms or been diagnosed with a chronic GI condition.

3.13.10 Parent lay beliefs

Parents were asked to state their agreement to six statements related to acute diarrhoea and vomiting [Table 7].

Table 7. Parents' responses to six statements related to health beliefs of GE.

Count of responses to each statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
"The best way to treat diarrhoea in children is by stopping usual food / feeds until they are better"	2	2	2	3	2
"It is important to consult the GP every time a child has diarrhoea and or vomiting"	1	3	3	3	1
"Antibiotics help treat diarrhoea and or vomiting"	4	3	4	0	0
"Probiotics are a way to treat diarrhoea and vomiting in children"	0	5	5	1	0
"Diarrhoea and vomiting is usually caused by food poisoning"	5	3	2	1	0
"Hand-washing is necessary in controlling the spread of diarrhoea and vomiting"	0	0	0	2	9

3.14 Discussion

This section will summarise the results from the case series, discuss the limitations of this work, compare the results of this chapter with previous work and explore the implications of these results for patient care and clinical practice.

3.14.1 Summary of results

42 patients consulting with their GP were identified as being eligible, of which 39 were invited to take part in the study, with the assumption that the 42 patients represented all possible eligible patients, the recruitment rate was 93%. 11 parents participated in completing the baseline questionnaire and symptom diary, resulting in a response rate of 28%.

The majority of presenting patients were aged between 8 months and 3 years. Symptoms present during GE varied patient to patient however abdominal pain, lethargy and loss of appetite were most frequent after diarrhoea and vomiting. Patients typically presented to primary care after 4 days of diarrhoea and/or 2 days of vomiting. By day 8 vomiting and diarrhoea symptoms had ceased for the majority of patients.

Oral rehydration solutions were commonly advised or prescribed by clinicians, two patients were prescribed an antibiotic however no other medication was given specifically to treat the diarrhoea or vomiting symptoms. The majority of parents did record however, that they gave their child medication for their fever/pain.

Several parents reported receiving dietary advice during their consultation which varied from excluding dairy products to continuing a normal solid diet. Many parents altered their child's diet during the 14-day diary, even if it had not been recommended by their clinician.

Some parents reported seeking other sources of advice before consulting primary care, however, the majority reported that this was their first contact with healthcare services for the GE episode.

One in five patients were requested to provide a stool sample and no patients were admitted to hospital on the day of the initial GP consultation. However, over the next 14 days of parents reporting their child's illness, one child was admitted to hospital. The average number of GP consultations for paediatric GE was 1.7 times with a maximum of 3 times over 14 days.

Five parents reported having time off work and five children were reported to have been off school over the 14 days. The average duration of time off school/nursery was 3 days.

No patients reported any recurrence or persistent of symptoms during the 6 months subsequent to the episode of GE and no patients were diagnosed with any chronic GI condition.

Parents indicated varied beliefs about dietary management, when to consult their GP when their child had diarrhoea or vomiting, and were unsure as to the place of probiotics in managing this condition. Parents were more consistent in the belief that antibiotics don't help treat diarrhoea or vomiting, that food poisoning is usually the cause of the illness, and that hand washing helps control the spread of D&V.

3.14.2 Other work in this area

It is not clear how many participants were not invited to the study during the recruitment period.   We calculated that an average practice could recruit 14 participants in a 12 month period.   In six months, 39 were recruited from 9 practices, suggesting that 24 potential patients may have been missed $\left(\left(\frac{14}{2}\right)*9\right)-39=24$. However, determining the actual number would require searching through the practices' patient records. Diarrhoea and vomiting is a sporadic condition that often presents in outbreaks so peaks and troughs in consultation rates are highly likely. We may have been attempting to recruit during a trough in consultations. The average GP presentation rates of paediatric GE could be determined by analysing consultation trends in the Clinical Practice Research Datalink (CPRD), and would provide a useful estimate of the potential recruitment rate in this study.

The clinical features for acute GE depends on the pathogen. It is not clear from our data what pathogen (if at all) infected the patients and therefore we cannot separate the patients into sub-groups based on the infecting pathogen. We aimed to describe the presentation, management and outcome of this common illness and provide the range of symptoms and duration of these symptoms. Uhnoo et al. (1986) characterised the clinical features of various pathogenic diarrhoeal illnesses. The average duration of diarrhoea ranged from 6 to 14 days depending on the pathogen isolated and the average time before consulting a clinician was four days of symptoms. In our study, the duration of diarrhoea ranged from 1 to 14 days and patients most frequently consulted their GP on day 4. Therefore, despite the small

number in this study, the findings are compatible with previous findings. It would be interesting to investigate whether the symptom duration is the main reason parents take their child to the GP or whether there are other factors that influence parents' decisions to consult their GP. This will be discussed during the qualitative interviews with both the carers and primary care clinicians to ascertain the reasons for consulting and perhaps gain an understanding from the clinicians perspective if duration of diarrhoea is an appropriate measure of whether to consult or not.

Previous work suggest the duration of vomiting and fever both average 2.4 days (Uhnoo et al. 1986) which is comparable with 2.8 and 2.4 days (respectively) calculated here.

Medicinal management

Six parents recorded giving ORT to their child for an average duration of one day. ORT is advised by NICE guidance as the main method to prevent and treat dehydration (NICE 2009). For children with no clinical signs of dehydration, other fluids should be encouraged and breastfeeding should continue throughout the episode. It is not clear whether the reason these 6 parents were giving their child ORT to treat dehydration or as a means to prevent dehydration. Decisions regarding fluid management during an acute episode of GE would be an interesting area to explore in the interviews with carers.

The NICE guidance clearly states, under "other therapy", to not use antidiarrhoeal medications however mentions no other advice regarding other medications such as anti-emetics, anti-pyretics or probiotics (NICE 2009, ©NICE 2009). Parents in this study did not give their children either antidiarrhoeals, antiemetics or probiotics at any point over the 14 days recorded. They did, however, give their child medication for fever.

No probiotic supplements were recommended by GPs and no parents reported giving their child a probiotic supplement over the 14 days recorded.

Dietary management

A Cochrane review concludes that introducing feed during or immediately after starting rehydration (also advised in the NICE guidance) does not affect the number of vomiting episodes or the development of persistent diarrhoea. It also discusses the heterogeneity of data around duration of diarrhoea and early / late re-feeding therefore despite the NICE guidance advising early re-feeding it is unclear of the

advantage or detrimental effect of this on patients. The majority of parents in this study gave their child a liquid only or limited solid diet for an average of 2 and 3 days respectively which does not conform to the NICE guidelines of a "*normal solids diet*" as soon as child has been rehydrated. It is unclear whether this had a detrimental effect on presence and / or duration of symptoms, as the study was not powered to investigate this. It is clear, however, that there is a variety of dietary management methods that parents follow, whether this is what they had previously been told by their GP or from their own experience of managing this illness is not clear. It is an important question to ask and will be a focus in the interviews with carers and also clinicians as to what they advise.

Stool sample requests

The rates of stool sample requests in this study (one in five) were higher than reported elsewhere - IID2 Study reported that 4.5% of disease in community is captured in stool sample and 1.1% of community illness is positive by routine lab test (Tam et al. 2012). However, this is averaged for all ages. We will investigate stool request rates in the paediatric population using CPRD data. It will also be interesting to understand the clinicians' decisions behind requesting stool samples – this will be done during the clinician interviews.

GP consultation rates

Incidence of GE was a lot lower than expected, as previously discussed during the decision to continue / cease recruitment after 6 months of the start of recruitment. Previous estimates based on figures from IID2 study indicated 50 under 16's per year would be expected to present to their GP in a practice with a list size of 6000 patients. Therefore, in the 6 months of recruitment with 9 practices, we expected to identify upwards of 225 eligible participants into the study$(9 * 25 = 225)$.

Hospitalisation rates

One patient was reported to attend hospital during the 14 day diary follow up period. This is unexpected due to the low numbers of children requiring hospitalisation due to acute GE. Szajewska and Dziechciarz (2010) reported that for every child with a rotavirus cause of D&V that one in every 54 patients will require hospitalisation. As we do not know the cause of the child's illness, and do not have details as to why this child needed to attend hospital we cannot compare this with other cases. The CPRD database could be used to ascertain how many patients are hospitalised due

to acute GE. Qualitative research methods could be used to explore with parents and clinicians their perceptions of when hospitalisation is appropriate.

Time off work / school

45% of children were reportedly off school / day care with an average duration of 3 days. Roberts et al in a study of the cost of illness infectious GE has on the community found that 30% took time off school for an average of 4 days, and 45% of parents reported time off work, probably to look after those that were off school / day-care (Roberts et al. 2003).

It is not possible to determine how long parents waited before returning their child to school / day care in my study as it is unclear where the weekends fell during the 14 days of data collection or whether it was school holidays. Interestingly, although the average diarrhoea duration was 7 days, parents reported only keeping their child off school/nursery for 3-5 days. It is not clear where the weekends fall but it appears likely that in some instances parents are sending their children back to nursery/school during or within 48 hours of the illness.

Lay beliefs

The NICE guidance indicates that solid food should be stopped during the acute phase of the illness and during the first few hours of re-hydration and then normal diet should resume. All respondents varied with their attitudes towards this recommendation and this is a key area to be investigated during the interviews with carers. Carers also reported varying beliefs about whether or not to consult a GP every time their child has diarrhoea and vomiting.

Encouragingly, all believed that antibiotics were not indicated in the treatment of for GE, only certain bacterial causes of GE require antibiotics, and these would be severe cases (McClarren et al. 2011). Another encouraging response was supporting the belief that hand-washing is necessary in controlling the spread of GE – hand washing is the most effective way to reduce the risk of diarrhoea (Curtis and Cairncross 2003).

The use of probiotics for the treatment of acute GE has not consistently been proven to be effective and is thus not included in the NICE guidance. Parents reported mixed views as to whether they support probiotics and is an interesting area to pursue in the interviews with parents but also when discussing recommendations clinicians give.

3.14.3 Strengths / Limitations

The main limitation in this study was small number of recruited participants. With larger numbers, it would have been possible to investigate the impact of management on the symptoms, symptom duration and medium term outcomes of the illness. Unfortunately only a description of the symptoms, management and outcomes was possible.

Despite this, there were interesting findings, which will form the basis of further work in this thesis and also future work beyond the remit of this PhD research.

The variation in dietary management is a particular important area to investigate further, to better understand the beliefs and attitudes behind this behaviour.

Prospective data from the patient log described the point at which a parent brought their child to the GP, the prescriptions and stool sample request rates, which indicates the impact of acute GE on primary care resources.

3.14.4 Lessons learnt

There were three main delays discussed in this chapter and the impact on the time-line was discussed. This section will discuss these delays with respect to lessons learnt and what could be done in the future to avoid a repeat of premature study closure.

Impact of R&D delays

Throughout the study set-up, gaining R&D approval proved less than efficient, despite the recently introduced [July 2011] streamlined approach to gaining health board approval through NISCHR PCU. Lessons learnt from this aspect of study set-up is largely allowing more time than anticipated, to make every detail of the study procedures as clear and obvious as possible and determining any potential concerns as early as possible in order to provide responses as rapidly as possible.

Impact of Trial Torrent

The areas of impact from the use of Trial Torrent covered study approvals, practice recruitment, study set-up in practices and even during recruitment. The premise that the software would create a simple platform for GPs to recruit patients was largely accurate, the problems elsewhere were not apparent, expected or communicated in a manner in which they could have been avoided.

In future, this or a similar software would need to have been piloted in the practices before study set up to ensure the practice, the IT system, the health board and the GPs were all on-board before beginning the study. Clear timelines and deadlines would also be required in order to ensure the study progressed as per the agreed schedule.

Recruitment

From the patient log it is unclear how many patients were not approached, as it seems that only participating patients were recorded on the log. Practice managers who showed an interest themselves seemed to inspire the GPs to recruit, of the practices that recruited provided a steady, albeit slow, recruitment of patients so it is unlikely that the study was forgotten. An upfront payment plus payment per patient recruited appeared to work with those practices who recruited patients.

The problem was, however, the practices that had gone through all the study approvals, software installation and were "live" and then did not recruit any patients. Thus missing out on the upfront payment (which was transferred upon their first patient recruited) and any further payments. Communication with these practices was all through the practice manager, therefore, a future approach may be to communicate directly with the individuals who will be identifying the patients.

Where do we go from here?

The proposed study was not able to answer any of the objectives with high statistical power therefore all conclusions are working hypotheses. For this PhD, the aim was to answer as many of the objectives using alternative methods such as the use of the retrospective observation data and / or by exploring the answers using qualitative methods. The majority of the objectives can be answered using either or both of these methods [Table 8], however investigation into possible associations between an acute episode and further GI problems is unlikely to be approached in this work.

Retrospective data could look at the numbers of chronic GI conditions in those patients who presented with an acute D&V episode, however, a prospective case series would have considered more of the confounders associated with chronic GI problems and perhaps enlightened GPs into the most appropriate management following an acute episode in order to reduce the risk of chronic problems. This would be an area to focus on in future work rather than briefly touch on whilst describing the retrospective observational data.

Table 8. Comparison of Case Series Objectives and how these will be answered in this thesis

Case Series Objectives	How can this be answered?
Primary	
To provide a description of the presentation of acute diarrhoea and vomiting [D&V] in children consulting a general practitioner.	Incidence of D&V related GP Presentations using retrospective observational data. Describe by Age, Region, Gender.
	Explore using qualitative methods the reasons why and when parents present to their GP.
To describe the current management of acute diarrhoea and vomiting in primary care including: - The prescribed and recommended medication,	Rates of prescriptions, Stool sample requests, hospital referrals and re-consultations using retrospective observational data.
- The dietary advice given to carers and their interpretation of dietary advice by their clinician and the actual dietary management carried out.	Explore using qualitative the diet parents use to manage their child's illness, their beliefs around nutritional management. Also discuss with GPs their recommendations around diet and their beliefs.
	Also explore with both parents and GPs their beliefs around medication, stool samples and reasons for hospitalisation.
To describe the short and medium term outcomes of acute D&V in children presenting to primary care	Repeat episodes can be identified using the retrospective observational data. Perceived outcomes by GPs can be investigated using qualitative methods.
	The retrospective observational data would also be able to investigate further GI problems following an acute episode – although this would be outside the remit of this PhD.

3.15 Chapter Summary

A prospective case series of 384 patients presenting with acute GE to primary was designed and developed. Data collection methods included a baseline CRF to capture the presenting symptoms and demographics of all eligible patients, a questionnaire and 14-day symptom diary for participating parents to return and a six month follow up form to identify any further GI problems subsequent to the reported episode.

Primary outcomes were to describe the symptoms, medication and dietary management prior to and subsequent to a primary care consultation as well as capturing the burden of GE on both the parent, patient and primary care resources.

GP Practices were recruited to identify and invite patients and their parent to take part in the study and a piece of software (Trial Torrent) was used in half of the practices to aid in recruitment. Delays in approvals and recruitment resulted in the study closing after six months.

42 patients were recorded in the baseline CRF and 11 parents completed the questionnaire and symptom diary. Home management of GE was variable for both dietary management and medication. Recommendations from clinicians were not always in line with current guidance and was variable across and within practices.

The burden on primary care resources was found to be higher than previously reported especially with regards prescription rates and stool sample request rates. The burden on parents and the child, although considerable, was found to be in agreement with current literature.

Parents indicated varied beliefs about dietary management, when to consult their GP when their child had diarrhoea or vomiting, and were unsure as to the place of probiotics in managing this condition. Parents were more consistent in the belief that antibiotics don't help treat diarrhoea or vomiting, that food poisoning is usually the cause of the illness, and that hand washing helps control the spread of GE.

The subsequent chapters aim to explore these findings in more detail using a large patient data set or on an individual basis during qualitative interviews.

Novel findings – Despite the small sample, this study identified considerable variation in home management and GP consultations for patients experiencing similar clinical symptoms.

CHAPTER FOUR:
RETROSPECTIVE, OBSERVATIONAL STUDY OF ANONYMISED PATIENT DATA

4.1   Introduction

This chapter aims to answer most of the objectives from chapter 3 using anonymised patient data from UK patients. An explanation about what the data comprise and how they were obtained is followed by how they were used for this project. After outlining the planned analysis, the results are presented and a comparison with current literature is made. The chapter concludes with a discussion of the limitations of this study.

4.2   Clinical Practice Research Datalink

CPRD, formally known as the General Practice Research Database [GPRD], is a UK database of anonymised NHS clinical patient records derived from primary care. Patient data are prospectively collected from primary care consultations, anonymised, validated and checked for quality. Participating GPs currently contribute data on more than five million patients and are broadly representative of the UK population in terms of age, gender and region (Wood and Martinez 2004). CPRD comprise data on patient demographics, medical diagnoses, all GP prescriptions (electronic issue), referrals to secondary care and clinical sample tests.

4.2.1 Read Codes

Patient findings and procedures are coded with Read Codes (a coded thesaurus of clinical terms). The structure of all Read Codes are alphanumerical and are organised in a hierarchical system. The first level contains chapters and subsequent levels contain sub-chapters e.g.:

Level 1 - **A….00** Infectious and Parasitic diseases

> Level 2 - **A0…00** Infectious Intestinal Diseases

>> Level 3 - **A07y000** Viral gastroenteritis

Prescriptions are arranged in chapters and sections based on the British National Formulary [BNF] (BNF 2014) e.g.:

9 Nutrition and blood

9.2 Fluids and electrolytes

9.2.1 Oral preparations for fluid and electrolyte imbalance

9.2.1.2 Oral sodium and water > Oral rehydration therapy (ORT)

4.2.2 Data Quality

CPRD uses quality markers to ensure both patient-level and GP Practice-level data are of appropriate quality. Patient records are flagged with 0=unacceptable or 1=acceptable based on patients having a valid gender, a birth year, no events prior to birth year and a valid registration date. Practices are marked with an "up-to-standard" [UTS] date from which practice data is of research quality.

4.3 Aims of the Observational Study

4.3.1 Primary aims

The primary aims were:

- ♦ To describe the annual consultation rates for paediatric acute GE.
- ♦ To describe the number of episodes per year a child consults their GP regarding acute GE.
- ♦ To quantify referral rates of these patients to secondary care.
- ♦ To quantify stool sampling rates in paediatric patients consulting with GE.
- ♦ To describe the prescriptions associated with paediatric GE.

4.3.2 Secondary aims

The secondary aims were:

- ♦ To describe trends in consultation rates over 10 years.
- ♦ To explore associations between patient demographics and reported clinical management and patient outcome.

4.4 Methods

4.4.1 Study Design

This study was a retrospective observational study using routine data from primary and secondary care medical records of patients that presented with acute GE over a ten year period.

4.4.2 Study Population

Inclusion criteria: Cases were children aged 0-16 years inclusive, with a diagnosis medical code indicating acute GE between January 2003 and December 2012 (inclusive).

Sample size: In 2009, the community cohort study of IID2 study reported consultation rates for infectious intestinal disease of 133 per 1000 person-year (95% CI 92 to 199) – this represents all ages. In 2003, CPRD represented approximately 3.6 million active patients therefore using the 2003 population estimate of 19% to represent patients aged ≤16years (thus n=684,000) it was expected that data that would be available for upwards of 909,720 patients over the 10 years of observation $(684 * 133 * 10)$.

Patients were identified based on their diagnostic code (related to acute GE) entered at the time of consultation. All prescription, test and hospital data linked with the consultation were included.

Age of patient

Using the NRES guidance, paediatric patients were defined as individuals up to the age of 16 years (NRES 2012).

Diagnostic codes

Diagnostic codes were identified from a list of all 103,666 diagnostic Read Codes available. All those that were related to symptoms or diagnosis of acute GE were included. These were established from a list already developed for use by Trial Torrent software (Chapter 3) that identified eligible patients for Phase One of this project. Primary care clinicians also checked over the list to ensure it covered all possible Read Codes.

[See Appendix 4.1 for all included Read Codes].

4.5   Data Management

4.5.1   Terminology

For this chapter, the following definitions are applicable to the following terms:

Consultation – An individual patient-clinician meeting in a primary care setting i.e. a patient consults their GP with a GE complaint.

Episode – Represents the entirety of one illness i.e. a patient suffered from an episode of GE that lasted 3 days.

Patient Record – The electronic medical record of a patient for one consultation.

Case – The data available in a single row of the dataset – this does not necessarily represent the entirety of the patient record.

4.5.2   Data Extraction

Using the CU license for use of CPRD data and the approved protocol for use of the data for this project, we requested the desired patient data [See Figure 15].

Variables: All data variables from within eight linked data tables were requested from the primary care database, and from three data tables within the secondary care database.   Variables included gender, month & year of birth, date of consultation, therapy product etc.

[See Appendix 4.2 for full list of CPRD variables included]

We were then provided with eight lookup tables containing data matching the criteria of patient age, year of consultation and diagnostic read codes. This data was then linked by the variables *patid* and *consid* (patient and consultation unique identifiers) to form a flat file of data.

All patient data extracted was flagged by CPRD as being "acceptable" research quality and whose event/s occurred during periods where their GP practice was 'up-to-standard' [UTS] according to CPRD quality indicators.
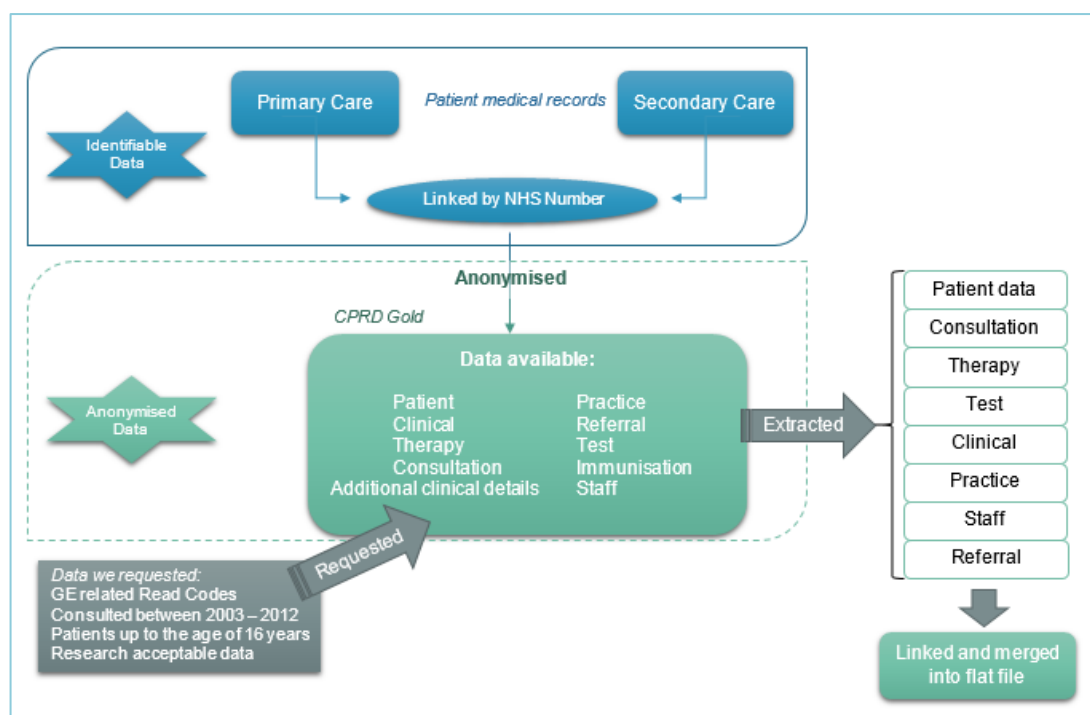
Figure 15. Flowchart of how identifiable patient data becomes available as anonymised data for researchers and the data requested for this project.

4.5.3 Data Cleaning

Data was initially checked against the inclusion criteria used to extract the data. All consultations were within the date range of 2003 and 2012 and all patients were 16years or younger at the time of consultation. All consultation data included one of the pre-defined Read Codes. All cases were checked for missing patient identifier information. Missing data in variables associated with clinical sample test, referral to secondary care or prescription variables were assumed to be consultations where none of these management outcomes occurred.

Records pertaining to a single consultation were identified and aggregated into one 'case' therefore each case represented all information related to a unique consultation. The unique identifiers used were patient id (*patid*) and consultation id (*consid*). Age was calculated using the variables *month of birth*, *year of birth* and *date of first consultation*. [Date of consultation – mmm/yyyy]. Siblings were identified using *family number* as the identifying variable.

4.6 Analysis

An SAP was developed based on the study objectives and the types of data available in CPRD.

4.6.1 Primary analysis

We aimed to describe:

- The annual consultation rates for acute GE.
- The average number of consultations per patient per year.
- The number of consultations per episode of GE.
- Stool sample request rates per consultation.
- Prescription rates per consultation.
- The most frequent prescriptions associated with GE.
- Hospital referral rates per consultation.

4.6.2 Secondary Analysis

We aimed to:

- Conduct a time series analysis over 10 years of monthly consultation rates.
- Explore associations between patient demographics and:
  - Hospitalisation
  - Stool Sample Requests
  - Prescriptions

4.6.3 Planned statistics

Univariate analyses described patient characteristics such as age and gender, the seasonality of consultations and rates per year. These were described using means, modes and ranges, and presented in frequency tables and graphs where appropriate.

Consultation rates were calculated using practice denominator data of the number of patients aged 0 – 16 years registered at the practices each year. A simple linear regression was used to analyse trends over time using year as the predictor.

Our original definition of what an acute GE episode was classed as was lasting no longer than 14 days. Using this definition, we have assumed that any consultation after 14 days (of the previous consultation) indicates a new episode. Calculating the time difference between each patient consultation allowed the number of (consulted) episodes each year a patient experienced.

Time series analysis on consultation rates were run over the 10 years of data available. Seasonality of GE consultations were presented using spectral plots and line graphs.

Associations were explored using Chi-square tests and logistic regression and summarised using *p*-values and 95% confidence intervals [CI]. Confidence intervals were calculated from Newcombe (1999) & Bland and Altman (2000). Data was analysed in SPSS[2] and graphical outputs were presented using Microsoft Excel.

4.7 Results

4.7.1 Identifying unique consultations

The flat file database for all extracted patient records contained 97 variables and 1,995,986 cases. The dataset contained multiple cases per patient record - the number of cases representing one unique consultation ranged from 1 – 749 [Figure 16].

Using *patid* and *consid* unique consultations were identified. The patient records that contained multiple cases held information on prescriptions, test requests and prescriptions. For each additional variable, a new case (row in SPSS) of data was created, therefore resulting in multiple cases, each containing some unique data [Figure 17].

For describing patient and practice demographics, consultation rates and referral rates one row of patient data was required. Therefore these were selected into a separate dataset and analysed. For rows where test and prescription information differed, these cases were reformatted into variables to allow identification of each test/therapy.
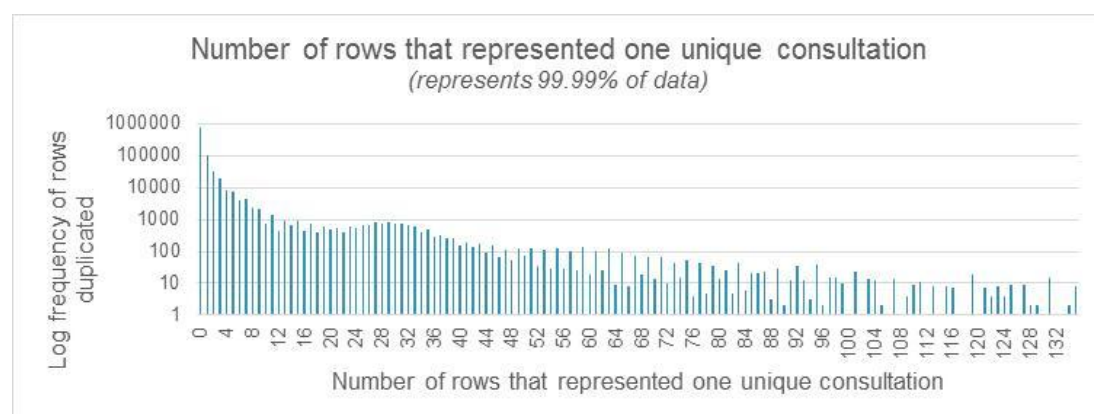
Figure 16. Graph describing the number of multiple cases that made up the dataset

[2] IBM SPSS Statistics 20.0

Figure 17. Example of how the dataset looked and what the multiple cases could represent

4.7.2 Characteristics of data

In the dataset, 106 different Read Codes were identified that related to acute GE. 9 Read Codes represented 91% of the data with "Vomiting" and "Diarrhoea" both representing over 25% each [Figure 18].
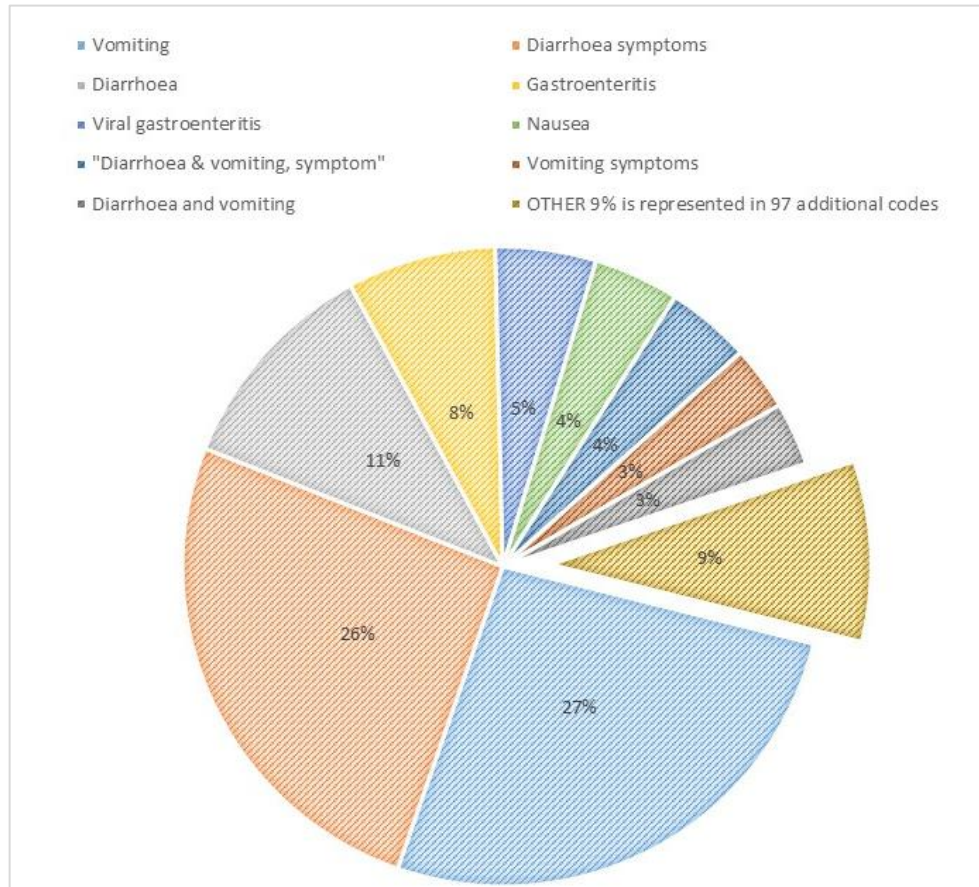
Figure 18. Percentages of Read Codes relating to acute GE.

4.7.3 Patient demographics

Between 2003 and 2012, there were 951,098 patient consultations that met the inclusion criteria for this study. These comprised 535,471 individual patients.

Gender

Nearly all patient records contained gender information. Males represented a higher proportion of the data then females [Table 9]. 3 patients were recorded as "Indeterminate" and accounted for 0.00032% of the patient population and thus were removed when describing data by gender.

Table 9. Count and Percentage of patients gender in the whole dataset

	Count	Percentage
Female	449769	47.29%
Male	501326	52.71%
Indeterminate	3	0.00%

Age

Patients aged 0-2years represented over 50% of the study population [Table 10 and Figure 19].

Table 10. The count and percentage of patient age in the whole dataset

Age	Count	%
0 years	117441	12.35%
1 years	267051	28.08%
2 years	150351	15.81%
3 years	81575	8.58%
4 years	55533	5.84%
5 years	42981	4.52%
6 years	34207	3.60%
7 years	27672	2.91%
8 years	23187	2.44%
9 years	21240	2.23%
10 years	19994	2.10%
11 years	19119	2.01%
12 years	18901	1.99%
13 years	17815	1.87%
14 years	17179	1.81%
15 years	17714	1.86%
16 years	19136	2.01%
Total	951096	100.00%
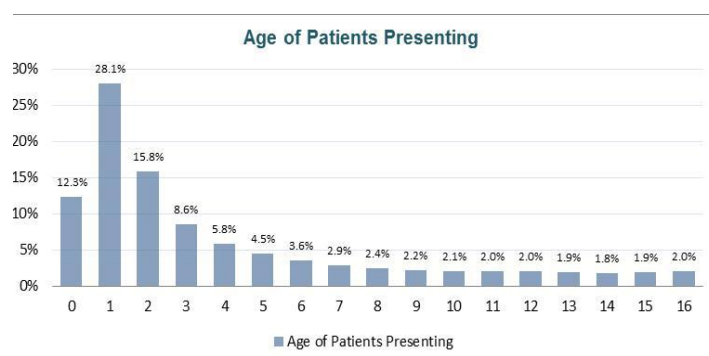
Figure 19. The distribution of patients by age for the dataset

Siblings

The vast majority of families had 3 or fewer siblings (99.99%) and most patients had no sibling (94%) [Figure 20].
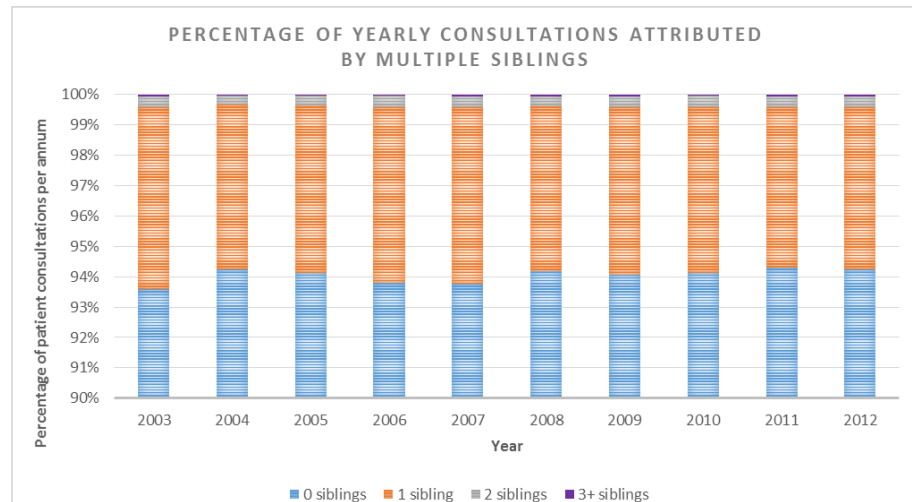
Figure 20. The percentage of consultations attributed by multiple siblings each year

Country

The countries that the data represented were England, Northern Ireland, Scotland and Wales. Most patients were from England (~81%, n=772,737) [Figure 21].
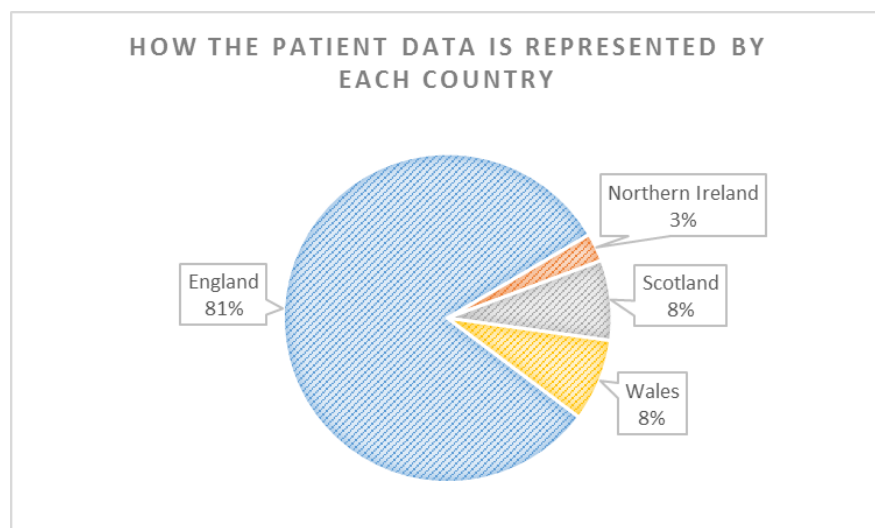
Figure 21. The percentages each country in the UK is represented in the data

4.7.4 Consultation rates

Consultation rates increase between 2004 and 2006 [Table 11 and Figure 22] and then slowly decline for the subsequent 6 years. Consultation rates range between 68.8 and 84.8 patient per 1000 person-year (95% CI 68.3 – 85.3).

A simple linear regression showed that the rates of consultations have decreased by a rate of 0.386 per year on average, and this relationship was statistically significant (95% CI 0.767 – 0.006, p=<0.05).

Table 11. Consultation rates over 10 years; * Rate per 1000 person-years; **Confidence intervals were calculated from (Newcombe 1999)

Year	Patient Consultations	Patients registered *per annum*	Rate*	95% Confidence** lower	upper
2003	96101	1207780	79.6	79.1	80.1
2004	95138	1221372	77.9	77.4	78.4
2005	96649	1230323	78.6	78.0	79.0
2006	105990	1249617	84.8	84.3	85.3
2007	102343	1247773	82.0	81.5	82.5
2008	99654	1237288	80.5	80.0	81.0
2009	98269	1226188	80.1	79.7	80.6
2010	94342	1217555	77.5	77.0	78.0
2011	83040	1186779	70.0	69.5	70.4
2012	79569	1156526	68.8	68.3	69.2
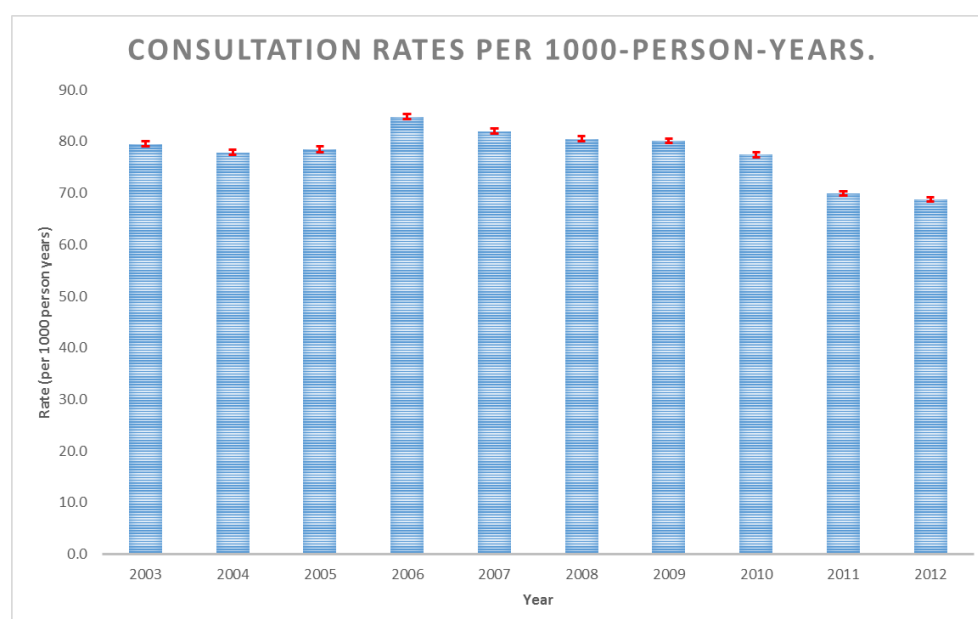
Figure 22. Consultation rates for paediatric GE between 2003 and 2012

Consultation rates by gender

The percentages of male to female was consistent over the 10 years changing by just one percentage [52% to 53% in male population and 48% to 47% in female population] [Figure 23].
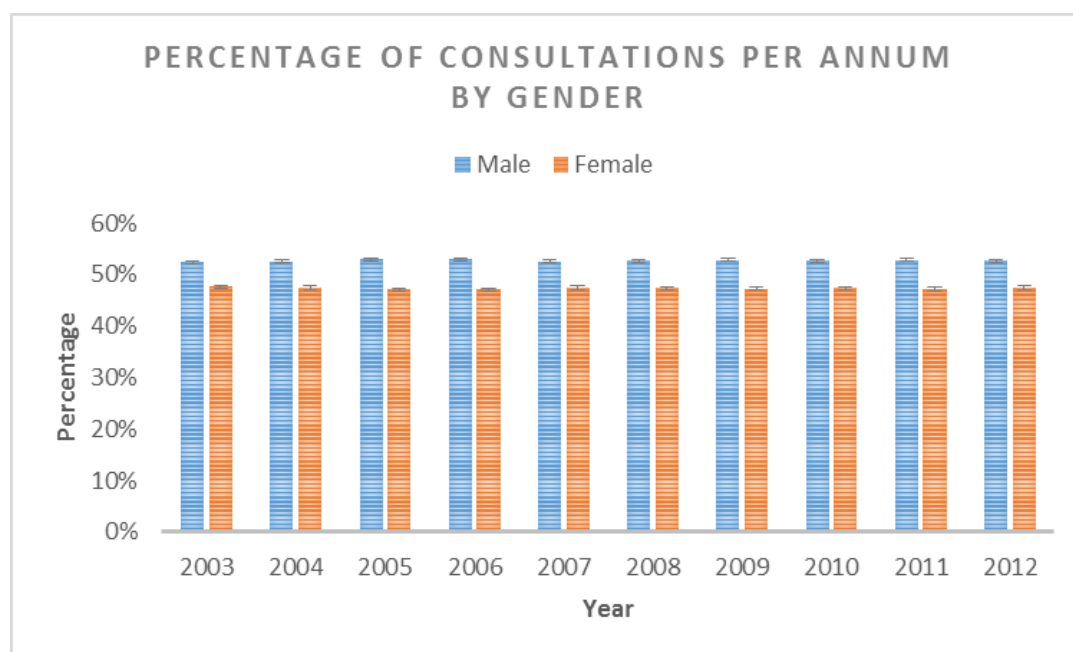
Figure 23. The distribution of male and female patients presenting with GE between 2003 and 2012

Consultation rates by age

Consultation rates were highest in the age group 0-3 years [Figure 24] with 1 year olds presenting most frequently [Figure 25]. There was a considerable increase in consultation rates between 2005 and 2006 in ages 1 and 2 years [Figure 24]. Consultation rates for ages 4 to 16 years are a fifth of the consultation rates in 0-3 year's age group. Rates decrease between 2003 and 2012 in all ages [Figure 25 and Table 12].
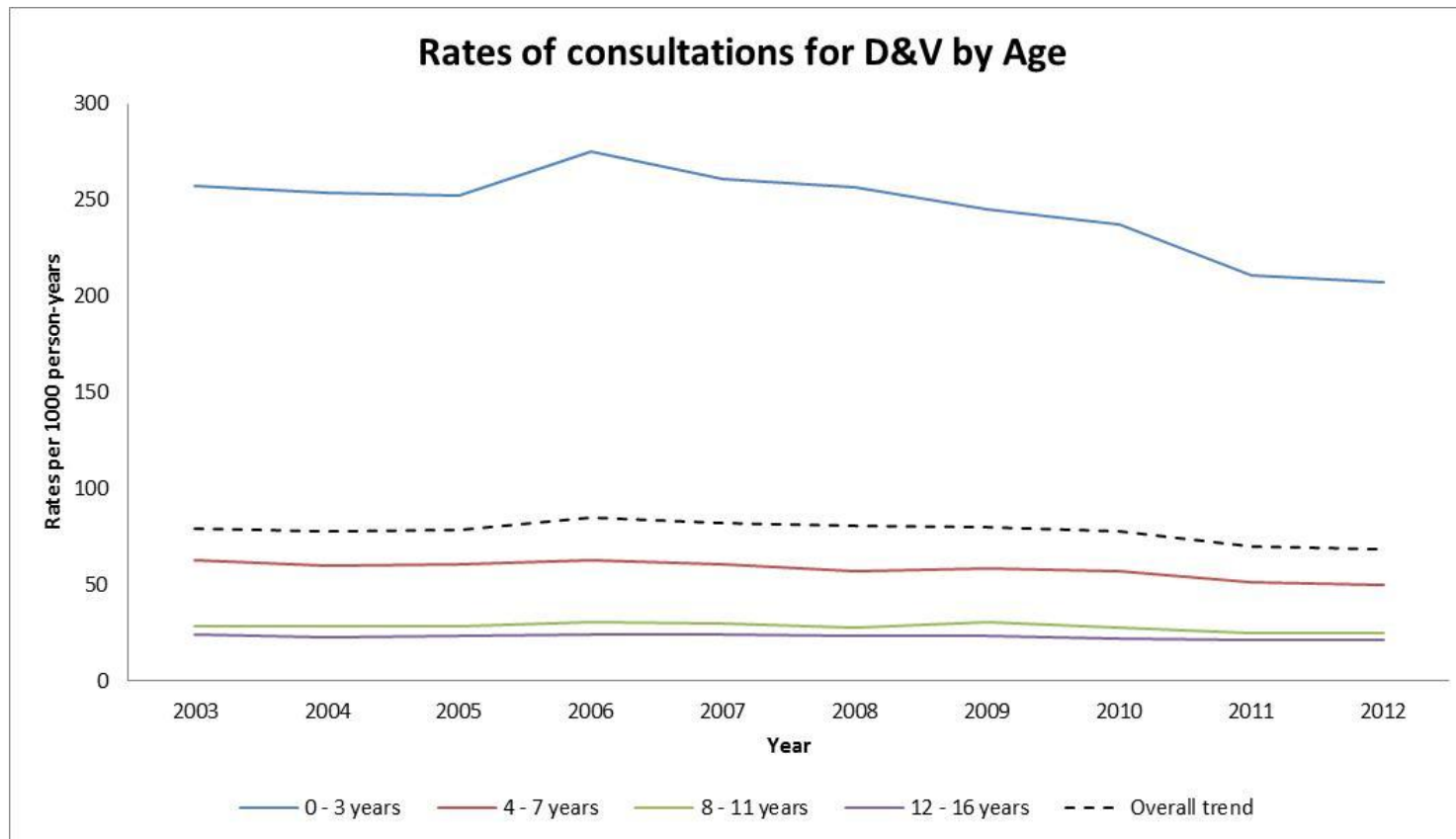
Figure 24. Consultation rates of patients in 4 age groups over 10 years. Rates per 1000 person-years.

Table 12. Consultation rates for all ages 0 to 16 years between 2003 and 2012

Age	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
0 years	231.21	216.40	219.60	236.03	239.61	235.48	220.32	202.84	190.94	191.45
1 years	423.64	437.42	417.99	468.73	443.35	436.44	416.48	400.02	357.14	348.96
2 years	238.39	237.81	241.69	259.58	234.10	230.26	222.79	224.94	192.68	189.64
3 years	135.67	123.62	129.50	135.73	125.79	122.51	119.51	120.26	101.47	98.05
4 years	90.15	85.35	84.06	89.00	86.74	78.20	79.37	79.49	71.14	69.88
5 years	67.74	63.42	65.76	66.32	64.79	60.70	63.55	61.64	55.19	53.69
6 years	51.52	50.24	50.93	53.24	51.37	48.56	50.94	48.05	43.16	42.57
7 years	40.78	39.46	41.33	41.79	39.24	40.21	40.23	39.20	34.92	34.28
8 years	33.68	32.25	33.77	34.52	33.84	32.87	32.80	32.31	27.83	28.69
9 years	29.71	28.71	29.27	31.60	31.73	28.54	30.99	28.15	26.88	24.54
10 years	26.27	26.24	27.17	28.93	29.30	27.03	29.80	26.26	23.05	24.00
11 years	25.56	25.67	25.26	27.52	25.33	23.91	27.65	25.51	21.22	22.76
12 years	26.83	22.33	23.50	26.24	26.72	23.34	25.64	24.14	22.04	22.38
13 years	23.89	22.57	22.98	23.59	23.24	22.93	23.71	21.09	21.26	20.78
14 years	21.60	21.97	22.18	23.04	21.27	23.22	22.55	20.19	20.36	20.73
15 years	22.71	22.21	23.33	24.00	22.89	23.01	23.77	20.25	21.50	20.38
16 years	25.83	24.61	24.41	25.68	25.75	24.59	23.57	22.99	23.16	21.18
Overall	**79.57**	**77.89**	**78.56**	**84.82**	**82.02**	**80.54**	**80.14**	**77.48**	**69.97**	**68.80**
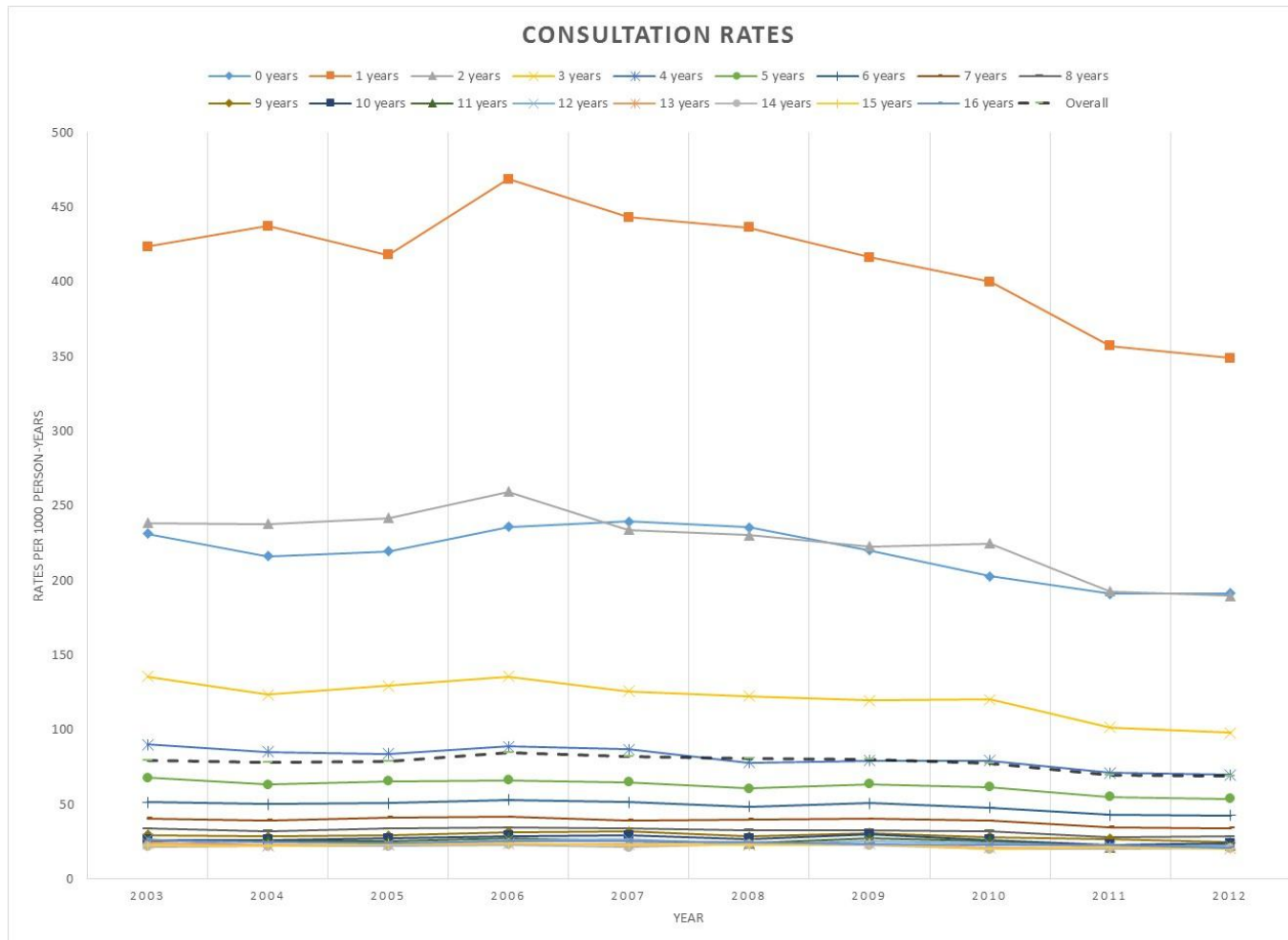
Figure 25. Line graph of consultation rates for all ages 0 to 16 years between 2003 and 2012; Rates per 1000 person-years

4.7.5 Consultations per patient

On average, 79% of patients consulted to primary care once each year with an acute GE related complaint. 99.2% of patients consulted between 1 and 4 times per year, the remaining 0.8% ranged from 5 to 26 consultations per year [Table 13].

Table 13. Number of consultations a patient has per year relating to GE

Number of Consultations	Frequency	Percentage	Cumulative Percentage
1	569967	78.58%	79%
2	110386	15.22%	93.79%
3	29878	4.12%	97.91%
4	9411	1.30%	99.21%
5 or more	5735	0.79%	100%

4.7.6 Episodes per patient

99% of patients experienced between 1 and 3 episodes per year (episodes which they consulted to primary care) with the majority consulting for just one episode (87.9%) [Table 14].

Table 14. Number of (consulted) episodes per patient per year

Number of Episodes	Frequency	Percentage	Cumulative Percentage
1	637270	87.9%	87.9%
2	74407	10.3%	98.1%
3 or more	1370	1.89%	100.0%

Multiple episodes were more common in patients aged 1 year - representing 48% of the patients who presented with 3 or more episodes a year [Figure 26]. There was no large difference between male and female patients [Figure 27].
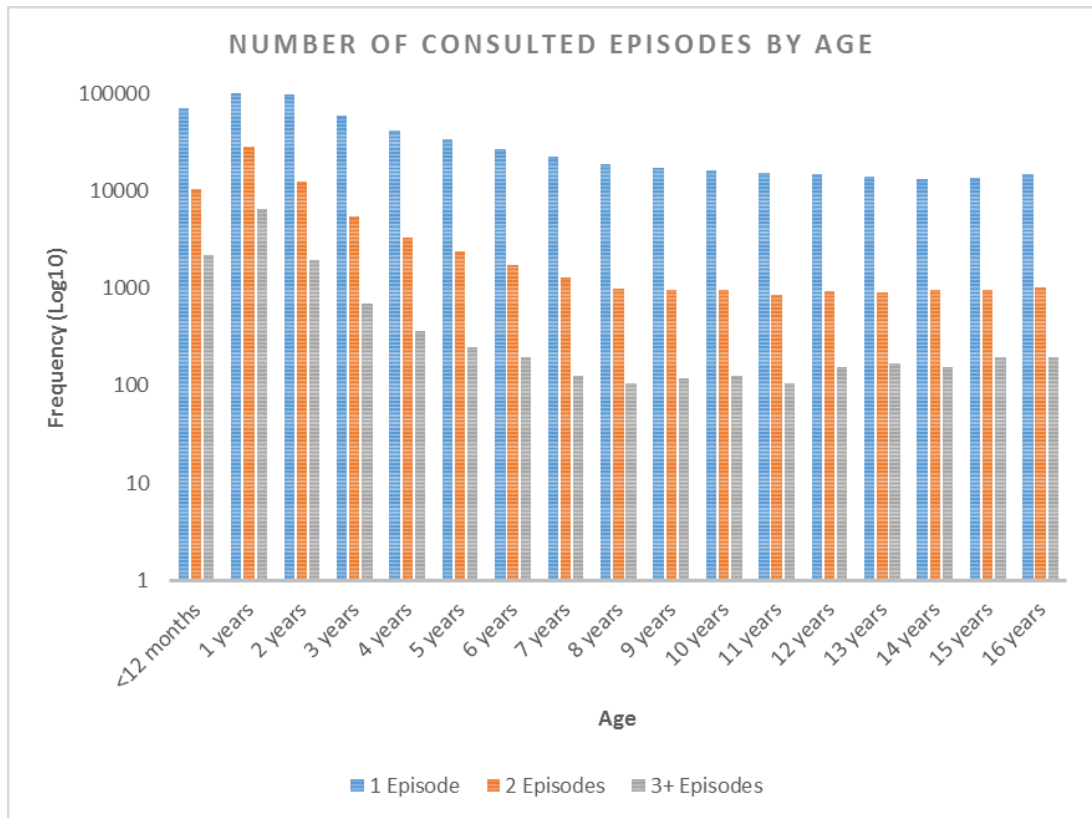
Figure 26. The number of (consulted) episodes by age on average between 2003-2012
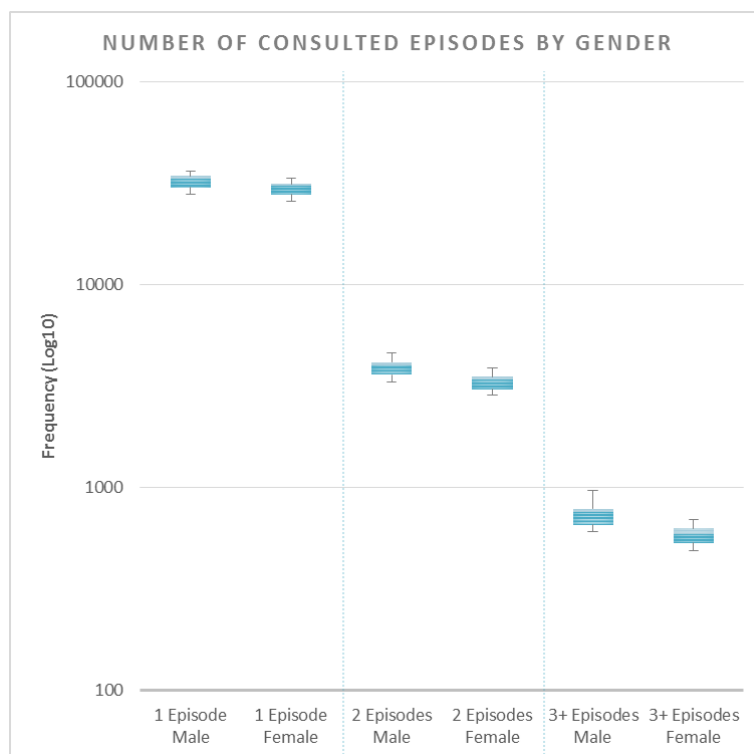
Figure 27. The number of (consulted) episodes by gender on average between 2003-2012

4.7.7 Referral rates

Of the 951,098 consultations, 46,365 consultations (4.87%) reported a referral to secondary care.

A total of 2,617 Read Codes were identified that described the 46,365 referrals.

Of those patients who had been referred there were 23 codes (0.88% of codes) that represented ~54% of the referrals [Table 15].

Table 15. The most frequently used Read Codes to describe a patient referral; Grouped into similar categories. Data represents those patients who had been referred following the primary care consultation.

	Percentage	Cumulative Percentage
Referral to paediatrician; Paediatric referral; Referral for further care; Referral to community paediatrician; ENT referral; Emergency hospital admission; Admit paediatric emergency	23.39%	23.39%
Vomiting; Vomiting Symptoms	11.44%	34.83%
Diarrhoea symptoms; Diarrhoea	8.03%	42.86%
Laboratory test requested; General Pathology; Refer for microbiological test; Sample sent to lab. For test; Blood test requested; Stool sample sent to lab.; referral for laboratory tests	7.80%	50.66%
Abdominal pain	1.00%	51.66%
Gastroenteritis	0.98%	52.63%
Diarrhoea and vomiting; Diarrhoea & vomiting, symptom	1.29%	53.93%
Other 46% of referral represented by 2,594 codes	46.07%	100.00%

Patients aged 1year represented 25% of the referrals. Patients aged 7 up to 16 years each represented less than 3% of referrals over the decade [Figure 28].

Using consultation numbers as a denominator, the rate of referral was calculated. Across all ages, the referral rate was 55 patients per 1000 consultations. Age groups <12 months and 15-16years show the highest rates in referral within their age categories [Figure 29].

A simple linear regression showed that the percentage of patients that are referred have increased by a rate of 0.66 per year on average, and this relationship was statistically significant (95% CI 0.126-1.206 p=0.022).

Rates of referrals increased between 2003 (46.25 per 1000 person-years) and 2010 (54.47 per 1000 person-years), however in the preceding 2 years fell to 48.23 per 1000 person-years [Figure 31].
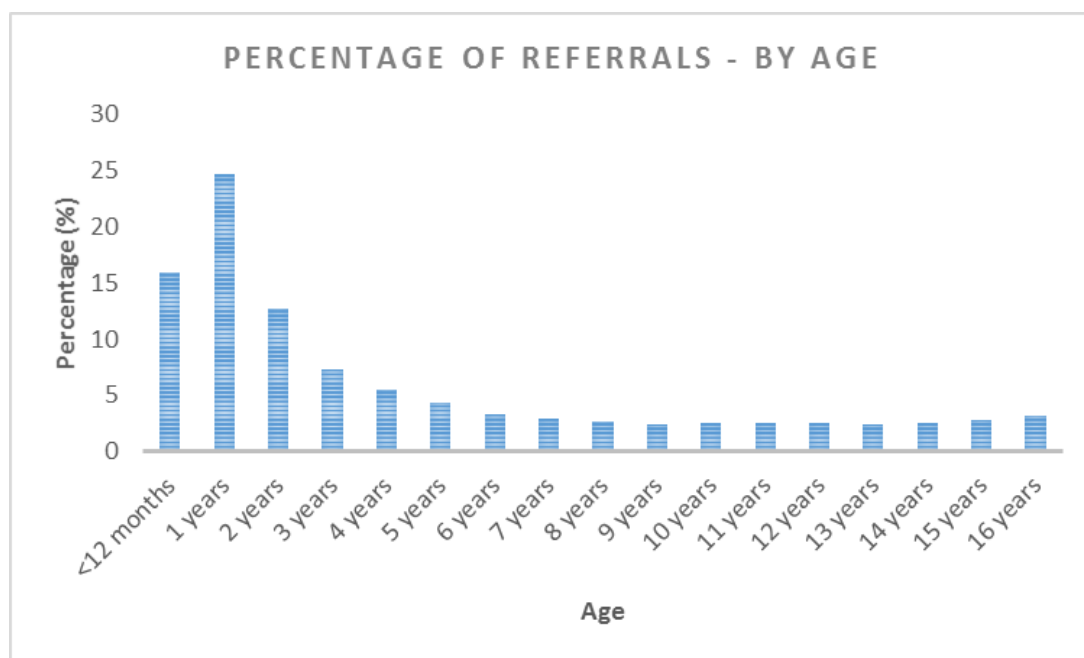
Figure 28. The percentage of referrals, by age over the 10 years (2003-2012)
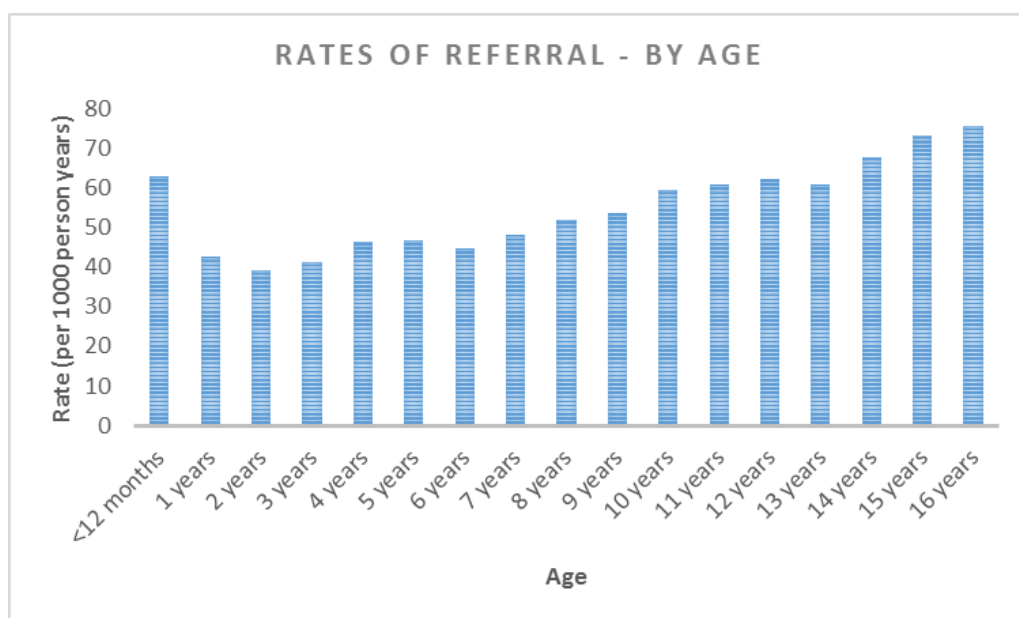
Figure 29. Referral rates of those patients who consulted primary care by age
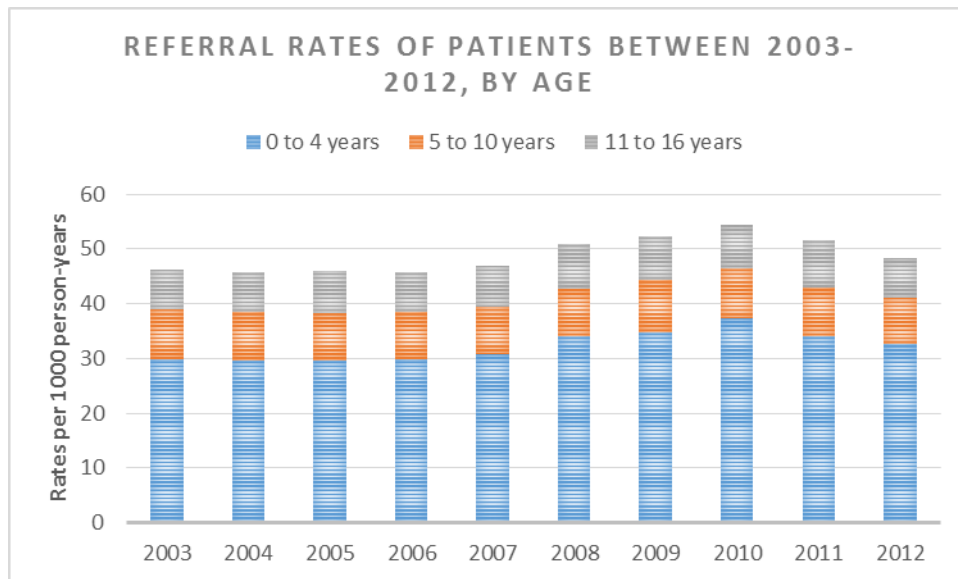
Figure 31. Referral rates for GE from primary care over a 10 year period by age group

Figure 30. Percentage of referrals by gender

More male patients were referred than females (55.1% and 44.9% respectively) [Figure 30].

Table 16. Referral rates by country

	Percentage of referrals represented by country	Rate of referral (per 1000 consultations)
England	79.64%	47.8
Northern Ireland	4.92%	86.3
Scotland	6.77%	41.9
Wales	8.67%	52.2

England represented almost 80% of patient referrals over the ten years with a referral rate of 47.8 per 1000-consultations. The rate was almost double for patients in Northern Ireland - 86.3 patients referred per 1000 person-years [Table 16].

4.7.8 Stool Sample request rates

Of the 951,098 consultations, 103,230 consultations (10.85%) reported stool requests.

A total of 1,165,451 records were initially identified that related to test requests. Within these records, 274 unique test codes were identified, of which 4 were associated with stool sample requests or vomit examination [Table 17].

Table 17. Frequency of stool sample / vomit examination codes identified

	Frequency	%	Cumulative %
Examination of faeces	27173	26.3	26.3
Other bacteriology tests	62729	60.8	87.1
Stool culture	13305	12.9	100.0
Vomit examination	23	.0	100.0

Between 2003 and 2011, stool sample request rates have gradually increased (per annum) from 97.1 to 121.2 per 1000 person years respectively [Table 18]. Between years 2010 and 2011 rates increased significantly. Rates decreased significantly to 114.5 in 2012 [Figure 32].

A simple linear regression showed that the percentage of patients receiving a stool sample requests has increased by 3.41% per year on average, and this relationship was statistically significant (95% CI 2.34-4.47, p=<0.01).

Stool requests are most frequent for patients aged 0-3years of age [Table 19].
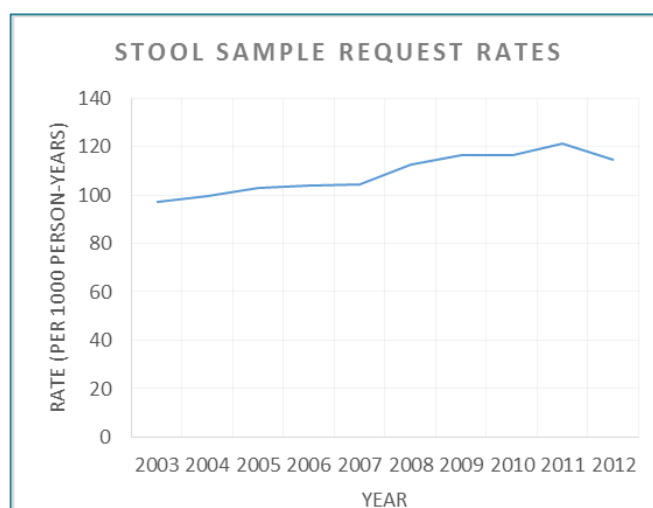
Figure 32. Stool request rates between 2003 and 2012

Table 18. The percentage of consultations resulting in a stool sample request between 2003 and 2012.

Year	Tests requested *Frequency*	Patient Consulted *Per annum*	% of patients resulting in a test request	95% Confidence Interval *Lower*	*Upper*
2003	9331	96101	9.71	9.52	9.90
2004	9451	95138	9.93	9.75	10.13
2005	9942	96649	10.29	10.10	10.48
2006	11029	105990	10.41	10.22	10.59
2007	10664	102343	10.42	10.23	10.61
2008	11235	99654	11.27	11.08	11.47
2009	11422	98269	11.62	11.42	11.83
2010	10980	94342	11.64	11.44	11.84
2011	10064	83040	12.12	11.90	12.34
2012	9112	79569	11.45	11.23	11.67

Table 19. The percentage of patients who had a stool sample request by age

Age	Frequency	% of Patients Presenting
<12 months	13785	11.74%
1 years	34095	12.77%
2 years	17648	11.74%
3 years	8693	10.66%
4 years	5317	9.57%
5 years	3798	8.84%
6 years	2738	8.00%
7 years	2236	8.08%
8 years	1895	8.17%
9 years	1770	8.33%
10 years	1746	8.73%
11 years	1694	8.86%
12 years	1625	8.60%
13 years	1633	9.17%
14 years	1405	8.18%
15 years	1557	8.79%
16 years	1595	8.34%

4.7.9 Prescription rates

Of the 951,098 consultations, 302,168 consultations (31.77%) reported prescriptions.

3,346 Read Codes were found to describe these prescriptions. We therefore grouped these by product type using the BNF chapters.

Oral rehydration solutions [ORS] were the most frequent prescription representing 33% of all prescriptions and 14% of all GE related consultations. Products that contained paracetamol were the second most frequent prescription contributing to 15% of prescriptions and 6% of consultations [Table 20].

Table 20.   Frequency of prescriptions by product; the percentage that each product contributes to overall prescriptions; and the percentage each product is prescribed per consultation.

	Frequency	Percentage of prescriptions	Percentage of consultations
ORS*	133297	32.98%	14.02%
Paracetamol containing products	59824	14.80%	6.29%
Antibiotics	31301	7.86%	3.29%
NSAIDs**	10079	2.49%	1.82%
Antimotility Products	6793	1.68%	0.71%
Anti nausea / Vertigo products	4588	1.14%	0.48%

*Oral Rehydration Solutions; **Non-Steroidal Anti-Inflammatory Drug

The most frequently prescribed antibiotics were Amoxicillin (45.1% of antibiotic prescriptions), Clotrimazole (14.6%) and Erythromycin (13.6%).

Of those who received a prescription, 74% received just one prescription and 25% received 2 or 3 prescriptions. The maximum number of prescriptions per consultation per patient was 13 [Table 21].

Table 21. The frequency of prescriptions per patient per consultation

	Frequency	Percentage	Cumulative Percentage
1 prescription	222789	73.73%	73.73%
2 prescriptions	62160	20.57%	94.30%
3 prescriptions	13343	4.42%	98.72%
4+ prescriptions	3876	1.28%	100.00%

Over the 10 years, the rate of antidiarrhoeal prescriptions have decreased from 8.02 to 4.79 per 1000 person-years and by contrast, rates in ORS have increased from 125.41 to 148.22 per 1000 person-years. Rates of other prescription products have remained constant.

4.7.10 Time Series Analysis

Time series analysis was run on monthly consultation rates over the 10 year study period. The periodogram and spectral density plots indicated that there was an annual periodic component [represented by the peak at 0.8333 on Figure 33]. The other peaks on these plots were equally spaced along the x axis signifying that the annual periodic components were not sinusoidal.

Annual periodicity means that, each year, the same peaks and troughs are present during the 12 months. The absence of sinusoidal periodicity indicates that the peaks and troughs are not equally spaced throughout the year.
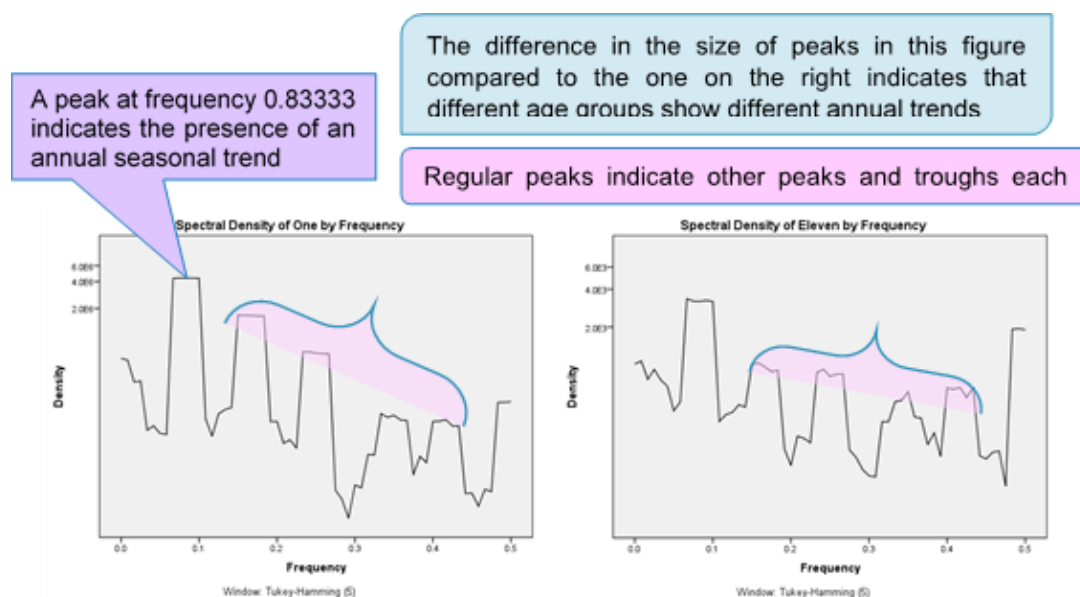
Figure 33. Interpretation of the Spectral Plot Outputs from SPSS to determine seasonality

Monthly consultation rates over the 10 year period demonstrate these peaks [Figure 34]. The cumulative consultation rates for all ages by month shows clear peaks in March and November; however, the annual periodicity is not the same for all age groups. Therefore, as well as looking at the overall monthly trend of consultations [Figure 35] four graphs of grouped ages demonstrates the differences in the monthly trends [Figure 36]. For patients <12 months, there is only a peak in

November. For ages one to four years the peak in March is more prominent than the November peak by almost half. For ages five to ten years the consultation rates are considerably lower but indicate the two peaks also. For the age groups eleven to sixteen years there are peaks in March and November as well noticeable peaks in June and September.
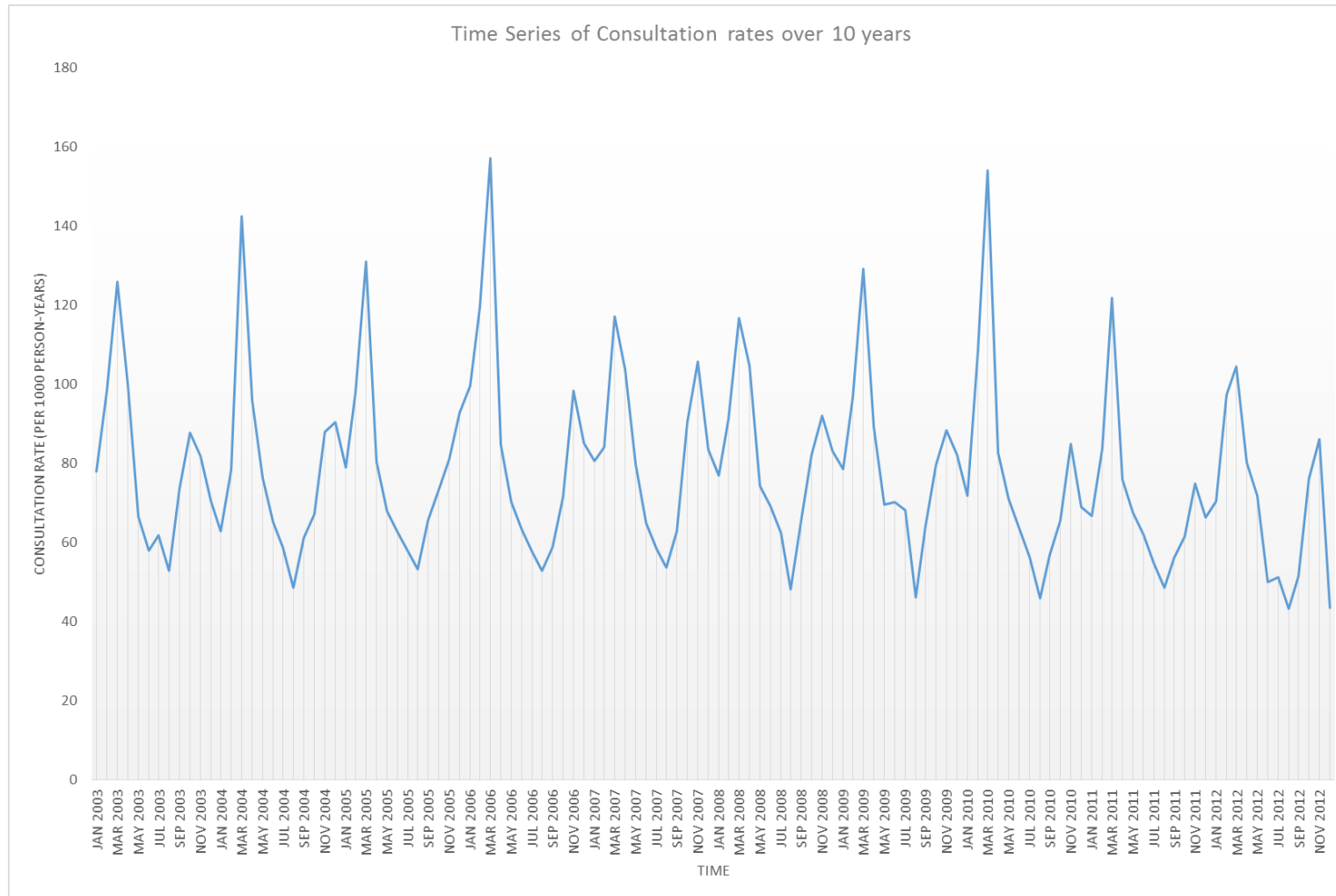
Figure 34. Monthly consultation rates over 10 years
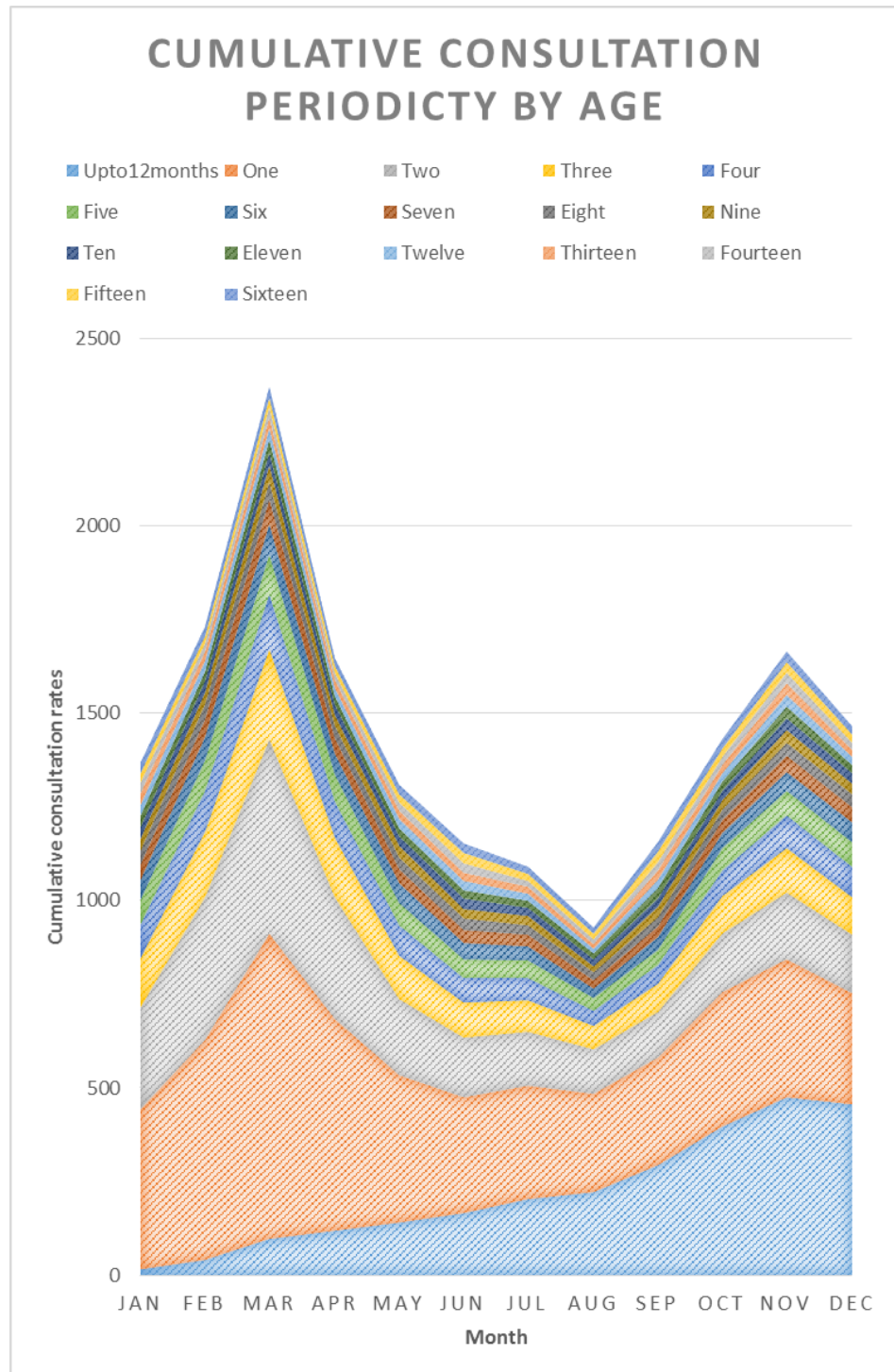
Figure 35. Cumulative consultation rates over 10 years for all ages
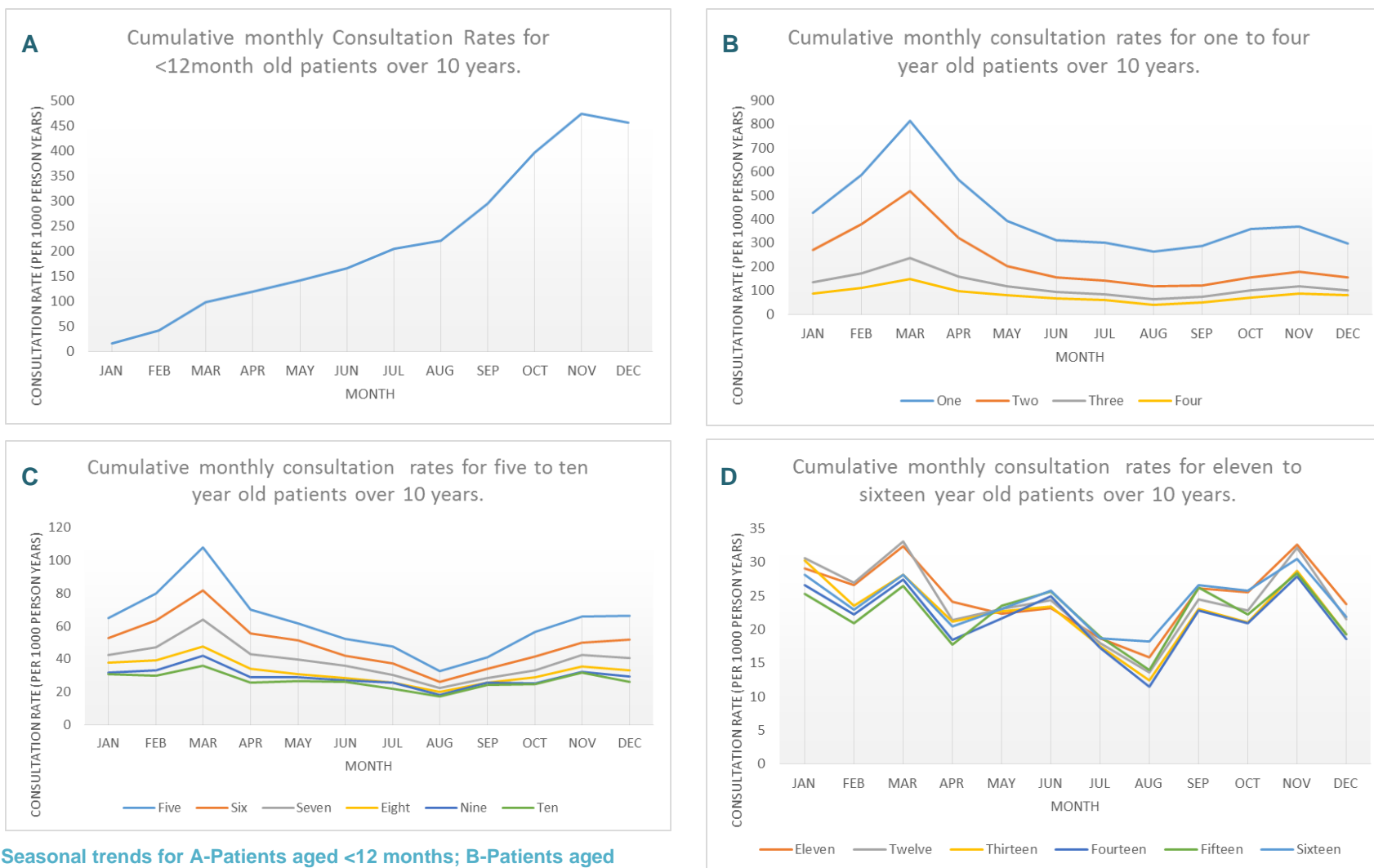
Figure 36. Seasonal trends for A-Patients aged <12 months; B-Patients aged One to Four; C-Patients aged Five to Ten; D-Patients aged Eleven to Sixteen

4.7.11 Exploring Associations

Gender as a predictor of patient outcome

There was a significant association between gender and whether or not patients would receive:

- a stool sample request $\chi^2(1)=191.82$, $p<0.001$ - the odds of a patient receiving a stool request were 1.10 times higher if they were male than female (95% CI 1.08 to 1.11).

- a referral $\chi^2(1)=111.246$, $p<0.001$- the odds of a patient receiving a hospital referral were 1.11 times higher if they were male than female (95% CI 1.086 to 1.127).

- a prescription $\chi^2(1)=73.187$, $p<0.001$ - the odds of a patient receiving a prescription were 1.04 times higher if they were male than female (95% CI 1.035 to 1.057).

Although the chi-square test statistic indicates a strong association between gender and these three patient outcomes, the odds ratio indicates that the effect size is minimal. Cramérs statistics for all three patient outcomes were all <0.02 out of a possible value of 1, representing a non-statistically significant association between gender and patient outcome. These values were all highly significant ($p<0.001$).

Age as a predictor of patient outcome

There was a significant association between the age categories 0 to 4 and 5 to 16 (pre-school and school age) and whether or not they would receive:

- a stool sample request $\chi^2(1)= 2103.903$, $p<.001$ - the odds of a patient receiving a stool request were 1.48 times higher if they were aged between 0 and 5years (95% CI 1.453 to 1.503).

- a referral $\chi^2(1)= 593.538$, $p<.001$- the odds of a patient receiving a hospital referral were 0.77 times lower if they were aged between 0 and 5years (95% CI 0.760 to 0.792).

- a prescription $\chi^2(1)= 1498.242$, $p<.001$ - the odds of a patient receiving a prescription were 1.28 times higher if they were aged between 0 and 5years (95% CI 1.262 to 1.294).

Again, the chi-square test statistics indicate a strong association between the age categories and these three patient outcomes. The odds ratio for stool sample request and a prescription as well as the accompanying Cramérs statistics (0.47

and 0.40 respectively) indicates the effect size is significant and is representative of the population. The association between referral and the age group 0 to 5 years indicates a substantial increased likelihood that a patient will be referred if in this age category. The Cramérs statistic (0.25) indicates a medium effect size.

4.8 Discussion

4.8.1 Summary of Main Findings

Consultation rates for paediatric GE between 2003 and 2012 have slowly decreased from 79.6 per 1000 person-years (95% CI 79.1 to 80.1) to 68.8 per 1000 person-years (95% CI 68.3 to 69.2). Patients aged 1year consulted most frequently at an average rate of 415.02 per 1000 person-years (range: 348.96 to 468.73) over the 10 year period and patients between the ages 0 to 2 years represented over 50% of the patient population presenting. On an average over the 10 years, 80% of patients presented just once each year for a GE related condition. However, patients aged 1 year most frequently presented with multiple episodes each year.

Of those who presented to primary care, ~5% were subsequently referred to secondary care, 11% received stool sample requests and 32% received a prescription. Referral rates have increased over the 10 years, as have stool request rates – although not as dramatically. Overall prescription rates have remained similar. Individual prescription products have, however, altered in rate, over the ten years, antidiarrhoeal's have seen a decrease in use and ORS on the contrary, an increase.

Consultation rates peaked in March and November each year during the 10 year period with lowest consultation rates in August. The height of the peaks was variable across the ages, and patients aged 11 to 16 also experienced a peak in consultation rates in June.

Patients aged 0 to 5 years were at increased likelihood of receiving a prescription and stool request but decreased likelihood for a referral to hospital when compared with patients aged 6 to 16years. Male patients were at an increased likelihood than females for prescribing, stool requests and referrals (all ages).

4.8.2 Other work in this area

Consultation rates in UK primary care for (confirmed) infectious intestinal disease [IID2 Study] in patients aged less than 5 years were estimated to be 133 (95% CI 92 to 199) per 1000 person-years (Tam et al. 2012). Our study shows that

consultation rates vary considerably between the ages of patients (range 20.19 to 468.73 per 1000 person-years) and consultation rates for patients aged 0 to 2 years (range 190.94 to 468.73) are substantially greater than this estimate by Tam et al. All other ages fit within the confidence intervals of the rates estimated by the IID2 study. Average rates for 2008-2009 (when IID2 was collecting data) were 80.54 and 80.14 respectively [across all ages].

Overall hospital admissions in England have increased in frequency between 2003 and 2010 (including referrals from primary care) (Gill et al. 2013) and although it is not possible to relate the frequency with our calculated rate of referral, the general trends are similar. The increase in frequency could have been attributed to the growing population in England, however the rates calculated in this study use annual denominator populations to allow for this.

It was estimated by Szajewska and Dziechciarz (2010) that one in 54 paediatric patients with rotavirus GE would require hospitalisation. Our study has found that one in 20 patients were referred (not specific to rotavirus) which is significantly higher. It is not clear from our data the severity of GE or the presence of other symptoms (indicatory of other conditions i.e. appendicitis) that resulted in the need for patients to be referred. Many of the referral codes referred to the type of referral (Emergency hospital admission/Referral to paediatrician) rather than the symptoms present. Vomiting represented 11% of the referral codes which could indicate a norovirus infection or a range of other illnesses unrelated to GE.

Stool requests rates have increased over the 10 year period. There is limited data on UK stool request rates in the time period studied here. A multicentre European study focussing on the burden of rotavirus GE in seven countries reported that no stool requests were made between October 2004 and September 2007 in primary care in England (Giaquinto et al. 2007b). This however was based on only 14 participants therefore doesn't represent the whole of primary care in the UK. In addition, participants who presented to primary *and* secondary care were grouped into the secondary care population (where 59% of patients received a stool request). Our data suggest that one in ten patients were requested to submit a stool sample, which is surprisingly high if using the criteria set out in the NICE guidance for determining when a stool sample is appropriate. NICE states that for most cases, a stool sample request is not necessary and only if the clinician is in doubt of a diagnosis or the patient is showing signs of complications/persistent that laboratory tests should be carried out. It is unclear from the data we have whether this is the case for these patients, however, the reasons for stool requests are

explored in the clinician interviews in an attempt to shed light on other factors the NICE guidance has not considered.

The only prescription recommended for acute GE in ages <5years by NICE guidance is ORS, which is recommended for all patients with GE. The guidance also specifically identifies that antidiarrhoeals are not recommended. Our data suggests that 14% patients are prescribed ORS and less than 1% are prescribed an anti-diarrhoeal. Both of these prescription rates have changed over the 10 years (ORS: increased, antidiarrhoeals: decreased) however changes do not coincide with the introduction of NICE guidance in 2009 therefore unlikely to have been in response to this. Almost one in three patients received a prescription, however, it is unclear if the prescriptions were appropriate or in response to other factors. Parent and patient expectation is known to influence prescribing behaviours in other common illnesses such as sore throat (Butler et al. 1998). Exploring reasons behind prescribing (or not prescribing) for paediatric GE is important if we are to ensure adherence to prescribing recommendations.

The seasonality of GE consultations reported in this study show similar peaks to reports of laboratory confirmed cases of norovirus GE in the UK (Lopman et al. 2003). Peaks in March and November mimic the seasonality reported from laboratory samples. The presence of a summer peak is also recognised by Lopman et al. and their work indicated norovirus peaks in the summer in addition to winter. Campylobacter has been shown to peak in June in the UK which may explain the peak seen in patients aged 11 to 16 years (Meldrum et al. 2005).

Patients in the age group 0 to 5 years represent a substantial percentage of burden on both primary and secondary care resources. Consultations, prescriptions, stool requests and referrals were all highest in this age group. This could be explained by the increased risk of deterioration in younger children therefore more care is needed. Although research suggests paediatric patients are the main sufferers of this illness, the data found in our study indicates a larger burden than originally estimated.

4.8.3 Limitations of using patient records for research

The major benefit for using CPRD as a resource for research is the ability to access data from a large population of patients across the UK. The raw data undergoes rigorous quality control and validity checks before release to researchers. However, it is important to remember that the data are collected primarily for clinical and routine use rather than specifically for research. Therefore, clinicians may code a

consultation using a variety of Read Codes that could refer to the symptom/s, diagnosis, investigations or treatment. The use of non-specific Read Codes such as "brief examination of patient" or "patient reviewed" represents a large percentage of the data CPRD holds, and the use of all of these Read Codes is not standardised within or between practices. The impact of this for research is primarily loss of patient data. Patients were included in this study if their Read Code matched a diagnostic or symptom code related to GE. Patients that had been recorded under other Read Codes were therefore missed and without any additional data available, it is not possible to calculate how our dataset represents the actual patient population. Some of the Read Codes included in this study were not specific to GE, especially symptoms of nausea and vomiting. These Read Codes could indicate a range of minor to severe conditions unrelated to GE therefore our results may be an overrepresentation for acute GE.

The data available on the actual consultation was limited. Information on the history of the illness (symptom duration, severity, and likely cause), the consultation procedure (physical examination results) and other management (i.e. advice offered to parents) was not available. Variables that were empty for prescription, stool request or referral were assumed to indicate that these outcomes were not present for those patients however it may be that they were prescribed etc. and data was missing. This assumption might reflect an under-representation of any of these three patient outcomes.

4.9   Chapter Summary

Anonymous patient data on primary care consultations for acute paediatric GE was used to describe clinical management of this common condition over ten years. Between 2003 and 2012 consultation, prescription, referral and stool request rates were analysed for all patients recorded in patient records provided by CPRD. Consultation rates have decreased over the ten years however, referrals and stool requests have increased. One in twenty patients were referred to secondary care following a primary care consultation and one in ten received a stool sample request. One third of patients received at least one prescription and ORS was the most frequently prescribed product. The findings from this study have described the significant burden of GE on both primary and secondary care resources, the subsequent studies in this project aim to explore this from the perspective of both parents and primary care clinicians as well as exploring their attitudes toward this common illness.

Novel findings – This study has identified that the burden on primary care is considerably higher than previously reported with regards consultation rates and stool sample request rates. The variable use of read codes to report this condition has demonstrated the difficulties in reporting conclusive rates for referrals, consultations and indeed diagnosis of GE. The rates of stool sample requests are considerably higher than expected and indicates an overuse of tests during GE consultations.

CHAPTER FIVE:
QUALITATIVE STUDY METHODS

5.1   Introduction

This chapter focuses on the methods of the two qualitative studies with primary care clinicians (Phase Two) and parents (Phase Three). They were conducted following the closure of Phase One [**Chapter Three**] and explored the management of paediatric GE from both the clinical and lay perspective.

Following the findings from Phase One, we were particularly interested in the variation of management during a paediatric GE episode, the beliefs behind the variation and the possible impacts this had on clinicians, parents and patients.

Theory and theoretical perspectives are described in the context of this project and the methods employed. A justification of the qualitative method used is then presented including the method of sampling. The methods of recruitment and procedures are then described, specific to each study.   Finally, the methods for data collection and analyses conducted are summarised.

5.2   Theory and World Perspectives

"Theory is central to research" (Green and Thorogood 2009).

Theoretical assumptions about how the world works, e.g. how health care or doctor-patient interaction is organised, outline the questions that are considered of importance to ask and how one chooses to answer them.

Macro-theories shape inquiry at a large and somewhat abstract level (e.g. analysis of socials systems and whole populations). They focus on broad societal trends and can be used to better understand societies, cultures and organisations (Rimer 2008). Middle range theories link these abstract ideas to the grounded, observable behaviour of individuals in everyday settings, such as the management of illness.

5.2.1 Epistemology

Epistemology is the *theory of knowledge* i.e. how we come to know the world and how we have faith in the truth and validity of that knowledge (Green and Thorogood 2009). As research is essentially about producing knowledge about the world that we claim as valid, a consideration of epistemology is fundamental.   Three of the

main epistemological perspectives, positivism, interpretivism and constructivism will be described followed by how this project fits within these perspectives.

Positivism

Many of the epistemological assumptions of qualitative research arise from *criticising* Positivism. The positivist vision assumes that there is a stable reality and that phenomena (such as disease, bacteria and health), exist whether we are researching them or not.   Furthermore, it supports the idea that these events exist in exactly the same way, whether we understand them or not.

Positivism supports three beliefs, that research is *Empirical* and knowledge can only be acquired through experimental methods and observations of the world. Secondly, positivists support the belief that at the point of "maturity", all sciences will share the same method of enquiry (termed *the unity of method*). Finally, positivists hold the belief that science is to be held separate from society and that knowledge derived from scientific inquiry is not bound up with emotional, subjective or political viewpoints, and is true for all times and places. This is defined as *value-free inquiry.*

Interpretivism

Some see the positivist worldview as an unachievable and inappropriate perspective for research into human *behaviour*. For example, humans differ from plants and atoms because they are more complex, highly unpredictable and reflective of their own behaviour. Therefore the methods used in the natural sciences are unlikely to be useful for studying individuals and their behaviour. From this perspective, the research questions are not necessarily about *the reality of the world*, but how each person *interprets the world*.

This interpretive tradition characterises much qualitative work in health research, which focuses on the *meaning* of phenomena (symptoms / health behaviour) for individuals and their associated behaviour.

Constructivism

The positivist assumption that "there is one stable, pre-existing reality waiting to be discovered" has also been criticised. Researchers argue that reality has been socially constructed using historical, social and political processes rather than as a result of maturing understanding of reality. Social constructivism recognises that

under different social and political pressures, varied beliefs and behaviours to phenomena are likely to exist.

5.2.2 Ontological considerations

Ontology are the beliefs around *"the nature of being"* (The Oxford Dictionary) and considers the basic assumptions concerning what *reality* is.

Naturalism refers to a preference for studying phenomena in their natural environment. Behaviour is contextual i.e. people behave differently when they are being observed / studied. Studying health behaviour in a natural environment compared with an artificial environment, allows individuals *"to tell their own story"* (Green and Thorogood 2009) and provide access into the way they see the world, rather than how a researcher see's their world. It is arguable, however, that any research-imposed observation truly see's the reality and will always result in a biased perspective of what the individual wants the researcher to see.

5.2.3 Where this project fits in

I have come from a background of research in microbiology where methods of enquiry were purely experimental. After identifying the areas of enquiry for this project however, we identified that before trials or interventions could be developed an understanding of the current burden and impact of GE was required. In order to approach these project aims, an interpretive view on individual's behaviour and their beliefs of illness was required in order to see their barriers and influences on their actions. We also accept that behaviour should be interpreted within the boundaries of that society and it is important to recognise influences such as the NHS can have on individual beliefs and behaviour.

5.3 Qualitative Data Collection

"Without an empathetic understanding of why people behave as they do, we are unlikely to identify the possibilities for change." (Green and Thorogood 2009)

Qualitative research is concerned with seeing the world through the eyes of the participants being studied and to uncover the aspects of health experience that cannot be quantified – such as the "why's" and "how's" of a phenomenon (Green and Thorogood 2009). When the aim is to determine answers that cannot be directly observed such as motives behind a decision or contradictions between observed behaviour and reported attitudes, qualitative research allows a space for

participants to explain their actions and beliefs. Qualitative research starts by asking not what people get wrong or don't know, but instead seeks to identify what they *do* know, how they maintain their health and what the underlying rationality of their behaviour is.

One-to-one, semi-structured telephone interviews were selected as the method for data collection for both qualitative studies.

5.3.1 Qualitative Interviews

Interviewing is the most common qualitative method that is used to enable an understanding of the behaviours and actions of participants (Fontana and Frey 2003).   Interviews aim to be interactive, flexible and also sensitive to the meanings and language used by the participant. Interviews can "go below the surface of a topic" in discussion and will uncover concepts and topics that were not anticipated at the start of the research.

Structuring the interview

In a structured interview, also known as a standardised interview (Bryman 2012), the researcher would ask all participants the same, pre-established, questions usually with a limited set of responses in which they may choose. The main advantage to this structure is the consistency of questions, order of questions and choices of response so that participants' responses can be reliably aggregated (Bryman 2012).   What this method does not do, however, is investigate a participants' motives and beliefs behind their responses, or provide additional information related to the topic area that is not specifically asked about. In-depth interviewing can be classed as the "opposing" method to this as it allows the participant to provide their responses in their own words based on their own beliefs and what they feel is important to them. During this style of interviewing, the researcher may only ask a single question and following the dialogue provided by the participant, may probe areas "*worthy of being followed up*" (Bryman 2012). A semi-structured interview technique sits between these two methods and allows structure in the interview whilst allowing the participant to provide their own account and beliefs of the topic area especially, what is important to *them*. The researcher will set the agenda of the topics to be covered, but the participants' responses will determine the course of the interview and the order of questions and topics. The role of the researcher is to provide clarification of the participants' responses and probe the participant when appropriate.

The objectives of the project included seeking a deeper understanding of parents' and clinicians' views of particular topics of interest, therefore, the interviews needed a semi-structured format to focus the participants to the specific topics in mind whilst still allowing them to present their beliefs in their own order and manner.

Telephone interview

The decision to conduct interviews over the phone was based largely on the geography of participants and the cost effectiveness of telephone versus face-to-face interviews which the costs of travel strongly influenced. Participants were recruited from Wales and England and face-to-face interviews would have required either the participant or researcher to travel for the interview ensuing considerable travel costs. Specifically for the parents, it was important to interview them soon after their child's illness to reduce recall bias and it was agreed within the team that it would be more practical to interview over the phone at a time suitable to the parent rather than the time and costs ensued by organising face to face interview. A study conducted by Sturges and Hanrahan (2004) concluded that there were no differences between the "quantity, nature and depth of responses" when comparing interviews conducted face-to-face and over the telephone.

It is with these rationales that the more feasible and practical approach of telephone interviews was used as the method for interviewing all participants.

5.3.2 Sampling

Methods of sampling and the definitions of terms vary between researchers (Coyne 1997). Figure 37 demonstrates what these, and other terms *can* be defined as (based on work by Glaser (1967) and Patton (1990)).

Terms such as selective and purposeful sampling have been used interchangeably to describe the same method of sampling for qualitative research. Theoretical sampling describes an alternative approach in which uses a less structured approach to selecting participants.

For both studies in this project, there were clear research questions and the population of participants was known, therefore a theoretical (grounded theory) approach would not have been appropriate. The sampling methods for both qualitative studies fit under the term "purposeful" however the specific selection varied between the two studies. Further details are described in sections 5.4.3 and 5.5.3.

Sampling

Theoretical
Researcher collects, codes and analyses the data and subsequently decides what data should be collected next and where to find it. This method therefore allows the themes to constantly evolve and the sampling method then reflects this.

Purposeful

Researchers who believe all sampling methods are purposeful in nature

Maximum variation - aims to capture and describe the central themes across a varied sample e.g. of different ages

Opportunistic - Taking advantage of new opportunities during data collection… find someone interesting to interview, just do it rather than not including as it was not planned etc.

Convenience - doing what's fast and convenient e,g, easy access and/or inexpensive.

Snowball - after an interview with a participant who has a lot of information rich data, asking them if they know anyone else who could take part and provide information.

Figure 37. Terminology used to describe some of the sampling strategies used in qualitative research.

5.3.3 Sampling framework

"Sometimes the researcher has no choice and must settle for a theoretical scheme that is less developed than desired" (Strauss and Corbin 1998).

Qualitative research does not attempt to generalise a population or provide statistically significant findings therefore numbers can be relatively small, this is because more data does not necessarily mean more information (Mason 2010). Sample size is also determined by factors such as the depth and duration of interviews and what is feasible for a single interviewer (Britten 1995).

Data saturation is the point during data collection at which no new themes or data are emerging relevant to the research topic/s. There are no clear guidelines for researchers in defining this *point* and the scope of the individual study and research questions will influence how many participants/interviews are required (Marshall 1996).

5.4 Parent interviews

This section describes study methods specific to the parent interviews [Phase Three].

5.4.1 Study aims

We aimed to:

♦ Explore parents' experience of GE illness in their child.

♦ Gain a greater understanding of how they manage GE illness in their children, and the associated beliefs that drive their management decisions.

♦ Explore parent's beliefs and attitudes towards the illness itself.

5.4.2 Inclusion criteria

Parents were eligible to take part in this study if their child (age <16 years) had recently (within 3 months) suffered an episode of acute GE. The age was kept consistent with Phase One of the project and the 3 months limit was to minimise recall bias.

5.4.3 Recruitment

Parents were identified via three methods of purposeful sampling:

Identified by participating GP Practice

Primary care clinicians taking part in Phase One [Chapter Three] identified eligible parents and invited them to take part in the interview. Parents who indicated their interest to participate were given a study information leaflet and provided their contact details to the clinician who forwarded them on to the research team. Parents were contacted within 48 hours to organise the completion of the consent form, which was posted to them.

As these parents were identified as part of Phase One, this used a convenience sampling method. This method of recruitment specifically identified parents who had consulted primary care; other methods were deployed to identify children who had received home-management with consulting primary care.

In response to advertisement on Mumsnet[3]

An advertisement was posted onto the social media websites Mumsnet and Mumsnet local, inviting parents to get in touch if they were interested in taking part. Parents were directed to the study website and contacted the research team via the contact form or by email. Parents who met the eligibility criteria were sent the study information leaflet and consent form.

Snowballed

Parents were also invited by asking parents that had already participated to invite relevant friends, family or colleagues. These individuals then contacted the research team and were supplied with further information. Those who met the eligibility criteria were sent the study information leaflet and consent form.

[See Appendix 5.1 for study information leaflet and consent form]

5.4.4 Interview Schedule

The interview schedule for the parent interviews was developed prior to the first interview and then modified several times between interviews. The first draft was developed through a careful review of the literature in relation to the research aims and then distributed and discussed within the research team and modified appropriately. The questions were divided into topic areas and questions were formulated around these. The intention was to ask a general starting question about their experience of their child's illness giving the participant the opportunity to tell their story and concentrate on what was important to them. The interviews then proceeded by exploring topics further using the schedule as a template for the topics not yet covered as well as exploring further areas covered by the participant. As new themes emerged during interviews, the subsequent interviews and topic guide was updated to reflect these additions and thus continued to evolve as interviews were carried out.

[See Appendix 5.2 for the original interview schedule]

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[3] Mumsnet is a global online network for parents, although most users are UK-based. It is the largest website for parents, with 10 million visits and 60 million page views each month. It hosts discussion forums for users to share peer-to-peer advice and information on parenting, products and many other issues. The website is funded mainly by advertising. Mumsnet also has a network of 200 local (geographic-specific) sites [Mumsnet local].

5.4.5 Interview procedure

Upon receipt of the consent form the interview date and time was confirmed. Reminders were sent by email, if requested, on the morning of the arranged date.

Parent characteristics

Parents provided brief demographic information prior to the interview such as:

- ◆ Age
- ◆ Gender
- ◆ Current employment
- ◆ Number of children in household
- ◆ Postal address

Deprivation was calculated for participants in England and Wales, according to the electoral wards by the 2011 census and the Wales Index of Multiple Deprivation as of 2011. For both countries, a high, medium or low deprivation score was given to each area of where the participant lived.

Interview

Participants were asked to allow 30 minutes for the interview, and if using a mobile phone were asked to find an area of constant signal. Participants were also advised to find a private quiet room for the duration of the call.

Before the recorded interview began, participants had the opportunity to ask any questions or discuss any concerns. In addition, the following was explained to all participants:

> *"None of these questions are a test, and there is no right or wrong answer, I am simply trying to get an idea of the different management and treatment options parents follow and why. Also, it is obviously not the most pleasant of topics to be discussing so if you are at all uncomfortable with discussing any aspects, please just let me know. And finally, just to emphasize, I'm not a GP or clinician therefore I unfortunately won't be able to answer any clinical questions or confirm that your management is correct - I am only here to ask and listen. If you do have any questions or concerns at the end we can discuss them and I may be able to provide a contact or information. "*

Following the completion of the interview participants had another opportunity to ask questions or discuss any aspects of the interview. Participants were thanked for their time and the phone call ended.

Compensation

All participants received a £10 gift voucher in the post as monetary compensation for completing the interview.

5.5 Clinician Interviews

This section describes study methods specific to the clinicians' interviews [Phase Two].

5.5.1 Study aims

We aimed to:

- ♦ Explore primary care clinicians' description of their usual management during a consultation for paediatric acute GE and the associated belief and attitudes
- ♦ Understand the influences impacting on their management decisions
- ♦ Explore how they managed any (perceived) parental expectations
- ♦ Explore their awareness, knowledge and use of guidelines for paediatric GE

5.5.2 Inclusion criteria

Primary care clinicians working in Wales who were responsible for the management of paediatric GE were eligible to take part in this study.

5.5.3 Recruitment

Clinicians were recruited by three methods:

Clinicians from Phase One

Upon the closure of Phase One at participating practices, clinicians were approached and invited to take part in the telephone interview. Study information leaflets were sent with the documents relating to study closure.

Clinicians responding to email invite

All practice managers within Cardiff and Vale and Aneurin Bevan were contacted by email to request they forward an invitation to take part in the study to all clinicians at their practice. A PDF version of the study information leaflet was attached with the email. Clinicians interested in taking part responded by email either directly to the research team or via the practice manager.

Following the interview, participating clinicians were asked to invite their colleagues to take part. Interested clinicians got in touch with the research team via email. If they had not received information on the study, they were sent the information leaflet in PDF format. We used the method of snowballing for this study to look at intra-practice variation and beliefs of clinicians.

For all participants, consent forms were posted to the practices and the interviews were arranged at a time convenient to the clinician.

[See Appendix 5.3 for study information leaflet and consent form]

5.5.4   Interview schedule

As with the parent interview schedule, the clinician interview schedule was developed prior to the first interview and then modified between interviews. The first draft was developed based on the results from Phase One, review of the current literature and following discussions with the supervisory team (of which 2 are primary care clinicians). A comprehensive list of topic areas was developed in relation to the project aims. Questions around those topic areas were developed, focussing on their management of paediatric GE and their associated beliefs. As new themes emerged during interviews, the subsequent interviews and topic guide was updated to reflect these additions and thus continued to evolve as interviews were carried out.

[See Appendix 5.4 for the original interview schedule]

5.5.5   Interview procedure

Clinicians were contacted in order to arrange an interview date and time following receipt of a signed consent form. Reminders were sent to clinicians that had shown interest but not returned their consent form. Those who declined participation at any point were not contacted again. Clinicians were sent an email reminder the morning of the arranged interview date.

Clinician characteristics

Clinicians provided brief demographic information prior to the interview such as:

- Years qualified
- Practice location (urban / rural)
- Practice size

Deprivation was calculated for clinicians practice based on the Wales Index of Multiple Deprivation as of 2011. For each practice a high, medium or low deprivation score was given to each area.

Interview

Clinicians were asked to allow up to 20 minutes for the conduct of the interview and if using a mobile phone, to ensure they had signal coverage.

Before the recording of the interview began, clinicians had the opportunity to ask any questions about the study or interview. Prior to the interview starting, the following was explained to every clinician:

"None of these questions are a test, I may ask you to explain or define something during the interview, but this will be purely for me to understand – I am not a clinician therefore I may need some points clarified during the interview. All of the questions I will be asking will be related to patients presenting with symptoms indicatory of gastroenteritis. As well as discussing how a typical consultation proceeds, I am just as interested in the situations where there is uncertainty or external factors influencing those decisions."

Once the interview had ended and recording had stopped, clinicians had a final opportunity to ask any questions. Clinicians were thanked for their time and the phone call ended.

Compensation

All clinicians received £40 in gift vouchers as monetary compensation upon completion of the interview.

5.6   Data Collection

All interviews were audio recorded, allowing me to fully listen to the participants responses rather than taking notes throughout the interview. I made brief notes during the interview, especially during any narrative sections, to remind myself to follow up on aspects discussed. I also ticked off topics I felt were fully covered and starred topics to go back to before the interview was over. I made brief reflective notes following each interview in my reflective diary and added anything new in the interview schedule I felt I needed for future interviews.

The interview recordings were transcribed verbatim following the development of a transcribing protocol. All interviews were transcribed in their entirety.

5.7   Thematic Analysis

"The researcher needs to remain open to the possibility that the concepts and variables that emerge may be very different from those that might have been predicted at the outset"
(Britten 1995)

Thematic analysis is the most common method of analysis in qualitative research (Guest et al. 2011). Analysis of qualitative data begins with an inductive approach where codes and patterns are discovered from the data (Patton 1990). It involves multiple stages which are described here in relation to this project: familiarisation, coding, data saturation, grouping codes, developing a coding framework, interpretation, and presentation. Following the steps outlined by (Ziebland and McPherson 2006)[4] the data from both parent and clinician interviews was analysed and interpreted [Chapters 6 to 8].

5.7.1   Familiarisation with the data

I transcribed the first 20 interviews myself so as to fully immerse myself in the data. I also conducted initial coding at the same time. Following the first 20 transcripts it became more practical and time efficient to outsource[5] the remaining transcribing work. To ensure full immersion in the remaining transcripts, initial coding was carried out whilst listening to the recording. Each transcript was read through following transcription and reflective notes were made.

5.7.2   Initial Coding

All transcripts were printed and initial coding was carried out by writing on the document. This involved writing words or sentences to describe what was being discussed in each section of the interview. Many codes were linked to the interview topics and questions such as "symptom severity" or "medication" however others not directly related to the schedule included perceived emotions i.e. "parental anxiety" or descriptions i.e. "talk about natural history".

These codes were recorded as a list in Excel. As each interview transcript was coded, any new codes were added to this list using the participant ID to identify

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[4] I attended a two day course provided by Health Experience Research Group, University of Oxford. This reference summarises the steps focussed on during the course.

[5] Transcribing was outsourced to an approved Cardiff University supplier of professional transcription services – Essential Secretary Ltd.

where the new codes had emerged. This list of codes was used to identify data saturation.

Identifying Data Saturation

In order to determine data saturation for these two studies, coding was conducted alongside data collection. All codes were listed for each interview and new codes were noted. Following an interview that resulted in no new codes, I conducted a further three interviews to confirm that the topics were saturated. When four consecutive interviews resulted in no new codes, this was at the point of data saturation.

[See Appendix 5.5 for the list emerging codes]

5.7.3 Grouping codes into themes

During the coding of transcripts, codes were combined and/or grouped together into over-arching themes, or umbrella terms. Examples include combining codes such as "worry", "concern" and "anxiety" or grouping specific symptoms into "typical symptoms" and "symptoms of concern". This reduced the number of codes into a more manageable quantity and a coding framework (also known as coding book) was developed.

Computer assisted data analysis software [CAQDAS]

NVivo 9[6] was used for storage and management of all data from both the parent and clinician interviews. Codes and themes developed (as described above), were input into NVivo and stored as nodes. Transcripts were coded within NVivo into these nodes so that node reports could be printed to provide a summary of all quotes related to a specific theme or code.

5.7.4 Coding framework

A document was developed to define what each code and theme meant in relation to the data. Codes were grouped by theme, for example: Burden of illness contained codes "Impact on family"; "Impact on Education"; "Time off work". This coding framework was then used within nVivo for the next step of the thematic analysis - one sheet of paper.

[See Appendix 5.6 for final coding framework]

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[6] Software developed by ©QSR

Validation

Once the coding framework had been developed, this was then tested by two individual qualitative researchers for reliability. This involved using the coding framework to code 15% of the transcripts using only the themes and codes listed. If, during this validation process, new codes had been identified that were not included in the framework it would have meant that the framework was not reliable. Any discrepancies were discussed following this exercise and the coding framework was amended following these discussions to clarify a code / code description further. This process ensured that the framework could reliably be applied to all transcripts and represent all data collected.

5.7.5 The OSOP method

The One Sheet of Paper [OSOP] approach involved printing a node report of all quotes associated with a theme or code and then noting down (on one sheet of paper) all issues raised by that node. These issues were then grouped together into broader themes to describe what was "going on" in the data and how beliefs were grouped by participant characteristics (for example, parents with babies talked more about anxiety).

[See Appendix 5.7 for an example of the OSOP method]

5.7.6 Presenting the data

The following three chapters explore the themes and patterns identified from both the parent interviews and clinician interviews. Quotes were chosen that illustrated the theme and where appropriate, alternate perspectives are provided to demonstrate controversial or varied stances.

After each quote a participant identifier has been included:

- ♦ For all quotes provided by parents, this is indicated as PXX;
- ♦ For all quotes from primary care clinicians, this is indicated as CLINXX

(where XX indicates the participant ID number)

Where there is a dialogue between the interviewer and the participant the text from the interviewer is enclosed in square brackets within the quoted text of the participant.

5.8   Chapter Summary

After considering the importance of theory and world perspective on research methods, this chapter has summarised the justification for the use of semi-structured telephone interviews as the method of data collection in the two qualitative studies. The methods for both parent and primary care clinician involved purposeful sampling and data collection ceased at the point of data saturation. Parents were recruited via their GP Practice, Mumsnet or the method of snowballing. Clinicians were identified within practices in Wales and invited to take part. All interviews were conducted over the phone, recorded and transcribed. Data was analysed thematically using a six-step method. The following three chapters describe the findings of these two qualitative studies.

CHAPTER SIX:
PARENTS PERCEPTIONS OF ACUTE GASTROENTERITIS IN CHILDREN

6.1 Introduction

This is the first of two chapters exploring the experience and management of GE from the parents' perspective. This chapter will focus on parents' attitudes, beliefs and their emotional reaction toward childhood GE, and elucidates how differences in their attitudes and beliefs can influence their behaviours in relation to prevention of illness and actions taken during the infectious period. The chapter concludes with a discussion of how these findings fit in with previous research in the field.

6.2 Parent characteristics

Telephone interviews were conducted with 28 parents from Wales and England between November 2012 and June 2013.

All participants were females. Participant age ranged from 26 to 40 years old. 30% of participants were un-employed at the time of interview, 35% of participants classed their jobs as within public sector roles and the remaining 35% were in private sector job roles. The number of children each participant had ranged from 1 to 5 and the type of day-care usage included home care (43%), nursery (43%), child-minder (11%) and school (54%) (Combinations of the above are included in the percentages shown). Participants lived in a range of areas of high, low and average deprivation [Table 22].

As per the inclusion criteria, all participants had recently (in the last 3 months) had a child who suffered from an acute episode of GE. 13 participants had consulted their GP during this episode of illness and 15 participants reported managing the illness without consulting with a healthcare professional. In many of the families (9 of the 21 households with multiple children), participants reported that more than one child had suffered from diarrhoea / vomiting at around the same time. In these situations participants were asked to differentiate between each child's illnesses where appropriate. On some occasions one child was taken to the GP whilst their sibling received home-care only.

Table 22. Parent Characteristics from Phase Three - Telephone Interviews

Participant ID	Age	Gender	Job Sector	Deprivation Index	Consulted GP?	Number of children	Recruitment Method	Country
P01	26	Female	Public	High	No	2	Snowballed	Wales
P02	32	Female	Public	High	Yes	2	Mumsnet	England
P03	29	Female	Unemployed	Medium	No	1	Snowballed	England
P04	39	Female	Public	Medium	No	2	Snowballed	Wales
P05	38	Female	Public	High	Yes	2	Snowballed	Wales
P06	34	Female	Unemployed	Medium	Yes	2	From their GP	Wales
P07	26	Female	Public	High	Yes	2	Snowballed	Wales
P08	39	Female	Unemployed	Low	No	1	Snowballed	Wales
P09	39	Female	Public	High	No	1	Mumsnet	England
P10	30	Female	Unemployed	Medium	No	2	Mumsnet	England
P11	36	Female	Unemployed	Medium	No	2	Mumsnet	England
P12	38	Female	Private	High	No	4	Mumsnet	England
P13	30	Female	Private	High	No	1	Mumsnet	England
P14	38	Female	Private	Medium	Yes	2	From their GP	Wales
P15	30	Female	Unemployed	High	Yes	1	From their GP	England
P16	30	Female	Private	Medium	No	1	Snowballed	England
P17	40	Female	Private	Low	Yes	2	From their GP	England
P18	39	Female	Public	Medium	No	3	Mumsnet	England
P19	35	Female	Private	Low	No	2	Mumsnet	England
P23	30	Female	Public	Medium	No	2	Mumsnet	England
P24	36	Female	Public	Medium	Yes	5	Mumsnet	England
P25	30	Female	Public	Low	No	1	Mumsnet	England
P27	40	Female	Private	Medium	No	2	Mumsnet	England
P28	27	Female	Private	Low	Yes	2	From their GP	Wales
P29	26	Female	Unemployed	Low	Yes	2	From their GP	Wales
P30	31	Female	Private	Low	Yes	2	From their GP	Wales
P32	31	Female	Private	Medium	Yes	2	From their GP	Wales
P34	32	Female	Unemployed	Low	Yes	2	From their GP	Wales

6.2.1 Recruitment and Data Saturation

36 parents expressed interest to participate, of these, 28 parents were interviewed - the remaining 8 interviews were not conducted as data saturation had been achieved. Following 19 interviews, saturation was reached within those who had not consulted a GP, and therefore subsequent interviews were arranged with only those participants who had consulted a GP. From the three methods of recruitment, 10 participants were recruited from Mumsnet, 8 participants through their GP and 10 participants via snowballing from within these participants.

6.3 Parents beliefs about paediatric GE

Parents in this study had a variety of beliefs about the causes and risks as well as a variety of associated emotions relating to this common childhood illness. These beliefs influenced their behaviour and attitudes toward the illness.

6.3.1 Beliefs about causation

Parents discussed what they perceived to be the main causes of acute GE in children, with the majority using terms such as *"virus"* or a *"bug"* to describe the source. Germ was also a term used by parents, though not as prominently as the two other phrases. Medical anthropologist, Cecil Helman (1978), discusses that germs that cause gastro-intestinal symptoms are more likely to be visualised as "insect-like" by individuals and therefore are more commonly termed as *bugs*, which is what was found here.

Virus and bug were, for many parents, used to describe the same cause rather than distinguishing between two separate causes of illness.

"you know a virus that's picked up - as in a tummy bug that's going" P01

"A virus or a tummy bug, well, it's the same thing isn't it" P02

This could be due to influences such as the media, who use these terms interchangeably, especially when referring to norovirus and rotavirus. The media also use the phrase "winter vomiting bug" in headlines related to norovirus outbreaks during the winter months. The winter of 2012, during which participants were recruited, saw an increase in media coverage on D&V related illness. Many parents referred to national news stories when discussing the impact of this acute

illness and many identified norovirus as the cause for their child's illness without a stool sample having been sent for testing. Some parents admitted that they did not know the cause of their child's illness but assumed it was norovirus as it was during the time the "winter vomiting bug" was at its peak. A paper led by Ben Lopman (2008) discusses the evolution of terminology used to describe norovirus in particular and the use of terms such as gastric flu and winter vomiting bug within the media. He discusses the implication that the illness is then likely associated with seasonality and with that, an association with other seasonal illnesses such as influenza.

Media reports during November 2012 and February 2013 covered a number of norovirus related outbreaks, on a cruise ship, hospitals and the workplace in the UK [Figure 38].

"   Winter vomiting cases at 1.1 million   'One in five' struck by norovirus in Scotland, say experts

Winter vomiting bug cases up 40 per cent: Health Protection Agency

Winter vomiting bug hits 700,000 people as   Norovirus on Oriana cruise ship: More than 400 early onset of virus catches NHS 'unawares'   passengers suffer

Tens of thousands hit by norovirus winter vomiting bug

Norovirus on Celebrity Cruises' ship Constellation   "

Figure 38. Media headlines about GE during November 2012 and February 2013

These stories were referred to by parents during their interviews, therefore perhaps there was an increased awareness following the headlines of winter 2012.

"they always end up with a lot of people in the hospital with it and in the nursing homes and they keep having outbreaks like on a cruise ship, all this sort of thing" P11

"there were so many people ill in hospital with winter vomiting bugs" P19

It is unclear how much of an influence these media reports had on the parents' health behaviour. However, many parents indicated an awareness of the impact GE has on the community and used examples from the media or referred to local outbreaks in their area.

Many parents assumed their child's most recent episode was due to a virus, when asked to distinguish between viral and bacterial, many parents discussed the rate of transmission and the difficulty in preventing spread as important indicators.

"[Participant lists 4 family members who had had GE recently] Hence my theory that it was viral because it spread ridiculously quickly, my … I think if it was bacterial then it probably would've actually been slightly harder to spread because we'd been ridiculously careful about hand washing and things." P19

Food poisoning seemed to be perceived as a less common cause of GE in children and was rarely mentioned. A few parents did, however, indicate that food poisoning was unlikely to be cause of their child's most recent episode and this was linked to the food that children eat.

"Very very rarely food, I don't think she really eats that many things that could potentially cause it ((laughs)) or maybe apart from chicken or things like that but yeah:: I think norovirus is possibly the main one" P08

Parents are the main provider of meals for their child and therefore in control of the food and standard of food their child eats and thus for the majority of meals, can control the risk of food poisoning. Although seen as an unlikely cause of GE, parents did indicate that if food poisoning was suspected they would be more concerned about their child. Symptoms were expected to last longer and the severity of the illness increased, if the cause was food poisoning.

6.3.2 Insignificance of illness

Most parents did not judge GE as serious. For example, four parents used the word 'just' when referring to the illness, as in *"Just D&V" (P01, P04 & P05)* or *"just acute diarrhoea" (P10)*. Others used phrases such as *"a typical stomach bug" (P07)*; and *"Run of the mill tummy bug" (P02)* to imply a sense of triviality of the illness.

Some mothers discussed how the symptom of diarrhoea was common and not a threat to their child's health and were therefore not concerned if their child experienced diarrhoea or vomiting.

"I just think it's natural for everyone to have diarrhoea at some point" P29

"I don't tend to worry too much about these things" P10

Some parents seemed to view their child's illness through the lens of their own illness experience, often with the result that they negated the potential impact of their child's symptoms. For example, one mother compared her child's illness to her own personal previous experience of a severe episode of food poisoning.

"I've had food poisoning from king prawns before ... so I know the worst possible end that it could be ... so a little bit of D&V isn't actually that big a deal." P12

The use of *little* before describing the symptoms weakens the significance of the illness. This participant used their memory of food poisoning as a benchmark of illness severity. By doing this, she may have underplayed the significant of her child's symptoms, as the perception of pain and other symptoms may be different in a child compared to an adult.

There were other examples of parents using their perception of illness severity to assess their child's episode and thus possibly downplaying the distress that the child may have experienced as a result of the illness.

"I mean, waking every couple of hours isn't awful" P18

In this example it could be argued that feeling nauseous or experiencing vomiting every 2 hours could be highly distressing for a young child.

One parent discussed how their child is not concerned by diarrhoea and vomiting and therefore as parents, they have a positive approach toward handling the illness.

"We've always had quite a positive attitude towards it ((laughs)) like the minute she has diarrhoea, it's literally, 'right we just have to get it contained'....she's just really quite blaze about it. ((laughs)) She doesn't really think that it's really that much of an issue" P08

Parents in this study also referred to the illness as "doing the rounds" as though it was considered normal for their children to get GE.

"[as long as] something's doing the rounds... 'oh yeah everybody's had that' you think 'oh well it, it'll just be over and done within a few days' " P05

Individuals appear to consider infections that are *"going round"* as a lesser risk to their child's health. Helman discusses this type of behaviour as a social relationship with others – *"community of victims"*. They feel that they are blameless that their child is sick and less likely to "*feel uneasy or unsure of the condition"* (Helman 1978). In addition, parents might feel reassured that their child's illness is the same as others and if other children are experiencing a relatively mild episode, they expect the same for their own child's episode.

A perceived lack of threat of illness and insignificance of symptoms could impact on how parents respond to the threat of illness and increase the risk for the rest of the

family. Not all parents had such a relaxed attitude toward GE; some demonstrated different perceptions of the risk of the illness and distress of the symptoms associated with GE.

6.3.3 Perception of GE as a serious illness

Within the study population, several parents indicated significant distress about GE and some directed this exclusively to one specific cause of GE, namely norovirus. As many perceived their child had experienced norovirus GE (without any confirmation through stool sample analyses) much of the talk related to norovirus and the negative impact it had.

" norovirus … it's no laughing matter" P09

"norovirus is very short-lived so you can certainly have it and then a few weeks later you know you have it again which is what seems so unfair about it really...even if your hand washing is absolutely perfect ...Which is another reason why it feels so mean! It's so hard to avoid, once if you've got it in the household...I don't want to worry excessively about it...I probably really really dislike it a dis-proportionate amount" P11

This participant portrayed an excessive worry toward norovirus and the inevitability of it spreading throughout the household. Some of this negative emotion may be in response to feeling unsuccessful in preventing transmission or guilt that despite excessive hand-washing, it didn't help.

As well as specific causes influencing perceptions towards the illness, parents discussed their feelings towards the symptoms associated with the illness.

"fever, sickness, diarrhoea, it was cruel" P12

This quote was in reference to the symptoms experienced throughout the whole seven member household. The use of the term *cruel* also portrays the family as victims of the illness.

Another aspect in which parents indicated their concern toward the illness was how their child's illness impacted on them both physically and emotionally.

"There comes a point where you run out of sheets...I just think, 'Oh for crying out loud'" P19

The burden of illness is discussed [Section 7.3] but it is clear that the burden associated with GE impacts their perception and attitudes toward the illness.

Resignation

Many parents indicated a feeling of resignation in relation to the illness, in particular regarding transmission of the illness.

"we know that we're going to catch it anyway because my boys sleep in the same bedroom...I knew there was a bug going round in the school and obviously with them being in the primary school and a nursery school I knew they were going to catch it anyway" P34

"There's not much else you can do really...I'd sort of resigned myself to the fact that they'd probably both get it if it was a bug" P11

Also the risk to the rest of the family:

"I figure that if one of us has got it, pretty much everyone's going to end up having it" P10

"If it seems to be spreading that fast you're going to get it" P19

As already mentioned, there appear to be a wide variation of attitudes towards this common illness. In this work it was noticeable that many of the participant's actions and decisions stemmed from these attitudes and thus introduce a wide variation in many areas of management and decisions. A prime example is the attitudes towards vaccinating against viral GE in which, depending on their feeling towards the illness, their attitudes towards vaccinating also varied.

6.4   Attitudes toward vaccinations to prevent viral GE

This topic emerged when a participant referred to a recent news article regarding the introduction of the rotavirus vaccine [Rotarix[7]] to the UK's routine childhood immunisation schedule in July 2013. Around the same time, the development of a norovirus vaccine was also in the news due to the impact norovirus had had on the UK in December 2012-January 2013. These topics of interest were seen as an important and relevant area to explore in subsequent interviews and thus added to the end of the interview schedule. Parents were asked of their knowledge of the vaccines and the introduction of Rotarix into the UK immunisation schedule. Those parents who were unaware were given an explanation of the premise of both vaccines. Participants' attitudes toward these vaccines were explored.

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[7] Developed by GlaxoSmithKline

During the analysis of this theme and using the OSOP method, it became clear that there were various beliefs and attitudes towards the use of vaccines for viral GE and that these appeared to be related to their perceptions of the illness itself.

Of the 28 parents that were interviewed, 20 discussed their attitudes towards vaccinations. All indicated or inferred that their children's vaccinations were up-to-date, and therefore this was a sample of parents who seemed broadly supportive of routine vaccination and did not include any individuals who had chosen not to vaccinate their child/ren.

Four participants indicated they did not support and therefore would not be willing to vaccinate their child against viral causes of GE. The remaining participants (n=16) supported the use of vaccines for viral GE and indicated they would accept a vaccination for their child should a vaccination program be introduced.

6.4.1 Parents that did not support viral GE vaccines

Parents who were not supportive of a vaccination program tended to perceive a low or limited threat to their child from these diseases, were likely to see no or few benefits from the vaccines and discussed at length the reasons (and barriers) for not vaccinating.

"when my kids have got [diarrhoea & vomiting] they have never got them particularly badly it's just an inconvenience, so I'm not sure I'd want to put a vaccine in them" P10

The symptoms, diarrhoea and vomiting, and their most common causes – rotavirus and norovirus, were seen as a minor threat when compared with other health conditions that are currently vaccinated against:

"Don't get me wrong, I've vaccinated my children for MMR and all those things, but they're killers and they spread in a different way, but [not for] something like rotavirus and norovirus" P12

This firstly indicates that this individual supports the general concept of vaccinations, however, perceives the threat of viral GE as too small to act in a preventative way. Parents also appeared to weigh up the benefits and risks as a means to make a decision. The lack of threat they associate with viral GE to be would lessen the perceived benefits of a vaccine therefore tipping the balance toward perceived risks of the vaccines.

"I would definitely not give my son that. Only because I just think diarrhoea and stuff is just a natural part I just think it's, you know, natural for everyone to have diarrhoea at some point....and I really, really hate putting ... you know, I hate giving him needles anyway. So I don't think that I would... Unless [rotavirus] was obviously dangerous then maybe I would, yeah. "P29

"I'm not that keen on things like adding further things to the body…He had that [MMR vaccine], he had an injection for that but something which isn't life threatening as such which I don't believe that norovirus is.. I'm more keen on trying to manage it holistically or without medication." P27

This second quote from P27 indicates, again, a perception that norovirus infection does not represent a serious threat. An additional barrier, however, is evident here - the belief that vaccines are not the best method to prevent norovirus and that other approaches would be more suitable.

Another important barrier in this group was the perception that vaccines are not necessary because the human body can develop sufficient immunity against infections causing GE, and therefore a vaccine is not warranted.

"I know rotavirus is one of the ones where you tend to get it badly the first time and as you get further episodes of it, it tends to be milder and milder and by adult you've generally got some immunity." P11

"It's my understanding that I think once you've caught a certain type of norovirus or rotavirus you won't get it again anyway and [um] I just assumed that there's so many different types that it wouldn't, you wouldn't catch the same one each time" P10

Along similar lines, this parent (P10) believed that a vaccine could not be developed against either rotavirus or norovirus as they evolved and altered during replication. Another parent also appeared sceptical about the success of developing a rota/norovirus vaccine, even upon being told that the rotavirus vaccine has been in distribution in the US since 1998.

One of the recurrent issues in these interviews within the discussion around vaccinations was the nature of the virus and the effect of natural immunity. Parents believed that being vaccinated was the same as suffering from the illness, and that once you have had it once you won't get it again.

"oohh:: I think that if you vaccinate for anything, something new comes along doesn't it, and by allowing them to have it, they build up their own, um immunities to it, but it strengthens

their immunity... so then I don't really think that there's much point, when people can cope with it themselves, why, it's almost like you're knocking their own immune system out by giving everybody vaccines for everything... there's always going to be another virus of some sort around the corner, and you vaccinate against one thing and it will develop into something else so no. ((laughs))" P12

This particular participant (P12) indicated a belief that having an infection from one disease helps to increase a general immunity against other causes. A vaccine therefore is perceived to take away this opportunity of an "immune boost" and thus a barrier to supporting vaccines.

Along similar lines, parents were unsure if a vaccine would actually work / could be developed as their perception of the viruses are that they are constantly evolving and therefore one would never get the same strain twice:

"If you could actually vaccinate against one of these rapidly evolving viruses, I'm not convinced you could" P18

All of these barriers have added another dimension around the decision to support viral GE vaccinations. None of the participants in this group indicated perceived benefits the vaccines could bring, for their child or the wider community.

6.4.2 Parents with strong support for vaccination in general (and therefore were supportive of viral GE vaccines)

Participants grouped into this category displayed an inherent trust in the scientific and medical community (who develop and implement vaccines). They demonstrated a belief that if a vaccine was available then it must be safe to use.

"I think I would always choose to vaccinate [um] yeah I think it's a positive thing that [vaccines] are being developed" P13

"I'd always consider [a new vaccine] yeah if it was, you know, been approved and it was out there and people you were… giving it out then I'd definitely consider it." P25

"I think if there's any injection that helps prevent an illness, you know, is a hundred per cent [worthwhile]..." P28

A few of the participants simply stated that they would be willing to vaccinate their child, as long as everyone else was:

"Yeah, If everyone was doing it you know... depending on the advice really." P32

This behaviour has been described as "bandwagoning" - a desire to do what is the cultural norm or what most other people do (Benin et al. 2006).

Two parents discussed barriers to vaccinating, however, they viewed the risks associated with vaccines as inconsequential when compared to the risk of not vaccinating. For these parents, the perceived benefits of a vaccine outweigh the potential risks.

"But if it didn't have many side effects, sort of the benefits outweighed them, then I would probably be pro it." P16

"at the end of the day there's always risks with these injections. So I think if this going to do any good, you should have it." P28

Overall, these parents did not consider the rotavirus / norovirus vaccines as anything other than any other vaccination program and thus treated it with the same trust and confidence associated with all other vaccination programs already in place.

6.4.3 Parents that supported specifically viral GE vaccines

Some of the parents considered vaccines for viral GE separately to all other previous vaccines and thus their attitudes towards these vaccines were given a separate amount of consideration.

It was apparent that the parents who would opt for their child to be vaccinated specifically against viral GE perceived the threat of the illness in a different light to those that would not opt for the vaccine. Parents in this group also considered the impact and threat of GE on themselves, their child and also the wider community.

"I know so many families that it's really knocked for six." P09

"That sounds like a really good idea, absolutely because it is so common and you know distressing for the little ones and if there is a vaccine towards it then I am definitely for it, definitely." P24

[Regarding specifically vaccine for norovirus] "I would be delighted if they brought out a vaccine for that, [um] purely because I feel like I spend most winters waiting for them to go down with it and it's so, so contagious [um] I mean, I know they always end up with a lot of people in the hospital with it and in the nursing homes and they keep having outbreaks like on a cruise ship, all this sort of thing [um] and it's so unpleasant to have and yeah, I'd be very happy if they brought out vaccine, I'd be first in the queue." P11

Parents also considered the potential benefits of the vaccines for the wider community.

"I mean apart from anything, rotavirus and norovirus cost the NHS millions every year, [um], I mean our local hospital was on [um], black alert a couple of months ago, and they were having to [um], cancel operations for people because they were full of people being sick. And you know, they, they, they were cancelling operations that potentially even had the ability to be lifesaving just simply because there were so many people ill in hospital with winter vomiting bugs...So, yes, so I'm all in favour of vaccination." P19

One parent mentioned the risks associated with vaccines and adverse effects, a concern previously highlighted as an important issue to address in many other qualitative studies (Mills et al. 2005). Interestingly, this risk was stated in a positive light in which the carer states they are not concerned about the adverse effects:

"I don't believe vaccines are harmful in general...My children have already been vaccinated against other things so if they were going to be amongst the rare people who are sensitive to ingredients in vaccines I think that would've already manifested itself." P18

This group displayed a belief that GE results in a significant burden on individuals and society and therefore perceived vaccination as likely to convey important benefits. The benefits perceived in this group were considerable and outweighed the concern of risks.

In addition to preventing GE using vaccines, we also explored how parents prevent illness and transmission of illness using hygienic measures.

6.5   Preventing GE through hygiene

We sought to understand parents views on methods used to prevent spread of illness. In order to do this we firstly explored their beliefs on how they thought GE is spread, specifically between children. We found that there was a huge variety of perceived ways in which GE spreads, many related to hygiene (or lack of) [Figure 39].
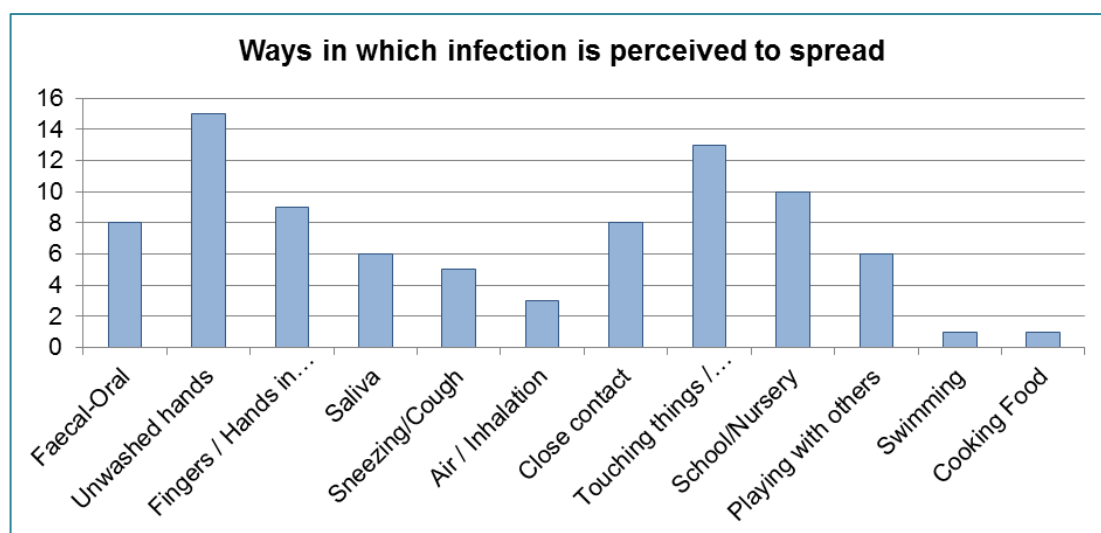
Figure 39. Summary of the main ways in which GE is spread between children.

Direct causes such as spread of illness by faecal-oral route, activities and environments were also perceived to be central to the spread of GE.

"I'm convinced that every time I take her to a playgroup, like a play centre, then she tends to gets sick a couple of days after I've exposed her to somewhere like that..." P25

This participant did not explain *how* they thought their child caught GE. However, they did indicate that they believed that the *cause* of illness was related to their environment. Another parent presented a similar association with a different environment:

"Personally in my mind it might have been the swimming, he might have swallowed some water which caused him to be sick" P28

As there were many ways in which parents perceived their child to catch GE there were therefore various methods they employed to prevent the spread of illness. Prevention can be grouped into two categories – Primary prevention and prevention of transmission.

6.5.1 Preventing GE

Some parents indicated they had a strict routine to prevent their child from catching GE in the first place.

"Okay well what we do do is we, we always wash our hands after we change nappies...We always wipe down where we've changed the nappy or we change on a mat. We always

ensure that we wash our hands before we prepare the food for the children, and we always
wash our hands after we've finished food." P05

Interestingly though, this same participant discussed alternative beliefs when outside of the home.

"Well I wouldn't stay away...I'd just make sure that I cleaned my child's hands and things regularly and just to be a bit more alert really, but generally, I know it sounds ridiculous but I, I'm not adverse to them picking up the odd infection and will deal with it. It's [um], I would rather that they were having fun, than me running around spraying them with alcohol spray every 2 minutes" P05

This altered behaviour could indicate a dilemma of what it means to be a "good parent". The need to be a "good parent" in the eyes of society (and allow their child to have fun), in this instance, outweighs the "good parent" who, at home would have strict hygiene measures.

6.5.2 Prevention of Transmission

Preventing the transmission of illness once one person is symptomatic was also explored. The main prevention measures that parents discussed were hand-washing and segregating those with and without symptoms, there were however specific measures that parents used which varied from opening windows to disinfecting the whole house [Figure 40].
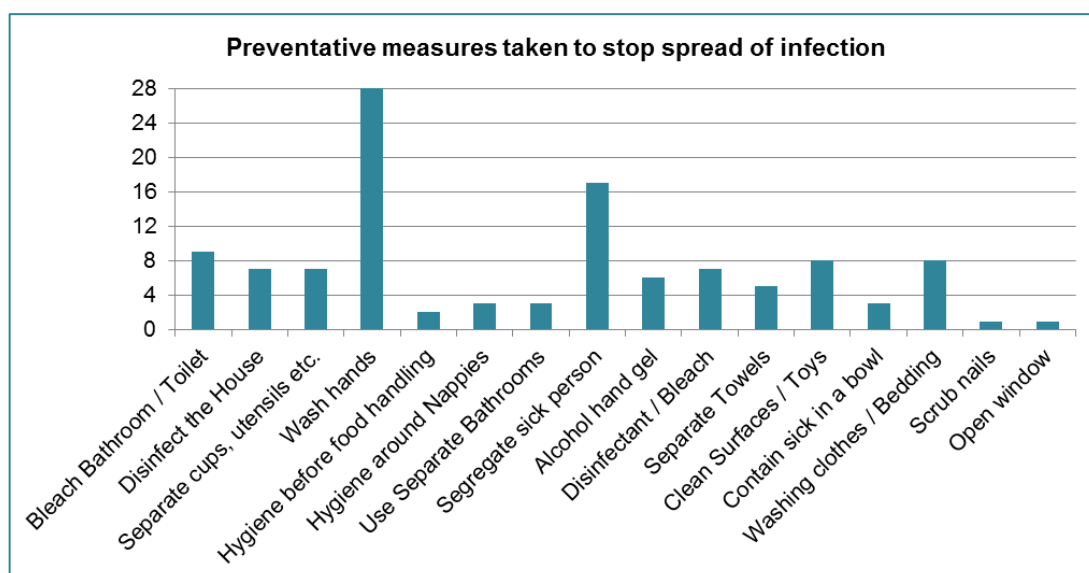
Figure 40. Ways in which participants prevented the spread of illness in the home

There was a variation in the amount of precaution parents took to prevent the spread of illness in the home as the following two quotes demonstrate.

"Definitely [um] I would be probably be going through a bottle of bleach a day" P04

"Well to be honest I don't take many precautions, I just make sure they wash their hands" P34

These differences in attitudes could be linked to the participants' belief of the associated risk of their child catching the illness.

For those participants who linked a specific environment to the likely cause of their child catching GE, they were asked to consider what precautions they might or have put in place to prevent this happening again.

"I don't think there's much you can do when they're in ball pits and playing with toys and you know you never know how frequently their equipment is washed and sterilised so I don't think there's much you can do really other than just kind of washing your hands and that's it really" P25

This is another indication of where a parent is balancing the risk of infection against the child's happiness (opportunities for play / fun). Again, the balance is tipped toward the child's happiness and perhaps the desire to fit in with what other parents expect.

6.6   Infectious period

Along similar lines to ways to prevent the rest of the household from catching their child's illness, there was variation with regard to the period of time after an illness in which the child was viewed as infectious, or capable of transmitting the infection to others.

On discussing time to wait before swimming, no parents indicated they would wait two weeks (as advised by HPA and NICE guidance), many referred to a 48hour rule and some indicated they would not even wait that long.

"[Interviewer: how long before you go swimming with them?] Well, they probably would say three days but I mean I wouldn't wait three days, I'd wait a day to be honest" P01

Parents also discussed how long they would wait before returning their child to school and/or other activities.

If they're sick and then immediately seem to be better, I probably wouldn't take too many precautions but if they're still sick or pale and listless and obviously still ill I'd probably keep them at home. But if they puked and then seemed to be better I guess I'd probably take them out and expose their vile germs to the world at large, ((laughs)) irresponsibly ((laughs))" P02

Through the use of jokes and the use of the word *"irresponsibly"*, this participant indicates an awareness that her actions may not be in line with school policies or other infection control policies, instead they are basing their child's return to school on whether the child *feels better*.

This behaviour was recognised by other parents who did not agree with this attitude and many discussed the impact of this on their own child.

"I've always kept them off for the full 48hours myself…Because if everyone's going back early then my children are going to get it more often as well" P11

"It's quite difficult with the schools 'cause a lot of parents go to work don't they and they kind of push their children into school … then it spreads like wildfire" P04

Some parents reported that they are extra careful following an episode of GE and some showed an awareness of the positive impact their behaviour had on the community.

"if there's sickness and diarrhoea in the house the child needs to be absent for 48 hours. So I kept him off for the three days rather than the two, just to be sure" P30

"if my child has got the diarrhoea I make sure that the diarrhoea is fully gone and they are one hundred per cent before I allow them to go back to nursery or school, definitely I would never send them to school or nursery with diarrhoea, that is very unfair on my child and also unfair to other children as well" P24.

Many of the parents referred to their *"after diarrhoea policy"* as a generic rule for any cause of diarrhoea, there was however, one parent who referred to their own rule which differed dependent on the cause:

"If it is potentially a norovirus or something that it is contagious, I would agree with [the 48hour] policy and would keep her home... If it is something like food poisoning or we can root it to food then I don't think the incubation period's, I don't think, well, once she's well then I'm happy for her to go out" CP08.

This participants beliefs are inconsistent with scientific evidence that suggests that shedding of viral particles can continue for up to 2 weeks after the symptoms have ceased. There seemed to be a general understanding about why 48 hours is needed before contact with other individuals, although one participant tried to balance this knowledge with the practicality of doing it.

"My understanding of how long the incubation period tends to be, I know that they can still be shedding the virus you know in the poo for a while afterwards but you can only sort of stay in the house for a reasonable amount of time so that's, just sort of try and minimise the risk without being house bound for ever, otherwise you'd never go out again really" P11

On the reverse to this, some parents showed no knowledge of a 48hour policy or the knowledge of shedding infectious particles after the diarrhoea had stopped:

"To be honest I didn't actually mention it to the child-minder... And then on the Monday they all got ill...So it's quite likely it was [the participants daughter], I don't know how long it lingers after, I thought once the diarrhoea had stopped it was finished, but maybe there's still a bug there." P16

6.7 Interpretation and Impact of findings

Participant beliefs about and perceptions of GE appear to influence their decisions regarding reducing the risk of their child having GE. Participants' views on a vaccine for viral GE were considerably influenced by their views on the risk posed by an episode of GE on their child and on the community.

Prevention by vaccination

Previous studies have investigated parents' beliefs towards vaccination programs in general as a means to understand how and where vaccine uptake can be improved. By identifying and grouping similar beliefs together, improvements can be targeted appropriately.

"By understanding these barriers, policy makers and health care providers may be able to effectively address parental concerns" (Mills et al. 2005).

Early work on barriers and facilitators to behaviour change was led by Kurt Lewin (1935) and was developed in the 1950s into what is now known as the Health Belief Model [HBM] (Rimer 2008). The model was initially intended to understand "the widespread failure of people to accept disease preventives" (Janz and Becker 1984) and has since been applied to various efforts of preventative health services - such as the uptake of vaccination programs (Janz and Becker 1984).

The way the OSOP for this theme has identified three groups of beliefs toward viral GE vaccines within our population lent itself to be used within the structure of the health belief model.

The components of the model are derived from "*a well-established body of psychological and behavioural theory*" (Janz and Becker 1984) and have been conceptualised into the framework of health-related behaviour. There are four dimensions that make up the health belief model which will be described (as
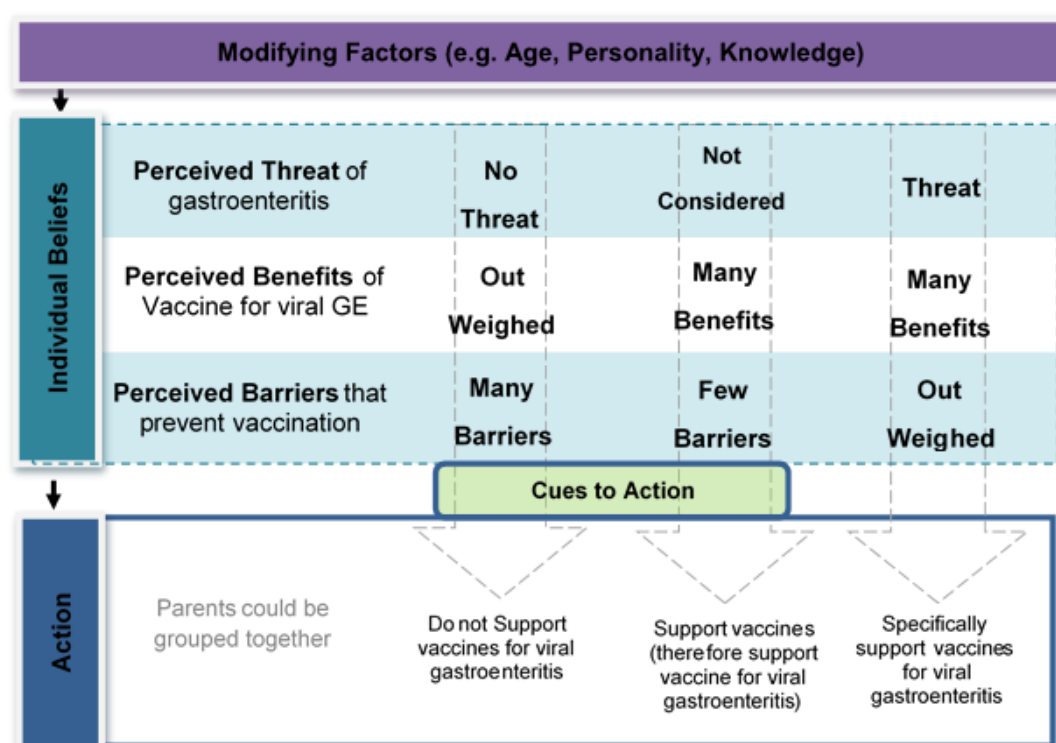
adapted) for this work [Figure 41].

Figure 41. Using the Health Belief Model to group participants beliefs and attitudes toward vaccines for viral GE

The first two dimensions; perceived susceptibility and severity of a health condition, in this case GE, can be collectively known as the "Perceived Threat" and provides *"the energy or force to act" in a preventative way*" (Janz and Becker 1984).

The perceived benefits and barriers of the preventative health measure (a vaccination against viral GE) forms the latter two dimensions of the model and these dictate the path of action an individual takes (Champion and Skinner 2008). The parents' final decision to vaccinate their child or not, can also be affected by other motivations, described in this model as *"cues to action"*(Champion and Skinner 2008).

As the HBM suggests, there is more than one dimension that leads to the actions and decisions individuals take. Parents who perceived few benefits of the vaccine were also likely to discuss the insignificance of a viral GE episode as well as focussing on the barriers that prevent them to support viral GE vaccines (e.g. side effects, don't believe they work). In order for this group of individuals in particular, to consider supporting this type of vaccine, according to the HBM, various cues to action could be required which would include overcoming the barriers already mentioned. Focussing information on the benefits of the vaccines in addition to providing evidence of their efficacy could help to influence their decision. Using data from other countries where there has been successful implementation of the rotavirus vaccine (such as America), by showing the reduction in illness and therefore burden, could help to influence parents that doubt the efficacy of these vaccines. Changing their beliefs of the threat of illness may be more challenging as many parents referred to the risk of mortality from GE indicating their perception of risk of illness is limited to risk of death versus no risk of death. Perhaps highlighting the morbidity and burden of the illness could address the other risks involved in a child with GE.

By identifying these three groups of beliefs it has enabled us to identify where vaccine uptake may be low and has indicated areas to focus on to enhance vaccine uptake. The two groups that supported vaccines for viral GE perceived more benefits to barriers, the difference between these two groups was the belief of threat of illness as well as one group simply accepting what the scientific community say and do not weigh the risks and benefits in their own minds. Parents who adhere in this way may make more informed decisions if they are encouraged to play a more active role in understanding the risks and benefits of vaccination, although this may result in a lower uptake amongst this group.

It is unlikely that the other group who support GE vaccines would need much persuasion to give their child these vaccines, but again, clear information should be provided to ensure they are fully informed. Finally, there were those parents who

were not aware of the vaccine therefore increased distribution of information would be helpful in this group of parents.

Prevention of transmission

All parents indicated they would use hand washing in order to prevent transmission of infection whilst their child was symptomatic. However, parent's beliefs and awareness of the ongoing infectious period, once the symptoms had abated, varied with many parents under-estimating the length of time required to become non-infectious.

Schools, nurseries and also workplaces ask that individuals follow a 48hour rule of being symptom free before returning. NICE guidance states:

- ◆ *"Children should not attend any school or other childcare facility while they have diarrhoea or vomiting caused by GE"*

- ◆ *"Children should not go back to their school or other childcare facility until at least 48 hours after the last episode of diarrhoea or vomiting"*

- ◆ *"Children should not swim in swimming pools for 2 weeks after the last episode of diarrhoea"*

The evidence base for the 48 hour policy is based on the length of time individuals shed viral / bacterial particles following a GE episode. This duration varies from pathogen to pathogen, however norovirus (the most frequently infecting pathogen) can be 2+ weeks.

Balancing Act

Parents in this study population describe balancing what they would like to do against what they think they should do. Some parents indicate wanting to keep their child away from others who are infectious, but also wanting their child to socialise and "have fun" with other children. This is an indication of the pressure that parents feel to fit in with society (i.e. if other parents aren't concerned about their child catching GE then neither should they).

Parents also indicate that they do not want to worry too much about their child catching GE when they are outside the home. However, their thorough hygiene measures indicate that they do worry about preventing their child from catching GE.

Keeping their child off from school has implications on both the parents (time off work) and the child (missing school activities). Many parents indicated that they had to balance how long the child was home for against work pressures or perceived pressures from other parents to return their child to activities.

6.8   Chapter Summary

This chapter has focussed on parent beliefs about GE and how the variation in these beliefs, regarding the causes of GE and associated risks, can influence their actions and attitudes around preventing further episodes, either through vaccination or hygiene measures.

The next chapter will focus on parents' experience of the illness, including how it impacts on them and their children, and their beliefs, attitudes and reported behaviours regarding management.

Novel findings – This study has described how the perception of the threat of GE can influence important decisions such as prevention of transmission of illness and the likelihood to vaccinate. If GE is not perceived as a threat, this can increase the risk of infection to others.

CHAPTER SEVEN:
PARENTS' EXPERIENCES OF MANAGING THEIR CHILD'S ILLNESS

7.1 Introduction

This chapter explores the management of paediatric GE from the perspective of the parent, including what caused them anxiety or worry, what lead to them consulting primary care as well as the impacts of the illness on the wider family. In addition, parents' descriptions of dietary management are described as well as the underlying beliefs regarding these dietary decisions. The chapter concludes by considering the impact and consequences these have on both the parent, child and primary care.

7.2 Causes of parental concern

This section focuses on the aspects of their child's illness that parents perceived as causing them the most concern. It explores the specific areas of concern as well as identifying when and why parents seek help from primary care. We also explore parents' expectations and experiences of consultations with regards to the specific area of concern.

7.2.1 Dehydration

Almost all parents indicated that the biggest worry they had during GE episodes was dehydration – both becoming dehydrated and whether their child was already dehydrated.

All parents talked about how they kept their child drinking whilst they were in the acute (vomiting) phase to make sure they did not get dehydrated, and that this was the most important aspect of looking after a child with acute GE.

For some parents, the anxiety related to dehydration was partly due to a previous GE episode that had resulted in their children being admitted to hospital for dehydration. As a result, these parents focussed a lot of their time and attention on maintaining fluid intake throughout the episode.

Other parents referred to advice they had received during past episodes from their GP.

"I called once and got a call back for advice, they diagnosed it over the phone y'know "there's a bug going round, just keep them hydrated" " P30

Advising parents to maintain and monitor hydration was the most frequent piece of advice given to parents in this study – as reported by parents.

Although many parents used phrases such as "*you have to watch for dehydration*" (P17), there was little reflection on how a parent should do this and to what level of observation or assessment this needed to be. This suggests that parents have received information about the importance of preventing dehydration, but they remain unsure about exactly how to assess for it.

Many parents commented that they monitored the amount their child drank. Only two parents mentioned they assessed urine output visually or used the "thumb test" (capillary refill time) as a means to identify dehydration.

One parent described how, after consulting the doctor, they went home and measured their child's hydration as advised. When I asked how they did this, they indicated that they just maintained fluid intake.

"Gosh, we didn't measure it, we just kept on feeding him water as often as we could" P17

Dioralyte was the only form of ORS mentioned in interviews. It was considered by some parents during their home management of dehydration. Its use seemed to be only by parents who had, in the past, been recommended ORS by a clinician and therefore this practice continued for subsequent episodes.

A few parents avoided using Dioralyte because of the taste and they found that it was easier to persuade a child to drink water. As the main concern for parents was reducing the risk of dehydration, most parents in this population were more focussed on getting *any* fluid into their child rather than focussing on Dioralyte. If Dioralyte wasn't going down and water was, parents would opt for water.

There were a few lay beliefs around what Dioralyte *did* or how it should be prepared. One parent explained that in order to get her child to drink the ORS solution, the sachet was prepared with less water than recommended.

"You have to keep your sugar balance as well as your water ((laughs)) which is why Dioralyte is you know, once you're really bad I think Dioralyte is your best option. But then they hate the taste of Dioralyte ((laughs)) but what I worked out, 'cause they recommend you put it in a large amount of water which you're never going to get down them but if you actually can just put it in a very small volume, although it tastes horrible, you can get it down them quicker ((laughs)) So ((laughs)) I think Dioralyte offers the best balance because it's getting liquid and it's getting some nutrients in as well 'cause obviously you're losing a bit of both" P08

Some parents had beliefs about the effects of Dioralyte that are inconsistent with scientific evidence.

"he'd had diarrhoea and vomiting for a few days and he didn't seem to be getting any better so we got some Dioralyte. I don't know if that made any difference or not … he just was probably coming to the end of it anyway" P05

This parent indicates that Dioralyte was purchased in order to stop the symptoms. It is not clear whether the parent attributed the reduction in symptoms to Dioralyte. However, the use of Dioralyte to treat dehydration or replenish electrolytes was not mentioned, indicating that Dioralyte was used for other purposes.

For many parents in this study, their concern over whether their child was dehydrated lead them to ring their GP for advice or emergency consultation.

For some, reassurance was sought to support their own conclusion that there was nothing else they could be doing to look after their child.

"I didn't think she was dehydrated, but I just wanted to make sure that I was right. The doctor said she was fine and to keep giving her fluids so yeah, I was right" P15

Following reassurance from the GP that their child's hydration status was not of concern, most parents felt confident they could continue managing their child at home.

"If I'd seen that they'd done all the checks then I'd go home and that would be okay but if they just sent me off without doing the checks then I wouldn't be happy" P01

This parent discusses "checks" but does not provide further information as to what these would consist of. It is also unclear whether this participant would raise this concern (if checks weren't undertaken during a consultation) with the clinician.

There were a few parents however, who indicated that despite their child being examined, they continued to feel anxious until the symptoms improved.

"I went on one appointment and they sent me home and then they were no better the next day, I took them back again just to say, you know, it's still ongoing, should it be going on for this long?" P04

This could be associated with a lack of trust in the clinician's assessment or that perhaps they expected more from the consultation. There is no indication of what the parent had expected as the outcome of either of the consultations however, this does suggest that perhaps more could have been done to provide support to this individual i.e. safety netting, information on natural history.

7.2.2 Fever

Fever above a "*threshold*" also caused significant anxiety for parents. Many parents discussed using antipyretics such as paracetamol to manage a high fever. An elevated temperature was not viewed as a cause for concern per se, just as a sign of infection. Parents who consulted their GP in this study did not indicate their child's fever influenced their decision to do so. However, parents indicated that they generally felt very concerned if they had treated their child with an antipyretic and they still had a fever.

"If her temperature had been really high and wasn't responsive to Calpol then I definitely would have got her seen [by a GP]" P09

All parents who discussed an "unresponsive fever" indicated they would look to their GP or NHS direct for help. These parents were discussing this hypothetically and therefore it was difficult to determine what "unresponsive" meant in comparison to what their child had experienced during this recent episode of GE. Some parents compared their child's fever during GE to other experiences of fever such as tonsillitis or urinary tract infection [UTI] as a way to determine severity.

Parents indicated that a high fever could indicate other (more serious) illnesses such as meningitis.

"I did, you know, simple things like saying "can you touch your chin to your chest?" and checked him for rashes and checked he could move his neck quite comfortably and stuff like that…I sat with him until the temperature bit had passed, even when he'd gone back to sleep I just sat with him until he cooled down a bit" P18

Considering more serious infections such as meningitis as the cause of diarrhoea and vomiting are likely to impact on their anxiety during their child's GE episode.

7.2.3 The unknown

Anxiety was particularly high for parents who were experiencing their child's first episode of GE. They expressed a lot more uncertainty about what they should be doing and if they were doing enough.

Some of these parents discussed how they contacted their GP to check they were managing the illness appropriately.

"I just wanted to make sure that I was right, doing all the right things really, and if there was anything else that I could do to help them, but there wasn't, I was doing all the right things"
P34

Parents who had more experience with managing a child with GE also compared their current management and levels of concern with how they managed during previous illness episodes. Parents with previous experience also benefited from being able to compare the intensity of symptoms and wellness of their child, enabling them to judge appropriate actions.

"Obviously we're both new parents…So after dealing with the first time and we were okay …so I'm a lot more sure going into it now if it happened again." P28

Parents experiencing acute GE for the first time are unlikely to have such a personal reference point to compare to.

7.2.4 Age

Most parents commented that they were aware that managing children at a younger age with GE was more worrying.

"They're more reliant, they can't tell you how they're feeling whereas when they're older, you know, you can pretty much judge how they are and what they're doing" P04.

This could partly be linked to the experience of managing the illness and recognising the symptoms over the years, but many parents with children of mixed ages indicated that younger children deteriorated more rapidly and were also unable to communicate their symptoms to them.

7.2.5 Gut feeling

Non-specific reasons were also mentioned by parents when discussing the point at which they became more anxious or consulted the GP. Parents mentioned features such as *"not [being] themselves"* (P01, P05, P32) or displaying differing symptoms to previous GE episodes and this became a reason to seek further help.

One parent indicated that their child wanted "*constant cuddles"* and that influenced their decision to consult primary care.

7.2.6 Symptom Duration

Parents commonly indicated that the length of time the child had symptoms was an influence on concern levels and an important factor in deciding whether to consult. One parent indicated that this was not just as precautionary measure, it was also because of the burden of the illness on the parent and child.

"No it was about six days in and I think that's when we'd come to ... you know, it was starting to get us down and he was really struggling with it too he was upset, so that's why we looked for guidance with the doctor" P28

This parent indicates that whilst the symptoms were not worsening over this time, it was purely the length of illness that was important in the decision to consult. It appeared that the parents' judgement over the six days altered from coping at home to needing to seek help as their physical and emotional resources depleted. Interestingly, the expectation of the consultation remained a need for reassurance rather than a specific intervention.

Other parents discussed their expectation of *"further tests"* i.e. a stool sample to be sent if the symptoms were persisting longer than "*a few days"*. This ranged from three to seven days among the participants interviewed.

7.3 Impact of illness

This section explores how a child's GE illness impacts upon parents and the wider family.

7.3.1 Practical

The two areas that stood out during the interviews with regard to burden of illness was the risk of themselves / partner / siblings catching the illness and the more practical impact of cleaning up after a child with D&V.

Almost all parents mentioned the increase in laundry required during the illness and the extra cleaning that they were doing – on top of caring for their child.

"The thing that drives me mad ((laughs)) is the having to do all the excess washing! And you know, the little one's not well, they want you cuddling them all day and you've got a house full of vomit ((laughs)) and carpets full of vomit and a sack of clothes in the kitchen that are covered with poo and you feeling like, I gotta get all these done as well and it's, it's all the extra work I guess, when really you just wanna be comforting your child 'cause they're not very well" P05

"Oh it was wearing, awfully wearing, because it was literally a change of clothing all the time, I was constantly, it was like for the whole week I was just like a robot" P14

In half of the households at least one other individual suffered the same symptoms as the child, and the illness was perceived as spreading through the family. In some cases, all family members were ill as well as it extending to others such as grandparents and child minders.

Other family members attempted to segregate family members into "well" and "sick" using separate bathrooms and bedrooms.

"We now try very hard to segregate, I know it might be too late but it seems to help. So whoever's being sick gets looked after by me, and my partner gets to look after the healthy ones…If someone is sick their clothes, my clothes are washed immediately if I was holding them and we shower together. We try very, very hard to wash off all the evidence… And, you know, kind of view areas of the house as contaminated and not contaminated and stuff. It sounds a bit extreme but when you've had twins around a year old doing simultaneous vomiting, you don't know who's going next, you get a bit extreme… I don't know, you worry for the next couple of days if the others are going to catch it, were you good enough at segregating them and stuff? And then because at two and five they're not very good at

obeying orders and the two year olds really like the five year old, so keeping them
segregated the next couple of days is quite tough." P18

This participant explores the difficulties at maintaining separation when one child is sick as well as indicating that as the main carer of the sick child this participant is putting themselves at risk of catching GE as well.

A few parents mentioned that their child would sleep with them during their illness which again puts them at risk of illness. To some of the parents in this study, this appeared to be an expected outcome.

"So I kept him, I kept him in bed with me and he was sick through the night about every
hour and a half he was sick" P34

"As long as I end up with it last and not whilst the others are sick I don't tend to worry too
much… because I have to look after everybody else, so it's easiest for me to do that if I'm ill
at the end and everyone else is well enough to sort of get on it with it" P10

Some parents looked to their own parents for support and help during their child's illness, for help with the more practical issues such as picking up other children from school or helping to look after the ill child once their symptoms have settled. Parents were aware of the risks of transmission [See section 6.5.2] but with external factors such as returning to work, some parents indicated they would ask family members once the symptoms have resolved.

"I mean, if she's really bad I don't like to leave her at all, obviously for my job it's hard then
'cause you have other people who are depending on you to come in but I always put her first
so if she is really unwell I will take time off for dependent's leave and stay with her. Once I
can see that she's actually recovering and she is fighting the infection or what have you and
she's more alert in herself then I'm happier to leave her with grandparents, unless we're
worried that it might infect them and that's obviously the other thing, weighing up" P08

7.3.2 Emotional

The impact on parent's emotional state was also an area focussed on by participants. The combination of constant care, lack of sleep and a feeling of helplessness resulted in parents *"feeling like a robot"* or referring to the experience as *"wearing"*.

Many parents explained they spent a considerable amount of time checking on their child, not wanting to leave them in case they deteriorated or choked during vomiting.

"I was up quite a bit during the night with her and we were worried that she might be sick and choke so we were trying to be extra careful with that" P13

"I was just very nervous I suppose and I was watching her every minute and the next day then we started to see the improvements so I felt a bit more at ease so yes it wasn't the nicest experience, no definitely not a nice experience" P24

This implies a lot of emotional energy spent on checking that their child wasn't any worse and trying to decide if or when they needed to look for help. Parents who had older children or multiple children seemed to find the experience less emotionally exhausting which is likely to be down to experience of the illness.

7.3.3 Financial

Plans were often cancelled and the cost of day care cancellation and time off work were also a considerable concern for some parents. Costs were also associated with the cleaning involved during and following their child's episode, for example, cleaning products, washing powder, new towels and clothes. Nappies were also a considerable expense – one parent reported using 85 nappies in eleven days during their child's most recent episode *(P28)*.

7.4 Variation in dietary management

This section explores parents' description of the diet they gave their child during their recent bout of GE and their beliefs regarding the dietary management of GE.

Although there appeared to be a variety of diets and food types considered by parents in this study, none of them indicated that they asked their GP for advice regarding nutrition. In addition, none of the parents indicated that they had been concerned when altering their child's diet, in fact, all parents appeared confident in what they did and why.

Looking on the internet influenced a few parents, with 11 parents reporting that they considering using the Banana Rice Apple sauce and Toast [BRAT] diet. However, only one parent reported that they tried all four elements (most only mentioning banana and toast).

Some parents were also influenced by what they, as a child, had been given during an episode of GE and therefore did not indicate specifically why those food types were considered, only that that's what their parents had done.

7.4.1 Fluids

Although there were many fluids parents discussed using to try and keep their child hydrated, water was the primary option. This was especially true for during the rehydration or acute phase of illness – defined in clinical guidance as usually lasting for about 3 or 4 hours (NICE 2009).

"I gave him a little bit of water and when he stopped, little sips, and when he stopped bringing that up I let him have a bit more" P10

Small sips were mentioned, especially in relation to children who were vomiting as this was perceived to reduce the risk of vomiting.

Other fluid management options included different types of fluid. Weak squash was popular within this group of parents, with two mentioning how the squash boosts their child's energy.

Mint tea with honey was mentioned by one parent who believed it would calm her child's stomach, as well as the belief that reduced fibre would be helpful to the child.

Two other parents mentioned they used flat lemonade / cola as a way to ensure calorie intake during their child's illness.

Fruit juices, such as orange juice was avoided by many parents.

"…like orange juice 'cause that would be horrible to bring back up so trying to stick to just water to drink" P11

One parent discussed how they were not concerned what their child drank, as long as they were hydrated.

"and then after their vomiting has finished they're allowed, they can drink whatever they want as long as it's not dairy so they can have squash or whatever they want, within reason [um] my, fruit juice or whatever, my usual rules are broken when it comes to them being sick, as long as they're drinking then that's fine" P10

Dairy was avoided by this parent and there were many more references to including or avoiding milk/dairy during a child's illness.

7.4.2 Dairy

There appeared to be a split in beliefs around dairy products and whether to give a child with acute GE this type of nutrition.

Many parents mentioned removing dairy from their child's diet in some form. A few mentioned this was on advice from friends / family / a clinician.

"My mother always said don't give them milk and so I tend to avoid milk an yoghurt, yoghurt if they were ill but I don't think it's based on anything scientific apart from my mother's advice" P02

"Well the reasons I did [avoid dairy] was obviously my cousins a paediatric nurse and she said just to give the tummy time to recover, because she'd [daughter] had so many bouts of it, her little tummy didn't have time to recover so just keep her on things like just plain vegetables and that, you know just in case it came back" P14

Others made this decision based on their own experience of managing their child's illnesses over the years. Some mentioned the curdling of dairy products in their stomach and the dislike of clearing up dairy-containing vomit as a key reason to avoid dairy.

"I've also found that clearing up half-digested cheese and half-digested milk is, the smell tends to linger so I tend to leave those until the last, one of the last things to get back just in case they're gunna be sick again, that's the worst thing to clear up." P10

Others believed it made the symptoms of diarrhoea or vomiting worse or re-starts a concluded episode of GE.

"Just through experience really that dairy, well my two certainly find it hard to keep down after they've been unwell, if we kind of try and give them a yoghurt a couple of days after they've been sick, it usually starts all over again ((laughs))" P07

Two parents discussed their belief that dairy should be avoided during GE as well as common colds. Three parents avoided dairy as they believed their child had lactose intolerance, however, the parents did not indicate whether this was a diagnosis from their GP or a presumed intolerance.

Of those who indicated they continued dairy products, their reasons were focussed mainly around what their child wanted or was able to eat/drink. For young babies, parents indicated there was no other alternative to milk or that their child would only drink milk and this intake was better than none. Some parents indicated that it does not make a difference.

> *"I know a lot of people say don't give dairy. But I know that there isn't really usually any need to cut out dairy. I know that some children will, can be a bit lactose intolerant temporarily after they've had an upset stomach but I don't think that, or unless you've actually got good reason to think they have become lactose intolerant I'm not a big believer in cutting out food groups just in case. Generally. That's my general policy I suppose. 'Cause I feel a lot of people are on very restricted diets for no good reason I just think it's a bit daft…I'd probably try and get proper live yoghurts rather than dairy based dessert types for when they're ill but yoghurts are nice, they like yoghurts so I wouldn't particularly withhold them. I mean I wouldn't give them while they're still acutely vomiting 'cause I wouldn't give anything that's going to be so smelly to get out the carpet to be honest ((laughs)) but once they're a little bit on the mend then no I don't withhold dairy or don't think it makes any difference. For most children." P11*

One parent held the belief that avoiding dairy was only necessary for certain causes of GE.

> *"As far as I understand, it's only useful when it's a bacterial rather than necessarily viral" P19*

This could indicate a belief that bacteria thrive in dairy and therefore dairy intake during a bacterial GE would encourage growth of bacteria thus worsening symptoms.

Another two parents included dairy products in a list of foods they considered to be bland *(yoghurt – P14 and porridge – P17)*.

> *"I mean the diet she was still drinking her milk but I was giving her like a bland diet of like toast and just like, mashed up banana and I was just giving her yoghurt but I wasn't giving her anything else, it would have irritated her really...yoghurt is supposed to be good for stomach"*

> [I later queried the use of yoghurt and whether they were probiotic]

> *"No, they were just like the normal Petit Filous" P14*

7.4.3 Diet

A few parents reported considering or actually removing all solid food intake during their child's acute episode. This was related to the symptoms the child presented with, for example vomiting, diarrhoea, loss of appetite.

"While they were being sick I didn't give them anything, just made sure they drank enough water" P34

Other beliefs regarding stopping solid food included resting the stomach, to stop the symptoms or to discourage the pathogen in the stomach.

"If you've got a tummy bug [try] not to eat anything to encourage the bacteria I suppose, just to try and kill it off a bit" P04

Some parents held varied views on reducing solid food during the illness. Many felt that children need energy to recover and therefore limiting food intake would prolong the illness. Other parents felt that starving would only make the child feel even worse.

"I know that some people do sort of starve them and believe that it's helpful to starve them, I think if you're gunna be sick, you're gunna be sick anyway. And if you're really really miserable 'cause you're dead hungry, you're gunna be miserable and hungry and still vomiting so you might as well eat a little bit but you know I wouldn't be giving them ice cream and chocolate buttons." P11

Once parents were giving their child solid food, the majority all mentioned bland / dry food as the starting point of nutritional intake. Most parents specifically mentioned toast and other common food types included crackers, dry cereal, rice/rice cakes, biscuits, cooked pasta. There was a variety of reasons for the choice of these food types including *"They are binding foods"*(P28), *"Easy to digest"* (P10; P14), *"Plain tasting" (P25), "Soak up toxins" (P01).*

With parents holding alternate views on dairy, there were obviously many contradictions with regards what would be best for a child during and following GE. Many mentioned dry cereal as an appropriate food type, but once milk was added to this cereal, parents held mixed views. Porridge and Weetabix were mentioned by a few parents as a food to start their child on due to its *"plain taste" (P17, P25)*, others watered this down with water due to wanting to avoid dairy and others felt

porridge/Weetabix should be avoided until full recovery due to its *"high fibre" (P18)* and the risk of it *"causing stomach pain" (P27)*.

Another food group that held various views was fruit. Apples were believed to be *"good for the stomach/digestive system" (P01; P15)*, have *"acidic properties which is good" (P09)* and banana *"won't irritate the tummy" (P14)*. Other parents felt that fruit was a food group to avoid as they are *"high in fibre" (P23)* and will *"upset the stomach wall" (P32)*.

Food that parents classed as *"junk food"* was considered inappropriate to give an unwell child due to the high fat and grease content *(P01, P11, P34),* although specific examples were not given. Other parents felt that if this was all that their child would eat then it would be better than nothing.

> *"I gave them fish fingers and chips just because it's something I figured they'd eat. If you know what I mean. There was no challenge to it at all, I knew they'd like it and my youngest wolfed it down… we'd been offering food all day, you know, 'Is there anything you want? Is there anything you'd like? Tell me if there's something you fancy', you know. And they'd sort of gone, 'No, no', all day, and then fish fingers and chips and they massively perked up…junk food, easy to get in, it's got plenty of calories in it and, I don't know, it's just a little bit of what you fancy." P19*

Mixed views were also found regarding salty or sugary foods. Many parents felt that these had similar properties to the ORS solutions and therefore topping up sugar and salt with food was also helpful. Foods such as boiled sweets or lolly pops were believed to be a *"good way to get calories in" (P12, P15)*; honey was felt to be appropriate as *"it's plain and sugary" (P09)* and salty foods such as marmite and crisps were *"good" (P09, P32)*. Other parents felt minimal sugar and salt were more appropriate.

All of these choices of food types (to either avoid or concentrate on) indicates an alteration to the *"normal diet"* their children would normally eat. NICE guidance recommends to continue a normal diet following a period of starving (no solid food) during the rehydration period (NICE 2009). Only one parent referred to the NICE guidance as reasons for the child's nutritional intake during the illness and confirmed that a normal diet was followed.

> *"Mostly, I think that it's not really going to make a big difference what they have to eat and drink and I know that that well, to the best of my knowledge, unless they've changed them in*

the NICE guidelines they say that you can just offer you know a normal diet really within reason." P11

Other parents did indicate that they followed a *"common-sense"* diet until the child was fully recovered and allowed the child to decide what and when to eat.

"I suppose you don't want to go giving them spaghetti bolognese if you're going to see it again three hours later, but really I think it's if, if they want to eat it, they're very good at managing their own appetites, they won't … they're not like Labradors, they won't just eat what's in front of them. So if they're not hungry they won't eat it, and if they don't fancy it they won't eat it so I wouldn't ever … I wouldn't exclude a particular food group for just, you know, believing that that will be the magic cure…I think the magic cure is your body fighting it off to be honest." P19

7.5   Summary of findings

Use of Primary Care

Parents consulted primary care for a range of reasons during their child's episode of GE however, most frequently parents sought reassurance. The reasons for reassurance varied, and this was linked to their concern(s) of their child's symptoms and/or their management. Expectations also varied although few parents indicated they wanted a prescription.

Parents' main focus during their child's illness was on dehydration but most were unable to articulate how they assessed this. This suggests that parents should be provided with more specific advice about how to monitor hydration, and that if such information was more widely known then there may be a reduction in primary care consultations for parents seeking reassurance about GE.

The average duration of diarrhoeal illness can range from 6 to 14days - depending on the pathogen isolated (Uhnoo et al. 1986) however many parents sought guidance purely with regards symptom duration on day two or three of the illness. It may be that consultations resulting in education only are contributing to the burden of GE within primary care.

Burden of illness

There were a range of physical, practical and emotional impacts on both the parent and child during their illness. Many of these impacts have not been recognised in

previous literature on the burden of the disease. The time, money and effort taken up in the caring for a child with GE is considerable. Parents knowingly put themselves at risk of catching the illness in order to provide quality care for their child.

Management inconsistencies

Although parents correctly identified that Dioralyte replaces sugar and helps to maintain hydration, there was a lack of appropriate preparation demonstrated by some parents. Inappropriate preparation can result in the increased risk of osmotic side effects (©Sanofi 2012). Parents also indicated using Dioralyte to stop symptoms of vomiting and diarrhoea rather than preventing / treating dehydration. If parents don't understand the reason for use of Dioralyte it may result in inappropriate use.

Reported dietary management varied considerably between parents in this study. The evidence supporting the NICE guidance on dietary management is limited and therefore it is unclear of the implications that variable dietary management has on illness recovery and subsequent outcomes (i.e. development of persistent / recurrent symptoms).

The reported lack of information provided by primary care clinicians is an important area to explore from the perspective of the clinicians.

It is also important to recognise that because parents do not consider diet as an area on which to seek advice or guidance, it therefore could be difficult to change or influence these dietary beliefs. This is especially important if evidence suggested that dietary management had a detrimental effect on recovery/outcomes.

7.6   Chapter summary

This chapter has explored the management and impact of paediatric GE in the home as well as primary care from the perspective of the parent. We now move to focus on primary care clinicians and their attitudes and beliefs during a consultation regarding acute GE.

Novel findings – This study has highlighted the expectations a parent has when consulting primary care as well as the main concerns when managing GE. Parents receive advice from GPs that they do not fully understand and therefore their

confidence in management remains low. This study has also identified that there are common misconceptions about what ORS is to be used for and how it should be prepared.   The variation identified in dietary management during and following an episode of GE also highlights the lack of information parents receive regarding nutritional management – areas such as dairy intake are of particular concern if dairy is detrimental to the recovery of GE.

CHAPTER EIGHT:
PRIMARY CARE CLINICIANS PERSPECTIVE ON MANAGING PAEDIATRIC GASTROENTERITIS

8.1   Introduction

This chapter explores the management of paediatric GE from the perspective of primary care clinicians working in Wales. The characteristics of participants will be reported. The variation in their accounts of management will be explored, with particular focus on requests for stool samples with microbiology laboratory analysis, prescriptions of medicines and hospital referrals. We then explore the influence parents can have on the outcome of the consultation as well as on how the consultation proceeds. The final two sections describe clinicians' accounts of the advice offered to parents during the consultation on areas such as nutritional management, as well as clinicians' perceptions of guidelines.

8.2   Primary Care Clinician Characteristics

We successfully recruited from 5 health boards and included primary care clinicians with a range of rurality, gender, experience and practice deprivation. The health boards these clinicians work within Abertawe Bro Morgannwg (n=1), Aneurin Bevan (n=2), Cardiff & Vale (n=9), Cwm Taf (n=3) and Hywel Dda (n=1).

Of the 18 primary care clinicians recruited, 7 were male and 11 were female, years qualified ranged from 6 to 35, with an average of 16 years.

Clinicians worked in a range of areas of high, low and average deprivation [see Table 23]. Setting was also recorded for each practice with Urban, Rural and Valleys as the three indicators. Two participants were employed as locum doctors and therefore had no one individual practice in which to record setting, deprivation or health board. Practice size varied among clinicians, a rating of small, medium and large was given to each practice based on the practice list size [Table 23].

As per the eligibility criteria, all primary care clinicians were working within Wales and the primary care management of paediatric GE was part of their practice scope.

8.2.1 Recruitment and Data Saturation

20 clinicians expressed their interest to participate, 18 were interviewed and the remaining two interviews were not conducted as data saturation had been reached. From the three methods of recruitment, 7 clinicians were recruited from within the case series study (Chapter 3), 7 responded to the email invitation and 4 were snowballed from these 14 clinicians.

Table 23. Characteristics of clinicians included in the qualitative study

Participant ID	Gender	Years Qualified	Location	Practice Size	Deprivation Index	Health Board	Colleagues	Method of recruitment
GP01	F	8	Urban	Medium	High	ABM		Phase One
GP02	F	6	Valleys	Small	Medium	CT		Phase One
GP03	F	24	Urban	Medium	Low	C&V	*	Phase One
GP04	M	7	Urban	Medium	Low	C&V	*	Phase One
GP05	M	24	Urban	Large	Medium	C&V	**	Email
GP06	M	15	Rural	Small	Low	C&V		Email
GP07	F	35	Valleys	Small	Medium	CT		Phase One
GP08	M	8	Valleys	Large	Medium	HD		Phase One
GP09	F	12	Rural	Medium	Low	CT		Phase One
GP10	F	23	Urban	Medium	Medium	C&V	***	Email
GP11	F	7	Valleys	Medium	Low	AB		Email
GP12	F	12	Rural	Small	High	AB		Email
GP13	M	6	Urban	Large	High	C&V	** [BS]	Snowballed
GP14	F	25	Urban	Medium	Medium	C&V	***	Snowballed
GP15	F	7	N/A	N/A	N/A	N/A		Email
GP16	M	7	N/A	N/A	N/A	N/A		Email
GP17	F	28	Urban	Large	Medium	C&V	**	Snowballed
GP18	M	35	Urban	Large	Medium	C&V	**	Snowballed

*/**/*** **indicates those participants who were colleagues;** [BS] indicates a Branch Surgery of another practice; **N/A applies to Locum doctors;** *Health Boards: [*ABM – *Abertawe Bro Morgannwg] [*AB-Aneurin Bevan] [C&V – Cardiff & Vale] [CT - Cwm Taf] [HD – Hywel Dda]*

8.3 Variation in clinical management

Clinicians described how they would typically proceed with a consultation of a child presenting with GE. Many aspects such as physical examination and the history taking were similar across all accounts - for example, accounts of assessment of hydration and temperature levels. The following sections focus on areas in which

reported management varied among clinicians and discuss the impact of this on both parents, NHS resources and the community.

8.3.1 Stool sample requests

Most clinicians' accounts were similar when it came to the factors that they considered indicated a need for stool sample requests, such as blood or mucus in the stool, a patient who had recently travelled abroad, and/or unusually long symptom duration. There was however, variation in what was perceived as a *"persisting"* symptom or *"longer duration"* of symptoms.

The duration of symptoms of an expected *"typical, self-limiting"* GE episode varied considerably between clinicians along with their evidence to support their decision.

"Well, I don't know if this is right, it probably isn't ((laughs)) but if it's been going on for 2 weeks I think I'd request a stool sample at that point" CLIN01

"If the child is doing well, then I would probably leave it a bit more longer. …if he was not well, then forty eight hours is what I would personally, I don't know, whether there is any evidence to it." CLIN16

The length of time clinicians stated they would wait before requesting a stool sample ranged from specific time periods such as 48 hours to 2 weeks. Some used less specific language such as *"weeks" (CLIN07)* or *"a few days" (CLIN06, CLIN18)*. Interestingly, there was considerable variation between those clinicians who worked within the same practice. For example, CLIN05, CLIN13, CLIN17 and CLIN18 were colleagues and their accounts varied considerably.

*"if their symptoms have been present for longer than **three** days" CLIN05;*
*"if it's gone on for **more than five days** as diarrhoea I would request" CLIN17;*
*"if the diarrhoea's persisted for **a few days** and there doesn't seem to be any, any let up in the, in the symptoms" CLIN18;*
*"occasionally parents expect a stool sample to be taken….but you know, **I never do** that" CLIN13*

The first three clinicians quoted here indicate a small variation in time period. However, the final clinician quoted above indicates a markedly different approach to stool sampling habits. For many practices, patients presenting with GE would typically be seen in emergency consultation slots, and therefore might not be seen by the same clinician on each occasion. The variability in practice reflected in these

accounts is likely to impact on the message parents take away from their consultation. Parents are likely to expect the same management as previously experienced and it is clear from these clinicians that that would be unlikely.

A clinician from another practice indicated that variation in management does affect patient expectations and that this has implications for practice.

"I think the only problems you get in practice are people who are keen to send samples off all the time…patients expect it next time you see…So it's sort of you start something that maybe you wish you hadn't started." CLIN03

Reasons for not requesting a stool sample were also explored. The most common reason was that it was unnecessary for most causes of GE.

[Interviewer: …could you elaborate on the reasons why?] …Erm because it's, the vast majority of these cases are viral, erm which can't be detected on a stool sample. With the stool samples we're really looking for you know the serious causes of diarrhoea, erm even in a lot of cases they don't require treatment with antibiotics. Erm, so they don't really hold a huge amount of value in diarrhoea presenting from people from you know who haven't been abroad." CLIN13

A few clinicians reported past experiences with the problems associated with interpreting stool sample results. Some clinicians indicated a lack of trust in laboratory testing.

"I don't know, they never seem to pick up anything when I send them so I just use my own judgement to be honest, unless it really is serious" CLIN06

One participant described an experience of multiple negative results before finally obtaining a result which indicated a potential pathogen that required treatment.

According to NICE guidance and recommendations from the HPA, clinicians are advised to send a stool sample for laboratory analysis if there is blood/mucus in the stool, and to consider sending if the patient had recently travelled abroad, if the diarrhoea has not improved after seven days, or there is uncertainty about the diagnosis of GE. Only about three clinicians appeared to follow this advice with eleven requesting samples earlier than recommended and three indicating that they would typically request a sample one week or more beyond the recommended time.

When clinicians were asked about their reasoning's for their specified time delay before requesting a stool sample, the main reason was in order to identify bacterial pathogens. None of the clinicians referred to current published guidance.

"I would normally leave it a week unless you know there was some compelling reason to do it sooner. [Interviewer: okay and the one week what is that based on?] It's based on kind of practice that I have always done and I have been taught really, I am not actually sure of the scientific, but you know assuming that most simple kind of viral gastroenteritis would have settled and any sort of bacterial causes maybe will be a bit more prolonged." CLIN11

"So really [a stool sample result] is only going to be of any use to you in diarrhoea that seems to be going on longer than a normal gastroenteritis, so I guess I'd use that sort of five days as a arbitrary sort of cut off as, 'Well okay, perhaps this isn't going to self-limit', in which case by another three or four days it would be useful then at that point to have some stool sample to show that erm, you know, to show what's going on" CLIN02

Impact on management

Despite clinicians reporting that they often requested stool samples earlier than recommended, clinicians indicated that their management of the patient's illness was unlikely to alter following the result.

"Very often it doesn't influence management that much because the child tends to be better by the time you've got that back as a negative sample, or even if it's positive, rotavirus or something like that there isn't anything you can do because it's 48 hours before you get the results back. You can phone the parents and just check how the child is and then say, just double-check the child has got better, explain what it was and the parents did the right thing" CLIN07

Many clinicians indicated that in most cases their management would alter only when there had been other indications of obtaining a stool sample (i.e. travel abroad, blood in stool) had antibiotics been considered. Few clinicians reported having identified a pathogen through stool sampling in paediatric GE.

The patient data from CPRD [Chapter 4] indicates high levels of stool laboratory testing, which has increased over the last ten years. With this evidence along, with the findings in this qualitative study i.e. the reported premature testing and the non-impact a stool test result has on management, this indicates stool samples are being overused, used inefficiently and are of minimal clinical value in most cases of paediatric GE. Clinicians admit to this - so why are they still being requested?

Influence of patients and parents

"[Interviewer: How does a stool sample result affect your management?] Well it doesn't, it's just for reassurance for, for the parent" CLIN18

Many clinicians indicated that by sending off a stool sample it provided reassurance to the parents that they had been taken seriously. This may be to build or maintain trust with the patients and their parents. Clinicians also indicated that by sending off a stool sample they were actively "*doing something*" for the patient and their parents. It is unclear whether this generally happens in response to parents that are unhappy with management, or whether this is just a perceived expectation. A further reason discussed was the use of a *negative* stool sample result to explain why medication is generally unnecessary for childhood GE.

"maybe if they seem very concerned about it, you may, you know, use it more because you feel that they're going to benefit from seeing the negative result than perhaps it's going to make any other difference to the treatment that you give, but I think sometimes maybe we, you know, get in to using stool samples for that reason as well. And I guess the people who you struggle to convince that this is a normal diarrhoea and vomiting bug and that it's not anything more serious, sometimes we use a test in order to try and convince them that yeah, this is just, you know, there's nothing showing up, there's no bacteria in the stool, you know, it is going to settle down hopefully. Obviously if it's still going on and not settling then you need to look in to it more but I think sometimes yeah that bit of a … as a convincer maybe" CLIN02

Almost half the clinicians interviewed indicated that a negative stool result provided them with a means to justify to the parent that a prescription was not necessary.

This is not the primary intended purpose of stool sample analysis. It is unclear how much these reasons for stool requests contribute to the overall stool request rate in the UK or Wales.

8.3.2 Treatment

The two most likely prescriptions clinicians discussed were paracetamol containing products and ORS.

Clinicians described prescribing paracetamol either for fever or pain. Only one clinician mentioned recommending paracetamol use for both symptoms, while the rest focussed on only fever or only pain. Ibuprofen was generally avoided and

parents were reportedly advised not to give their child this due to possible further gastrointestinal complications.

Many clinicians stated that they tended not to prescribe medication for acute GE. The main reason given was that there was nothing that could be prescribed that was of proven effectiveness to relieve the symptoms.

"But I don't think medication is actually making any difference if you know what I mean, because the natural cause of the illness, diarrhoea and vomiting will, will settle down eventually if you know what I mean. You know, it, it probably wouldn't shorten the illness, but it might just alleviate the symptoms, the suffering if you know what I mean…and parent anxiety. So that's one thing, that's one of the management of diarrhoea, vomiting in terms of vomiting, we tend not to give anything to children. It sounds very cruel doesn't it?"CLIN12

With regards ORS, there were varied beliefs as to *why* they might prescribe this and *when* they would prescribe them.

Clinicians reported many reasons why they would not generally prescribe ORS. Many believed that water, squash, flat cola/lemonade were just as effective (see section 8.5.1). Another belief mentioned by most clinicians was that children disliked the taste of ORS and thus it would not be used and the prescription would be wasted. A few indicated they believed that it would give parents the wrong message of needing to consult their GP and receive a prescription for every episode of GE.

"I don't often prescribe, I have given Dioralyte, erm … I tend not to do it that much partly because I know what it tastes like, it's revolting [but] sometimes patients will say 'can I have Dioralyte doctor?' and I will say have you tasted it… but if that is what they feel more comfortable… if they feel safer doing it that way and the child will take it well fair enough. But, because it tastes so dreadful I don't want to prescribe it willy nilly because I think it will get thrown out probably." CLIN07

"And you think, 'Well you know, they probably don't need Dioralyte really', they could manage fine on water or squash or whatever other fluid you were going to give them will probably do exactly the same job and so I guess I worry a bit about giving the wrong message out when you're treating diarrhoea and vomiting and not wanting to give out the message that this is something you need to come to the doctor's for every time your child has, you know, loose stool for a couple of days" CLIN02

A few clinicians discussed advising parents to purchase these medications (Dioralyte and/or paracetamol) themselves as part of a strategy to educate parents to self-manage childhood GE.

Most clinicians did not consider prescription ORS necessary for most self-limiting GE episodes and mentioned that they would only recommend or prescribe it if symptoms worsened.

"if they'd got actually diarrhoea and vomiting and couldn't hold anything down, then I might suggest to buy … to mum that she buys some electrolyte replacement fluids. I tend not to prescribe them to be honest, tend to advise them to buy them. Erm, and that they can sip those erm, to keep them going. But really it depends on the duration of symptoms, and it's unusual for a child not to be getting better and not to be able to take some fluids or food, in which case I don't think they're that necessary then." CLIN03

Other medications were occasionally mentioned if only to dismiss them: clinicians indicated that they did not support the use of antidiarrhoeals or anti-emetics for paediatric GE.

Antibiotics were only discussed in reference to a positive stool samples indicating a potential bacterial pathogen in the fact of on-going symptoms. When stool culture results did indicate a potential bacterial pathogen, the culture results would guide their choice of antibiotic.

8.3.3 Referral to hospital

Clinicians were in general agreement about the signs or symptoms that indicate a more serious case of GE and the point at which hospitalisation is required. Symptoms such as lethargy, blood in the stool, severe pain or excessive vomiting were all considered to alert the clinician that referral might be necessary. Assessment of hydration was the main focus of clinical examination, and clinicians indicated that a finding of moderate to severe dehydration indicated possible admission.

Other more subjective signs that clinicians indicated would lead to increased concern or reason for referral were an *"unwell child"* (some clinicians referred to NICE guidance on the unwell child). However, others indicated that this was based on their own judgement on how unwell they perceived the child to be. Phrases such as *"gut feeling", "eyeballing the patient"* and *"getting a feeling"* all indicated

that observations and decisions are based on their own experiences and knowledge and an overall assessment of how ill the child appeared to be.

Many clinicians indicated that it was unusual to refer patients for GE. However, a few indicated that they had a much lower threshold for referral with young babies.

Clinicians mentioned that they were less concerned about the child's illness if it was likely to be viral, caught from school, if the child was active and eating/drinking normally, and if the illness was following the *"typical course"*. The description of a typical course, however, varied between clinicians.

A few clinicians indicated that they were generally more concerned if the likely cause was bacterial GE or specifically food poisoning.

> *"Pointers that would suggest it wasn't a viral illness, like if they'd been having raw eggs the night before or had had a contamination with someone who'd had salmonella or a nasty e coli bug."* CLIN01

8.4 Influences on management

We have already seen that clinicians report that parent and/or patient wishes and expectations can impact on their stool requesting behaviours. The following section explores this in more detail to understand how clinicians manage these requests and expectations, as well as exploring other factors that influence their management.

8.4.1 Difficulties and influences on management decisions

Parent anxiety or the perception that the parent is not coping well can influence management decisions, as well as other factors at the GP practice. This section explores how clinicians manage parent anxiety, provide appropriate reassurance and offer other advice suitable to the parent request.

Identifying anxiety and providing appropriate reassurance

Most clinicians discussed how parental anxiety could affect their clinical decisions, and that identifying and addressing parent's main concerns is an important part of the consultation. Clinicians discussed how addressing parental concerns early on in the consultation provides insight into what is going to emerge and to give direction on how best to proceed.

"If the parental concern is high, then you have to recognise that as a red flag symptom on its own, as 'okay, you should take people's concerns seriously'. Obviously that depends and there's a spectrum of different sorts of parents, and obviously may depend on how well you know them and what you can assess as to their understanding of things…As to, you know, what they're saying. … But obviously if the parents have come multiple times very worried, then often it's 'what are they pushing for?' Whereas I guess if they've come multiple times just to be sure, and they're content every time with your explanation and you're very content with your findings, it may not be automatic that you would refer them in that case" CLIN02.*

The variety of parents presenting and their level of concern were reported to influence clinicians' decision making. As the quote above demonstrates, two parents may present with a similarly ill child, but one parent may be more anxious than the other. Therefore the amount of reassurance required will vary according to the parents' anxiety level and their ability to cope. Clinicians in this study discussed how important reassurance is during consultations for acute GE and most clinicians reported that reassurance is the perceived main outcome they aim to achieve from a consultation for this condition.

Clinicians considered that the main issue that concerns most parents of children with acute GE is the child's hydration. This concern can be addressed with a thorough physical examination and information about how to recognise symptoms of dehydration and monitoring urine output.

"I think it's quite simple a concept for people to grasp that okay, if they're getting enough fluid in enough fluid will be coming out. And so you can be reassured that, you know, that's the case because that tends to be one of people's big concerns" CLIN08

Although this clinician indicates that monitoring a child for signs of dehydration is a concept that is "simple to grasp", they do not indicate whether parents also find it simple. This is their perception of the task. Clinicians did not discuss how else they would recommend a parent to recognise symptoms of dehydration (i.e. capillary refill).

Clinicians also perceived that parents consulted to obtain reassurance regarding weight loss, or out of concern that their child is not eating.

"Because with small children, if they don't eat or drink for twenty four, forty eight hours, they start to lose weight so parents are obviously very worried and anxious about these things so the beauty of general practice is that we can always bring them back. You know, 'if you're

worried about them, and you're just not quite so happy, you know, you can contact us at any time or bring them again tomorrow and we'll just have a look at them' " CLIN12

Safety netting and education on self-management was discussed as a common goal of consultations, especially when the symptoms were mild and perceived to be self-limiting.

"I think it's important to be able to explain to the parents and child carefully regarding management advice. And I think that that generally allows them to self-manage the symptoms without having to return and without the risk of developing further problems. But I think it's also important just to, just to make sure you do give worsening advice, if the child worsens then signs to look out for really. I think that's the main thing is making sure that the parents know as and when they should return or call for further advice or bring the child back." CLIN04

"I think you do address their views, you have to finish your history and your examination and kind of come to your own opinion and then talk to them…they're sort of saying 'is this just totally normal?' and the answer is 'well yes, even if it's a viral thing, you know, it's part of growing up and it won't last very long' so the reassurance becomes more important than the actual diagnosis there. CLIN01

Clinicians perceived that parents with babies or parents who had limited experience of managing GE required reassurance that *"it is nothing more serious than GE"*.

"Because looking after a child with sickness and diarrhoea is pretty horrible isn't it? And so they want, you know, the reassurance that, you know, it is going to self-limit, they're going to get better and they like the fact that a doctor has checked the child over and said that everything is, you know, is okay, so I think there's a big, you know, expectation, not necessarily always for treatment but just, 'As long as you've checked him and he's okay and he's not dehydrated because that's what I was worried about then'. You know, 'I'm happy to, you know, to manage things at home'" CLIN06

Most clinicians indicated that other than providing reassurance and simple advice, no additional management was necessary for mild, self-limiting GE. There were some instances where clinicians faced difficult requests from parents and these will now be explored to identify how these difficulties were resolved.

Managing requests and expectations

Excellence in communication with parents was considered crucial when addressing difficult requests. The most common difficult consultations were those in which

parents were expecting a *"magic pill"* to stop the illness or when they were expecting the same management that was given during a previous episode and the clinician now wished to advise a different approach.

Many of the participating clinicians referred to parents' expectations for *"magic pill"* or a *"quick fix"* to stop the symptoms.

"some parents can be a bit demanding and wanting a solution or like an answer for the child to get better and that can sometimes be difficult just to explain the sort of you know the way the disease works and what is going to happen really but that can be quite difficult… you know some parents say 'well you are meant to be a doctor make my child better' so that can be difficult" CLIN11

"some of the mums, you know, they are fed up from the on-going diarrhoea and they're feeling they have to change nappies all the time and they are expecting that I'm going to do something and it will disappear. Maybe just putting my hand on the child and I can just tell them it's going to you know it will go completely, it will go away tonight... I can still remember a mum who was literally breaking out and she was expecting me to give her something to just stop it, and I was like 'no I don't have any magic medication it's a self-limiting condition it will take time to go' " CLIN15

Such pressure from parents represented challenges for clinicians and when this occurred, extra time was required to communicate that there was in fact no rapidly effective treatment and to describe the expected natural history of the illness. As well as talking this through with the parents, some clinicians found it useful to refer parents to websites or provide them with information leaflets to re-enforce and justify their decision.

"I'll often actually refer to a website so that they can see it in black and white. I think the written word is very supportive and powerful, they can see if from a recognised site that we're using and it's saying the same that I'm saying then they're a lot happier. And I like to give them, often if I don't give a prescription I will give a patient information leaflet. Which usually says on it that antibiotics are not needed and I find that very useful. I use patient information leaflets a lot. Sometimes patients forget what you've told them in the consultation. And it's useful for them to have that to read at home." CLIN03

8.5   Home Management

8.5.1   Fluids

All clinicians indicated that they would provide advice about fluid intake to maintain adequate hydration.

"just little sips, kind of regularly, rather than a big lot of it in one go to have ammunition (you have the need) to throw back up again ((laughs)) so just trickling it in and advise them to if they've got straws in the house to use that, it enables you to just have the little sips" CLIN01

Although their reported approach to advice about volume and frequency of fluid intake was consistent across all clinicians, the type of fluids they recommended varied considerably. Some clinicians advised *"anything that the child will drink"* or flat (fizzy), sugary drinks. Others, however, advised avoidance of sugary drinks, and avoidance or dilution of milky drinks, recommending that the child drink water only.

Those clinicians who did not believe that prescribing ORS was necessary were also those who indicated that advising sugary drinks were an appropriate method of maintaining fluid intake.

"I have suggested flat Coke because that is what is used in the tropics and you know I usually explain to people it is more passable than Dioralyte and for a child who is recovering from gastroenteritis it's not a bad … you know it's got plenty sugar, plenty of salt, and erm … I always explain to the patients that I don't recommend it at any other time, but it [is] quite good recovering from D and V." CLIN07

Reasons for recommending water / clear fluids included the belief that these would be less irritating to the child's stomach or the belief that sugary drinks were inappropriate.   Some clinicians referred to the guidelines to justify these approaches.

"as far as I know, and I've sort of read this on, on the NHS Prodigy or CKS guidelines, is that nowadays we tell people that they can eat and drink what they feel able to tolerate. The days of saying avoid this, that and the other seem to have gone and I follow the current advice from that information source to tell them to take what they fancy. We no longer advise the still Coca Cola or whatever, current advice is that that's not appropriate." CLIN03

Advice about intake of dairy products

There were mixed views on giving advice about the inclusion / exclusion of dairy (specifically milk) in the diet during and following an acute episode of GE. Some discussed how they would continue to advise the parent to give their child dairy / milk products when the child had GE. Their rationale was that if that was all the child would drink, then it is not advisable to remove the only form of nutrition and fluid intake.

"people ask about milk and I generally sort of say, 'Well, you know, clear fluids are probably less irritant maybe but if all they will take is milk then fine, it's better for them to have milk and to have the fluid than not to have any fluid in, you know, at all." CLIN02

"I think if a child, if a baby is being breastfed I encourage the mum to carry on breastfeeding. Um, I certainly … when, um, babies come in I don't say to stop the milk because I think it's important, um, for the, um, baby to continue that, um, and even with older children I never say avoid dairy." CLIN09

Other clinicians believed that dairy intake following an acute episode could cause prolonged diarrhoea due to transient lactose intolerance. Many provided examples or spoke from experience of seeing this transient effect on children as reasons to recommend that parents avoid giving their child dairy products. The dilution of dairy (such as milk) as well as complete exclusion was often strongly encouraged for younger children.

"usually for the bottle fed infants I'll say for the next twenty four to forty eight hours give dilute milk or no milk just other fluids, and re-grade. [I: and your reasons behind the dilution?] It's less unsettling for the stomach, the simple clear fluids are more easily absorbable, less likely to make them vomit …and they could get a temporary milk intolerance, so obviously giving milk isn't a good thing. So I might say exclude it for the next twelve hours and then just give dilute milk over the next twenty four hours re-grading up, but that tends to be just for the under twos really that I do, for the older children I'd say stick to a bland diet." CLIN17

Despite clinicians emphasising the importance of good hydration, the consistency appears to end there: advice on specific fluids varied considerably among clinicians. More worryingly, the advice reportedly given does not always adhere to current recommendations, especially with regards dairy products. Clinicians were more

influenced by having seen patients with transient lactose intolerance following an acute GE than by opposing information in guidelines.

Probiotics

The use of probiotics during and following an acute GE episode was only discussed with clinicians when I asked specifically if they recommended its use. Most clinicians reported that they did not consider recommending probiotics and only a few discussed their reasons for this.

> *"As far as I understand, there's some evidence that they'll work long term but I'm not sure that they're going to do anything short term… and I'm not aware of any guidelines, evidence that says we should be advising their use. But I tell parents that there's actually no harm in giving them. No, certainly there is no harm. I can't guarantee there's any good either"*
>
> *CLIN03*

The lack of information on the use of probiotics in guidelines/recommendations impacted on the clinicians' decision to not specifically recommend them. Although the NICE guidance does not recommend their use following an acute GE episode, a recent Cochrane review suggests the effectiveness of probiotics to manage this condition.

8.5.2 Dietary recommendations

The majority of clinicians stated they would recommend parents give their child a bland diet during and following an acute episode and listed food types such as toast, crackers, mashed potato as examples. Along with these food types, clinicians indicated they also recommend small regular portions throughout the day. Some clinicians also specified that the parents should be guided by their child with regard to food intake and that children generally will indicate how big their appetite is and what they fancy eating.

Experience was the main justification for recommending giving children with GE bland food types. However, not many discussed the biomedical rationale for suggesting such food types.

> *"if [parents] ask 'what shall I give them?' I usually say 'well the child will tell you when he is hungry, you know a toddler can do that very clearly, and to start off with plain things, bread, a bit of pasta something like that and not to go for anything that's rich, or fried or avoid fruit and vegetables for a day or so, that type of thing'. So it's just very plain food really, dry*

biscuits that sort of thing. [Interviewer: And in terms of that advice then…what do you base
that on?] Erm … I suppose it's my own experience really" CLIN07

As well as recommending certain foods, clinicians also provided lists of foods that should be avoided during and following an acute GE episode. Spicy foods such as curry, fatty and/or greasy food, fruit and vegetables and large pieces of meat were all mentioned by many clinicians - these food types were felt to be too rich or heavy for a recovering gastrointestinal system and the child would not be able to tolerate them.

"I do tell them to be a little bit sensible and not to dive in to a, a curry straight off, that it really
would not go down well. And that they need just to … as if they'd sprained a muscle, not to
overdo it, they've got to think that their tummy doesn't need any straining so be kind with
what you put in it." CLIN03

Many clinicians used the terms "common-sense" and "sensible" when discussing what advice they would offer parents regarding diet. A few clinicians indicated that they would not offer advice regarding diet or would suggest a normal diet. This latter advice is comparable with current guidelines that recommend an age appropriate normal diet.

The varied beliefs of nutritional intake during and following an acute episode of GE effects the recommendations given to parents and thus likely to cause misunderstandings of what is and appropriate diet for a child with acute GE.

All of the above clinical management and recommendations have impacts on parents education on how to manage GE at home.

8.6   Guidelines

Four clinicians referred to the CG160 NICE guidance on feverish illness in children and the traffic light system for identifying risk of serious illness.

"I suppose the only guideline I'd be thinking that I'd follow that applies is the NICE Fever in
Children guideline which is more to do with how you assess a sick child in general in terms
of, you know, the observations you take and what are warning sort of signs. So I guess
that's the sort of approach I tend to use for examining children in general anyway, and so

that applies to, you know, children with D&V as well. But I don't think I follow … I'm not aware of any guidelines I am following that are related specifically." CLIN02

"I do know that the HPA guidelines are available, um, and I've occasionally looked into them. There are the NICE guidelines, the traffic light system for assessing an unwell child, so sometimes I'd go into them, but rarely" CLIN09

Three clinicians indicated that they did not know of any guidelines specifically for diarrhoea and vomiting or on when to send stool samples.

The BNF was referred to when making decisions about antibiotic choices following return of positive stool culture result.

Four clinicians claimed that they did not use or consider any guidelines as they rely on their own knowledge and experience as their guidance.

"Guidelines? I've been a GP for thirty years, I'm afraid all the guidelines are in my head" CLIN18

This almost implies that this clinician has not read any guidelines about paediatric GE for 30 years.

8.7   Summary of Findings

Clinicians reported variation in their accounts of typical management of children with acute GE, especially with regards stool requests. Much of the reported clinical management does not adhere to current guidance on when to request a stool.

The variation in practice is likely to have an impact parent expectations for subsequent consultations and thus impact on colleagues who follow different approaches. Educating parents is an important aspect of managing this illness. This focussed on advice about home care as well as what management to expect from a consultation regarding GE. Very little active management is required for mild GE, and so parents need to understand that nothing more than supportive therapy is generally required.

The impact of parent expectations on clinical management can be considerable. Clinicians report sometimes requesting stool samples or prescribe ORS simply to prove to the parent that they are "doing something" rather than providing medically useful information or improving symptom resolution.

A qualitative study with GPs in Norway found similar alterations in management in order to satisfy patients especially regarding sending tests and referrals (Carlsen and Norheim 2005). These GPs indicated that not all tests and referrals are medically necessary but that this is not the only reason to do them. Patient anxiety was considered a key motivator for referrals, in order for GPs to reduce patient worry and ensure the patient is satisfied in their experience of healthcare provisions. Their belief in patient centred medicine suggested that saying *no* to a patient would be *"in conflict with other important objectives [of a] GP"* because patient satisfaction is more important (Carlsen and Norheim 2005).

A prospective study of patients presenting to GP (any health condition) explored the differences between patient expectations, clinician perceived expectation and the effect it had on the outcome of the consultation (Little et al. 2004). Clinicians reported that there was no or only slight medical need for 46% of the investigations carried out/ordered, for 19% of the prescriptions, and for 22% of patients referred. Perceived patient pressure was an independent predictor of clinician behaviour and a stronger predictor than the actual patients' preference. It is not clear how many of the patient outcomes were in fact necessary or appropriate however, it does indicate that clinicians need to elicit expectations in order to reduce *unnecessary* use of resources (Little et al. 2004).

Unnecessary stool sample requests, prescriptions and referrals are likely to impact negatively on the burden on NHS resources.

Clinicians do not provide consistent advice regarding nutritional management and very often recommendations are not congruent with current published clinical guidelines. It is not clear what effect this has on parents' confidence in home management or what effect conflicting nutritional advice has on children's recovery.

No clinicians referred to the CG84 NICE guidance and many indicated that they did not consider recommendations from published guidelines when managing acute GE. This could be because clinicians are generally experienced and confident in managing this illness. However, not reading or referring to these guidelines may result in guideline incongruent management.

8.8 Chapter Summary

Clinicians' reported clinical management varies considerably. This may be influenced by parental expectations. In additional, clinical guidelines many not be followed consistently. Awareness of guidelines is inconsistent. As management advice has changed over the years, those clinicians who have not updated their knowledge continue to manage GE as per their training days. The management approaches of newly qualified clinicians may differ with the approach of those who qualified many years ago.

Management that is not congruent with current clinical guidelines may impact on the use of scarce resources: inappropriate use of investigations and treatment costs has important implications for NHS resources.

We will now draw together all that has been found from this study as well as the three other studies in this programme, of research into acute childhood GE to identify where the major burdens of illness are and to identify possible targets for improvement in management and in the use of scarce health care resources.

Novel findings – This study has highlighted that primary care clinicians are not aware and therefore are not following current guidelines for the management of GE. Inappropriate management has been identified with regards stool sample requests and this is partly due to a perceived expectation that parents require this outcome. Management is variable within practices therefore there is a risk that parents are receiving mixed messages when consulting about their childs GE illness.

CHAPTER NINE: DISCUSSION

9.1 Introduction

This chapter integrates the main themes and critically appraises two quantitative and two qualitative studies that formed this project. It summarises the findings from the project and then considers the potential bias and limitations affecting each of the studies. Findings are considered in relation to existing research and then the implications of this work for practice and future research are considered.

9.2 Summary of Main Findings

To our knowledge, this project is the first (in the UK) to describe both the parents' and primary care clinicians' perspectives on management of paediatric GE. It is also the first to utilise routinely collected data from patient primary care clinical records to describe the current management and burden of paediatric GE in the UK. Combining both quantitative and qualitative methods has enabled us to explore in depth management decisions around paediatric GE and the associated impacts of the illness on children, their families and the health service.

The principal findings from this project are:

♦ There is considerable variation in both clinical and home management of paediatric GE [Chapter 3]. Reported clinical decisions were often not in line with current guidance from expert bodies such as CG84 NICE guidance [Chapter 8].

♦ Many clinicians were not aware of guidelines on the management of paediatric GE from expert bodies, and this might account for some of the variability in their management [Chapter 8].

♦ GE represents a major burden on both primary care and secondary health care resources - higher than previously reported [Chapter 4].

♦ Hospital referrals and stool sample requests have slowly but steadily increased over the last ten years without evidence of a change in the epidemiology of GE. For example, there is no evidence that GE has become more severe over time [Chapter 4].

- Patients aged one to three years account for the greatest proportion of primary care resource use in GE [Chapter 4].

- Parent reported expectations and clinician perceived expectations of consultations were variable and not congruent from each other especially regarding stool sample requests [Chapters 6, 7 & 8].

- Parents' attitudes toward GE impacted on their actions around prevention of illness and transmission. The variety of beliefs around causes of and threats from GE also influenced their actions [Chapter 6].

- Parent's reasons to consult health care varied, and were largely dependent on the parent's confidence in their own management as well as perceived threat of illness [Chapter 6 & 7].

- The burden of illness on the family is considerable, especially in terms of parental time off work and missed school time for children [Chapter 7].

9.3   Limitations of the project and potential sources of error

We applied a mix of methods to answer the research question in order to address limitations inherent to each method and explore questions that each method individually could not answer. This section focuses on the potential error and limitations of each method employed and describes, where appropriate, how we reduced these risks.

9.3.1   Prospective Case Series [Chapter 3]

Study population

Selection bias in the study population could have occurred at the GP Practice recruitment stage (external validity) as well as the patient recruitment stage (internal validity) [Figure 42].
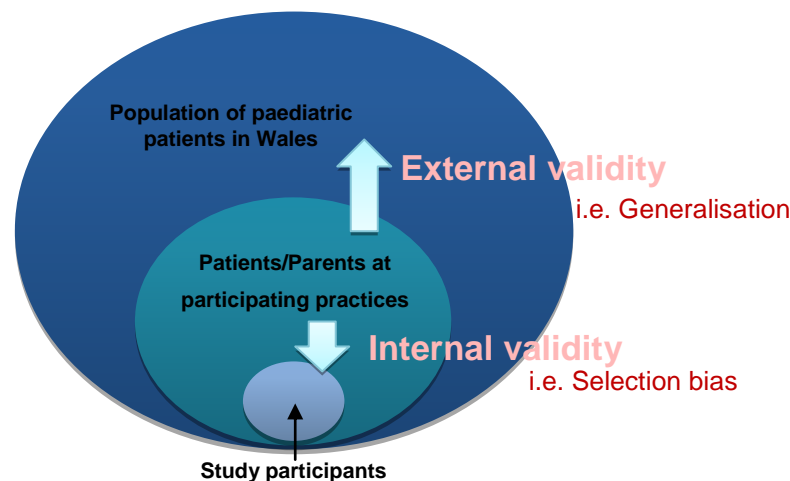
Figure 42. How external and internal validity are represented for study 1 - prospective case series

External validity

Do these results reflect all patients presenting to all GP Practices in Wales?

Bias can occur if participating practices are systematically different from non-participating practices and therefore are not generalizable to the rest of the population of practices.

In an attempt to avoid this we did not implement practice level exclusion criteria. All but one health board in Wales was represented by the recruited practices and practices included a broad range of patient list sizes.

There were however, some potential systematic differences between those practices who agreed to participate and those who did not. GP practices that were familiar with conducting research (and/or with Cardiff University) or were part of a research network were probably more likely to agree to participate. In addition, practices or partners with an interest in managing paediatric GE or self-limiting conditions may have been more likely to agree to participate. These biases may have introduced an overestimated familiarity with management guidance.

The use of the Trial Torrent software impacted on the decision to participate. For some practices, this had a negative effect and for others, a positive effect. Depending on the IT system the practice used, the delays on study set-up varied. Practices that experienced delays in set-up were more likely to withdraw their participation. This also resulted in practices being excluded from using Trial Torrent based on their IT system, which for some, resulted in declining participation or withdrawing from the study.

The time that it took to receive health board approvals is also likely to have impacted on the practices that took part. Some practices started two months after the others for this reason. Help from NISCHR CRC was also initially limited to one health board (Betsi Cadwaladr) resulting in a bias towards those practices that were available to contact.

There are inherent differences between the health boards in Wales. Betsi Cadwaladr (North Wales) is geographically the largest health board in Wales covering 6,000km^2 (Cardiff and Vale covers only 500km^2), it contains more rural than urban patients and averages a lower deprivation score than the southern health boards (Observatory 2009).

Despite intending to make all practices in Wales eligible, the problems and delays we had impacted upon the selection and recruitment of practices so that the final sample was possibly systematically different from all practices in Wales (i.e. more patients from rural areas). Therefore, we recognise that these may have had an impact on reducing the external validity.

Internal validity

Is there selection bias in the population of participants?

Although all clinicians within a practice were invited to participate, not all clinicians did. Therefore, eligible patients may have not have been invited to participate if they had consulted a non-participating clinician. Individual clinicians tend to gather a certain clientele, with children often being seen preferentially by certain clinics in a practice.

Participating clinicians were asked to record ALL eligible patients in the patient log. The intention was to use this information as a baseline for all eligible patients and identify anonymised demographic differences between those who participated and those who were not approached or declined participation. Without searching through the patient records is it unclear how many patients were not recorded in the patient log - who were eligible to be invited to participate. We therefore don't know with certainty to what extent there were any systematic differences between those who agreed to participate, those who were eligible but declined and those who were eligible but not approached.

There were no important differences between those patients who were recruited by practices using Trial Torrent and those who used the paper version of the study

materials (with regard baseline demographics) [Chapter three]. For those practices that were set up but did not recruit any patients, there were no important differences from those practices that did and did not recruit.

Parents who completed and returned the questionnaire & symptom diary represented only 26% of the invited participants. As we only collected demographic data on the child on the patient log, it is unclear if there were demographical differences between those who fully participated in the study and those who were recruited but did not fully participate. There were no important differences in patient symptoms or demographics.

There was therefore a risk of selection bias in that there were systematic differences between patients whose parents who returned the completed study forms and those that did not. However, the extent of the risk of bias arising from this is unclear.

Hawthorne effect

Did the awareness of being observed affect the clinicians/participants behaviour?

In order to reduce the risk of clinicians altering their management of paediatric patients with GE, only management choices that would be considered usual practice were included in the patient log. Use of primary care clinicians' knowledge and experience within the supervisory team was beneficial in developing a standardised tick box format for the patient log. It was decided that recommending probiotics was not usual practice for paediatric patients with GE, and so probiotic treatment was not included in the patient log. The symptoms that clinicians were asked to record were also considered part of the typical history taking for a patient presenting with GE.

The options in the symptom diary were as broad and inclusive as possible. This was to reduce the risk of parents reporting false information if they perceived one option more appropriate (or socially accepting) than another.

Clinicians and parents were asked to record their current management and the aims of the study were explained. We hoped that this would minimise altering the management by virtue of study participation, as we were not testing a hypothesis or attempting to change their management in any way. Because our aim was primarily descriptive, we also provided as many open-ended question boxes for parents to add in any further information and these comments did not indicate that we

excluded any options they wished to indicate. It is therefore unlikely that there was a risk of bias from this source.

Subjectivity

Did the participant's personal perspective / beliefs / experiences affect how they interpreted and responded to the questions?

There was subjectivity with regards to the symptom diary, where parents were asked to provide the severity of symptoms on a scale of 0 to 4 without giving an indication of what this meant. Every participant's experience of illness is different, as they use different baselines and comparisons to inform their judgement. From the qualitative study we recognised that parents compared their child's current illness with other illnesses their child had had in the past, whereas some parents used their own experience of GE to inform their judgement. Parents who had in the past taken their child to hospital for GE, used those symptoms as a baseline for interpreting the severity of further episodes.

In addition, by asking parents to record symptom severity prospectively, if their perception of symptom severity was high on Day 2 and they indicated a "4" on the severity scale and then the severity of the illness increased further, there would be no opportunity for them to indicate this using a 0-4 scale. This is called the, 'ceiling effect'. This problem in subjectivity affects the ability to use this data to answer some of the original questions, for example comparing *actual* (quantifiable) symptom severity across patients (as opposed to *perceived* severity).

In the future, it would be important to collect both symptom severity more objectively (by asking for specific stool frequency / recording of precise temperature) as well as subjective symptom severity as it is likely that both of these objective and subjective severities would influence a parent's decision to seek help or alter management.

9.3.2 Retrospective Observational Study [Chapter 4]

The data extracted from CPRD do not have these inherent biases that were present in the prospective data collection method. The CPRD patient data represents all possible patients at those practices reporting their data to CPRD, patients were not "recruited" into the study (therefore internal validity is not effected) and there is no Hawthorne effect. The practices are representative of the UK population therefore

results are likely to be more generalisable to the UK population (Wood and Martinez 2004).

There are limitations of using this patient data from CPRD such as the selection of Read Codes - which has been noted in Chapter 4. This section will consider other inherent limitations of using this data.

Ascertainment Bias

Are all patients represented in the sample?

Firstly, and most importantly, as this data was not collected for research purposes, it is not clear how complete and accurate it is - especially data from 5 to 10 years ago. In more recent years, practices knowingly participating in reporting these data are likely to have altered their practice by coding more accurately and more completely. This is, however, likely to have been a gradual process and it is therefore difficult to interpret some changes in trends (if it is likely to have been affected by clinicians altering how they report consultations).

Confounding variables

Are there any extraneous variables that could statistically interfere with the data?

Although confounders are likely to be present, age is likely to be the biggest risk factor in consultation outcome and this was adjusted for. As we have not chosen the variables recorded in the patient records, it is likely that some important information (to researchers) may not have been recorded by practices. There may have been information in the patient notes which was not available via data extraction that could have impacted on what the consultation outcome would be (e.g. physical examination indicated signs of dehydration). We also were unable to collect information on symptom duration prior (or subsequent) to consultations therefore this could also impact on management decisions and consultation outcome. For example information such as parent age or number of siblings could be confounders and thus impact on the data.

9.3.3 Qualitative Interviews [Chapter 5 to 8]

Credibility

How consistent are the findings with reality?

Ensuring credibility is an important factor in establishing trustworthiness of qualitative research (Lincoln 1985). There are multiple aspects to ensuring trustworthiness, which will be considered here in relation to the two qualitative studies in this project.

Previous studies exploring management and beliefs of common infections have used semi-structured interviewing (Leydon et al. 2010, Walsh et al. 2007). As a research team, we decided that this method would be most appropriate to capture beliefs and explore these in-depth. The use of telephone interviews was considered the most feasible means to interview participants as the risk of recall bias was important in this work as well as wide geographical access. Allowing parents and clinicians to pick the most suitable time for a phone-interview increased the uptake and reduced the risk of interruptions. The disadvantage of non-face-to-face contact is that body language cannot be used as an additional source of information (Opdenakker 2006). However, other social cues such as voice and intonation were available.

Ahead of all interviews, participants were asked to inform the researcher if they were uncomfortable with any of the questions. They were also informed that there was *"no right answer"* to any of the questions, and that the purpose was to better understand what they felt about the topic at hand. This helped build up trust and establish a rapport with the participant. It is important for participants in qualitative research to *want* to provide information and increases the honesty of the individual (Shenton 2004).

There were three subgroups of participants in the parent interviews: Those who were identified by a clinician and invited to take part; those who responded to social media advertisements and actively agreed to take part; and those recommended by a friend or colleague to take part. There were no important differences between the groups in participant characteristics. However, it is likely that their beliefs and attitudes toward research participation and/or managing GE impacted on their decision to participate. Those with strong views in either direction may have been more predisposed to agree to take part. We have no way of knowing whether or not

their views were typical of the group that were not invited to take part or who were invited but declined participation. Users of Mumsnet are often actively involved in commercial and academic research and may actively look for opportunities of interest to them. Financial incentives may therefore have resulted in systematic differences between those who agreed and those who did not agree to take part. Mumsnet users also have access to computers, the Internet and are likely to be computer literate, and those who do not use computers and Internet would have been under represented. Mumsnet respondents may therefore not be representative. Those participants who were recruited via snowballing are likely to reflect similar characteristics to those individuals who invited them to take part, which again may not reflect the wider population (Biernacki and Waldorf 1981).

In an attempt to explore the clinical management of GE in primary care we focussed on the perspective of both clinicians and parents to allow triangulation of some of the data. The use of triangulation can compensate for the individual limitations of each method (Brewer and Hunter 1989) or perspective and increase confidence that the results reflect reality. In addition, triangulating information from the prospective and retrospective studies allows us to support our interview findings with a numerical backdrop.

I maintained a reflective diary throughout the qualitative data collection so that I could record my initial impressions of the interviews, thoughts throughout the data collection phase including emerging themes and points of advice to myself for subsequent interviews. I found this a helpful exercise as it helped to define the point of saturation and define themes, sub-themes and merging of themes. It also allowed me to be acutely aware of my own perspectives and any possible pre-conceptions I might have had about the topic.

Throughout the data collection period for both qualitative studies, I discussed the findings with my supervisory team and other qualitative experts in an iterative, on-going format. This allowed possible bias and preferences (inferred by myself) to be identified based on their experiences and perceptions of emerging data and themes.   Regarding improving data collection, we discussed the best way to probe for further information from participants as well as decreasing the use of closed questions to participants. In addition to these discussions, I presented my work in a number of settings to allow scrutiny and feedback from colleagues, peers and other academics. This gave a fresh perspective on the methods and emerging data that helped me refine methods and themes.

The credibility of the findings from the two qualitative studies has therefore been considered throughout the design, conduct and analysis and we are confident that the findings are consistent with the participants' perspective of their reality. An additional way to consider credibility could have been to go back to the participants with a summary of the findings to ensure this was consistent with what they meant to say. We did not do this due to the resource implications this would have incurred such as time and money.

Transferability

To what extent can the findings of these studies be applied to other situations?

The question of "How transferable are the findings?" in qualitative research is the equivalent concept to "external validity" in quantitative research (Shenton 2004). It is not the aim of qualitative research to generalise findings to the wider population. Instead, qualitative research aims to achieve an in depth understanding of the views of the participants and therefore external validity is not central to the research findings. The results of this qualitative research should be considered in the context of the study population, time of year, external influences at the time of data collection, and geographical areas.

Elements of the study can be transferable to other study populations, but it is the responsibility of the reader to decide on the extent of the applicability. With this in mind, I attempted to provide sufficient contextual information (such as participant recruitment, participant demographics and the six steps in thematic analysis) to convey the boundaries of this work to the reader.

Dependability

If the work was repeated, in the same context, with the same methods and the same participants, would similar results be obtained?

Dependability in qualitative research is the analogous concept to reliability in quantitative research. Dependability relates to the degree to which another researcher would generate the same findings. The concept is problematic because individuals' beliefs and knowledge change over time. Unfolding experience also results in changed attitudes and behaviour. Any discrepancies in findings would not then in themselves imply the research was unreliable. Repeatability or stability of

findings over time may not be the most appropriate measure of reliability (Marshall and Rossman 2010).

We did, however, validate the coding framework[8] to determine its inter-rater reliability on 15 percent of transcripts and found it to be reliable. This generated confidence that the framework represented the data. The detailed description of methods employed for both qualitative studies (Chapter 5) should be sufficient for the study to be repeated in the future, although findings will need to be interpreted in the context of changed milieu and circumstances.

Confirmability

Are the findings the result of the experiences and ideas of the participants rather than the characteristics and preferences of the researcher?

To ensure researcher bias was minimised and the results reflected the participants interviewed, I have attempted to express the data from participants in such a way that the raw data is presented alongside my interpretation. I have recognised, where appropriate, alternate theories and interpretations, without stating that this was what the participant *actually* thought. By maintaining a reflective diary and continual contact with the research helped minimise bias resulting from my own actions and perceptions.

9.4   Synthesis and the importance of findings

The four studies have separately identified and explored aspects of the management and impacts of paediatric GE in primary care. This section will now examine how beliefs, behaviour and illness burden interrelate in this project. This project has shown how a combination of many factors influence both variation in management and the risk of unnecessary burden on both the NHS and the patient/family/community. Figure 43 illustrates how the study findings interact and affect both resource use and the impact on patients, family and community.

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[8] Two qualitative researchers second coded the transcripts using the coding framework to determine reliability of the coding framework.

This model also helps identify where interventions might reduce management variation and reduce unnecessary burden from the illness.
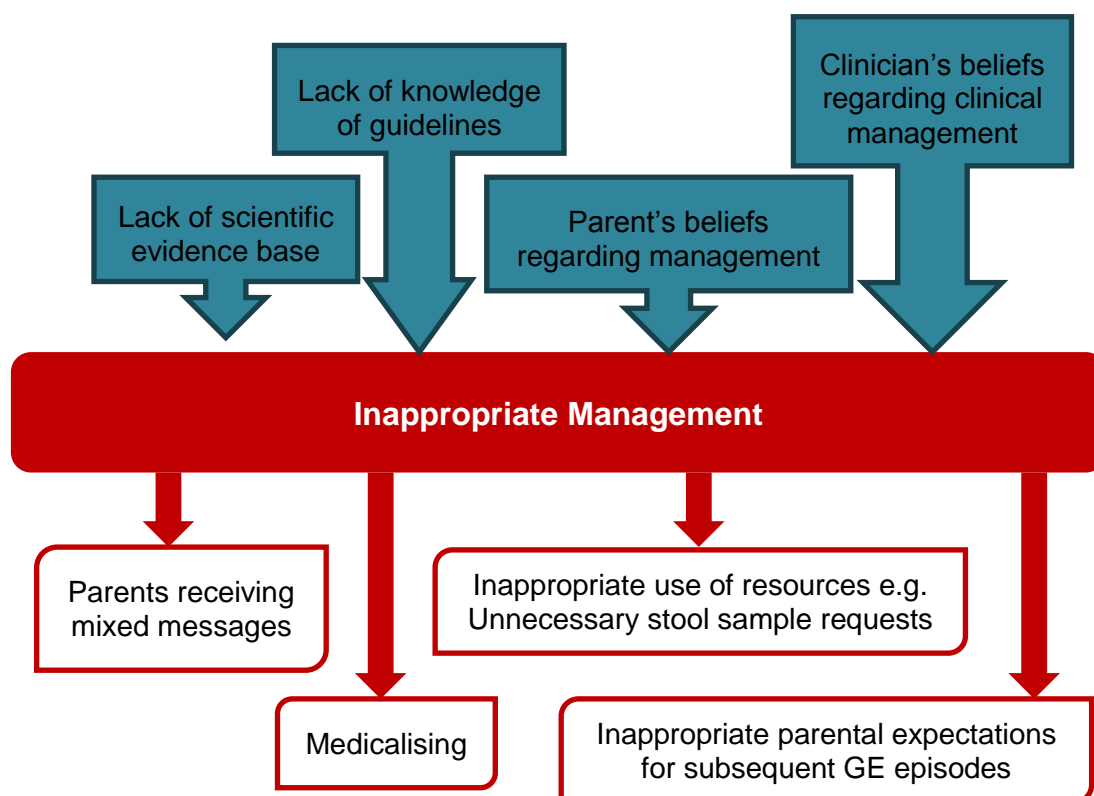
Figure 43 Flowchart of how inappropriate management is influenced and affects parent and clinician beliefs and management

9.4.1 Clinical management

From all four studies, a variety of clinical management decisions and patient outcomes have been observed. Variation in management was apparent for patients presenting with similar symptoms and symptom severity, as was variation in the advice given to parents during a consultation and variation in consultation outcome. Although it is unclear how much of the variation is inappropriate, it is unlikely that the wide variations in management observed in these studies is likely to be consistent with best practice.

What are the causes of inappropriate variation in clinical management?

The clinicians in this study did not perceive paediatric GE as being particularly challenging to manage, indeed they all indicated that they felt confident about managing a typical episode. Clinician's beliefs were influenced by their training,

their own knowledge and experience of the illness (as a clinician and on a personal level), and by what management aspects were "common-sense" to them. Over the years, the recommended management of GE has changed (NICE 2009). Therefore, depending on when clinicians were trained, their knowledge of appropriate management may differ. It has been reported previously that actions such as test ordering behaviour reflects a clinician's resident (registrar) training (Powell and Hampers 2003). Therefore, current test ordering behaviours might depend on when and where a clinician was trained.

In addition to training, years of GP experience (since qualifying) of managing typical versus complicated GE is likely to influence their management. This can also depend on the geographic area of the practice and patient demographic. "*Common-sense management*" is also going to call on their own experience of the illness and personal management as well as their perception of the lay individual. Making assumptions that certain aspects are common sense and therefore unnecessary to mention to a parent could be detrimental. Additional influences, such as being a parent themselves, could influence their clinical practice and perception of managing GE.

Clinicians were asked to discuss their reasons for their current management as well as discuss the use of guidelines or information to aid in their decisions. Most indicated that they were unaware of a suitable guideline or had no use of it. Their adherence to guidelines was not investigated in this project. However, we found a lack of agreement between their reported practice and the recommended evidence-based practice. This is reflected in the multiple combinations of patient outcomes seen in the retrospective observational study.

In an environment where guidelines or recommendations are being produced for a large number of health conditions each year, clinicians are likely to prioritise health condition management for either perceived importance or personal interest. The time required to stay up to date for *all* general practice health conditions is substantial and therefore guidelines for mild, self-limiting conditions are often going to be overlooked. In addition, it is unlikely that a clinician would seek out information for paediatric GE because, as this project has shown, clinicians generally perceive GE as a common, straightforward condition that does not require further guidance. This would explain why many clinicians participating in this project could not recollect any recent guidelines. A lack of awareness of specific

guidelines has been described by many clinicians as a barrier to changing practice behaviour in primary care (Cabana et al. 1999).

The NICE guidelines for paediatric GE were introduced in 2009 to reduce variation in practice for paediatric GE in the UK and reduce the burden on NHS resources (NICE 2009). The uptake of this particular NICE guidance across England and Wales is not well described. However, the findings from this project gave no indication that clinical management had changed since 2009.

Lack of uptake and lack of implementation of guidelines has been widely recognised as a major barrier to promoting improved care (Grol 2001, Mosca et al. 2005). Many barriers have been considered in understanding the uptake and adherence to practice guidelines (Cabana et al. 1999, Lugtenberg et al. 2009) which are relevant to this project. In understanding the barriers that clinicians face in changing management, we can better understand why behaviour does or does not reflect this. Factors such as clinicians' attitudes toward the need to change practice and/or the motivation to change have been identified as key influences on altering management (Rollnick et al. 2001). The health behaviour change model identifies "readiness to change" as a result of an individual's perception of the "importance to change" as well as their confidence in implementing the change. Many clinicians in our study indicated that they were confident in their current management and were largely unconcerned about their decisions. Therefore, they are unlikely to actively seek guidance or change their behaviour.

Clinically unwarranted variation in management is most commonly seen where evidence is lacking or is controversial (Landrigan et al. 2008). The evidence-base for many aspects of the management for paediatric GE is limited and not applicable to the UK population. Therefore, areas of particular controversy are reflected in management variation. An example of this is nutritional management and the inclusion/exclusion of dairy products. There is very little evidence regarding the effects of dairy products during and following an acute episode of GE derived from the UK paediatric population. Recent evidence suggests that the exclusion of dairy products from children's diet during an acute episode improves clinical outcomes in paediatric GE (MacGillivray et al. 2013). However, this is controversial, and is not recommended by the current NICE guidance. Clinicians in our study relied on their own experience for informing recommendations about the use / avoidance of dairy products. Their accounts included both examples of recommending inclusion and exclusion of dairy products. Some reported previously diagnosing a transient

lactose intolerance following an acute GE episode, and therefore they recommended avoiding dairy products. However, those who had not experienced this condition, advised parents to maintain dairy intake. The situation regarding probiotics is especially controversial, with a systematic review recommending their use in acute GE(Szajewska et al. 2007). However, these are generally dairy based interventions, and some have been taught that dairy products should be avoided because of lactose intolerance. Clinicians will use their own judgement and knowledge to aid their decision-making when the supporting evidence base is contradictory or absent.

Despite the variable patient outcomes reported in Chapter 4, the qualitative studies indicated that the main expected outcome by both parents and clinicians of a primary care consultation was reassurance, although some clinicians said that parental expectations impacted on their decision-making.

Parent beliefs impact on clinical variation

Interviews with parents revealed that parents expected little more than reassurance and advice on their own management during a primary care consultation. Clinicians, however, reported other perceived expectations from parents such as stool sample requests or prescriptions. It is not clear from the patient data how clinicians came to a decision, but it is possible that some of the consultation outcomes were influenced by parents and by efforts to maintain a trusting relationship with the family. It has been reported for other self-limiting conditions, such as a sore throat, that prescriptions can be used to prevent jeopardising the clinician–patient relationship (Butler et al. 1998).

Parent expectations are likely to stem from previous experiences of the use of healthcare, both for the same and other conditions. Patient (and therefore parents) previous experiences influence future decisions to consult, illness concerns and confidence in self-management. With regards to hospital admissions, previous satisfaction with illness management influences patient expectations and perceptions of illness and illness management for subsequent events (John 1992). Their expectations of illness management are that it will be of the same standard (or better) - *"whatever the form of expectations, they are based primarily on previous experiences…expectations are a function of satisfaction with previous experiences"* (John 1992). All health care experiences have an implicit influence on future health care encounters and if expectations are not met, the patient (and/or parent) may not

be satisfied. If a proposed change in management risks resulting in unmet patient expectations for care, then clinicians are less like to take up the proposed change.

9.4.2 Home management

All parents interviewed and those who completed the symptom diary in Phase One all managed their child's GE slightly differently from each other. Many parents indicated that their management decisions were based on what they, as a child, were given as well as advice from GPs, health websites and friends.

Considerable variation was found in the nutrition children received while they were ill. Parents did not indicate concern about their decisions around dietary intake, which could indicate their confidence in this aspect of management. Most of the confidence in managing their child's illness stemmed from self-efficacy of home management, their perception of the threat of GE and from experience of managing GE previously. When parents lacked confidence in managing GE they reported anxiety and proceeded to contact primary care for help and/or reassurance.

The results from the symptom diary and questionnaire administered in Phase One indicated that despite being provided advice, some parents did not adhere to this advice from clinicians. It is unclear why that is.

Parents' perception of the seriousness of illness varied, which impacted on many aspects of the wider management of GE. We have reported the effect that parental beliefs had on their attitudes toward viral GE vaccines as well as spread of infection in the home.

Other barriers such as social acceptance and doing right by their child impacted on their decisions to keep their child from school and other social activities.

Beliefs regarding when to access healthcare varied depending on the parent's character and beliefs. Many had, in the past, presented to their GP regarding paediatric GE and reported inconsistent management and advice. For those who had been told by clinicians *"there was nothing they could do"*, parents felt they wouldn't consult again because they would just manage as before. Others who were given prescriptions indicated they would consult again in order to receive the same prescription – this is known as medicalising (Little et al. 2004). Most parents, however, reported that they were largely just seeking reassurance that they were doing the right thing.

Parents generally wanted to conform to social norms of when they should manage illness at home and when to seek help without being viewed as incompetent. This has been reported in other research where clinicians act as *"agents of control"* who create *"informal social rules for parents' use of health services"* which parent's feel they should conform to (Cabana et al. 1999).

9.4.3 Impact of management variation

Variations in beliefs regarding management can ultimately result in *inappropriate* management (NICE 2009, Tieder et al. 2009). This may be the inappropriate use of resources (laboratory testing, clinician time, prescribing) or actions detrimental to patient health and/or to the family. On the assumption that adherence to current guidance results in standardised practice for most mild self-limiting presentations of GE, the variability of patient management outcomes for the majority of individuals indicates that there is no standardised practice.

Variation in clinician's beliefs regarding GE management can result in inappropriate resource use

From the CPRD patient data it is clear that the overall incidence of paediatric GE in the UK has changed little over the past 10 years. Despite GP consultations decreasing for paediatric GE, the frequency of both GE-related hospital referrals and stool requests is increasing. Data from IID2 study also indicated the increase in incidence of GE within the community (Tam et al. 2012).

It is not clear from our findings how often stool sample requests and hospital referrals were appropriately requested/made or how often non-medical factors influenced these decisions. It may be that consultations to primary care are being used more appropriately and therefore the patients now consulting have a more prolonged, severe or complicated illness. The increase in stool sample requests and referrals would then reflect this change in illness severity.

The belief that primary care is unnecessary for most mild GE episodes was reflected in many parent interviews, in particular those who were confident and experienced in managing their child's GE. Clinicians reported patient education as an important way for parents to feel confident managing at home and only consulting when necessary.

The cost of consultations, prescriptions, test requests and referrals is a considerable burden on the NHS. Although this study has not focussed on the cost

of the illness, it is clear from previous work that the increase in the use of some of these resources over the last 5 years will be significant for the NHS.

Patient hospitalisation can result in increased risk in GE outbreaks on hospital wards, which is a public health risk.

Variation impacts the patient, family and the community

There are important resource implications for families experiencing GE illness. These include time off work, arranging child care for other children as a result of exclusion from day care and school, costs of cleaning / nappies, and costs associated with help seeking and obtaining medication. These burdens have been previously reported for GE (Roberts et al. 2003). However, the emotional impact has received less attention in the past.

We have shown that parental confidence in managing GE impacts on their beliefs about the threat of illness. If parents believe the threat is minimal there is a risk that their child will return into the community while infectious and thus increase the risk of transmission. This can in turn result in further use of NHS resources.

Variation impacts parent's experiences of managing GE

A further impact of variation in management, including medicalising GE, is the cycle of expectation that both parents and clinicians contribute to and experience.

If parents are educated to manage their child with GE at home and only present to primary care in unusually prolonged or severe cases, this will more often result in the parent doing the same the next time their child experiences an episode of GE. If, however, the first time a parent experiences GE and consults primary care and is given a prescription / stool sample test / is referred, this medicalising will continue for all subsequent GE episodes.

Contradictory advice will decrease trust in NHS and perhaps a detrimental effect on a patient as they may avoid the use of services or manage from home inappropriately.

Parents who don't feel they can cope will access health care if clinicians haven't given them safety-netting advice or if they haven't left the consultation feeling confident. In addition, if primary care clinicians do not provide care that satisfies parents, parents may not feel they can cope and will access other health care

options such as presenting to A&E and therefore for subsequent episodes continue to present to A&E.

9.5   Recommendations

This section will outline recommendations for clinical practice and recommendations for further research in this area.

9.5.1   Recommendations from project findings

This project has identified the considerable social, emotional and resource burden paediatric GE has on both the NHS and the community. It has also shown that there is widespread variation in management and use of non-evidence based management, and that the publication of a national clinical guideline has not helped to address these problems. The beliefs held by both primary care clinicians and parents directly impact on clinical management and thus indirectly on use of resources. Therefore, it appears that in order to address the inappropriate use of primary care, interventions need to consider clinician and parent beliefs.

Encouraging patient and parent education about the appropriate management of paediatric GE could help to reduce expectations for further treatment and investigation. Ensuring parents are confident at coping at home could also reduce the likelihood of additional consultations or presentation to secondary care. In addition, addressing parent expectations of a consultation at the start of a consultation could aid in ensuring time is spent addressing the necessary areas of concern. Clinicians actively seeking these expectations may also address any mis-interpreted perceptions a clinician may have.

The motivation to change is also an important factor that needs to be addressed. Many participants (parents and clinicians) perceived GE as being of little importance because it posed little threat (low mortality rates and hospital admission rates in resource rich countries). Altering the focus away from mortality and instead on overall social and financial burden imposed on the NHS and parents may increase the perceived importance of the condition and result in more readiness to change behaviour.

By reducing the mixed messages parents received during a consultation, inappropriate management and the variation in consultation outcome can be

addressed. Evidence-based practice will ensure all patients receive all necessary care and it will also allow us to see the true burden of illness.

Rotavirus vaccination is now routinely offered in the UK to all babies at two and three months of age. This contact with primary care could be an appropriate opportunity to address parental beliefs and provide information on the appropriate management of GE at home, as well as safety netting advice, including information about expected natural course. This could be presented in an information leaflet or on a website.

The findings from the qualitative study also indicate that there are areas for improvement to firstly ensure parents are aware of the rotavirus vaccine. In addition, in order to address some of the barriers preventing uptake, information is needed to ensure parents understand the benefits and efficacy of the vaccine.

9.5.2 Recommendations for future work

What is inappropriate management?

There is very little evidence supporting management during and subsequent to a mild self-limiting GE illness derived from UK community settings. It is not clear therefore whether management advice from clinicians and carried out by parents is inappropriate – either detrimental to patient health or unnecessary use of NHS resources.

A clear evidence base for management such as guidelines for dietary management is required if we are to determine what should and should not be advised and given to a paediatric patient with GE in resource rich settings.

Controlling for confounders (e.g. breast fed vs. Cow's milk) and collecting management data prospectively will allow researchers to identify risk factors and predict patient outcomes based on symptom severity and patient demographic.

What is the cost of paediatric GE?

A cost analysis of all suspected paediatric GE illness should be conducted using the data from CPRD to identify the main resource burdens for the NHS. If there are areas which could be altered in order to reduce costs without impacting on patient care or patient outcome, this would be an important area to focus on.

Impact of rotavirus vaccine (Rotarix) on burden of illness?

This research has been conducted prior to the introduction of the rotavirus vaccine in the UK and can therefore be used as a benchmark in some ways. Using patient data in the future, it would be interesting to compare consultation rates with the rates reported here in order to identify any changes since the introduction of the vaccine. CPRD database collects information on a patient's immunisation status, which would be useful in comparing patient groups who received the vaccine with those who did not, to determine any differences in future GE illness. These data could aid in quantifying the (expected) impact of rotavirus vaccine on the burden of GE illness.

9.6   Conclusion

Despite study set-up and recruitment problems, we have been able to demonstrate on a representable scale the burden and variation in management of paediatric GE.

Conducting a small-scale study within primary care has been challenging for many reasons. The inconsistency of approvals required across the health boards initially resulted in a biased representation of GP practices within health boards. The time-delay between approvals and study set-up also impacted on GP practice engagement with the study and thus recruitment rate.

Conducting a study focussed on a common, self-limiting condition was also a challenge. This thesis has presented many participants' views that GE poses little threat to patients, results in low mortality rates (in the UK) and therefore is not important. These beliefs were apparent during recruitment of GP practices, clinicians and parents. This absence of research priority has been reflected by the lack of recent evidence regarding the management of GE. Engagement in the study (topic-wise) was therefore a challenge.

This thesis has presented four sub studies that attempted to deepen our understanding of the management of paediatric GE in the community. We found that beliefs about the illness held by parents and primary care clinicians (i.e. lack of seriousness) impact on the management of the illness and patient outcomes. The burden of illness on the NHS is considerable and we have suggested that some of this burden is due to unnecessary resource use and help seeking, or inappropriate

management. The illness also has considerable emotional and financial impacts on the family, which could be addressed by increasing confidence in self-care and in home management strategies. The community is also impacted by the variable beliefs of GE and by reducing the risk of illness transmission, the wider community would considerably benefit.

The beliefs held by participants in both of the qualitative studies are likely to represent some of the beliefs held by the UK population in general. In addition, the concepts generated by the qualitative research is likely to represent important factors that should be taken into account during consultations and in developing interventions aimed at enhancing the self-care and medical management of this common condition.

While addressing and reducing the unnecessary burden of paediatric GE is important, it is also necessary to better identify and define what constitutes *"inappropriate management"*. The evidence base supporting optimal care needs to be enhanced and this needs to be properly operationalized in self-care strategies and when patients consult, taking into account the beliefs and epidemiological data identified by this program of work.

Novel findings – Overall, this project has identified that:
- The burden of GE in primary care is considerably higher than previously reported
- There are areas for improvement such as ensuring stool sample tests are appropriately requested
- Parents are receiving variable advice and this impacts on their confidence to manage at home
- Medicalising of GE by GPs results in inappropriate management which in turn contributes to the burden of illness

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APPENDICES

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APPENDIX 1

1.1   Ethical approval letter

North Wales Research Ethics Committee (Central and East)

G1/G2 Croesnewydd Hall
Croesnewydd Road
Wrexham Technology Park
Wrexham
LL13 7YP

Telephone: 01978 726377

26 August 2011

Miss Fiona Lugg
Department of Primary Care & Public Health
3rd Floor, Neuadd Meirionnydd, Heath Park
Cardiff
CF14 4YS

Dear Miss Lugg

Study title:	**Acute Diarrhoea and Vomiting in Children – A description of the clinical presentation, management, health beliefs and attitudes.**
REC reference:	**11/WA/0262**
Protocol number:	**SPON 1001-11**

Thank you for your letter of 25 August 2011 responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

The documents reviewed and approved by the Committee are:

Document	Version	Date
Advertisement	1.2	21 July 2011
Covering Letter		11 August 2011
Covering Letter		25 August 2011
Evidence of insurance or indemnity		06 July 2011
Interview Schedules/Topic Guides	1.1	22 July 2011
Interview Schedules/Topic Guides	1.1	22 July 2011
Interview Schedules/Topic Guides	1.1	22 July 2011
Investigator CV		08 August 2011
Investigator CV		21 July 2011
Letter from Sponsor		08 August 2011
Letter of invitation to participant	1.2	21 July 2011
Letter of invitation to participant	1.1	21 July 2011
Letter of invitation to participant	1.3	21 July 2011
Letter of invitation to participant	1.1	21 July 2011
Letter of invitation to participant	1.1	21 July 2011
Other: Responses to peer review		04 August 2011
Other: Phase One - Thank you/reminder postcard	1.2	21 July 2011
Other: Phase One - symptom diary	1.4	21 July 2011
Other: Phase One - patient log	1.3	21 July 2011
Other: GANNT Chart	2.1	08 August 2011
Participant Consent Form: Phase One	1.2	15 June 2011
Participant Consent Form: Phase Two	1.1	21 July 2011
Participant Consent Form: Phase Three	1.1	21 July 2011

Participant Consent Form: Phase Four	1.1	21 July 2011
Participant Information Sheet: Phase One	1.4	15 June 2011
Participant Information Sheet: Phase Two	1.2	15 June 2011
Participant Information Sheet: Phase Three	1.2	15 June 2011
Participant Information Sheet: Phase Four	1.1	21 July 2011
Participant Information Sheet: Phase One for GPs	1.4	25 August 2011
Protocol	1.7	20 July 2011
Questionnaire: Phase One - GP	1.3	21 July 2011
Questionnaire: Phase One - Carer	1.3	22 July 2011
Questionnaire: Phase One - 6 month follow up	1.2	21 July 2011
REC application 83175/240184/1/277		11 August 2011
Referees or other scientific critique report		15 June 2011
Referees or other scientific critique report		24 June 2011
Response to Request for Further Information		25 August 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/WA/0262	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

T. a. Hugh

PP **Professor Alex Carson**
Chair

Email: Tracy.Hughes4@wales.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: Mr Chris Shaw
Research & Commercial Division
Cardiff University
7th Floor, 30-36 Newport Road
Cardiff, CF24 0DE

Professor J Bisson, Cardiff And Vale University Health Board
R&D Office
2nd Floor TB2, Room 1
University Hospital Wales
Heath Park
Cardiff CF14 4XW

APPENDIX 2

2.1 Search Terms

#	Term	Type	Results	Saved as
1	diarrh$.mp	Keyword	87165	
2	vomit$.mp	Keyword	55489	
3	gastroenteritis.mp	Keyword	18047	
4	exp Diarrhea/	MeSH	43561	
5	Gastroenteritis/	MeSH	12241	
6	Acute	Keyword	875259	
7	exp Acute disease/	MeSH	181653	
8	exp Vomiting/	MeSH	25041	
9	1 or 4		87165	
10	2 or 8		58125	
11	9 and 10		9378	
12	3 or 5		18047	
13	6 or 7		875259	
14	12 and 13		4911	
15	**11 or 14**		**13930**	**GE Terms**

#	Term	Type	Results	Saved as
16	Child, Preschool/	MeSH	743696	
17	Child/	MeSH	1347658	
18	Pediatrics/	MeSH	39840	
19	paediatric$.mp	Keyword	38164	
20	pediatric$.mp	Keyword	201672	
21	child*.mp	Keyword	1821201	
22	**16 or 17 or 18 or 19 or 20 or 21**		**1870411**	**Paediatric Terms**

#	Term	Type	Results	Saved as
23	Manage$.mp	Keyword	851164	
24	exp Disease Management/	MeSH	28016	
25	exp Health Knowledge, Attitudes, Practice/	MeSH	71147	
26	exp Practice Management/	MeSH	30190	
27	exp Practice Management, Medical/	MeSH	9259	
28	Knowledge/	MeSH	6775	
29	Attitude to Health/	MeSH	72286	
30	Attitude/	MeSH	39113	

#	Term	Type	Results	Saved as
31	attitude*.mp	Keyword	299026	
32	Health Behavior/	MeSH	33089	
33	Health Behavi$	Keyword	38513	
34	**23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33**		**1151867**	**Illness Management Terms**

#	Term	Type	Results	Saved as
35	exp Primary Health Care	MeSH	78153	
36	exp Family Practice	MeSH	60053	
37	exp General Practice	MeSH	63552	
38	Primary Care.mp	Keyword	65090	
39	General Pract$.mp	Keyword	64699	
40	Clinician$.mp	Keyword	121429	
41	Doctor$.mp	Keyword	83290	
42	**35 or 36 or 37 or 38 or 39 or 40 or 41**		**379787**	**Primary Care Terms**

#	Term	Type	Results	Saved as
43	carer$.mp	Keyword	7285	
44	parent$.mp	Keyword	327571	
45	caregivers/	MeSH	21007	
46	parents/	MeSH	41196	
47	**43 or 44 or 45 or 46**		**349812**	**Parent Terms**

#	Term	Results	Saved as
48	15 and 22	5058	**Paed GE**
49	48 and 34	491	**Management of Paed GE**
50	49 and 42	**60**	**Clinical Management of Paed GE**
51	49 and 47	**72**	**Parental Management of Paed GE**

APPENDIX 3

3.1 Patient Log

3.2 Study Pack materials

    3.2.1 Parent information leaflet

    3.2.2 Parent consent form

    3.2.3 Child information leaflet

    3.2.4 Child assent form

3.3 Data Collection Forms

    3.3.1 Questionnaire

    3.3.2 Symptom diary

The ADVICE Study

Do I have to take part? - It is up to you!

This

If you **do** decide to take part you will be asked to sign a consent form. Your child may wish to complete an assent form also.

You
becau
way and are free to choose the course of action that vomit they, and you, feel is the most appropriate for your child.

Your GP will examine your child's illness in the usual way and are free to choose the course of action that they, and you, feel is the most appropriate for your child.

You are free to withdraw at **any time** without giving a reason and without it affecting your healthcare you or your child receives.

This I

Please note that all information received about you or your child will only be used for the purpose of this research study.

What are the benefits and possible disadvantages of taking part in this study?

It is hoped that this study will provide a better description of the symptoms and management of diarrhoea and vomiting in children and you have the opportunity to contribute to this understanding.

W

We will ask you to take a few minutes everyday for 14days to complete the symptom diary, 10minutes to complete the questionnaire and another five minutes in six months time to complete 3 follow up questions.

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What do I have to do?

If you have agreed to **provide your contact details** for the purpose of this study, you will need to ensure your details on the doctor's computer system are correct.

You will be contacted within 3days of you providing your contact details to **answer any of your questions** and make sure you understand how to complete both the questionnaire and the symptom diary that are provided in your study pack.

- You will also need to complete a **consent form** and if your child is aged between 11 and 16years they may wish to complete an **assent form** saying they are happy for you to provide information on their behalf.

- A short **questionnaire** will be asking you for some information on your child's illness, what your doctor recommended to you for their treatment and your own beliefs on diarrhoea and vomiting.

- A **symptom diary** will then need to be completed for up to 14days which reports on your child's symptoms, medication, diet and other management aspects.

Once completed, the diary will need to be sent back to the researcher. Please use the pre-paid envelope provided in the study pack.

- After **six months**, you will be contact via post to ask you three short questions about your child's health after their illness. If your child has since been diagnosed with a relevant condition, we may wish to view their medical records.

  You will need to fill in a simple **tick box form** and send it back using the pre-paid envelope you will be provided with.

To compensate you for your time & inconvenience we will send you a £10 Marks & Spencer Gift Voucher at the end of your participation

CONFIDENTIAL

REC Ref: 11/WA/0262

SPON Ref: SPON 1001-11

PARTICIPANT STUDY NUMBER: n / n n n

ADVICE

Acute Diarrhoea and Vomiting in Children
Chief Investigator: Fiona Lugg

If you are interested in taking part in this study and have had time to read the study information, please complete this form and return one copy with the completed questionnaire and symptom diary. The second copy of this form is for you to keep for your reference.

Please *initial* all statements that you agree with:

*Please **Initial***

I confirm that I have read and understand the Participant Information leaflet *(version 2.1 dated 15/09/2011)* for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

If your child is aged 11years or over: I confirm that we have discussed the study together and they have completed the assent form *(version 1.1 dated 15/09/2011)* indicating they are happy for myself to participate in this study.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without mine or my child's medical care or legal rights being affected.

I understand that relevant sections of my child's medical notes may be looked at by the researcher of this study. I give permission for the researcher to have access to these records.

I agree to take part in the above study

_____   _____   _____
Name   Date   Signature
(Carer)

Received:

_____   _____   _____
Name   Date   Signature
(Researcher)

The ADVICE Study

Acute Diarrhoea and Vomiting in Children

We are asking if you and your parent would join in a research project to find the answer to the question how parents and doctors treat and stop diarrhoea and vomiting.

Before you decide if *you* want to join in, it's important to understand why the research is being done and what it will involve for you.

So please read this leaflet carefully.

Who is organising and funding the research?

The study is being organised by the Department of Primary Care and Public Health, Cardiff University.

The project has been funded by the Medical Research Council the Clinical Epidemiology Interdisciplinary research group and the department of primary care & public health.

Who has reviewed the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair.

Your project has been checked by the (Central & East) Proportionate Review Sub-Committee Research Ethics Committee and NHS R&D.

If you require any further information, please contact:

Miss Fiona Lugg
Department of Primary Care & Public Health
3rd Floor, Neuadd Meirionnydd Heath Park
Cardiff. CF14 4YS.
Tel: +44 (0)29 20687169
Email: luggfv@cardiff.ac.uk

Why have I been chosen?

You went to see your doctor because of your illness – Diarrhoea and Vomiting. We would like you and your parent to help us understand how this is treated and managed.

Why are we doing this research?

This research will look at how Doctors and parents look after children when they are poorly with diarrhoea and vomiting.

The information we get will help treat young people with Diarrhoea and Vomiting with better management in the

Who is the researcher?

All of the information will be collected and analysed by **Fiona Lugg**—a PhD Student of the School of Medicine at Cardiff University.

The ADVICE Study

Do we have to take part?

It is up to you!

If you are happy for your parent to tell the researcher about your illness and you are aged 11 or over, you need to sign the Assent form in the study pack.

If you don't want your parent to join the study, don't sign the assent form and then they will not be allowed to join.

Will anyone else know I'm doing this?

We will keep your information in confidence.

This means we will only tell those who have a need or right to know. Wherever possible, we will only send out information that has your name and address re-

What will happen if my parent does take part?

They will answer some questions about your illness:

- what the doctor said when you went to see him/her,
- what your parent/guardian/carer thinks is the best way to treat

They will complete a diary for 2 weeks on your illness:

- Your symptoms (example: if you have a stomach ache)
- What medicine you have
- What food and drink you have
- If you stay home from school or have to go into hospital

This will be completed over 2 weeks, and then your parent will send it back to the researcher with the questionnaire.

After **three months**, they will be sent another questionnaire and will need to answer three short questions about your health since your illness.

If you have been to the doctor about an illness similar to what you have now, we may need to check your doctor's notes.

Please note: All information received about you will only be used for the purpose of this research study.

REC Ref: 11/WA/0262

SPON Ref: SPON 1001-11

PARTICIPANT STUDY NUMBER: n/nnn

Acute Diarrhoea and Vomiting in Children
Chief Investigator: Fiona Lugg

ADVICE

Your parent has been asked to record some information about your Diarrhoea and/or Vomiting. We are interested in how they look after you, for example, what you eat, what medication you have to stop you feeling poorly and how quickly you get better.

If you are happy for this to be sent to a researcher, please talk to your parent and together, fill in this form.

Please circle all you agree with (or if unable, parent on their behalf):

Has somebody explained this project to you?	Yes / No
Do you understand what this project is about?	Yes / No
Have you asked all the questions you want?	Yes / No
Do you understand it's OK to say you don't want your carer to take part?	Yes / No

Please Circle

If you are happy for your parent to take part, please write your name below.

_____
Name
(Young person)

To the Parent – If you are happy that your child understood all of the questions above, please complete the consent form *(Version 1.1 dated 15/09/2011)* enclosed in your study pack and sign and date this form witnessing your child's assent to you participating.

_____   _____   _____
Name   Date   Signature
(Parent)

If you require any further information, please contact:
Miss Fiona Lugg
Department of Primary Care & Public Health
Tel:+44 (0)29 20687169
Email: luggfv@cardiff.ac.uk
Version 1.1   Page 1 of 1   15/09/2011

Draft

ADVICE

ADVICE Study
Questionnaire

CARDIFF UNIVERSITY

PARTICIPANT STUDY NUMBER: ☐ / ☐☐☐

This study aims to describe the symptoms and treatments of acute diarrhoea and/or vomiting in children. It is also interested in the management of this condition by both your doctor and yourself.

Please read each question carefully before you answer and try to answer every question. Please either *write* in your answer in the space provided or *tick* the appropriate box/boxes.

The information that you give us will be treated in **strict confidence**.

Today's Date: ☐☐ / ☐☐ / ☐☐☐☐
                d d / m m / y y y y

Patient Information
This section asks you for some details on your child and household contacts

Q.1   **Date of Birth**   ☐☐ / ☐☐ / ☐☐☐☐   dd / mm / yyyy

Q.2   **Sex**   ☐ Male   ☐ Female

Q.3   **How many people live in your household?** *[Including yourself]*

     Number of Adults: ☐☐ Adults
     [Aged 17 or over]

     Number of Children: ☐☐ Children
     [Up to 16years]

Q.4   **Has anyone else in your household** (apart from your child who you consulted the GP about today) **been ill with diarrhoea and/or vomiting in the last 7 days?**

     ☐ Yes   ☐ No   If "Yes", how many? ☐

Q.5   **In the 14 days before your child became ill; did they travel outside of the UK?**

     ☐ Yes   ☐ No   ☐ Not sure

     If "Yes", Where? ☐☐☐☐☐☐☐☐

Q.6   **Before consulting the Doctor, did you seek advice from any of the following because of the diarrhoea and/or vomiting illness?** *[Tick any that apply]*

     ☐ Visit the pharmacy or chemist shop

     ☐ Telephone GP out-of-hours

     ☐ Telephone NHS direct / NHS 24

     ☐ Visit Accident & Emergency (A&E)

     ☐ Internet

     ☐ None of the above

Patient Symptoms
This section asks you for some details on your child's illness

Q.7 **Has your child had any of the other following symptoms during their illness?**
[Tick all that apply]

☐ Diarrhoea (Loose stools) ☐ Headache

☐ Vomiting (Being Sick) ☐ Lethargy / sleepy

☐ Nausea (Feeling Sick) ☐ Cough / Sore throat

☐ Blood in stool ☐ Blocked / Runny Nose

☐ Stomach pain ☐ No appetite

☐ Fever

Q.8 **If your child has had diarrhoea:**
What was the largest number of loose stools in any 24-hour period?

☐☐ number of episodes

Q.9 **If your child has been vomiting:**
What was the largest number of vomiting episodes in any 24-hour period?

☐☐ number of episodes

Q.10 **Has your child stayed off school/ nursery/ pre-school because of this illness?**
☐ Yes ☐ No

Q.11 **Has your child's illness prevented yourself or another member of your household from going to work?**
☐ Yes ☐ No

GP Recommendations
This section looks at your experience during your consultation with the doctor

Q.12 **Were you recommended or prescribed Oral Rehydration Therapy treatment?**
☐ Yes ☐ No ☐ Don't know *[e.g. Dioralyte, Electrolade]*

Q.13 **Were you recommended or prescribed any Probiotic treatment?**
☐ Yes ☐ No ☐ Don't know *[e.g. Multibionta, Yakult, Activia]*

Q.14 **Did your doctor recommend any dietary advice (What to feed your child)?**
[Tick all that apply]

☐ Normal diet as tolerated ☐ Full strength baby formula

☐ Limited solids diet *[e.g. small portions]* ☐ Diluted baby formula *[e.g. half strength]*

☐ Avoid solids ☐ Continue breast feeding

☐ Avoid Dairy *[e.g. cheese, milk]* ☐ None

Q.15 **Were you offered any other advice?**

☐ Hygiene advice [e.g. handwashing]

☐ Keep child at home

☐ Come back if Child doesn't get better

☐ Other

If "Other", Please specify:

Your thoughts
This section asks you for your thoughts on the cause, management and treatment of your child's illness

For the following statements, please indicate how much you agree or disagree on a scale of 1-5 by *ticking* the relevant box.

(1) Strongly Disagree	(2) Disagree	(3) Neither agree or disagree	(4) Agree	(5) Strongly Agree

Q.16 The best way treat diarrhoea in children is by stopping usual food / feeds until they are better.

(1)	(2)	(3)	(4)	(5)
☐	☐	☐	☐	☐

Q.17 It is important to consult the GP everytime a child has diarrhoea and/or vomiting

(1)	(2)	(3)	(4)	(5)
☐	☐	☐	☐	☐

Q.18 Antibiotics help treat diarrhoea and vomiting in children

(1)	(2)	(3)	(4)	(5)
☐	☐	☐	☐	☐

Q.19 Probiotics ["live yoghurt"] are a way to treat diarrhoea and vomiting in children (such as activia, yakult, probiota)

(1)	(2)	(3)	(4)	(5)
☐	☐	☐	☐	☐

Q.20 Diarrhoea and vomiting is usually caused by food poisoning

(1)	(2)	(3)	(4)	(5)
☐	☐	☐	☐	☐

Q.21 Hand-washing is necessary in controlling the spread of diarrhoea and vomiting

(1)	(2)	(3)	(4)	(5)
☐	☐	☐	☐	☐

Thank You for taking the time to complete this questionnaire.

Once the Symptom Diary (also included in your study pack) is complete, please return this questionnaire in the pre-paid envelope provided.

If you have any questions about this questionnaire or any other aspects of the study, please contact the researcher on the contact details below.

ADVICE Study

Symptom Diary

Draft

ADVICE

CARDIFF UNIVERSITY

PARTICIPANT STUDY NUMBER: ☐ / ☐☐☐

Please count **day 1** as the first day your child <u>showed symptoms</u> of their illness of diarrhoea and/or vomiting;
Please note - this may not be the same day that you saw your GP.
Question 1: You are asked to indicated symptom severity on a scale of 0-4, please use the following system:
    0 = symptom not present   to   4 = symptom at its most severe (worst)
Questions 2 - 4: Please tick any of the options that apply to you that day.

Please see examples:

	Day:	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Example for Q.1		0	2	2	2	4	4	3	2	1	0	0	1	0	0
Example for Q.2 - 4		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Date symptoms started *(Day 1)*: ☐☐ / ☐☐ / ☐☐☐☐   [dd/mm/yyyy]

	Day:	1	2	3	4	5	6	7	8	9	10	11	12	13	14

Q.1   Symptoms - Please <u>*indicate severity*</u> on a scale of 0-4

Diarrhoea

Vomiting (Being sick)

Abdominal / Stomach cramps / pain

Fever / Temperature

Q.2   Medication - Please <u>*tick*</u> all that apply

Tablets or medicines for diarrhoea e.g. Imodium

Tablets or medicines for vomiting e.g. Pepto-Bismol

Tablets of medicines for fever / pain eg. Calpol

Antibiotics

Oral Rehydration Solutions e.g. Dioralyte

Probiotic supplement e.g Yakult, Activia

Q.3   Diet (Food intake) - Please <u>*tick*</u> all that apply

Babies
Breast-fed

Full strength Baby formula

Diluted strength Baby formula (e.g. half strength)

Older Children
Liquid only (No solids)

Limited solids diet

No Dairy products (Dairy free)

Normal

Q.4   Other Aspects - Please <u>*tick*</u> all that apply

Off school / nursery / daycare

Consulted GP

Sent a stool (faecal) sample

Admitted to Hospital

Went to A&E (Accident & Emergency)

Please State the Date Child Fully Recovered: ☐☐ / ☐☐ / ☐☐☐☐

Please tick this box if you feel your child has not fully recovered after the 14 days: ☐

If you are at all unsure, please do not hesitate to contact the researcher for this study

APPENDIX 4

4.1   Read Codes

4.2   CPRD Variables

Read Code	Description
1992	Vomiting
19F..11	Diarrhoea
19F..00	Diarrhoea symptoms
J43..11	Gastroenteritis
198..00	Nausea
19FZ.11	Diarrhoea & vomiting, symptom
19EA.00	Change in bowel habit
A07y000	Viral gastroenteritis
199..14	Vomiting symptoms
19F2.00	Diarrhoea
19G..00	Diarrhoea and vomiting
A....00	Infectious and parasitic diseases
198..12	Nausea symptoms
A083.11	Diarrhoea & vomiting -? infect
19F..12	Loose stools
199..00	Vomiting
A081200	Gastroenteritis - presumed infectious origin
A074300	Campylobacter gastrointestinal tract infection
A080300	Infectious gastroenteritis
A081100	Enteritis - presumed infectious origin
R070000	[D]Nausea
R070100	[D]Vomiting
J4z0.00	Non-infective gastritis NOS
1984	Upset stomach
A083.00	Diarrhoea of presumed infectious origin
A08..11	Gastric flu
A081000	Colitis - presumed infectious origin
A0...12	Food poisoning
A082.11	Travellers' diarrhoea
A020.00	Salmonella gastroenteritis
A08..00	Ill-defined intestinal tract infections
A061.00	Giardiasis - Lambliasis
19FZ.00	Diarrhoea symptom NOS
A074312	Campylobacter enteritis
19EB.00	Frequency of defaecation
19EA.11	Altered bowel habit
R070.00	[D]Nausea and vomiting
A3Ay200	Clostridium difficile infection
A076.11	Viral diarrhoea
A02z.00	Salmonella infection NOS
A076.12	Viral vomiting

19F4.00	Toddlers diarrhoea
199..11	C/O - vomiting
A04z.00	Food poisoning NOS
A082111	Viral gastroenteritis
19E6.00	Blood in faeces
19E..11	Faeces symptom
A07y100	Infantile viral gastroenteritis
J4z3.00	Non-infective colitis NOS
A0...00	Intestinal infectious diseases
19EC.00	Painful defaecation
A082.00	Infectious diarrhoea
1984.11	Upset tummy
41D2.00	Stool sample obtained
A020.12	Salmonella food poisoning
A0z..00	Intestinal tract infectious disease NOS
J437.00	Colitis
19E6.11	Blood in faeces symptom
A076200	Enteritis due to rotavirus
A033.00	Shigella sonnei (group D)
A02..00	Other salmonella infections
A076z00	Enteritis due to specified virus NOS
19E..12	Motions - symptom
198..11	C/O - nausea
19EH.00	Mucus in faeces
A080200	Infectious enteritis
A082000	Dysenteric diarrhoea
A3B4.11	E.coli infection
A03..00	Shigellosis
R070z00	[D]Nausea and vomiting NOS
19EF.00	Urgent desire for stool
A082z00	Infectious diarrhoea NOS
A074.00	Other specified gastrointestinal tract bacterial infection
199Z.00	Vomiting NOS
47D1.00	Stool sample - bacteriology
J4zz.00	Non-infective gastroenteritis NOS
19E..00	Faeces/motions - symptoms
19ZZ.00	Gastrointestinal symptom NOS
A3B4.00	Escherichia coli infection
198Z.00	Nausea NOS
A050.00	Acute amoebic dysentery
A074311	Diarrhoea due to Campylobacter jejuni
19EE.00	Increased frequency of defaecation
A78y111	Winter vomiting disease
J4zz.11	Diarrhoea - presumed non-infectious

Code	Description
A0...13	Vomiting – infective
A05..00	Amoebiasis
19EZ.00	Faeces symptoms NOS
J43..12	Enterocolitis
A064.00	Cryptosporidiosis
J43z.00	Other non-infective gastroenteritis and colitis NOS
A070.00	Escherichia coli gastrointestinal tract infection
A081.11	Colitis,enteritis ? infectious
J431000	Toxic gastritis
A020.11	Salmonellosis
A04..00	Other bacterial food poisoning
A082100	Epidemic diarrhoea
19Z..00	Gastrointestinal symptoms NOS
A080z00	Infectious colitis, enteritis and gastroenteritis NOS
A076100	Enteritis due to enterovirus
J4z..11	Presumed noninfectious diarrhoea
A080.00	Infectious colitis, enteritis and gastroenteritis
A00..00	Cholera
A080100	Infectious colitis
A083.12	Infantile gastroenteritis
J4z..00	Non-infective gastroenteritis NOS
A08z.00	Ill defined gastrointestinal tract infections NOS
19F3.00	Spurious (overflow) diarrhoea
A081.00	Colitis, enteritis and gastroenteritis presumed infectious
Z4A4300	Discussion about hygiene
41B3.00	Faeces test due

CODE	DESCRIPTION
A00	Cholera
A00.0	Cholera due to Vibrio cholerae 01, biovar cholerae
A00.1	Cholera due to Vibrio cholerae 01, biovar eltor
A00.9	Cholera, unspecified
A01	Typhoid and paratyphoid fevers
A01.0	Typhoid fever
A01.1	Paratyphoid fever A
A01.2	Paratyphoid fever B
A01.3	Paratyphoid fever C
A01.4	Paratyphoid fever, unspecified
A02	Other salmonella infections
A02.0	Salmonella enteritis
A02.1	Salmonella sepsis
A02.2	Localized salmonella infections
A02.8	Other specified salmonella infections
A02.9	Salmonella infection, unspecified
A03	Shigellosis
A03.0	Shigellosis due to Shigella dysenteriae
A03.1	Shigellosis due to Shigella flexneri
A03.2	Shigellosis due to Shigella boydii
A03.3	Shigellosis due to Shigella sonnei
A03.8	Other shigellosis
A03.9	Shigellosis, unspecified
A04	Other bacterial intestinal infections
A04.0	Enteropathogenic Escherichia coli infection
A04.1	Enterotoxigenic Escherichia coli infection
A04.2	Enteroinvasive Escherichia coli infection
A04.3	Enterohaemorrhagic Escherichia coli infection
A04.4	Other intestinal Escherichia coli infections
A04.5	Campylobacter enteritis
A04.6	Enteritis due to Yersinia enterocolitica
A04.7	Enterocolitis due to Clostridium difficile
A04.8	Other specified bacterial intestinal infections
A04.9	Bacterial intestinal infection, unspecified
A05	Other bacterial foodborne intoxications, not elsewhere classified
A05.0	Foodborne staphylococcal intoxication
A07.1	Giardiasis [lambliasis]
A07.2	Cryptosporidiosis
A07.3	Isosporiasis
A07.8	Other specified protozoal intestinal diseases
A07.9	Protozoal intestinal disease, unspecified
A08	Viral and other specified intestinal infections

A08.0	Rotaviral enteritis
A08.1	Acute gastroenteropathy due to Norwalk agent
A08.2	Adenoviral enteritis
A08.3	Other viral enteritis
A08.4	Viral intestinal infection, unspecified
A08.5	Other specified intestinal infections
A09	Other gastroenteritis and colitis of infectious and unspecified origin
A09.0	Other and unspecified gastroenteritis and colitis of infectious origin
A09.9	Gastroenteritis and colitis of unspecified origin
B96.2	Escherichia coli [E. coli] as the cause of diseases classified to other chapters
K29.6	Other gastritis
K29.7	Gastritis, unspecified
R11	Nausea and vomiting
R19.4	Change in bowel habit
R19.5	Other faecal abnormalities
R63.8	Other symptoms and signs concerning food and fluid intake
Y53.6	Antidiarrhoeal drugs

CPRD Variables- *GP Records*

Look up Table	Field name	Description

Patient

patid	Encrypted unique identifier given to a patient in GPRD
gender	Patient's gender
yob	Patient's year of birth
mob	Patient's month of birth (for those aged under 16). 0 indicates no month set

Practice

pracid	Encrypted unique identifier given to a specific practice in GPRD
region	Value to indicate where in the UK the practice is based. The region denotes the Strategic Health Authority for practices within England, and the country i.e. Wales, Scotland, or Northern Ireland for the rest
uts	Date at which the practice data is deemed to be of research quality. Derived using a GPRD algorithm that primarily looks at practice death recording and gaps in the data

Staff

staffid	Encrypted unique identifier given to the practice staff member entering the data
gender	Staff's gender
role	Role of the member of staff who created the event

Consultation

patid	Encrypted unique identifier given to a patient in GPRD
eventdate	Date associated with the event, as entered by the GP
sysdate	Date the event was entered into Vision
constype	Type of consultation (e.g. Surgery Consultation, Night Visit, Emergency etc)
consid	The consultation identifier linking events at the same consultation, when used in combination with pracid
staffid	The identifier of the practice staff member entering the data. A value of 0 indicates that the staffid is unknown

Clinical

patid	Encrypted unique identifier given to a patient in GPRD
eventdate	Date associated with the event, as entered by the

	GP
sysdate	Date the event was entered into Vision
constype	Code for the category of event recorded within the GP system (e.g. diagnosis or symptom)
consid	Identifier that allows information about the consultation to be retrieved, when used in combination with pracid
medcode	GPRD unique code for the medical term selected by the GP
staffid	Identifier of the practice staff member entering the data. A value of 0 indicates that the staffid is unknown
episode	Episode type for a specific clinical event
adid	Identifier that allows additional information to be retrieved for this event, when used in combination with pracid. A value of 0 signifies that there is no additional information associated with the event.

Referral

patid	**Encrypted unique identifier given to a patient in GPRD**
eventdate	Date associated with the event, as entered by the GP
sysdate	Date the event was entered into Vision
constype	Code for the category of event recorded within the GP system (e.g. management or administration)
consid	Identifier that allows information about the consultation to be retrieved, when used in combination with pracid
medcode	GPRD unique code for the medical term selected by the GP
staffid	Identifier of the practice staff member entering the data. A value of 0 indicates that the staffid is unknown
source	Classification of the source of the referral e.g. GP, Self
nhsspec	Referral speciality according to the National Health Service (NHS) classification
fhsaspec	Referral speciality according to the Family Health Services Authority (FHSA) classification
inpatient	Classification of the type of referral, e.g. Day case, In patient
attendance	Category describing whether the referral event is the first visit, a follow-up etc
urgency	Classification of the urgency of the referral e.g. Routine, Urgent
patid	Encrypted unique identifier given to a patient in GPRD
eventdate	Date associated with the event, as entered by the GP

Test

sysdate	**Date the event was entered into Vision**
constype	Code for the category of event recorded within the

	GP system (e.g. examination)
consid	Identifier that allows information about the consultation to be retrieved, when used in combination with pracid
medcode	GPRD unique code for the medical term selected by the GP
staffid	Identifier of the practice staff member entering the data. A value of 0 indicates that the staffid is unknown
textid	Identifier that allows freetext information on the event to be retrieved, when used in combination with pracid and event type 'Test'. A value of 0 indicates that there is no freetext information for this event
enttype	Identifier that represents the structured data area in Vision where the data was entered
data1	Qualifier
data2	Normal range from
data3	Normal range to
data4	Normal range basis
patid	Encrypted unique identifier given to a patient in GPRD
eventdate	Date associated with the event, as entered by the GP

	sysdate	Date the event was entered into Vision
	consid	Identifier that allows information about the consultation to be retrieved, when used in combination with pracid
	prodcode	GPRD unique code for the treatment selected by the GP
	staffid	Identifier of the practice staff member entering the data. A value of 0 indicates that the staffid is unknown
Therapy	textid	Identifier that allows freetext information (dosage) on the event to be retrieved, when used in combination with pracid and event type 'Therapy'. A value of 0 indicates that there is no freetext information for the event. Use the Common Dosages Lookup (constituting ~ 95% of dosage strings in data) to interpret values < 100,000
	bnfcode	Code representing the chapter & section from the British National Formulary for the product selected by GP
	qty	Total quantity entered by the GP for the prescribed product
	ndd	Numeric daily dose prescribed for the event. Derived using a GPRD algorithm on common dosage strings (represented by textid < 100,000). Value is set to 0 for all dosage strings represented by textid $\geq$ 100,000
	numdays	Number of treatment days prescribed for a

		specific therapy event
	numpacks	Number of individual product packs prescribed for a specific therapy event
	packtype	Pack size or type of the prescribed product
	issueseq	Number to indicate whether the event is associated with a repeat schedule. Value of 0 implies the event is not part of a repeat prescription. A value ≥ 1 denotes the issue number for the prescription within a repeat schedule

CPRD Variables - HES Data

Lookup table	Field	Description
Source	patid	The encrypted unique identifier given to patient in GPRD GOLD
	HESstart	Start of valid HES data collection for patient: max (01/04/1997, patient's current registration date (crd), practice UTS date)
	HESend	End of valid HES data collection for patient: min (31/10/2010, patient's transfer out date, practice last collection date (lcd), practice linkage date)
	match	Flag indicating strength of matching: 0 = No match (never hospitalised) 1 = Hospitalised (Linked using NHS, DOB, & gender)

Patient	**patid**	**The encrypted unique identifier given to patient in GPRD GOLD**
	pracid	The encrypted unique identifier given to a specific practice in GPRD GOLD
	birthyear	Patient's year of birth according to GPRD records
	gender	Patient's gender according to GPRD records
	ethnos	Patient's ethnicity derived from HES records in years 1997 – 2010
	HESstart	Start of valid HES data collection for patient: max (01/04/1997, patient's current registration date (crd), practice UTS date)
	HESend	End of valid HES data collection for patient: min (31/10/2010, patient's transfer out date, practice last collection date (lcd), practice linkage date)
Diagnosis	**patid**	**The encrypted unique identifier given to patient in GPRD GOLD**
	spno	Spell number uniquely identifying a hospitalisation
	discharged	Date of discharge
	ICD	An ICD10 diagnosis code

APPENDIX 5

What do I have to do?

Consent

If you agree to provide your contact details for the purpose of this study, you will need to **complete the consent form and provide some information about how to contact you.**

You will also need to **indicate your availability for the telephone interview.**

All of this will need to be sent back to the researcher.

Arrange a date & time

You will be contacted once all this information is received to arrange a half-hour telephone interview. If you have any questions you will have the opportunity to have them answered here.

Once the interview time and date is confirmed you will be sent a reminder either via post or email - which ever method of contact you prefer.

Telephone Interview

You will then take part in the half-hour interview.

It will be exploring your health beliefs and attitudes towards diarrhoea and vomiting and be asking how you manage this problem at home and what you do to prevent your child from becoming ill again.

The interview will be electronically recorded to enable all information you provide to be documented.

Thank you for taking the time to read through this leaflet.

Do I have to take part?

It is up to you!

If you do decide to take part you will be asked to sign a consent form (if you have not done so already) agreeing to providing the researcher with your contact details.

You are free to withdraw at any time without giving a reason.

Please note that all information received about you or your child will only be used for the purpose of this research study.

What are the benefits and possible disadvantages of taking part in this study?

It is hoped that this part of the study will provide a description of the treatments, management and attitudes parents and guardians have towards diarrhoea and vomiting in children and you have the opportunity to contribute to this understanding.

We will ask you to take half an hour of your time to complete the interview; this will be at a date and time that is convenient for you.

REC Ref: 11/WA/0262

SPON Ref: SPON 1001-11

PARTICIPANT STUDY NUMBER:

Acute Diarrhoea and Vomiting in Children
Main Contact: Fiona Lugg

ADVICE

If you are interested in taking part in this study and are willing to be contacted after you have had time to read the study information please complete this form and return to the researcher in the envelope provided.

Please provide your contact number for the telephone interview:

Phone number :

The table displays available dates, please **circle** the preferred date and **write in** the time for the researcher to phone.

Available Dates *(Please circle one)*:	Please write in a time between **9am and 8pm**

Please Initial

I confirm that I have received the Participant Information leaflet *(version 2.1 dated 04/01/2012)* for the above study

I agree to participate in a half hour interview and have provided my availability; the researcher may contact me to confirm the interview time and date

I agree that the interview may be electronically recorded

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected

_____   _____   _____

Name   **Date**   **Signature**

Thank you for agreeing to participate in the interview

1. Participant Information
Can I firstly collect some brief background information?
Date of Birth
What is your job title?
How old is/are your child/ren?
When did you consult the GP regarding your child's

2. Typical MANAGEMENT

<u>Diagnostic</u>
How would you describe diarrhoea?
Duration   Frequency   Consistency
What other symptoms do you expect to be present if your child was suffering from diarrhoea?   [prompts below]
Vomiting   Feeling Sick   Stomach pain / cramp Headache   Fever
Blood   Runny/blocked nose   Sore throat/cough   Other
What symptoms – from your experience, would be a concern to you if your child was suffering from diarrhoea?   [prompts below]
Vomiting   Feeling Sick   Stomach pain / cramp Headache   Fever
Blood   Runny/blocked nose   Sore throat/cough   Other
When   are   considering   your   childs   symptoms,   what   are   your concerns?[prompts]
Dehydration   Not being allowed at nursery/having to take time off work
A more severe illness – missing an important symptom

<u>Consulting a GP</u>
At what point (or what reasons) *would you take your child to see the doctor?* [prompts below]
Duration   Blood   Age of your child
Do you go to the doctors with a treatment/prescription in mind?
Would you expect the doctor to take a stool [faecal] *sample?*
Would / have you considered contacting NHS Direct Wales instead of going to the doctors?
Would you consider taking your child directly to hospital?

3. Beliefs on PREVENTION
How do you think diarrhoea and vomiting can be caused? [Use prompts if necessary]
Caught from another child / member of household
Food poisoning
Sign of a cold
Eating / drinking too much of one thing
Can you think of any way that diarrhoea can be spread to others?
Do you take any extra precautions hygiene-wise when you, your child or someone else in the household is suffering from diarrhoea and/or vomiting? If yes, please detail.
If you knew another child was suffering from diarrhoea and/or vomiting, would you remove your child from said environment?

4. Beliefs on TREATMENT

I am now going to go through various treatments doctors and carers use in the treatment of diarrhoea and vomiting in children.

Feeding attitudes
When your child has diarrhoea or vomiting, what do you feed them? [Example – Liquids only, light snacks, soup, normal diet, nothing until it stops]
And how often?
Do you think it would be best to keep feeding them their normal diet? If yes/no...why?
Are there circumstances where this would change?
What do you base these beliefs on? [GP, family, friend, colleague, experience]
If you read different feeding advice to what you normally do, would you change the way you feed your child while they have diarrhoea and/or vomiting? If no, why?

Probiotics
Have you heard of the term probiotics?
Does "good bacteria" mean anything to you? OR Does "Activia" mean anything to you? ... Summarise what probiotics are if necessary.
Do you give your children any probiotic supplements?
Have you ever heard of taking them as a treatment for diarrhoea and vomiting?
If a doctor recommended you to buy a "probiotic supplement" is this something you would consider? If no, why?
Would there be other people who you would preferably listen to if they told you probiotics were a succesful treatment? Who and why?
Do you believe probiotics can have a side effect?

Antidiarrhoeals
Have you heard of Antidiarrhoeals?
Could you tell me what they are and do?
Do you think this is a good way to treat diarrhoea in children?
Have you ever treated your childs diarrhoea with an antidiarrhoeal? What was the outcome? Do you remember what the antidiarrhoeal was called? [Example – Imodium].
Do you think antidiarrhoeals can have a harmful or side effect if taken?

Antibiotics
Do you think antibiotics will help treat your child with diarrhoea and vomiting?
Has your child ever been prescribed antibiotics for their diarrhoea and/or vomiting?
Do you remember what the antibiotic was called?
Would you ever specifically ask the doctor for antibiotics for your child if they were suffering from diarrhoea and/or vomiting?
Are you aware of any side effects of taking antibiotics?

Other medication
Do you recommend any other medication for children to take suffering with diarrhoea and/or vomiting? What is this based on?

Additional related issues may emerge during the interview or be initiated by the participant.

5. Any other questions
Do you have any concerns towards the treatment of acute diarrhoea/vomiting in children?
Do you think management of acute diarrhoea and vomiting could be improved at all?

Are there barriers to changing your management? If yes, what are they?

Are there any other issues that you feel we haven't talked about that you would like to mention?

Thank you for your time

Do you have any questions?

-END-

THE ADVICE STUDY

Do I have to take part?

It is up to you!

If you do decide to take part you will be asked to sign a consent form (if you have not done so already) agreeing to providing the researcher with your contact details.

You are free to withdraw at any time without giving a reason.

What are the benefits and possible disadvantages of taking part in this study?

It is hoped that this part of the study will provide a description of the treatments, management and attitudes General Practitioners have towards diarrhoea and vomiting in children and you have the opportunity to contribute to this understanding.

We will ask you to take fifteen minutes of your time to complete the interview; this will be at a date and time that is convenient for you.

Please note that all information received about you will only be used for the purpose of this research study.

What do I have to do?

Consent

If you agree to provide your contact details for the purpose of this study, you will need to complete the consent form and provide some information about how to contact you.

You will also need to indicate your availability for the telephone interview.

All of this will need to be sent back to the researcher.

Arrange a date & time

You will be contacted once all this information is received to arrange the telephone interview. If you have any questions you will have the opportunity to have them answered here.

Once the interview time and date is confirmed you will be sent a reminder either via email.

Telephone Interview

You will then take part in the 15 minute interview.

It will be exploring your health beliefs and attitudes towards diarrhoea and vomiting and be asking how you manage this problem, why you recommend certain treatments and what you do to prevent a patient from relapsing or suffering from persistent problems.

The interview will be electronically recorded to enable all information you provide to be documented.

Thank you for taking the time to read through this leaflet.

REC Ref: 11/WA/0262

SPON Ref: SPON 1001-11

PARTICIPANT STUDY NUMBER:

ADVICE

Acute Diarrhoea and Vomiting in Children
Main Contact: Fiona Lugg

If you are interested in taking part in this study and are willing to be contacted after you have had time to read the study information please complete this form and return to the researcher in the envelope provided.

Please provide your contact number for the telephone interview:

Phone number :

The table displays available dates, please **circle** the preferred date and **write in** the time for the researcher to phone.

Available Dates *(Please circle one)*:	Please write in a time between **9am and 8pm**

Please Initial

I confirm that I have received the Participant Information leaflet *(version 2.1 dated 04/01/2012)* for the above study

I agree to participate in a 15 minute interview and have provided my availability; the researcher may contact me to confirm the interview time and date

I agree that the interview may be electronically recorded

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected

_____   _____   _____
Name   Date   Signature

5.4   Interview Schedule to be used to interview General Practitioners

Thank you for agreeing to take part, a few things to mention before I begin recording…

Just to make it clear, none of these questions are a test, I may ask you to explain or define something during the interview, but this will be purely for me to understand .. I'm not a clinician therefore I may need some points clarified…
All of the questions I will be asking will be related to patients up to the age of 16 suffering from acute diarrhoea and vomiting.
As well as discussing what normally happens or what is expected to happen during consultations, I am just as interested in the situations where decisions might become difficult or there is an uncertainty and the factors around making those decisions.

Participant Information
If I could ask a few questions about the practice you work in?
Number of doctors
Branch surgeries
Location (urban / rural / valleys)
Can you describe your patient demographic?
On average, how many children do you think you deal with each week with D&V?
And how many of those cases do you deal with over the phone?

So firstly, if you could talk me through how it works at your practice in terms of if a parent rings up about their child suffering from D&V…
Prompts: ie. Would they be offered a telephone consult first? Is it up to the parent / receptionist what type of consultation? Would they be given an emergency appointment?

Telephone Consultation
(depending on response above) If telephone consultation… Discuss the types of questions you would ask the parent? *What are you trying to determine / looking for?*

What type of case would you be happy to deal with over the phone?
Age? Symptoms? Symptom duration? Parent? History?

What sort of advice might you offer to the parent at this time?
Symptoms to look out for / keep an eye on? Medication / treatments? Diet?

And so on the flipside of that situation, could you explain the factors and reasons why you might want to, or from your experience have, asked the child to come to the practice?

Face-to-face Consultation
Right, so if we move on slightly to discuss a patient presenting to you at your practice.

Could you talk me through how the consultation would proceed…
Would you discuss the potential causes of illness?
Viral / Travelled abroad / Food poisoning

Are there any examinations that you would typically carry out?
Prompt: what circumstances might you carry out physical examination? What would you do? Why? Are there / have there been circumstances where this would be different?

What would you look for that would be a potential cause for concern?
Are there specific symptoms? Parental concern? Knowledge of child / child's history? Gut feeling / instinct?

Are there any differences between patient demographics?

Do you find that parents have any expectations of the consultation?
If yes, do you ask them? how do you manage their request / expectation?

How do you differentiate between a potentially serious case and a self limiting case?
Red flags?

Under what circumstances would you request a stool sample?

Are there circumstances where you might advise the child to go to hospital?

Are there any situations or have there been any situations that would cause you uncertainty in your diagnosis, treatment, recommendations?

Treatment
Could you talk me through any medication you might advise or prescribe?
ORS / Calpol / Antibiotics / Nothing
For how long, what are your reasons?
Differences for different ages / presenting symptoms / other?

How do you decide whether to prescribe [above mentioned medication]?
What do you base that decision on?

Do you follow any guidelines for treatment decisions?
What in particular do you follow? Are there any exceptions?
[if no to guidelines – what are your reasons for this?]

Under what circumstances would you consider prescribing antibiotics?

Are there any factors that have an effect on your prescribing decisions?
Patient/Carer expectations / Practice …Do you find patient/carers often ask for a specific treatment/prescription?
…How does is affect or change your decision?

If you prescribe any medication how do you explain your decision to the patient/parent?
On the other hand, if you decide not to prescribe anything, do you explain why?

Advice
Is there any dietary advice you would suggest to parents?

If yes, what? What do you base that advice on? Is this for all patients? Are there any exceptions? Any foods you might recommend? Or recommend to avoid? Why…?
If no, Is there any reason you don't? If a parent asked for dietary advice, what would you advise?
And how about fluid intake?

Thoughts around Probiotics?

Are there circumstances where you might offer advice regarding hygiene or infection control?
If yes, what advice?? Circumstances? Rest of the time? How important do you think this is?
If no, are there reasons why you don't offer any advice?

Do you offer any advice about removing the child from school / nursery?
If yes, what? Based on…?

<u>Final thoughts</u>

What are your thoughts around links between chronic gastrointestinal conditions and acute gastro episodes?

Do you have any concerns towards the treatment of acute diarrhoea/vomiting in children? Or Do you think management of acute diarrhoea and vomiting could be improved at all?
Are there barriers to changing your management? If yes, what are they?

Are there any other issues that you feel we haven't talked about that you would like to mention?

Thank you for your time

-END-

5.5   Emerging Codes List

Initial Codes

Carer 04

Symptoms - Dehydration
Symptoms - Description of diarrhoea
Symptoms - Temperature
Symptoms - Lethargy
Symptoms - Headache
Symptoms - Explanation of symptoms
Symptoms - Duration of illness
Symptoms - Blood
Symptoms - Sinister causes
Burdens - Hygiene
Burdens - Prevention
Burden - Time off work
Burdens - School
Burden - Concern
Burden - Caring for child
Burden - stool sample
Burdens - Other parents
Diet - Fluids
Diet - Decrease food
Diet - Bland food
Diet - Starve
Diet - Dried food
Diet - Beliefs
Diet - From own Childhood
Diet - Symptom based
Diet - Duration
Information / Support - Experience
Information / Support - Family
Information / Support - Online
Information / Support - Friends
Primary Care - GP
Primary Care - OOH
Primary Care - Expectation of GP
Primary Care - Clinical Sample
Primary Care - Prescription
Primary Care - Trust
Primary Care - Reassurance
Primary Care - Referral to hospital
Medication - For Temperature
Medication - Painkillers
Medication - Probiotics
Medication - Antibiotics
Health beliefs - Causes of D&V
Health Beliefs - Insignificance of D&V
Health Beliefs - After Illness

Additional codes

Carer 01

Symptoms - Age dependent
Symptoms - Signs of distress
Symptoms - Stomach pain
Symptoms - Frequency of episodes
Burdens - Nursery / Daycare
Burdens - Childcare
Diet - baby specific
Diet - Dairy
Diet - Fat free
Diet - Strict
Diet - Resuming normalilty
Diet - Vomiting specific
Diet - Diarrhoea specific
Diet - Other peoples' approaches
Information / Support - Guidelines
Information / Support - Daycare
Information / Support - Knowledge
Medication - Antidiarrhoeals

Carer 03

No New Codes

Carer 05

Symptoms - Mood changes
Symptoms - Test of time
Symptoms - Loss of appetite
Burdens - Consequences
Information / Support - NHS Direct
Diet - BRAT
Diet - Normal
Information / Support - Work
Primary Care - Diagnosis
Medication - Rehydration

Carer 06

Medication - Other
Primary Care - Advice

Carer 07

Primary Care - Intervention
Primary Care - Investigate Cause
Diet - From Experience

Consulted GP

Carer 10
Beliefs - Role as a mother
Beliefs - Feelings towards the illness
Symptoms - Story of illness
Medication - antiemetics
Medication - Beliefs
Vaccinations

Carer 11
Burden - Impact of non-adherence
Empathy for child
GP unnecessary
Previous illness
Behaviour change

Carer 02
Concern - Age differences
Parental instinct
Hypothetical Hospital
Illness = Joke
Food poisoning more of a concern

Carer 08
Food poisoning = separate illness
Illness - positive attitude
Impact of norovirus
Child takes priority
Grandparents
non-infectious D&V
Food poisoning less of a concern
Test for dehydration
Old wives tale
Dislike of Dioralyte
Non-adherence to instructions
Alternative management
Comparison to other illnesses
Overuse of Primary Care

Carer 09
Importance of hygiene
Other parents nonadherence
Soothing child
"know your child"
"Felt mean"
Information leaflet
Praise for NHS Direct
"Sanity check"

Carer 12
Nothing to stop D&V spreading
Segregate during illness
No policy at school
Spread through family
Impact - ruined Christmas
been through it so many times
Norovirus specific advice
Feelings towards Doctors
Diet - whatever child wants
Calorie counting
Food intolerance
Consequences of Dairy
TV influence - Probiotics
Building immunity

Carer 18
Extreme measures - prevention
Symptom - delusions
Low fibre diet
Breastfeeding

Carer 14
Assumed diagnosis
Impact - "wearing"
Sources of dietary advice
Foods to avoid
Norovirus on the increase

Carer 17
Walk-in clinic at Hospital
Nervous / "fear"
Symptom - weight loss

Carer 28
No New Codes

Carer 16
Vitamins
Reporting illness to childcare
Exercise / fresh air helpful

Carer 15
No New Codes

Consulted GP

Carer 24
Advised to go to A&E
Not reassured after seeing GP
Feelings towards A&E visit
non-adherence to GP advice
Kaolin medication

Carer 13
Herbal Remedies

Carer 19
No New Codes

Carer 23
No New Codes

Carer 25
No New Codes

Carer 27
No New Codes

Carer 29
No New Codes

Carer 30
No New Codes

Carer 32
No New Codes

Carer 34
No New Codes

Consulted GP

5.6 Parent Interview Coding Framework

Umbrella Term	Code	Description
Dietary Approaches	Alteration of Normal Diet	Any mention of the child's diet altering from "Normal" during an episode of D&V e.g. BRAT diet, Diarrhoea specific diet, Starving.
	Beliefs of Diet during D&V	Parents beliefs held about why they follow this diet during illness e.g. from their own childhood, certain positive / negative properties in food type. Also include beliefs held by their family and friends.
	Fluid Management	Talk about how parents maintain child's fluid intake during illness
	Occurrence of Diet Alteration	The duration, frequency and end to altered diet / food intake e.g. little and often, resume normal after 24hours of no vomiting.
	Perceived Normal Diet	What parents perceive as a normal diet.
Experience of Primary Care	Advice Offered	What advice or information Clinician provides during consultation. This can also include reassurance, OTC medication, return if symptoms get worse etc.
	Consultation procedure	What happened during the recent consultation include prescriptions, physical examinations, offered diagnosis.
	Expectation of consultation	Talk relating to any expectations parent had from a consultation with GP e.g. prescription. Also include any hypothetical situations the parent mentions e.g. "If there was blood, I would want some antibiotics".
	Other Primary Care Usage	Any mention of using e.g. NHS Direct / Out of hours, as well as the circumstances / reasons for doing so.
	Reason for visit	Talk about why the parent chose to consult the GP e.g. concerning symptoms, duration of illness.
	Referral to hospital	Talk about previous experience or hypothetical situations where child is referred to / taken to hospital this includes skipping primary care.
Illness Experience	Concerns	Any talk relating to the concerns parents have during their child illness ("I was worried that it wasn't viral") and anything that they look out for that would be a cause for concern e.g. "if their fever gets worse"
	Duration of illness	When parents are discussing their child's recent illness, any mention of the duration of illness or duration of certain symptoms.
	Management based on	If parents mention their management of the illness was based on their experience of dealing with the illness, their knowledge of how to manage the illness, what their parents did when they were young etc.

	Experience	Also include their knowledge of their child e.g. "She always gets diarrhoea 12 hours after vomiting".
	Story of recent illness	When the parent produces a narrative of their child's recent illness, the whole section is to be coded.
	Symptoms	Talk relating to presenting symptoms during child's illness.
Impact of illness	Caring for child	When parents are talking about how their childs illness affects them emotionally and their sympathy towards their child e.g. "I wish I could have it and not them", "I hate seeing her suffer".
	Impact on Family or Friends	The wider impact of the childs illness on the parents friends, childs friends, and the wider family Examples. "her brother caught it too", "he couldn't go out and play" "I had to cancel my friend coming round" "couldn't visit grandparents".
	Impact on Parent	Talk relating to the impact the illness has on the parent / parents
	Education	Talk regarding the child having time off school or nursery, include being sent home from educational institution. Also include any mention of the guidelines schools / day care providers have regarding D&V.
	Time off work	Parents mentioning having to take time off work to look after their child. Also include any mention of the ease of doing this e.g. "I can work from home so it wasn't too bad", "I work for a university, so they're very good if my child's sick".
Lay Belief of illness	After illness	Beliefs the parent has regarding returning their child to normal life after suffering from D&V and their reasons for these beliefs e.g. "I will always wait 48hours", "If they look better then that's good enough for me"
	Age	Talk regarding how the age of the child makes things different during the illness "when they're young they can't tell you whats wrong", "It's easier now that they're older". Also include how decisions around medication are affected by age of child.
	Causes of D&V	Beliefs parents hold on the cause of D&V and how it is transmitted / not transmitted. Also include their thoughts on how they think their child caught D&V recently.
	Description of Diarrhoea	Parents description of diarrhoea e.g. "any loose movement", "for 2 days".
	Feelings towards illness	Talk about the parents perception of the illness positive or negative e.g. "I hate it!", "it's a fact of life".
	Health beliefs	Other beliefs parents hold about the illness not coded in the other categories.
	Insignificance of D&V	Talk relating to how in/significant D&V is to the parent. E.g. "It's only a bit of diarrhoea", "It's no laughing matter".
	Other parents	Mention of other children's parents (e.g. at school) and how their actions affect or influence participant. E.g. "If someone says it's doing the rounds, I feel a lot more relaxed" "Parents return their child to school

		when they're still green in the face".
Lay Belief of illness (Cont.)	Parental instinct	Talk about how parents use their instinct in the management of D&V and when to become concerned / relaxed. "when it's your own child, you just know"
	Prevention	Talk about the measures parents take to prevent spread of D&V. Include hygiene precautions and cancelling visits e.g. with grandparents.
	Prior knowledge	Talk relating to knowledge / experience they have relating to D&V e.g. a nurse, a microbiologist, epidemiologist
	Vaccines	Talk relating to beliefs held about vaccinations for rotavirus / norovirus
Medication	Beliefs regarding medication	Beliefs parents hold on medication use for D&V. Also include thoughts on side effects of medication and dosage of medication.
	Medication to treat cause	Talk relating to the use of medication for specific causes of D&V (rather than to treat symptoms) e.g. for bacterial, for food poisoning
	Probiotics	Any mention of probiotics, their use, their properties etc.
	Rehydration	Medication mentioned by parents used / considered for rehydration e.g. Dioralyte
	Medication to treat symptom	Talk relating to the use of medication to treat a symptom of D&V e.g. for fever, for vomiting
Sources of information and or support	Advice from Nursery or School	Talk around the advice or information Day care providers or schools give to parents re. their child's illness NOT including e.g. sending them home
	Family	Talk relating to advice and support offered from Family, including help with caring for child
	Friends	Talk relating to support and advice offered from Friends of Parent during child's illness
	Guidelines	Parents referring to following / looking up a guideline e.g. NICE guideline
	Online	Talk relating to parents looking up information, looking for support through the internet e.g. blogs / mumsnet
Vaccines	Negative	Talk associated with negative views / feelings towards vaccinations
	Neutral / Unsure	Talk associated with vaccinations, participant appears neutral or unsure with their feelings
	Positive	Talk associated with positive views / feelings towards vaccinations

VACCINES

For

"All for vaccines" C02

"Sounds pretty safe" C11 [Edward]

"I'd be first in the que" C11 [Alan]

"I generally support vaccinations" C03

"I would always chose to vaccinate" C03

"Think it's a positive thing that they are being developed" C13

"They're good" C14

"I would be all for it, to have it" C14

"I definitely conside giving it to [Ryson]" C17

"Jump at the chance" C18

"All in favour" C19

"I would definitely" C24, C28, C30

"Give it a go - after all the testing is done" C24

Parents of...
(heading unclear)

"I know so many people
it's knocked for six" C09

"feel like I spent most winters waiting
to go down with" [Norma]

"Vaccines... on the increase" C14

"would help reduce hospitalisations C14
inconvenience & money of coronavirus C18

"R & N our NHS millions" C19

"People would welcome it" C19

"It's been bad with flu this year" C24

"so common & dismally for [child]" C24

"I've vaccinated [child] against everything" C09

"I don't believe vaccinating one themselves" C18

"Children been vaccinated against other things... if they were
going to be... sensitive to ingredients [we'd know]" C24

"Always consider - once exposed" C25

"I hate giving [an] needless" C29

"I'm not against
vaccines" C34

"depending on actual needs" C32

Give my kids whatever was going" C02

Experience - No such thing...

"maybe your body... need to ride it out" C03 [Alan]

"I'd say enough to fight it" C17 [Alex]

"if Nannies... you won't get it again" C10

"So many different types, you wouldn't
catch same one twice" C10

"Coronavirus - get it bad first time,
further episodes are milder :: suspected immunity" C11

"you get very limited immunity" C11 [Alex]

"suspect I've got immunity. So... was ill & she
didn't get it" C11 [Clare]

"natural for your body
to have diarrhoea" C09

Current immunisation series/Current vaccines... (?)

"said no to flu vaccine" C09

"I'd consider it differently to flu jab" C09

"if it was my first baby then I probably would" C10

"it's not GP's to be honest" C10

"with MMR - I looked into that because of the furore" C23

"If it didn't have many side effects, benefit outweighed them" C16, C28
... figures showing risks

"definitely not
give that to
my son" C29

"If you vaccinate for anything something new comes along" C12

"I think vaccinations can just get
no-one dying from it (in UK) so... not multiple" C12
something new comes along C27

"Like you're knocking their own immune
system out by giving vaccines for everything C12

"there's always going to be another virus
around the corner" C12

"vaccine against one thing it develops
into something else" C12

Against
Not sure it's worth it - C10
not serious enough C27

"I'm not keen on adding further things to the
body... not keen on previous things he's had
before" C27

"prefer to manage individually" C27

"I'd wanna look into it" C09 [Norma]

"Not something I'm particularly clued up on" C16

"if you could vaccinate against that rapidly evolving
viruses - I'm not convinced you could" C18

"there would have to be quite a lot of literature
available... to make a decision on it" C23

Research / ... trust/Info