POINT OF CARE (POC) ULTRASOUND (US) AND THE INTRODUCTION OF THE HAEMOPHILIA EARLY ARTHROPATHY DETECTION WITH ULTRASOUND (HEAD-US) PROTOCOL ACROSS THE SOUTH THAMES HAEMOPHILIA NETWORK (STHN)

Grant ID: 29008101

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Abstract

The goal of this service development exercise is to embed the use of the Early Arthropathy Detection with Ultrasound (HEAD-US) protocol in the assessment process of severe and moderate patients with haemophilia (PWH) within the South Thames Haemophilia Network (STHN). The project can be defined as a quality improvement programme. The methodology is pragmatic and supportive in design. It includes a series of interventions designed to address the barriers that prevent a network introduction. Individual interventions include strategies to raise awareness of the value of HEAD-US, provide technical support and training, introduce a governance framework and provide short-term material support in the form of US machines. The project will be evaluated through site-specific audits against a set of service standards. The minimum service standards will state that seventy five percent of severe and moderate PWH over the age of five should be assessed using the HEAD-US within a calendar year by a competent HEAD-US trained clinician. The audit will also report on the impact of HEAD-US on patient management and evaluate patient satisfaction/dissatisfaction with the introduction of the HEAD-US protocol.

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Attachments	Excel	Budget
	PDF's	Staff biosketches/CV's
		Letters of commitment

Reviewer Comments

a) Sustainability

Sustainability of this quality improvement exercise is essential. The project will provide the opportunity to position US machines throughout the haemophilia network and collect robust data to justify the subsequent purchase of machines. The issue of US machine investment has been discussed with the centre directors at St Thomas', St George's and the lead consultant at the Evelina Hospital. It is the intention that the service commissioners will fund the acquisition of the US machines directly when presented with the project data, as there is considerable interest in identifying patient outcome measures that quantify the effectiveness of treatment in haemophilia care. Investment by the commissioning authorities cannot be guaranteed, due increasing constraints on NHS financing. However, the centre directors have agreed that if the project goal and objectives are met, proving the viability of the service development, that they would be willing to purchase machines directly through centre funds. We are fortunate to have the staffing capacity to enable us to sustain the use of US assessment after the project has ended.

b) Patient level outcomes

The LOI submitted stated that the project would utilise patient satisfaction questionnaires. These questionnaires will be used to measure the value of US assessment from the perspective of the PWH. The project will also report on any differences in the assessment findings between HEAD-US & physical assessment and evaluate any changes to patient management that arise as a result of the introduction of the HEAD-US protocol into the patient review process.

Goals and Objectives

Project goal

To embed the use of the HEAD-US protocol in the assessment process of PWH (severe and moderate) within the STHN. A network-wide service standard will be set. The minimum service standard will state that greater than seventy five percent of severe and moderate PWH registered within the network will be annually assessed during clinical review using the HEAD-US protocol. This is to be achieved by 1 June 2018.

Project objectives

- Identify the local barriers and enablers for implementation of the HEAD-US protocol (as perceived by the various stakeholders) using site-specific brain storming workshops. The results will be categorised using the World Health Organisation's (WHO) health system building blocks (WHO 2016) and ranked in order of significance by the session participants. The results of the exercise will be presented using a Ishikawa (fishbone) diagram (Tague & Nancy 2004). This exercise will be completed by February 2017.

- Develop a local competency framework for the clinicians who will be undertaking the HEAD-US protocol. This framework will be developed by May 2017 and fully tested for scale up by December 2017.

- Develop competence and confidence amongst the networks physiotherapists to perform the HEAD-US protocol within their local clinical environments. All network physiotherapists will have completed the competency framework and be working independently by January 2018.

- Build an awareness and knowledge of the value of the HEAD-US protocol within the networks community of PWH/their families, the haemophilia physicians, the service commissioner and other clinicians. This objective will be on-going throughout the service development project. Clinician awareness and knowledge will be measured through the evaluation of intervention specific questionnaires. Patient awareness and knowledge will be measured by evaluating the patient satisfaction questionnaires. All data will be collected by June 2018.

This goal is clearly aligned with the focus of the RFP. Achievement will entail successfully addressing and identifying the barriers within the STHN which have prevented a network-wide adoption of the HEAD-US protocol. The goal reflects the focus of Guy's and St Thomas' NHS Trust's mission to *"provide world-class clinical care, education and research that improve the health of the local community and of the wider populations that we serve"*. It will have a direct impact on the clinical care of patients with haemophilia (PWH) locally and within the wider communities that GSTT serves. The goal also aligns with the GSTT vision of being "*a high quality, high performing and innovative integrated academic healthcare organisation."*(2015). Therefore, this goal embraces the Trust's ambitions of enhancing quality and introducing innovation in healthcare.

Current Assessment of Need

a) What is

Haemophilia is a disease which predominately affects the musculoskeletal system. Greater than eighty percent of haemophilia-related bleeds are musculoskeletal, the majority of these occur in the hinge joints of the elbow, knee and ankle (Rodriguez & Merchan 1994). The STHN currently has 251 registered severe and moderate PWH. The STHN has access to three physiotherapists. These physiotherapists undertake formal musculoskeletal (MSK) reviews of the adult patients at least twice a year, paediatric patients are reviewed quarterly. The United Kingdom Haemophilia Clinical Doctor's Organisation (UKHCDO) has a quality standard that all severe and moderate patients are assessed using the Haemophilia Joint Health Score (HJHS) (Feldman et al 2011). This is a joint score that is currently validated for use in the paediatric population but is used nationally across all age ranges. Local clinical records demonstrate that the STHN compliance with this quality standard is excellent, greater than eighty percent in 2015. The national target is fifty percent (UKHCDO 2012).

The nature of joint disease in PWH is changing. Within the UK the degree of joint disease amongst the younger population of PWH is significantly lower when compared to older generations. This can be partially accounted for by the progressive nature of arthritic joint disease (Johnson and Hunter 2014). It also reflects the significant strides that have been made in maintaining patients' haemostasis through the availability of paediatric and adult prophylaxis (Manco-Johnson 2007). The advent of longer acting factor products, the development of novel treatment agents and the future of gene therapy all suggest that there will be even greater improvements in patient management moving into the future (Peyvandi et al 2016). This national trend is reflected within the STHN. The mean paediatric HJHS within the network is 2/124 and the range is 0-15/124[1]

Changes in disease presentation have led to a shift in focus in the MSK management of PWH. The emphasis of the physiotherapy role in this cohort of patients is increasingly directed at prevention rather than the disease management. This patient group still present with joint bleeds. Haemtrack data[2] and local clinical records indicate that twenty five percent of this cohort of STHN patients reported a musculoskeletal bleed in the last twelve months. The consequences of haemarthrosis remain serious. A single joint bleed can cause irreversible and progressive joint disease. Silent or sub-clinical bleeding events may also occur and remain undetected until significant joint changes become evident (De Minno et al 2013). Musculoskeletal assessment needs to remain thorough and vigilant. The lifetime cost of an early degenerative joint cannot be over-estimated for a patient, having a direct impact on their quality of life (QOL). The wider societal cost and financial impact on healthcare are also highly significant (Cavazza et al 2016).

[1] The HJHS is a numerical scale between 0-124. 124 being the greatest measurable degree of joint arthropathy

[2] The United Kingdom Haemophilia Doctor's Organisation (UKHCDO) national reporting database that includes an application which allows patients to self report bleeding events.

Physical examination can alert clinicians to pre-symptomatic joint changes. The HJHS is a tool that can be used within a physical examination. However, significant numbers of patients within the younger patient cohort present with HJHS's of 0/124, both nationally and locally. This suggests that the HJHS may not have the required sensitivity to identify the earliest signs of joint change. Ultrasound has been reported as a useful diagnostic tool in haemophilia care for many decades (Alderman 1987). Technological advances and the reduced cost of Point of Care (PoC) means that ultrasound has become available across a range of clinical setting (Dietrich et al., 2016). Interest in the use of ultrasound within haemophilia care is steadily growing but its use is not widespread either within the UK or internationally (Di Minno et al 2016). Studies have reported that US can effectively identify very early changes to joint cartilage (Luz et al 2016) and synovial hypertrophy (Tamas et al 2013) and is as effective as MRI in the detection of haematomas (Sierra Aisa et al 2013). The HEAD-US protocol provides the non-expert clinician/sonographer with a simple scoring protocol that allows a trained clinician to identify and calibrate haemophilia-related joint changes (Martinoli et al 2013). Robust research assessing the value of US directly in haemophilia care is not yet available. A strong evidence-base is difficult to establish in such a rare disease especially with the limited availability of US technology within haemophilia centres internationally. Evidence is emerging that ultrasound and physical examination pick up haemophila-related pathology that is undetected by the other form of assessment (Altisent et al 2015). This creates a powerful argument to undertake both forms of assessment on PWH.

There are no UKHCDO standards or recommendations for the use of US within haemophilia care. There are no local, regional or nationally agreed competencies for the use of US/HEAD-US within haemophilia care. There are a few small haemophilia centres within the UK that are currently using the HEAD-US protocol, mainly on an ad-hoc basis. The project lead is unaware of any UK haemophilia network that has fully embedded the use of the HEAD-US protocol into their assessment process.

The St Thomas' haemophilia physiotherapist has access and expertise in using US imaging. Currently no access or expertise is available at the other STHN sites including the Evelina Children's Hospital. The St Thomas' site currently uses US on an ad-hoc basis to identify acute bleeds and assess joint health using the HEAD-US protocol. The St Thomas' centre has assessed twenty five severe/moderate PWH using the HEAD-US protocol in the last year. Of the patients assessed using this protocol, three incidences of joint synovitis were identified that were not detected during physical examination or the subjective assessment. This translated into changes in patient management that included changes in prophylaxis regime, a radiosynovectomy and lifestyle advise. The local experience of using the HEAD-US protocol is that it is a valuable adjunct to the physical examination, enhancing the sensitivity of the overall assessment.

b) What should be

All severe and moderate PWH over five years of age registered within the STHN should be assessed using the HEAD-US protocol to ensure that every attempt is made to identify and manage any early signs of joint disease before joint changes become irreversible. The use of HEAD-US should be incorporated within the patient review process to ensure that it is being performed routinely and the information is used in conjunction with other physical assessment processes. HEAD-US assessment should be delivered by a suitably trained and competent physiotherapist. The literature clearly reports that the effectiveness of US in joint surveillance is linked to operator skill (Strike et al 2015).

US and the use of the HEAD-US protocol should not replace other forms of radiological examination within this patient group. It is recognised that the gold standards' for joint imaging include magnetic resonance imaging, computerised tomography and x-ray. These assessment modalities provide highly sensitive and specific images of joint pathology. However, these imaging modalities are not practical clinical tools for regular joint screening. They can expose patients to unnecessary dosages of ionising radiation and children may require sedation prior to certain forms for formal radiological examination.

Patient impact of proposed HEAD-US quality improvement project

STHN PWH with HEAD-US score in last 12 months	25
STHN PWH whose management has changed as a result of HEAD-US in the last twelve months	3
Total STHN patients	251
Target number of PWH with annual HEAD-US Score	188 (minimum)
Estimated number of patients with new pathology discovered used ultrasound during year one	19 (minimum)
Estimated number of patients whose management will change as a result of HEAD-US assessment during year one	19 (minimum)

3) Target Audience(s)

a) Moderate and severe PWH

The network registration of severe and moderate PWH is two hundred and fifty one. These patients are registered at four hospital sites across South London. St Thomas' Hospital, the Evelina Children's Hospital, St George's Hospital and a small number of patients registered at the satellite unit at University Hospital Lewisham. The population age range is < one year to seventy nine years. The target audience of the project is all registered PWH over the age of five years. It will not be necessary to actively recruit, as the HEAD-US protocol will form part of the routine multi-disciplinary clinical review.

b) Network physiotherapists

There are three network physiotherapists. Their dedicated hours within the network equate to two full-time working equivalents. Two of the physiotherapists specialise in adults and one specialises in paediatrics. All the physiotherapists are senior with a minimum National Health Service (NHS) grade of band seven. The physiotherapists are all experienced in assessing for haemophilia-related musculoskeletal conditions. One of the physiotherapists is an experienced user of HEAD-US, one has previously undertaken the HEAD-US preceptorship with no subsequent clinical application and one has no experience using US. All the physiotherapists have pre-consented to train and participate in this project. The target audience is therefore one hundred percent.

c) The clinical/non-clinical STHN community

This staff population is > forty. The target is to engage ninety percent of this population within the appropriate interventions, increasing knowledge and awareness of the value of the HEAD-US protocol. This community includes clinical, administrative and management staffing groups. The key decision-makers, the centre directors, have pre-consented to participate in this project. Knowledge and awareness of the value of US throughout the wider community is essential in order to promote the use of US amongst the community of PWH and to facilitate the necessary adaptations to the multi-disciplinary clinics. The ability to demonstrate a quality service improvement to the service commissioner will help ensure the long-term maintenance of the programme. The centre directors have agreed that in the absence of commissioning funds they will meet the costs of purchasing US machines if the programme goals, objectives and targets are met

d) Beneficiaries

The main beneficiaries of the programme will be the severe and moderate PWH within the STHN who will have access to an enhanced level of joint disease surveillance, reducing their risk of life-changing joint arthropathy.

Long-term improved disease surveillance will benefit the STHN and local health economy, potentially reducing the need for surgical intervention, the burden on the local health systems and the rates of pathology within this patient population.

It is anticipated that this service development will provide a model for care that can be transferred to other haemophilia networks/centres within the UK. A significant number of UK haemophilia centres have direct access to physiotherapy services. It is anticipated that the published results of the project will provide evidence of the feasibility and clinical value of this service development. The tools developed within the project, including the competency scale, will be made available for use without cost.

4) Project Design and Methods

a) Overall project strategy

The project can be classified as a quality improvement project. It loosely follows the Institute of Health Improvements (IHI) model of "How to improve" (IHI 2016). The service change is designed around the "plan do study act" cycle, although not overtly stated.

The project adopts a flexible mediator strategy, adapting to the individual stakeholder interests, constraints and practice (Seth et al 2006). A number of potential project barriers have been anticipated and interventions have been devised to address these. These have been established based on the local clinical environment and informed by the potential gaps outlined in the research funding proposal (RFP) published by Pfizer (Pfizer 2016). The final design and nature of the interventions will be informed, adapted and amended by the results of site-specific brain-storming workshops, designed to identify the barriers preventing the introduction of the HEAD-US protocol. The project will provide on-going support for the individual site clinicians to embed the use of HEAD-US into their clinical practice.

b) Identifying barriers/enablers to implementation of HEAD-US

Intervention	Site specific brain-storming workshop
Facilitator	Project lead PWH/parent of PWH (experience of US), PWH/parent (no experience of US), consultant haematologist, nurse, administrator/manager, commissioner (St Thomas' only) and site physiotherapist
Format	Introduction (5 minutes) Facilitated brain-storming (45 minutes) Categorisation of the barriers and enablers using WHO's health system building blocks to ensure all areas of the health system are accounted for (WHO 2016). Sub-categorisation will be undertaken where appropriate (10 minutes) Plotting results on a fishbone diagram (5 minutes) Ranking the significance of barriers and enablers (5 minutes)

c) Barriers and interventions

Lack of knowledge and awareness of HEAD-US amongst staff within the STHN.

Intervention One	Site Specific Presentations
Presenter	Project lead
Audience/participants	STHN Clinical/non-clinical staff
Format	Introduction (15 minutes) The value of US in MSK care of PWH (15 minutes) Demonstration of the HEAD-US scoring (15 minutes) Patient perspective on the value of US/HEAD-US (5 minutes) Interactive opportunity to use US machine (20 minutes)
Evaluation	Pre-post questionnaires rating using Likert scale (Cox 1980)

Clinic organisation and logistics within the STHN

Intervention Two	Site specific management meetings
Participants	Site centre manager, site centre director/lead, site nurse, site physiotherapist, patient representative
Timeframe	75 minutes
Format	Introduction Agenda to include clinic timetabling, space allocation, resource & manpower planning, training and any other issues Task allocation with timeframes
Outcome	Site specific action plan for introduction of the HEAD-US protocol

Risk/anxiety associated introduction and use of a new technology/assessment technique that is not widely used within the haemophilia clinicians scope of practice

Intervention Three	Development of a competency Framework
	Initial competency framework to be developed by project lead and KCL. The competency framework will first be evaluated by two expert HEAD-US users who will be asked to provide written feedback. Further amendments will be made through the pilot exercise and throughout the period the physiotherapists are being supported in clinic (see Initiation of Head-US clinics). Once the physiotherapists have completed the competency framework they will be observed/assessed over three examinations to ensure that framework competency translates to real-world clinical competence. This will be undertaken by the project lead, the KCL collaborator and the project lead. It is anticipated that the tool will be fit for purpose/scale up by December 2017.

Lack of availability of US machines across the STHN

Intervention four	US machine rental
Machine numbers/model	Three GE Logic E US machines
Rental period	Eighteen months
Machine locations	St George's Hospital and The Evelina Children's Hospital**.**

Skill gap amongst the cohort of network physiotherapists

Intervention five	HEAD-US training
Trainers	Project lead and paediatric consultant radiologist
Course overview	A two and a half day course (in two parts) broadly following the curriculum of the Pfizer HEAD-US Preceptorship programme. Low trainer to trainee ratio and the addition of paediatric specific training. The course will combine a mix of lectures and hands-on practical sessions. Models will be recruited from inside and outside the haemophilia community
Format	Part A HEAD-US
Day one	Pre course test/quiz (10 minutes) Principles of ultrasound (60 minutes) Nobology (30 minutes) Introduction to the HEAD-US scoring system (60 minutes) Scan demonstration and anatomy of the knee. Practice on models without pathology (60 minutes) Scan demonstration and anatomy of the elbow. Practice on models without pathology (60 minutes) Scan demonstration and anatomy of the ankle. Practice on models without pathology (60 minutes)
Day two	Haemophilic arthropathy and how to score using the HEAD-US protocol (30 minutes) Supervised scanning on 4 PWH (180 minutes) 10 minutes Post course test quiz 10 minute Joint image test on HEAD-US 10 minutes Course feedback, questions and problems
Half day	Part B HEAD-US- (paediatric specific training) Pre course quiz/test (5 minutes) The application of HEAD-US as a clinical tool on paediatric PWH (60 minutes) Supervised scanning practice on 4 paediatric PWH (180 minutes) Post course quiz/test (5 minutes) Joint image test (5 minutes) Course feedback, questions and problems (15 minutes)
Evaluation	Pre/post quiz/tests and course feedback

Intervention Six — Clinical support within the review clinics

For the duration of the project the new US users (physiotherapists) will receive clinical support. The project lead will initially attend all the review clinics until the physiotherapists have completed their competences and feel confident in undertaking the HEAD-US protocol independently. On-going support will be offered during the project on a request basis. The consultant radiologist will also be available input/support at the Evelina site.

Educational principles — Interventions five and six aim to develop learning through declarative knowledge, through procedural knowledge, through to competence and performance using educational principles which have been adapted from Moore et al (2009)

d) Initiation of the HEAD-US clinics

Phase One - Pilot of review clinic using HEAD-US protocol

A four week pilot using rental US machine and supported by project lead will commence at the Evelina site. The paediatric radiologist will also be available for consultation. Stakeholders will be advised to give informal feedback throughout the pilot period. The pilot will be evaluated by undertaking fifteen minute semi-structured interviews with the site physiotherapist, consultant and two patients. Questions will be themed around the WHO healthcare building blocks (WHO 2016). Issues will also be categorised using the same framework and be discussed and managed by convening a site-specific management meeting (see intervention two).

Phase Two - Network-wide introduction of review clinics using HEAD-US assessment

HEAD-US assessment will be undertaken within the weekly review clinics at the Evelina Hospital, the bi-monthly review clinics at St George's and the bi-weekly review clinics at St Thomas'. These will include Lewisham patients who are dual registered at either the Evelina or St Thomas' hospitals'. The organisation of the clinics will be adapted (where necessary) by the pilot evaluation through the site-specific management teams. Clinics at The Evelina and St George's will be supported by the project lead until the site physiotherapist's have completed the competency framework and are confident in undertaking the HEAD-US protocol independently. The project will undergo on-going evaluation. Fifteen minutes semi-structured interviews will be undertaken with the physiotherapist, consultant and two patients after eight weeks (see pilot). Staff will be advised to contact the project lead with any service issues related to the introduction of the HEAD-US protocol. Any issues will be addressed by re-convening further site-specific management meetings.

e) Originality

An electronic keyword literature search was undertaken using Medline via NHS Athens, CINAHL via Athens and Embase via NHS Athens on the 20 July 2016. The search terms used were haemophilia, hemophilia, ultrasound, sonography and HEAD-US. These search terms were combined using AND/OR. The search was limited to publications < 10 years old and written in English. No publications were identified which pertained to quality improvement projects aimed at introducing the HEAD-US protocol.

f) Dissemination

The project lead intends to publish the results of this quality improvement project using Squire, a recognised format for the publication of quality improvement projects (Squire et al 2008). The project will be published in conjunction with academic support from King's College London. The target journal for publication will be Haemophilia. The authors intend to apply for open access to maximize the journals distribution. Application will also be made to present the project results at World Federation of Haemophilia Meeting in Glasgow 2018. The interim results of the project will be presented at the United Kingdom Haemophilia Physiotherapy Special Interest Group's national meeting in February 2018.

g) Analysis

This will use simple descriptive statistical methods. It is anticipate that the analysis will be undertaken using Microsoft Excel software.

5) Evaluation Design - In order to analyse the impact of the HEAD-US project, applications will be made to the hospitals' audit committees to interrogate patient/hospital records. Project evaluation will include;

a) Evaluation against set service standards - Greater than seventy five percent of all the network's severe or moderate PWH over the age of five are to be assessed within their annual clinical review using the HEAD-US protocol. This standard represents a one hundred percent change in review clinic assessment practice and a sixty percent improvement on the current HEAD-US scoring frequency within the STHN.

All HEAD-US assessments will be undertaken by a physiotherapist deemed competent. Competence will be measured by completion of a local competency framework. The development of the local competency framework will form part of the scope of the quality improvement project. Therefore, the current proportion of physiotherapists deemed competent within the network is zero percent. It is anticipated that the STHN will achieve a one hundred percent competency amongst the physiotherapy clinicians within six months[3]

[3] Patients will only be assessed by a physiotherapy deemed competent or being supervised by a competent colleague

b) Patient outcomes - Currently there is no clear baseline measure for the degree of joint pathology identified using US which is not evident on physical examination. Clinicians will be asked to annotate in the medical notes when new pathology has been identified through US examination alone. It is anticipated that at least ten percent more pathology will be identified using US (in the first year).

Currently there is no baseline measure for the degree to which HEAD-US assessment will influence patient management. Clinicians will be asked to annotate in the medical notes when US has changed or influenced medical management. These changes will be sub-categorised into pharmaceutical, surgical, other medical, advice or physiotherapeutic. It is anticipated that the use the HEAD-US protocol will lead to the initiation of a minimum of a 10% change in some form of patient management (within the first year).

c) Patient satisfaction - All patients will be asked to complete a brief patient satisfaction questionnaire asking them to rate the value of US examination within their clinical review. It is predicted that the majority of patients > 50% will perceive the introduction of the HEAD-US protocol as beneficial. It is not possible to measure this against any baseline.

6) Workplan/deliverables

a) Workplan

01/01/2017 – 31/01/2017

This initial planning period will entail collation of staff lists, contact telephone numbers and email addresses. During this period the US machines will be ordered via the rental company. It is anticipated that the machines will be in-situ by 1st March 2017. Doodle polls with potential dates for the barrier workshops, management meetings, staff presentations and ultrasound training will be drafted and delivered. Dates will be set for the afore-mentioned interventions and staff will be informed and asked to confirm attendance. Suitable rooms and resources will be booked for these interventions. The project lead will meet with the King's College London collaborators and a draft HEAD-US competency framework will be produced. A feedback tool to be used to adapt the draft will also be developed.

01/02/2017-28/02/2017

During the early part of this month the project lead will prepare for the barrier workshops. They will check room bookings at St Thomas', The Evelina Hospital, and St George's Hospital. They will ensure that a laptop, projector, white board and pens are available and confirm the availability of the attendees. It is anticipated that the workshops will take place during the second half of February 2017. The results of this exercise will be disseminated to the study participants and to the staff that will be involved in the management meetings via email. The draft competency framework will be reviewed in practice by two external HEAD-US users. The reviewers will be asked to provide feedback using the developed tool. After evaluation a working draft of the competency framework will prepared for use in the project pilot. During the early part of the month a PWH will be recruited to act as a model

and speak briefly about the value of HEAD-US from the patient perspective at the staff presentations. A further eight PWH (four adult/four paediatric) will be recruited to act as models at the US training course.

01/03/2017-31/3/2017

The rental ultrasound machines will arrive, allowing the project lead and the other network physiotherapists an opportunity to familiarize themselves with the machines and undertake some informal training. The staff presentation material will be prepared by the project lead including the feedback forms and questionnaires. Room bookings will be confirmed at St George's, St Thomas' and the Evelina Hospitals'. Checks will be made to ensure the availability of a laptop, projector, plinth, US machine, ultrasound gel and paper roll at each site. The project lead will ensure that the availability of the attendees. It is anticipated that the presentations will take place during the middle of March 2017. During the second half of the month checks will be made to ensure room bookings and staff availability for the site-specific management meetings. Emails will be distributed with the agenda items informed by the barrier workshops. Participants will be invited to add any relevant agenda items. Final agendas will be distributed by email.

01/4/2017-30/4/2017

It is anticipated that the site-specific management meetings will be undertaken in early April 2017. The meeting action plans will be distributed to all the participants via email. Participants will have ownership of specific tasks and these will be SMART [4]. It is anticipated that the actionable tasks will be completed by 30/4/2017. In early April the project lead will collate the course materials for the US training course and develop the Head-US training tests and questionnaires. The room booking at St Thomas' will be confirmed as will the availability of a laptop, projector, four plinths, three US machines, ultrasound gel and paper roll. Checks will be made to ensure the continued availability of the physiotherapists, the paediatric consultant radiologist and the course models. It is anticipated that HEAD-US training course will take place during late April. At the end of April checks will be undertaken to ensure that all the necessary actions have been fulfilled to allow for the commencement of the HEAD-US pilot at the Evelina clinic. This will include checking the ultrasound machine availability, ultrasound gel stocks, space allocation, HEAD-US scoring sheets and the competency framework paperwork. The project lead will prepare the semi-structured interview questions for the Pilot/ HEAD-US clinic evaluation using the WHO building block framework for healthcare (2016). The project lead will also develop the patient satisfaction questionnaire for the main project development exercise. Both the semi-structured interviews and the patient questionnaires will be developed with academic input from Kings College London.

01/5/2017-30/5/2017

The four week pilot of the HEAD-US assessment will commence in the weekly paediatric haemophilia review clinic at the Evelina Hospital. This will be attended by the project lead. At the beginning of May the project lead will schedule individual fifteen minute semi-structured interviews with the site physiotherapist, consultant and lead nurse to take place at the end of the four week period. The project lead will schedule a site-specific management to discuss and action any issues that are raised. This will be scheduled for the

[4] Specific measureable attainable relevant and time-bound

last week in May. If no issues are identified the meeting will be cancelled. Any non site-specific issues will be communicated to the other site-specific management groups. At the end of May final checks will be undertaken to ensure that all the necessary actions have been fulfilled to allow for the commencement of the HEAD-US pilot at St Thomas' and St George's Hospitals'. This will include checking the availability of the ultrasound machine, ultrasound gel stocks, space, HEAD-US scoring sheets and the competency framework paperwork.

01/5/2017-31/08/2017
Network-wide introduction of HEAD-US assessment will be undertaken within the weekly review clinics at the Evelina Hospital, the bi-monthly review clinics at St George's and the bi-weekly review clinics at St Thomas'. These clinics will be supported by the project lead until the physiotherapists have completed their competency framework. Fifteen minutes semi-structured interviews will be undertaken with the physiotherapist, consultant and two patients after eight weeks (see pilot). Staff will be advised to contact the project lead with any service issues related to the introduction of the HEAD-US protocol. Any issues will be addressed by re-convening further site-specific management meetings. It is anticipated that the physiotherapists will be competence prior to December 2017. However, the project lead and paediatric radiologist will be continue to be available for ad-hoc questions and trouble-shooting for the duration of the project.

01/01/2018-31/01/2018
The project lead will make an application to interrogate the hospital records to the audit committees of the three participating hospital sites.

01/02/2018
The project lead will prepare an interim project report and present the findings to the United Kingdom Physiotherapy Haemophilia Special Interest Group Annual Meeting. The project lead will also submit an abstract to World Federation of Haemophilia (WFH) Conference Glasgow with interim data.

01/04/2108
The project lead will register for WFH Glasgow.

01/05/2018
During early May the project will be fully audited. The project lead will receive assistance from the KCL collaborator and St Thomas' paediatric radiologist. During early May the project lead will prepare presentations for the STHN and for WFH Conference in Glasgow. It is anticipated that the STHN presentation will take place during mid-May and the WFH will take place between 20th and 24th May.

The successful implementation of the HEAD-US protocol, proven adaptations to the infrastructure, development of competency and training framework and the anticipated improvements to patient management will mean that the project lead will be in a position to initiate procurement of US machines for the network. It is anticipated that this will be a protracted process so the rental machines will be kept until August 2018 to ensure service continuity.

01/06/2018-31-08-2018
During this period the project lead will write-up the project for publication with the assistance of the KCL collaborator and the paediatric musculoskeletal radiologist. It is planned that the first draft article will be submitted to Haemophilia by the end of August 2018.

b) Deliverables schedule- See Appendix A

7) Table of deliverables schedule – Appendix

Deliverable	**Schedule**
Barrier Analysis workshop	February 2017
Development of competency framework	February 2017
Staff presentations	March 2017
Site specific management meetings	April 2017
US hire	March 2017
US training	April 2017
Pilot clinic at Evelina	May 2017
Completion of adaptions to Competency Framework (if required)	May 2017
Trust wide HEAD-US review clinics	June 2017
Applications to Trust audit committees	January 2018
Presentation of interim results at United Kingdom Physiotherapy Special Interest Group's Annual General Meeting	February 2018
Full project audit	May 2018
Presentation of results to STHN	May 2018
Conference presentation Glasgow WFH	May 2018
Procurement process for ultrasound machines	May 2108
Return of rental ultrasound machines	August 2018
Project write up and journal submission	Sept 2018

8) References

ALTISENT, C., MARTORELL, M., CRESPO, A., CASAS, L., TORRENTS, C. & PARRA, R. 2015. Early prophylaxis in children with severe haemophilia A: clinical and ultrasound imaging outcomes. *Haemophilia*.

ANDERSON, D. D., CHUBINSKAYA, S., GUILAK, F., MARTIN, J. A., OEGEMA, T. R., OLSON, S. A. & BUCKWALTER, J. A. 2011. Post-traumatic osteoarthritis: improved understanding and opportunities for early intervention. *J Orthop Res,* 29**,** 802-9.

CAVAZZA, M., KODRA, Y., ARMENI, P., DE SANTIS, M., LOPEZ-BASTIDA, J., LINERTOVA, R., OLIVA-MORENO, J., SERRANO-AGUILAR, P., POSADA-DE-LA-PAZ, M., TARUSCIO, D., SCHIEPPATI, A., ISKROV, G., GULACSI, L., VON DER SCHULENBURG, J. M., KANAVOS, P., CHEVREUL, K., PERSSON, U. & FATTORE, G. 2016. Social/economic costs and quality of life in patients with haemophilia in Europe. *Eur J Health Econ,* 17 Suppl 1**,** 53-65.

CEPONIS, A., WONG-SEFIDAN, I., GLASS, C. S. & VON DRYGALSKI, A. 2013. Rapid musculoskeletal ultrasound for painful episodes in adult haemophilia patients. *Haemophilia,* 19**,** 790-8.

COX EP(1980). The optimal number of response alternatives for a scale: a review. Journal of Marketing Research, 17, 407-442.

DI MINNO, M. N., AMBROSINO, P., QUINTAVALLE, G., COPPOLA, A., TAGLIAFERRI, A., MARTINOLI, C. & RIVOLTA, G. F. 2016. Assessment of Hemophilic Arthropathy by Ultrasound: Where Do We Stand? *Semin Thromb Hemost,* 42**,** 541-9.

DI MINNO, M. N., IERVOLINO, S., SOSCIA, E., TOSETTO, A., COPPOLA, A., SCHIAVULLI, M., MARRONE, E., RUOSI, C., SALVATORE, M. & DI MINNO, G. 2013. Magnetic resonance imaging and ultrasound evaluation of "healthy" joints in young subjects with severe haemophilia A. *Haemophilia,* 19**,** e167-73.

DIETRICH, C. F., GOUDIE, A., CHIOREAN, L., CUI, X. W., GILJA, O. H., DONG, Y., ABRAMOWICZ, J. S., VINAYAK, S., WESTERWAY, S. C., NOLSOE, C. P., CHOU, Y. H. & BLAIVAS, M. 2016. Point of Care Ultrasound: A WFUMB Position Paper. *Ultrasound Med Biol*.

DOLAN, G., MAKRIS, M., BOLTON-MAGGS, P. H. & ROWELL, J. A. 2014. Enhancing haemophilia care through registries. *Haemophilia,* 20 Suppl 4**,** 121-9.

FELDMAN, B. M., FUNK, S. M., BERGSTROM, B. M., ZOURIKIAN, N., HILLIARD, P., VAN DER NET, J., ENGELBERT, R., PETRINI, P., VAN DEN BERG, H. M., MANCO-JOHNSON, M. J., RIVARD, G. E., ABAD, A. & BLANCHETTE, V. S. 2011. Validation of a new pediatric joint scoring system from the International Hemophilia Prophylaxis Study Group: validity of the hemophilia joint health score. *Arthritis Care Res (Hoboken),* 63**,** 223-30.

FOPPEN, W., VAN DER SCHAAF, I. C. & FISCHER, K. 2016. Value of routine ultrasound in detecting early joint changes in children with haemophilia using the 'Haemophilia Early Arthropathy Detection with UltraSound' protocol. *Haemophilia,* 22**,** 121-5.

GUY'S AND ST THOMAS' NHS FOUNDATION TRUST (GSTT) 2016 *About us* Available from http://www.guysandstthomas.nhs.uk/about-us/about-us.aspx Accessed October 2016

INSTITUTE OF HEALTH IMPROVEMENT (IHI) 2016 Institute of Health Improvement - How to improve Available from; *http://www.ihi.org/resources/Pages/HowtoImprove/default.aspx* [Accessed July 2016]

JOHNSON, V. L. & HUNTER, D. J. 2014. The epidemiology of osteoarthritis. *Best Pract Res Clin Rheumatol,* 28**,** 5-15.

LEE N. 2006 Service quality models International Journal of Quality and Reliability Management Vo:22 p 913-949

LOBET, S., HERMANS, C. & LAMBERT, C. 2014. Optimal management of hemophilic arthropathy and hematomas. *J Blood Med,* 5**,** 207-18.

LUZ, K. R., PINHEIRO, M. M., PETTERLE, G. S., DOS SANTOS, M. F., FERNANDES, A. R., NATOUR, J. & FURTADO, R. N. 2016. A new musculoskeletal ultrasound scoring system (US10) of the hands and wrist joints for evaluation of early rheumatoid arthritis patients. *Rev Bras Reumatol Engl Ed,* 56**,** 421-431.

MANCO-JOHNSON, M. 2007. Comparing prophylaxis with episodic treatment in haemophilia A: implications for clinical practice. *Haemophilia,* 13 Suppl 2**,** 4-9.

MANNUCCI, P. M. 2002. Hemophilia and related bleeding disorders: a story of dismay and success. *Hematology Am Soc Hematol Educ Program***,** 1-9.

MARTINOLI, C., DELLA CASA ALBERIGHI, O., DI MINNO, G., GRAZIANO, E., MOLINARI, A. C., PASTA, G., RUSSO, G., SANTAGOSTINO, E., TAGLIAFERRI, A., TAGLIAFICO, A. & MORFINI, M. 2013. Development and definition of a simplified scanning procedure and scoring method for Haemophilia Early Arthropathy Detection with Ultrasound (HEAD-US). *Thromb Haemost,* 109**,** 1170-9.

MARTINOLI, C., DI MINNO, M. N., PASTA, G. & TAGLIAFICO, A. 2016. Point-of-care ultrasound in haemophilic arthropathy: will the HEAD-US system supplement or replace physical examination? *Haemophilia,* 22**,** 20-1.

PEYVANDI, F., GARAGIOLA, I. & BIGUZZI, E. 2016. Advances in treatment of bleeding disorders. *J Thromb Haemost*.

PFIZER RFP (2016) *RFP HEAD-US Haemophilia Early Arthropathy Detection with UltraSound (HEAD-US) Protocol for Routine Joint Assessment of Haemophilia Patients* Available from http://www.pfizer.com/sites/default/files/rfp_files/IGLC_RFP_2016HM1_Ultrasound Haemophilia_Europe.pdf

RODRIGUEZ-MERCHAN, E. C. 1994. [Pathology of the knee in the hemophiliac patient]. *Rev Clin Esp,* 194**,** 498-502.

Accessed October 2016

SIERRA AISA, C., LUCIA CUESTA, J. F., RUBIO MARTINEZ, A., FERNANDEZ MOSTEIRIN, N., IBORRA MUNOZ, A., ABIO CALVETE, M., GUILLEN GOMEZ, M., MORETO QUINTANA, A. & RUBIO FELIX, D. 2014. Comparison of ultrasound and magnetic resonance imaging for diagnosis and follow-up of joint lesions in patients with haemophilia. *Haemophilia,* 20**,** e51-7.

ST GEORGE'S HEALTHCARE TRUST (SGHT) 2016 *About us*
Available from https://www.stgeorges.nhs.uk/about/
Accessed October 2016

STRIKE, K. L., IORIO, A., JACKSON, S., LAWSON, W., SCOTT, L., SQUIRE, S. & CHAN, A. K. 2015. Point of care ultrasonography in haemophilia care: recommendations for training and competency evaluation. *Haemophilia,* 21**,** 828-31.

TAGUE AND Nancy R (1990) Seven Basic Quality Tools The Quality Toolbox Milwaulkee, Wisconsin

TAMAS, M. M., REDNIC, N., FELEA, I. & REDNIC, S. 2013. Ultrasound assessment for the rapid classification of early arthritis patients. *J Investig Med,* 61**,** 1184-91.

TIMES HIGHER EDUCATIONAL SUPPLEMENT (2016) *World University rankings*
Available from https://www.timeshighereducation.com/world-university-rankings
Acccessed October 2016

UNITED KINGOM HAEMOPHILIA DOCTORS ORGANISATION (UKHCDO) 2013 *Outcomes Group minutes* Available from http://www.ukhcdo.org/docs/AnnualReports/2012/3bClinical%20Outcomes%20Group%202012.pdf
Accessed October 2016

WILSON, D. J., MCLARDY-SMITH, P. D., WOODHAM, C. H. & MACLARNON, J. C. 1987. Diagnostic ultrasound in haemophilia. *J Bone Joint Surg Br,* 69**,** 103-7.

WORLD HEALTH ORGANISATION (WHO) (2016) Health System Building Blocks
Available from http://www.wpro.who.int/health_services/health_systems_framework/en/
[Accessed July 2016]