

## Bursary recipient Progress Report

Part 1: Project Details			
Principal grant holder's name	Katie Morris and Mark Kilby		
Contact email	XXXXXXXX		
Contact telephone number			
Organisation where grant is held	Birmingham Women's Hospital		
Project title	Core Outcome Set - Twins		
Project start date	January 2019	Project end date	April 2020
Type of project (project, studentship fellowship)	Project		
Date report due	31/12/2019		
Part 2: Progress report			
<p><b>Please provide a detailed report describing the progress of the research, the extent to which the original aims and objectives of the research have been achieved and the scientific and/or technological achievements of the research. This should be not more than two pages of A4.</b></p>			
<p>There are three distinct stages in the COS development: 1) Identifying all possible twin pregnancy outcomes via a systematic review and qualitative interviews; 2) Determining which of those outcomes should form the COS via a Delphi survey; 3) Deciding how each core outcome within the COS should be defined and measured via a consensus meeting. We are currently midway through the second stage and will have completed the project by April 2020.</p> <p>Initially we conducted a systematic review to identify outcomes that have previously been reported in twin pregnancy randomised control trials and their follow up studies. This systematic review was registered on PROSPERO (CRD42019133805) and COMET database and performed according to recommended methods and reported according to PRISMA and COMET guidance. Electronic database searches were executed on multiple relevant databases and the search located 1113 primary articles, of these, 661 duplicated articles were removed. The titles and abstracts of 452 articles were reviewed by two review authors of which 344 were excluded leaving 108 potentially relevant articles for full manuscript review. Of the 108 articles, 51 were not eligible and therefore excluded consequently, 57 trials were eligible for data analysis; 48 RCTs and 9 RCT follow up studies.</p> <p>Data was then extracted in duplicated using a piloted data proforma and descriptive analyses were completed. 1225 verbatim outcomes were reported which were categorised into 170 unique outcomes, these outcomes will be used to form part of the comprehensive outcome inventory required for the Delphi survey. Furthermore this systematic review also illustrates the significant heterogeneity across outcome reporting within clinical trials in twin pregnancy and also highlights the inconsistencies within outcome definitions and measurements. The Systematic review is in the final stages of the write up and will be submitted for publication thereafter.</p> <p>The necessary study documents for the Qualitative focus groups including the IRAS form, study protocol, patient information sheet, consent form and patient recruitment posters have been created and finalised. All study documents have been reviewed and approved by Health Research Authority (HRA) (IRAS project ID 263702) and a favourable opinion has been given by Yorkshire &amp; The Humber - South Yorkshire Research Ethics Committee (19/YH/0191). The study has been accepted for sponsorship by</p>			

The Birmingham Women's Hospital Foundation Trust (18/BW/MAT/PO36) and has also been adopted as a NIHR CRN West Midlands portfolio study. The study is awaiting confirmation of capacity and capability from the Research and Development (R&D) department of Birmingham Women's and Children's Foundation Trust. Once we have received this correspondence, which we have been advised will be no later than the 20/12/2019 patient recruitment into the focus groups will commence. Patients will be recruited from focused twin pregnancy antenatal clinics, twin parent education classes and twin parent toddler support groups. Focus groups are being held on the 15/01/2020 and will be executed by our research fellow Nicola Farmer. Once the focus groups have been completed, transcribed and analysed the outcomes identified will be combined with the outcomes collected in the systematic review to form a comprehensive outcome inventory. An international Delphi survey will be commenced in February and completed by April if there are three round of Delphi survey required. However most Delphi surveys only require two rounds of survey and therefore we believe the Delphi survey will be completed by March with the consensus meeting being held mid-March. If the Delphi survey does require three rounds the consensus meeting will be held mid-April to formalise the Core Outcome Set.

All funds provided from TAMBA are being used to employ our research fellow Nicola Farmer who will complete the project. Nicola Farmer is currently completing an MSc in Research at the University of Birmingham and is using this project as her thesis, therefore the Delphi survey software is being provided for free by the University of Birmingham. The monies for the transcription of the focus groups and consensus meeting are coming from other funds. Once Nicola Farmer has been appointed there was a delay in her starting her post due to matters out of our control.

Month	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	mar	Ari
Study set up & ethical approval	X	X	X	X						
Systematic review	X	X	X	X						
Write up and publication					X	X				
Focus group enrolment						X				
Focus groups							X			
Focus group analysis							X			
Panel enrolment						X	X			
Delphi phase 1							X			
Delphi phase 2								X		
Delphi phase 3 (may not be required)									X	
Consensus meeting										X

**Please describe the main conclusions you have reached from the research.**

**Have there been any deviations from the original research plan? If yes, please give details.**

The timeline for the project has been delayed secondary to the appointment of a suitable research fellow to conduct the project.

This has now been brought back on track and we anticipated a fully developed COS to be published in 2020.

**Please describe any problems you have encountered during the project.**

### **Part 3: Lay language progress report**

**Please describe the progress of the research in lay language.**

There are three phases in Core Outcome Set (COS) development: 1) Identifying all possible twin pregnancy outcomes via a systematic review and qualitative interviews; 2) Determining which of those outcomes should form the COS via a Delphi survey; 3) Deciding how each core outcome within the COS should be defined and measured via a consensus meeting. We are currently midway through the second stage and will have completed the project by April 2020.

Initially we conducted a systematic review to identify outcomes that have previously been reported in twin pregnancy randomised control trials and their follow up studies. This systematic review was registered on PROSPERO (CRD42019133805) and COMET database and performed according to recommended methods and reported according to PRISMA and COMET guidance. Electronic database searches were executed on multiple relevant databases

1225 as documented outcomes were reported which were categorised into 170 unique outcomes, these outcomes will be used to form part of the comprehensive outcome inventory required for the Delphi survey. Furthermore this systematic review also illustrates the significant heterogeneity across outcome reporting within clinical trials in twin pregnancy and also highlights the inconsistencies within outcome definitions and measurements. The Systematic review is in the final stages of the write up and will be submitted for publication thereafter.

### **Part 4: Future Research**

**Please describe your future plans based on the outcomes of this research.**

The COS will be useful to all projects conduct research involving twins.

Further work will be needed to define definitions for some of the outcomes selected.

**Has the research led (or do you expect the research to lead) to other successful or pending grant applications? If yes, please provide details below.**

The research has already contributed to a grant application SLIGHT for a HTA funded study to determine whether an RCT for the management of selective IUGR in MCDA twins is feasible/appropriate. It is anticipated that through the consensus meeting other questions for research/themes will be identified. We shall work with the collaborators within this project to develop these as either PICOS for submission to the HTA or other funding bodies e.g. RfPB.

**Has the research led to other academic or industrial collaborations? If yes, please provide details below.**

This research has led to academic collaborations with qualitative researchers and researchers within a similar field at other institutions across the UK is anticipated through the Delphi and consensus meeting

**Part 5: Outputs and outcomes**

**Please list all publications that have arisen from this grant to date, including any that are currently in press. If possible, please send a copy of publications with this report.**

Nil at present.  
 Anticipate the systematic review of the outcomes in twin studies.  
 Qualitative outcomes and then final COS.

**Please list all oral and poster presentations that have arisen from this grant to date, including any that are currently submitted. If possible, please send a copy of the abstracts with this report.**

Nil at present.  
 Abstract for systematic review submitted to Perinatal 2020

**Has the research led to any commercial or potential commercial exploitations to date? If yes, please describe the nature of this and if patents have been filed please give details.**

No

**Please provide a full financial summary of this project. If additional rows for staff are required please insert these. Please provide a breakdown of materials and consumables cost.**

	Year 1	Year 2	Total
<b>Staff costs</b>			
Post 1 Basic Salary (name staff)			
Employers contributions			
<b>Materials and Consumables</b> (please provide a breakdown)			
Expenses – please detail			
<b>Total</b>			

**Are there any variations between the original awarded costs and the full financial summary of this project? Please provide an explanation below.**

**Part 6: Signature of principal grant holder and financial authority of your institute**

Print Name	Signature	Date	Position
R K Morris		17 <sup>th</sup> February 2019	Chief Investigator

**Thank you for taking the time to complete this final report and informing us of your progress**