THEME [HEALTH.2010.3.4-2]
[Feasibility and community effectiveness of innovative intervention packages for maternal and new-born health in Africa]

Grant agreement for: Collaborative project[*]

Annex I - "Description of Work"

Project acronym: ETATMBA

Project full title: " Enhancing Human Resources and Use of Appropriate Technologies for Maternal and Perinatal Survival In Sub-Saharan Africa "

Grant agreement no: 266290

Version date:

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A1:
Project summary

Project Number [1]	266290	Project Acronym [2]	ETATMBA

One form per project

General information			
Project title [3]	Enhancing Human Resources and Use of Appropriate Technologies for Maternal and Perinatal Survival In Sub-Saharan Africa		
Starting date [4]	01/02/2011		
Duration in months [5]	42		
Call (part) identifier [6]	FP7-AFRICA-2010		
Activity code(s) most relevant to your topic [7]	HEALTH.2010.3.4-2: Feasibility and community effectiveness of innovative intervention packages for maternal and new-born health in Africa		

Abstract [9]

Most African women face childbirth without access to skilled health workers when obstetric and neonatal emergencies arise. Providing and retaining skilled health workers is vital in attempts to save the 600,000 women and 7 million babies who die annually in Africa. In the modern world this tragedy is unacceptable and largely preventable. Education and training for health professionals is the key to improving healthcare for mothers and babies in Africa. Non-Physician Clinicians (NPCs) are an effective and retainable health solution for doctor-less rural and some urban areas of Africa. Task shifting to NPCs needs to be extended, enhanced, endorsed and supported by the healthcare community and will be the aim of Work Package 1 (WP1) and WP3.
The project aims to develop, implement and evaluate clinical service improvement through clinical guidelines and pathways in WP2, structured education and clinical leadership training (WP3) and workforce development of NPCs and faculty (WP1, WP3). A key element will be continuing support for NPCs in the workplace using communications technology and mentorship from local and international physicians (WP1, WP3).
All service improvements will be sustainable, scalable, cost-effective, transferrable and co-developed by professional partners in Africa. Bringing together key European and African partners with GE Healthcare to address the major issues of enhancing a sustainable healthcare workforce and enhancing appropriate training in the use of existing technologies should help to significantly reduce the loss of mothers and babies in Africa.

A2:
List of Beneficiaries

Project Number [1]	266290	Project Acronym [2]	ETATMBA

List of Beneficiaries

No	Name	Short name	Country	Project entry month[10]	Project exit month
1	THE UNIVERSITY OF WARWICK	Warwick	United Kingdom	1	42
2	KAROLINSKA INSTITUTET	KI	Sweden	1	42
3	Malawi Ministry of Health	MMOH	Malawi	1	42
4	IFAKARA HEALTH INSTITUTE TRUST	IHI	Tanzania (United Republic of)	1	42
5	GE HEALTHCARE LIMITED	GE	United Kingdom	1	42
6	UNIVERSITY OF MALAWI	UOM	Malawi	1	42

A3:
Budget Breakdown

Project Number [1]	266290	Project Acronym [2]	ETATMBA

One Form per Project

Participant number in this project [11]	Participant short name	Fund. % [12]	Ind. costs [13]	Estimated eligible costs (whole duration of the project)					Total receipts	Requested EU contribution
				RTD / Innovation (A)	Demonstration (B)	Management (C)	Other (D)	Total A+B+C+D		
1	Warwick	75.0	T	592,432.53	0.00	180,726.00	58,694.40	831,852.93	0.00	683,744.00
2	KI	75.0	T	650,001.60	0.00	3,500.00	0.00	653,501.60	0.00	491,000.00
3	MMOH	75.0	T	115,468.80	0.00	2,588.00	10,563.20	128,620.00	0.00	99,752.00
4	IHI	75.0	T	1,061,795.20	0.00	2,588.00	10,563.20	1,074,946.40	0.00	809,497.00
5	GE	50.0	S	20,000.00	0.00	0.00	0.00	20,000.00	0.00	10,000.00
6	UOM	75.0	T	671,168.00	0.00	2,588.00	0.00	673,756.00	0.00	505,964.00
Total				3,110,866.13	0.00	191,990.00	79,820.80	3,382,676.93	0.00	2,599,957.00

Note that the budget mentioned in this table is the total budget requested by the Beneficiary and associated Third Parties.

*** The following funding schemes are distinguished**

Collaborative Project (if a distinction is made in the call please state which type of Collaborative project is referred to: (i) Small of medium-scale focused research project, (ii) Large-scale integrating project, (iii) Project targeted to special groups such as SMEs and other smaller actors), Network of Excellence, Coordination Action, Support Action.

1. Project number

The project number has been assigned by the Commission as the unique identifier for your project, and it cannot be changed. The project number **should appear on each page of the grant agreement preparation documents** to prevent errors during its handling.

2. Project acronym

Use the project acronym as indicated in the submitted proposal. It cannot be changed, unless agreed during the negotiations. The same acronym **should appear on each page of the grant agreement preparation documents** to prevent errors during its handling.

3. Project title

Use the title (preferably no longer than 200 characters) as indicated in the submitted proposal. Minor corrections are possible if agreed during the preparation of the grant agreement.

4. Starting date

Unless a specific (fixed) starting date is duly justified and agreed upon during the preparation of the Grant Agreement, the project will start on the first day of the month following the entry info force of the Grant Agreement (NB : entry into force = signature by the Commission). Please note that if a fixed starting date is used, you will be required to provide a detailed justification on a separate note.

5. Duration

Insert the duration of the project in full months.

6. Call (part) identifier

The Call (part) identifier is the reference number given in the call or part of the call you were addressing, as indicated in the publication of the call in the Official Journal of the European Union. You have to use the identifier given by the Commission in the letter inviting to prepare the grant agreement.

7. Activity code

Select the activity code from the drop-down menu.

8. Free keywords

Use the free keywords from your original proposal; changes and additions are possible.

9. Abstract

10. The month at which the participant joined the consortium, month 1 marking the start date of the project, and all other start dates being relative to this start date.

11. The number allocated by the Consortium to the participant for this project.

12. Include the funding % for RTD/Innovation – either 50% or 75%

13. Indirect cost model
A: Actual Costs
S: Actual Costs Simplified Method
T: Transitional Flat rate
F :Flat Rate

Workplan Tables

Project number

266290

Project title

ETATMBA—Enhancing Human Resources and Use of Appropriate Technologies for Maternal and Perinatal Survival In Sub-Saharan Africa

Call (part) identifier

FP7-AFRICA-2010

Funding scheme

Collaborative project

WT1
List of work packages

Project Number [1]	266290	Project Acronym [2]	ETATMBA

LIST OF WORK PACKAGES (WP)

WP Number [53]	WP Title	Type of activity [54]	Lead beneficiary number [55]	Person-months [56]	Start month [57]	End month [58]
WP 1	Developing the workforce by training Non-Physician Clinicians in more advanced obstetric care	RTD	4	142.00	1	42
WP 2	Developing improved clinical guidelines and pathways for local African Context and evaluation.	RTD	2	72.00	1	42
WP 3	Clinical Education, leadership management training and creation of a professional support network	RTD	1	86.00	1	42
WP 4	Dissemination and outreach	OTHER	1	7.00	1	42
WP 5	Project Management	MGT	1	74.00	1	42
			Total	381.00		

WT2:
List of Deliverables

Project Number [1]	266290	Project Acronym [2]	ETATMBA

List of Deliverables - to be submitted for review to EC							
Delive-rable Number [61]	Deliverable Title	WP number [53]	Lead benefi-ciary number	Estimated indicative person-months	Nature [62]	Dissemi-nation level [63]	Delivery date [64]
D1.1	50 NPCs as advanced leaders will be recruited and trained	1	1	85.00	R	PU	24
D2.2	Improved clinical guidelines developed	2	2	32.00	R	PU	12
D2.3	Evaluation Report on the impact of the interventions	2	2	32.00	R	PU	36
D3.4	Develop programme and engage local medical staff in delivery of training in clinical education, lea	3	1	27.00	R	PU	24
D3.5	Pilot professional support and mentoring network	3	1	27.00	R	PU	24
D4.6	Website developed	4	1	7.00	R	PU	3
			Total	210.00			

Project Number [1]	266290	Project Acronym [2]	ETATMBA

One form per Work Package

Work package number [53]	WP1	Type of activity [54]	RTD
Work package title	Developing the workforce by training Non-Physician Clinicians in more advanced obstetric care		
Start month	1		
End month	42		
Lead beneficiary number [55]	4		

Objectives

• To develop and implement a training/structured educational programme for NPCs who can diagnose, prescribe and perform surgery and through mentoring, support and resource turn this healthcare workforce into more advanced leaders in obstetric care.

• To fully involve the local medical profession in the educational leadership and support of this workforce and in the research to evaluate the evidence.

• To develop the clinical knowledge and skills coupled with training on the use of non-surgical treatments and technology that will enable this workforce to improve outcomes (1,8,10,11,12).

• To produce clinical guidelines and pathways for NPCs that support clinical decision-making, audit and professional development.

• To research the costs and benefits for continued clinical education, on the job managerial training and structured continued professional development for NPCs.

• To establish academic and managerial rigour in clinical service improvement in maternal and neonatal healthcare by training local medical profession and managers in this new discipline so they can undertake their own local monitoring and redesign to ensure continuous improvement.

Description of work and role of partners

Background

NPCs in Malawi and Tanzania can diagnose, prescribe and perform surgery and NPCs with specialist skills exist in 25 of 47 nations of sub-Saharan Africa (10) and already some perform major obstetric surgery in four of them (Mozambique, Tanzania, Malawi and Zambia) (1,6,11,12,13). A recent review from Tanzania has provided evidence that training this workforce can provide emergency obstetric surgery and management that is as effective as the care provided by physicians (6). Non-Physician Clinicians have been shown to be the effective health solution for doctor-less rural areas of Africa (1,6,11,12,13) where their retention rates are high (11). While a recognised success, they need frameworks of professional development and full integration and recognition within the health communities of sub-Saharan Africa. This remains a key component for sustainability of what has been an extremely effective, economic and pragmatic solution to the local medical acute shortfall in physician manpower.

Description of work and role of participants

1.1 Curriculum assessment and teaching resource development.
We will customise and develop the learning objectives and curriculum from the Gotland courses that have been held annually in Sweden and pioneered over years. Develop distance learning and e-learning tools to facilitate and augment the delivery of this package. Develop robust, reliable and accepted assessment methods

of clinical competences. Leadership skills and understanding the clinical systems improvement philosophy and management training will be integrated in all teaching.

1.2 Selection of Advanced Leaders from Malawi and Tanzania from existing NPCs.
50 NPCs from participant countries will be selected as suitable for advanced leader status and training and invited and funded to attend the structured education programme. These course participants will become local experts to develop the 'Gotland- in-Africa' courses to NPCs in their own regional areas. This will allow for a cascade of development for the African NPC workforce. The advanced leaders will act as foci for educational leadership throughout Tanzania and Malawi and will establish in their own regions training modules and work with local faculties that are derived from specialist experts. Distance learning materials and expertise will be provided and GE Healthcare will be involved in stimulating and supporting the delivery of management training to advanced leader NPCs and doctors at a local level.

1.3 Engagement of local medical profession.
Postgraduate training courses in leadership, critical appraisal of evidence, research methodology and clinical systems improvement and management will be developed and targeted on key established medical professionals who will be recruited to support the project. International collaboration and the support of providing new advanced skills and knowledge and involvement in the research and teaching programme will be incentives for the engagement of the profession and success of the integration of the NPCs. Staff from Warwick, Karolinska and GE Healthcare working closely with partner institutes will identify the clinical leaders that can drive this process forward. It is anticipated that the key role of Senior Clinical Research Fellow will be of professorial status with joint appointments across African partner universities and will develop as the African champion for this development.

1.4 Establish local faculties for training and research and to build capacity in Tanzania and Malawi.
Capacity building will include the development of research students (4 PhD/Masters) engaged in the healthcare delivery and appropriate technology aspects of the project and joint supervisors will assist in the development of local faculties. Training and research training opportunities will be provided in health data monitoring, critical analysis of healthcare performance, research methodology and will include management and leadership training.

1.5 Establish evaluation of the effectiveness of intervention.
After data collection to establish baseline and implementation of training evaluation to establish the evidence of the effectiveness of the training will be designed and reported.

Person-Months per Participant

Participant number [10]	Participant short name [11]	Person-months per participant
1	Warwick	13.00
2	KI	16.00
3	MMOH	16.00
4	IHI	56.00
6	UOM	41.00
	Total	142.00

List of deliverables

Deliverable Number [61]	Deliverable Title	Lead beneficiary number	Estimated indicative person-months	Nature [62]	Dissemination level [63]	Delivery date [64]
D1.1	50 NPCs as advanced leaders will be recruited and trained	1	85.00	R	PU	24
		Total	85.00			

Description of deliverables

D1.1) 50 NPCs as advanced leaders will be recruited and trained: 50 NPCs as advanced leaders will be recruited and trained [month 24]

Schedule of relevant Milestones

Milestone number [59]	Milestone name	Lead beneficiary number	Delivery date from Annex I [60]	Comments
MS2	Engage with local healthcare community and establish baseline data, contracts, agreements.	4	6	Reports on baseline data
MS8	Recruit NPCs for ‘Advanced Leader’ training	4	12	Report to steering and sponsors
MS12	Faculty development programmes established and delivered and initial 20 NPCs trained as Advanced Lea	1	18	Programme and Periodic report 1
MS14	Final 30 NPCs trained as Advanced Leaders	1	24	Report
MS18	Third year report on audit and development of obstetric process indicators	2	36	Periodic report 2

WT3:
Work package description

Project Number [1]	266290	Project Acronym [2]	ETATMBA

One form per Work Package

Work package number [53]	WP2	Type of activity [54]	RTD
Work package title	Developing improved clinical guidelines and pathways for local African Context and evaluation.		
Start month	1		
End month	42		
Lead beneficiary number [55]	2		

Objectives

• Overall objective is to effectively adapt existing evidence-based clinical guidelines in maternal and newborn health to low resourced health communities.

• To determine appropriate clinical guidelines and pathways for the triage and treatment of emergency maternal and newborn cases.

• To develop guidelines and systems in postnatal care that are grounded in the limitations of available resources and staffing and develop innovative local support mechanisms.

• To design intervention studies and criterion based audit to assess effect of application of guideline technology on clinical practice, perceptions and maternal and neonatal outcomes.

• To evaluate the effect of guidelines, training, clinical education and mentorship support of NPCs in changing practice.

• To establish research and build research capacity in the evaluation of the effectiveness of this intervention programme.

Description of work and role of partners

Background

Considerable variability exists in patient management in obstetric and neonatal practice and poor clinical practice exists in both rural and urban areas of Africa. It is recognised that major improvements can be made in service delivery by achieving standardisation of approach. There is a need to define, analyse and refine clinical systems to improve reproductive healthcare. Problems need to be solved locally by local professionals: training in management and clinical leadership skills and in the ability to safely innovate is crucial to this workforce development. Evaluations of improvements that have been made in clinical services suggest that the biggest gains, especially in low income countries, derive from the consistent and reliable delivery of care that we already know to work.

Description of work and role of participants

2.1 Form groups with experts in service improvement in Tanzania and Malawi to analyse local clinical practice and develop clinical guidelines and pathways. Training in the ability to safely innovate in reaching solutions for local problems will be a crucial part of the ethos of the technology developed.

2.2 Engage international experts in scrutiny and development of these guidelines.

2.3 Develop pilot studies on feasibility and acceptability of guidelines deriving feedback from end users to reformulate guidelines and pathways. Research into the improvement of clinical systems and the most effective utilisation of healthcare resources are key constituents.
Much of this work will occur in an exploratory trial in these centres which will scope the fit for each area and refine the application of the complex intervention.

2.4 Introduce regular (monthly) criterion based audit sessions on implementation of guidelines as part of in-service staff and NPC training.

2.5 Develop, evaluate and report obstetric process indicators.

2.6 To assist NPCs in triage of maternal and neonatal care and to further support data gathering for audit and research. It is proposed to link pregnant women and new mothers via mobile phones to advanced leader NPCs for advice and the detection and earlier transfer of problems in pregnancy.

2.7 Engage local and international ethics committees on issues related to guidelines and research methods and gain approvals from all local, government and university governance processes.

2.8 Disseminate and publish guidelines and pathways and the initial experience and audits utilising their own websites and national and international journals.

2.9 The evaluation of the training, guidelines, clinical education and support network will involve;
a) Process evaluation of the implementation of the training.
b) Educational evaluation for the assessment of the educational impact of the training.
c) Description of obstetric need and practice in the localities where the trainees practice.
d) Analysis, identification and description of changes in obstetric need and practice as a result of the training.
2.10 Developing Research.
As part of developing research infrastructure high quality PhD programmes based in Malawi and Tanzania, but with supervision from Warwick and Karolinska and linked to internationally recognised training schemes, will be developed and involved in research into evaluation.

Person-Months per Participant

Participant number [10]	Participant short name [11]	Person-months per participant
1	Warwick	2.00
2	KI	22.00
3	MMOH	6.00
4	IHI	36.00
6	UOM	6.00
	Total	72.00

List of deliverables

Deliverable Number [61]	Deliverable Title	Lead beneficiary number	Estimated indicative person-months	Nature [62]	Dissemination level [63]	Delivery date [64]
D2.2	Improved clinical guidelines developed	2	32.00	R	PU	12
D2.3	Evaluation Report on the impact of the interventions	2	32.00	R	PU	36
		Total	64.00			

Description of deliverables

D2.2) Improved clinical guidelines developed: Improved clinical guidelines developed [month 12]

D2.3) Evaluation Report on the impact of the interventions: Evaluation Report on the impact of the interventions [month 36]

Schedule of relevant Milestones

Milestone number [59]	Milestone name	Lead beneficiary number	Delivery date from Annex I [60]	Comments
MS2	Engage with local healthcare community and establish baseline data, contracts, agreements.	4	6	Reports on baseline data
MS5	Design of evaluation	1	9	Design reports at 12 mths
MS6	Initial training of research staff	4	12	Training programme
MS9	Finalise design of curricula, guidelines, content and assessments of all training programmes	2	12	Written guidelines curriculum documents and assessments
MS10	Establish criterion based audit sessions	2	12	Programme
MS11	Annual summary report of development of obstetric process indicators	2	12	Written report
MS16	Second report of audit and development of obstetric process indicators	2	24	Report
MS17	Evaluation report on interventions and training	1	36	Reports, symposia, abstracts, papers

WT3:
Work package description

Project Number [1]	266290	Project Acronym [2]	ETATMBA

One form per Work Package

Work package number [53]	WP3	Type of activity [54]	RTD
Work package title	Clinical Education, leadership management training and creation of a professional support network		
Start month	1		
End month	42		
Lead beneficiary number [55]	1		

Objectives

• To improve maternal and perinatal morbidity and mortality by improving clinical education, leadership training and the creation of a professional support network.

• To establish a culture of team working and engagement through training and shared educational resources.

• To pilot a round-the-clock communications systems to provide professional support for NPCs and outreach health workers in their delivery of emergency obstetric care in remote and rural areas.

• To empower all healthcare professionals to improve reciprocal respect, reduce isolation, enhance standards and improve performance.

• To effectively implement adapted clinical guidelines in maternal and newborn health with a low cost model of training and certification.

Description of work and role of partners

Background

The concept of this work package is that clinical practice could be improved with new models developed locally and with sustainable continuing education. Karolinska has provided international leadership in pioneering training for NPCs and evaluating its effectiveness (1,6,11,12,13,14). Warwick has the capacity and reputation in professional training in health and the track record of providing this on a large scale. Warwick advanced leader programmes have allowed over 10,000 health professionals to be trained in disease management. In the UK in the last decade this approach has facilitated the safe management of diabetes from secondary to primary care staff (15,16,17). The principles of this design and a combination of distance delivery technologies will allow the delivery of an education programme that enhances the knowledge and professional skills of NPCs in rural Africa.

3.1 Initial and continuing clinical Education to support implementation of clinical guidelines.
Clinical education will be planned and delivered across the clinical workforce to support new and improved clinical pathways. A programme of education designed for the specific needs of NPCs and medically qualified clinicians working in remote areas will be delivered by a combination of a distance and local delivery model using the principle of advanced leaders pioneered in Warwick. The principles of this design will allow the delivery of an education programme that enhances the knowledge and professional skills of healthcare staff. The training model development will be co-created by Warwick, Karolinska and local African partners to be low cost, effective locally, adapted and scalable.
Expertise exists at Warwick and Karolinska in the design and delivery of this educational programme and we have the skills to provide an innovative distance delivery package. All programmes will include full assessment. The option of accreditation of this learning by local universities will be explored.

3.2 Warwick will provide overall leadership of this work package but as the distribution of resources reflect most of the delivery will be in Malawi and Tanzania. In the design of the ‘Advanced Leader’ model Warwick will;
a) support the Malawi Ministry of Health (MMoH) and Ifakara Health Institute (IHI) to develop an ‘Advanced Leader’ model fit for the Malawian and Tanzanian contexts;
b) support MMoH and IHI to identify the range and balance of content in the advanced leader programme;

c) support MMoH and IHI to develop suitable applications of technology – enhanced learning to the advanced leader model (and the subsequent network) to reflect the local context.
In the provision of content expertise for the Advanced Leader programme, Warwick will develop;
i) Educational skills of Advanced Leaders (including mentorship and quality assurance and enhancement);
ii) Service improvement and safety.
Karolinska will provide;
i) Criterion based audit skills;
ii) Obstetrics and gynaecology and neonatal specific content.
GE Healthcare will provide content expertise on leadership, change management, influencing and networking skills. Detailed development of the Advanced Leader programme and its continuing delivery and shaping content to reflect context will be taken forward by IHI and MMoH together with academic and service accreditation of the programme.

3.3 Creating a Professional support and mentoring network. Clinicians locally will be recruited to participate in piloting an overarching helpline/mentoring facility that uses appropriate and available communication technology such as mobile phones/texting to support NPCs in obstetric and neonatal care in remote and rural areas. We hope that working alongside other enthusiastic clinical experts in a real-time virtual support community will prove professionally stimulating. Improving the delivery of emergency obstetric care in remote and rural referral units will empower the regional obstetricians working with advance leader NPCs in a cascade effect to improve maternal and perinatal morbidity and mortality. Engaging the local clinician experts in leadership and mentorship roles in this way should empower professionalism in all healthcare workers.

3.4 For the task of creating a professional support network it is planned that Warwick and Karolinska develop the design of a pilot professional support network and support MMoH and IHI to identify the most appropriate approaches to establishing a professional support network for NPCs that reflect the contexts in the two countries. Detailed development with evaluation and sustained provision of this professional support network will be led by IHI and MMoH. Warwick and Karolinska will be involved in design of evaluation and supervision and research training of doctoral students and research staff.

Person-Months per Participant

Participant number [10]	Participant short name [11]	Person-months per participant
1	Warwick	12.60
2	KI	4.00
3	MMOH	6.00
4	IHI	36.00
5	GE	1.00
6	UOM	26.40
	Total	86.00

List of deliverables

Deliverable Number [61]	Deliverable Title	Lead beneficiary number	Estimated indicative person-months	Nature [62]	Dissemination level [63]	Delivery date [64]
D3.4	Develop programme and engage local medical staff in delivery of training in clinical education, lea	1	27.00	R	PU	24
D3.5	Pilot professional support and mentoring network	1	27.00	R	PU	24

List of deliverables

Delive-rable Number [61]	Deliverable Title	Lead benefi-ciary number	Estimated indicative person-months	Nature [62]	Dissemi-nation level [63]	Delivery date [64]
		Total	54.00			

Description of deliverables

D3.4) Develop programme and engage local medical staff in delivery of training in clinical education, lea: Develop programme and engage local medical staff in delivery of training in clinical education, leadership and management for 50 NPCs [month 24]

D3.5) Pilot professional support and mentoring network: Pilot professional support and mentoring network [month 24]

Schedule of relevant Milestones

Milestone number [59]	Milestone name	Lead benefi-ciary number	Delivery date from Annex I [60]	Comments
MS3	Design context specific Advanced Leader model.	1	6	Design report
MS4	Design of pilot professional support network	1	9	Design report at 12 mths
MS7	Content of Advanced Leader programme determined and ready for delivery	1	12	Training curriculum
MS9	Finalise design of curricula, guidelines, content and assessments of all training programmes	2	12	Written guidelines curriculum documents and assessments
MS13	Faculty development programmes established and delivered and initial 20 NPCs trained as Advanced Lea	1	18	Programme and Periodic report 1
MS14	Final 30 NPCs trained as Advanced Leaders	1	24	Report
MS15	Establish professional network to create NPC support and mentoring	1	24	Report to sponsor and publications

WT3:
Work package description

Project Number [1]	266290	Project Acronym [2]	ETATMBA

One form per Work Package

Work package number [53]	WP4	Type of activity [54]	OTHER
Work package title	Dissemination and outreach		
Start month	1		
End month	42		
Lead beneficiary number [55]	1		

Objectives

• The objective of this Work Package is to disseminate evidence obtained by the project on the effectiveness and feasibility of strategies and interventions to promote maternal and newborn health to relevant African and international stakeholders by a range of appropriate methods for ensuring maximum outreach.

• This will be achieved by ensuring the integration of the project into the fabric of the healthcare system in the partner countries and by ensuring the active collaboration of local and national governments, as well as relevant international stakeholders. In this way, the sustainability of the approaches developed by the project will be ensured, developing the model as a beacon for educational development across the continent.

• The Project Coordinator (Professor Peter Winstanley) will be responsible for the overall delivery of the WP, with substantive contributions from all project partners. Some deliverables relevant to the objectives of this Work Package will be achieved as part of the overall project management and are outlined in that WP (see D5.1.3 and D5.1.4).

Description of work and role of partners

4.1 Stakeholder network established. Relevant stakeholders will be identified in order to target dissemination activities to them during the project, including local and government health agencies and international agencies supporting the health sector in Malawi and Tanzania and regionally, medical scientists and educationalists at all professional levels in the two countries, and respected health sector academics from Africa and internationally.

4.2 Communication and outreach programme developed (as part of the internal and external communications plan for the project (see Work Package 5)). This will ensure appropriate coverage to all stakeholders over the lifetime of the project and beyond.

4.3 Communications programme implemented. This is likely to include a launch conference and website development, and subsequently training of health professionals at various levels, international exchange of relevant professionals, public awareness programmes in the two African partner countries and regionally, presentations at relevant national and international conferences and journal publications.

4.3.1 The initial pan-African conference on educational development and training will allow early establishment of contacts and networks used throughout the project and will provide a basis for the development of later phases of the project.

4.3.2 The dedicated project website will allow easy access to protocols, guidelines, published papers and research progress to be made available, as well as other relevant information on project progress, and forum facilities for public participation and comment.

4.3.3 The international exchange of researchers and guest academics will build research and education capacity in partner and neighbouring countries. The exchanges will be achieved by a variety of means including through Warwick's Institute of Advanced Study (http://www2.warwick.ac.uk/fac/cross_fac/ias)

4.3.4 Public awareness will be maintained by producing publications targeted at a range of different audiences, from high impact academic journals (preferably open access journals) to local level print and broadcast media.
4.3.5 Dissemination activities will be coordinated by the Project Coordinator, supported by the Project Manager,

working with Work Package Leaders and their teams. Research output will be approved by the project Steering Committee before publication. Each partner will have access to specialist staff at their institutions to advise on and input to the communications and dissemination activity, including Warwick's Communications Office, including Warwick Research TV, Warwick iCast, Warwick Podcast and Media Centre; and GE Healthcare's public relations team.

Person-Months per Participant

Participant number [10]	Participant short name [11]	Person-months per participant
1	Warwick	7.00
	Total	7.00

List of deliverables

Deliverable Number [61]	Deliverable Title	Lead beneficiary number	Estimated indicative person-months	Nature [62]	Dissemination level [63]	Delivery date [64]
D4.6	Website developed	1	7.00	R	PU	3
		Total	7.00			

Description of deliverables

D4.6) Website developed: Website developed [month 3]

Schedule of relevant Milestones

Milestone number [59]	Milestone name	Lead beneficiary number	Delivery date from Annex I [60]	Comments
MS1	Establish Website	1	3	Access to site
MS2	Engage with local healthcare community and establish baseline data, contracts, agreements.	4	6	Reports on baseline data
MS9	Finalise design of curricula, guidelines, content and assessments of all training programmes	2	12	Written guidelines curriculum documents and assessments
MS17	Evaluation report on interventions and training	1	36	Reports, symposia, abstracts, papers

WT3:
Work package description

Project Number [1]	266290	Project Acronym [2]	ETATMBA

One form per Work Package

Work package number [53]	WP5	Type of activity [54]	MGT
Work package title	Project Management		
Start month	1		
End month	42		
Lead beneficiary number [55]	1		

Objectives

• The objective of this WP is to create an organizational framework that facilitates the successful execution of the ETATMBA project. The framework will ensure that each partner institution is integrated equally into decision-making and processes of the Consortium, and that the project remains sensitive to the needs of the Non-Physician Clinicians and the results of medical interventions. The WP will also deliver the effective management of financial resources, communications and intellectual property.

• The Project Co-ordinator (Prof Peter Winstanley) will be responsible for the overall delivery of the WP. Dr. Paul O’Hare (Warwick) will assist the Project Co-ordinator in quality assurance matters. The Senior Clinical Research Fellow (SCRF) will co-ordinate activities working across partner sites.

Description of work and role of partners

The organisation of the project as a whole and the administrative tasks of ETATMBA will be dealt with in this WP. A detailed description of the overall approach to management can be found in Section 2.1 of this proposal.
5.1 Steering Committee. The project will be planned, managed and controlled by a Steering Committee which will be chaired by the Project Co-ordinator, and consist of representatives from each partner, the Senior Clinical Research Fellow, Work Package Leaders and the Project Manager.

5.1.1 Project Co-ordinator (PC). The PC will continuously monitor the progress of the project and will ensure that milestones are reached, and that the criteria for their evaluation are met. The PC is responsible for all aspects of the project and reporting to, and communicating with, the EC as well as for the marketing of the project.

5.1.2. Quality Assurance Co-ordinator (QAC). The QAC will assist the PC in the delivery and quality assurance of the education and training and the assurance of research quality.

5.1.3. Senior Clinical Research Fellow (SCRF). The SCRF will be based in Africa, and will manage the clinical issues arising out of the project. This includes clinical ethics and research governance, day-to-day oversight and co-ordination of the trial components, liaison between the partners on clinical and associated technological matters, and advising the PC on clinical issues. The SCRF will manage academic and clinical issues in developing, sustaining and evaluating the training programmes.

5.1.4. Project Manager (PM). The PM will ensure that the project is carried out according to plan, particularly in terms of time, cost, scope and quality. The PM will be responsible for planning, problem solving and associated administrative work, and will be the main point of contact for stakeholders.

5.1.5. Work Package Leaders (WPLs). The WPLs will be responsible for the implementation of the tasks allotted to their Work Package(s). This will include the design, co-ordination and supervision of research and training developments, the monitoring of deliverables, and reporting to the Steering Committee.

5.2 Quality Management. The Quality Management Committee (QMC), led by Dr Paul O’Hare (Warwick), will monitor the quality of the research and teaching with a particular emphasis on the efficacy of both the education and support provided for Non-Clinical Physicians and on the technological solutions tested. The QMC will advise and support the WPLs, who are responsible for the quality of their work.

5.3 Ethics. The Ethics Advisory Committee (EAC), chaired by Dr Anne-Marie Slowther (Warwick), will monitor the ethics issues arising from the project. The EAC will advise and support the WPLs, who are responsible for the implementation of appropriate ethical standards in their work.

5.4 Professional and administrative support. Specialist staff at the PCs institution will provide support in contract negotiation, financial management, post-award administration, legal matters and communications. African partner organisations will provide local administration for the project. Karolinska Institute will support the administration of Gotland educational initiative for NPC education and the transfer to 'Gotland-in-Africa' education initiatives.

Person-Months per Participant

Participant number [10]	Participant short name [11]	Person-months per participant
1	Warwick	30.00
3	MMOH	8.00
4	IHI	18.00
6	UOM	18.00
	Total	74.00

List of deliverables

Delive-rable Number [61]	Deliverable Title	Lead benefi-ciary number	Estimated indicative person-months	Nature [62]	Dissemi-nation level [63]	Delivery date [64]
		Total	0.00			

Description of deliverables

Schedule of relevant Milestones

Milestone number [59]	Milestone name	Lead benefi-ciary number	Delivery date from Annex I [60]	Comments
MS1	Establish Website	1	3	Access to site
MS4	Design of pilot professional support network	1	9	Design report at 12 mths
MS11	Annual summary report of development of obstetric process indicators	2	12	Written report
MS12	Faculty development programmes established and delivered and initial 20 NPCs trained as Advanced Lea	1	18	Programme and Periodic report 1
MS18	Third year report on audit and development of obstetric process indicators	2	36	Periodic report 2
MS19	Provide overview project summary of results and future direction to sponsor participant institutions	1	42	Final written report on awareness and societal implications

WT4:
List of Milestones

Project Number [1]	266290	Project Acronym [2]	ETATMBA

List and Schedule of Milestones

Milestone number [59]	Milestone name	WP number [53]	Lead beneficiary number	Delivery date from Annex I [60]	Comments
MS1	Establish Website	WP4, WP5	1	3	Access to site
MS2	Engage with local healthcare community and establish baseline data, contracts, agreements.	WP1, WP2, WP4	4	6	Reports on baseline data
MS3	Design context specific Advanced Leader model.	WP3	1	6	Design report
MS4	Design of pilot professional support network	WP3, WP5	1	9	Design report at 12 mths
MS5	Design of evaluation	WP2	1	9	Design reports at 12 mths
MS6	Initial training of research staff	WP2	4	12	Training programme
MS7	Content of Advanced Leader programme determined and ready for delivery	WP3	1	12	Training curriculum
MS8	Recruit NPCs for ‘Advanced Leader’ training	WP1	4	12	Report to steering and sponsors
MS9	Finalise design of curricula, guidelines, content and assessments of all training programmes	WP2, WP3, WP4	2	12	Written guidelines curriculum documents and assessments
MS10	Establish criterion based audit sessions	WP2	2	12	Programme
MS11	Annual summary report of development of obstetric process indicators	WP2, WP5	2	12	Written report
MS12	Faculty development programmes established and delivered and initial 20 NPCs trained as Advanced Lea	WP1, WP5	1	18	Programme and Periodic report 1
MS13	Faculty development programmes established and	WP3	1	18	Programme and Periodic report 1

Milestone number [59]	Milestone name	WP number [53]	Lead beneficiary number	Delivery date from Annex I [60]	Comments
	delivered and initial 20 NPCs trained as Advanced Lea				
MS14	Final 30 NPCs trained as Advanced Leaders	WP1, WP3	1	24	Report
MS15	Establish professional network to create NPC support and mentoring	WP3	1	24	Report to sponsor and publications
MS16	Second report of audit and development of obstetric process indicators	WP2	2	24	Report
MS17	Evaluation report on interventions and training	WP2, WP4	1	36	Reports, symposia, abstracts, papers
MS18	Third year report on audit and development of obstetric process indicators	WP1, WP5	2	36	Periodic report 2
MS19	Provide overview project summary of results and future direction to sponsor participant institutions	WP5	1	42	Final written report on awareness and societal implications

WT5:
Tentative schedule of Project Reviews

Project Number [1]	266290	Project Acronym [2]	ETATMBA

Tentative schedule of Project Reviews

Review number [65]	Tentative timing	Planned venue of review	Comments, if any
RV 1	6	Teleconference	Planning, design of training
RV 2	12	Warwick	Report, evaluation design
RV 3	18	Teleconference	Periodic Report 1
RV 4	24	Teleconference/Warwick	Report. Some staff to gather in Warwick, others to join the meeting via teleconference.
RV 5	36	Warwick or KI	Periodic report 2
RV 6	42	Teleconference	Final written report

WT6:
Project Effort by Beneficiary and Work Package

Project Number [1]	266290	Project Acronym [2]	ETATMBA

Indicative efforts (man-months) per Beneficiary per Work Package

Beneficiary number and short-name	WP 1	WP 2	WP 3	WP 4	WP 5	Total per Beneficiary
1 - Warwick	13.00	2.00	12.60	7.00	30.00	64.60
2 - KI	16.00	22.00	4.00	0.00	0.00	42.00
3 - MMOH	16.00	6.00	6.00	0.00	8.00	36.00
4 - IHI	56.00	36.00	36.00	0.00	18.00	146.00
5 - GE	0.00	0.00	1.00	0.00	0.00	1.00
6 - UOM	41.00	6.00	26.40	0.00	18.00	91.40
Total	142.00	72.00	86.00	7.00	74.00	381.00

WT7:
Project Effort by Activity type per Beneficiary

Project Number [1]	266290	Project Acronym [2]	ETATMBA

Indicative efforts per Activity Type per Beneficiary

Activity type	Part. 1 Warwick	Part. 2 KI	Part. 3 MMOH	Part. 4 IHI	Part. 5 GE	Part. 6 UOM	Total
1. RTD/Innovation activities							
WP 1	13.00	16.00	16.00	56.00	0.00	41.00	142.00
WP 2	2.00	22.00	6.00	36.00	0.00	6.00	72.00
WP 3	12.60	4.00	6.00	36.00	1.00	26.40	86.00
Total Research	27.60	42.00	28.00	128.00	1.00	73.40	300.00
2. Demonstration activities							
Total Demo	0.00	0.00	0.00	0.00	0.00	0.00	0.00
3. Consortium Management activities							
WP 5	30.00	0.00	8.00	18.00	0.00	18.00	74.00
Total Management	30.00	0.00	8.00	18.00	0.00	18.00	74.00
4. Other activities							
WP 4	7.00	0.00	0.00	0.00	0.00	0.00	7.00
Total other	7.00	0.00	0.00	0.00	0.00	0.00	7.00
Total	64.60	42.00	36.00	146.00	1.00	91.40	381.00

WT8:
Project Effort and costs

Project Number [1]	266290	Project Acronym [2]	ETATMBA

Project efforts and costs

Benefi-ciary number	Beneficiary short name	Estimated eligible costs (whole duration of the project)						Total receipts (€)	Requested EU contribution (€)
		Effort (PM)	Personnel costs (€)	Subcontracting (€)	Other Direct costs (€)	Indirect costs OR lump sum, flat-rate or scale-of-unit (€)	Total costs		
1	Warwick	64.60	365,446.33	2,726.00	152,758.00	310,922.60	831,852.93	0.00	683,744.00
2	KI	42.00	334,563.00	3,500.00	71,688.00	243,750.60	653,501.60	0.00	491,000.00
3	MMOH	36.00	33,246.00	2,588.00	45,524.00	47,262.00	128,620.00	0.00	99,752.00
4	IHI	146.00	415,240.00	2,588.00	254,984.00	402,134.40	1,074,946.40	0.00	809,497.00
5	GE	1.00	0.00	0.00	16,667.00	3,333.00	20,000.00	0.00	10,000.00
6	UOM	91.40	112,800.00	2,588.00	306,680.00	251,688.00	673,756.00	0.00	505,964.00
	Total	381.00	1,261,295.33	13,990.00	848,301.00	1,259,090.60	3,382,676.93	0.00	2,599,957.00

1. Project number

The project number has been assigned by the Commission as the unique identifier for your project. It cannot be changed. The project number **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

2. Project acronym

Use the project acronym as given in the submitted proposal. It cannot be changed unless agreed so during the negotiations. The same acronym **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

53. Work Package number

Work package number: WP1, WP2, WP3, ..., WPn

54. Type of activity

For all FP7 projects each work package must relate to one (and only one) of the following possible types of activity (only if applicable for the chosen funding scheme – must correspond to the GPF Form Ax.v):

• **RTD/INNO =** Research and technological development including scientific coordination - applicable for Collaborative Projects and Networks of Excellence

• **DEM =** Demonstration - applicable for collaborative projects and Research for the Benefit of Specific Groups

• **MGT =** Management of the consortium - applicable for all funding schemes

• **OTHER =** Other specific activities, applicable for all funding schemes

• **COORD =** Coordination activities – applicable only for CAs

• **SUPP =** Support activities – applicable only for SAs

55. Lead beneficiary number

Number of the beneficiary leading the work in this work package.

56. Person-months per work package

The total number of person-months allocated to each work package.

57. Start month

Relative start date for the work in the specific work packages, month 1 marking the start date of the project, and all other start dates being relative to this start date.

58. End month

Relative end date, month 1 marking the start date of the project, and all end dates being relative to this start date.

59. Milestone number

Milestone number:MS1, MS2, …, MSn

60. Delivery date for Milestone

Month in which the milestone will be achieved. Month 1 marking the start date of the project, and all delivery dates being relative to this start date.

61. Deliverable number

Deliverable numbers in order of delivery dates: D1 – Dn

62. Nature

Please indicate the nature of the deliverable using one of the following codes

R = Report, **P** = Prototype, **D** = Demonstrator, **O** = Other

63. Dissemination level

Please indicate the dissemination level using one of the following codes:

• **PU =** Public

• **PP =** Restricted to other programme participants (including the Commission Services)

• **RE =** Restricted to a group specified by the consortium (including the Commission Services)

• **CO =** Confidential, only for members of the consortium (including the Commission Services)

• **Restreint UE =** Classified with the classification level "Restreint UE" according to Commission Decision 2001/844 and amendments

• **Confidentiel UE =** Classified with the mention of the classification level "Confidentiel UE" according to Commission Decision 2001/844 and amendments

• **Secret UE =** Classified with the mention of the classification level "Secret UE" according to Commission Decision 2001/844 and amendments

64. Delivery date for Deliverable

Month in which the deliverables will be available. Month 1 marking the start date of the project, and all delivery dates being relative to this start date

65. Review number

Review number: RV1, RV2, ..., RVn

66. Tentative timing of reviews

Month after which the review will take place. Month 1 marking the start date of the project, and all delivery dates being relative to this start date.

67. Person-months per Deliverable

The total number of person-month allocated to each deliverable.

REVISION 6
27th June 2012

COVER PAGE

Part B

Proposal full title:

Enhancing human resources and the use of appropriate technologies for maternal and perinatal survival in sub-Saharan Africa

Proposal acronym:

ETATMBA
Enhancing Training and Appropriate Technologies for Mothers and Babies in Africa

Type of funding scheme:

SICA Collaborative Project (small or medium-scale focussed research project)

Work programme topics addressed:

HEALTH.2010.3.4-2: Feasibility and community effectiveness of innovative interventions packages for maternal and newborn health in Africa. FP7-CALL-FOR-AFRICA-2010

Name of Coordinator:

Professor Peter Winstanley

Participant no.	Organisation	Short name	Country
1 (Coordinator)	University of Warwick	Warwick	UK
2	Karolinska Institute	KI	Sweden
3	Ministry of Health	MMOH	Malawi
4	Ifakara Health Institute	IHI	Tanzania
5	GE Healthcare	GE	UK
6	University of Malawi	UOM	Malawi

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Enhancing human resources and the use of appropriate technologies for maternal and perinatal survival in sub-Saharan Africa

Abstract

Most African women face childbirth without access to skilled health workers when obstetric and neonatal emergencies arise. Providing and retaining skilled health workers is vital in attempts to save the 600,000 women and 7 million babies who die annually in Africa. In the modern world this tragedy is unacceptable and largely preventable. Education and training for health professionals is the key to improving healthcare for mothers and babies in Africa. Non-Physician Clinicians (NPCs) are an effective and retainable health solution for doctor-less rural and some urban areas of Africa. Task shifting to NPCs needs to be extended, enhanced, endorsed and supported by the healthcare community and will be the aim of Work Package 1 (WP1) and WP3.

The project aims to develop, implement and evaluate clinical service improvement through clinical guidelines and pathways in WP2, structured education and clinical leadership training (WP3) and workforce development of NPCs and faculty (WP1, WP3). A key element will be continuing support for NPCs in the workplace using communications and mentorship from local professionals (WP1, WP3). All service improvements will be sustainable, scalable, cost-effective, transferrable and co-developed by professional partners in Africa. Bringing together key European and African partners with GE Healthcare to address the major issues of enhancing a sustainable healthcare workforce and enhancing the appropriate training in the use of existing technologies should help to significantly reduce the loss of mothers and babies in Africa.

PROPOSAL

1. Scientific and technical quality

1.1 Concept and objectives

Maternal mortality and morbidity associated with pregnancy remain major challenges to improving health in Africa. Six hundred thousand women die every year as a result of complications from pregnancy and childbirth and most are preventable (1). Human resources and the effective service delivery of appropriate sustainable technologies have been identified as key areas that need support if this global inequity in health is to be improved. The Millennium Development Goals 4 and 5 of reducing maternal mortality and perinatal death can only be achieved by developing and evaluating innovative transferrable and sustainable solutions through collaboration between African and International partnerships.
Maternal mortality in most of sub-Saharan Africa remains obstinately high (2). In Malawi, for example, the maternal mortality ratio is 1100 whereas in the UK it is 13 (2,3). Whereas there has been a steady decline in maternal mortality in Europe over the past 60 years, in Africa even long periods of stability and increases in health spending have had little apparent effect in some countries (4) . The UN has set a target for maternal case fatality rate of less than 1%. Less than 50% of women in low-income countries are attended by skilled health personnel, yet life-threatening complications that require emergency care will arise for around 15% (4). Neonatal mortality is 12 times higher than maternal mortality and accounts for seven million deaths: about three million babies are stillborn and four million die in the neonatal period. Much of this loss is preventable (2,4,5). The major causes of the almost four million neonatal deaths in low-income countries in or around the first week of life are infection, pre-term birth and asphyxia (5).

Models of healthcare that have developed in Europe, based on highly trained medical specialists using complex technology, are unlikely to be a practical way forward or sustainable in sub-Saharan Africa. There is much evidence to support a different model of service provision in Africa, whereby the relatively scarce resource of medical obstetric specialists are focused to train and support a service mainly provided by healthcare staff other than doctors, i.e. non-physician clinicians (NPC) such as assistant medical officers, clinical officers, midwives and outreach community health-workers. In this model, the medically trained specialist obstetricians, mainly operating in large centres and capital cities, can focus their attention on management of difficult clinical cases and on providing support, leadership and training for NPCs. In sub-Saharan Africa, due to training and retention difficulties, there are only 5 doctors per 100,000 people (1). Many women in rural and urban communities in Africa give birth without any trained assistance for their pregnancy and childbirth. Programmes of training for health-workers to provide safe outreach community healthcare are being developed but these need to be systematic, transferable, and able to be scaled up to meet the needs of these woman across Africa. A health delivery model of non-physician clinicians (NPCs) and with support and supervision of the physician specialist obstetricians would be an affordable and sustainable system for these communities.

Much work has been done to assess the efficiency of training NPCs (assistant medical officers, clinical officers and specialist midwives) in the skills of clinical decision-making and surgical intervention (1,6). Training skilled attendants to prevent, detect and manage major obstetric complications, including undertaking emergency caesarean surgery in complicated deliveries is arguably the single most important factor in preventing maternal deaths and protecting the human rights of women (1,6,11,13). To be effective NPCs need appropriate equipment, drugs and technology essential for managing obstetric complications in rural or deprived communities.

Task shifting from physicians to non-physicians appears to be both safe and effective in countries that have organised and supported the extension of their maternal care in this way

(1,6,10,11,12,13). Major surveys consistently show that extra training and support can achieve task shifting and improve maternal and fetal mortality and morbidity in the areas where these schemes have been piloted (6,11,12). Most of the maternal population in sub-Saharan Africa lives outside the major cities and for these women there remains major challenges to effective maternal care. Solutions must include outreach of effective care to this population. In addition to lack of available trained manpower, factors that have been identified as contributing to the higher maternal and perinatal mortality, include poor availability of relatively cheap drugs and simple technologies for managing post-partum haemorrhage (PPH); shortages of immediately available blood; lack of access to senior advice on 24/7 basis; access to facilities and staff for emergency Caesareans; and delays and inadequacies in the safe transport to hospital when complications arise. There can also be a problem in recognising complications early enough for effective action, (for example; breech, transverse lie, placenta praevia, pre-eclampsia and anaemia). Early detection of these could be improved with training. It is estimated that 75% of maternal deaths and more than 60% of perinatal deaths are caused by 8 major conditions. For the mother the 5 major killers are post partum haemorrhage, sepsis, hypertensive disorders of pregnancy, obstructed labour, and unsafe abortion and the 3 major causes of perinatal child death are low birth-weight, birth asphyxia, and infection (6,8).

Clinical Service Improvement in maternal and neonatal Healthcare in Africa

Training needs to be sustained and reinforced for professionals to continue to perform to the highest standards of their competence. The new models in sub-Saharan Africa of using non-physician clinicians need to integrate and be supported by the medical establishment for a seamless effective healthcare system that prioritises skills to the needs of patients. A leadership role in training local medical specialists in mentorship and providing emergency advanced obstetric and paediatric advice would be an integral part of the emerging healthcare systems of these communities. Research should establish the effectiveness and cost-effectiveness of these systems.

We propose systematic programmes to develop the decision-making and clinical management skills of the local workforce by means of enhanced training for NPC and improved record keeping. This is based on the curricula and experience over many years in African countries and pioneered by structured education exemplified by consistently well-evaluated components of the training and update courses for NPCs in Gotland in Sweden(1). The training elements will be widely disseminated in the African intervention sites to support effective and sustainable task shifting to NPCs. Training will include understanding the best use of appropriate technologies to reduce maternal and neonatal mortality and morbidity. Access to staff trained in this way could cut maternal mortality by 75%. For this to happen, not only do the NPCs need to be able to correctly diagnose and manage maternal emergencies but they need to be supported to sustain this work, including skills maintenance for their surgery (11,12,13). Integrating these systems with local clinical leaders through research and mentorship should provide an effective platform for sustained development. Designing clinical systems that optimise the potential of a workforce of NPCs who have undergone enhanced training, and who are equipped with existing and appropriate sustainable technology solutions is feasible, though challenging, but is clearly urgently required.

Primary Objectives of the project

1. To develop, implement and evaluate a programme of locally based clinical service improvement including clinical guidelines and pathways, structured education, leadership training and workforce development. This will be linked to specialist support. This clinical service improvement will implement best existing practice and provide the context for understanding the additional health gain from the use of appropriate available technologies designed to reduce morbidity-specific maternal case-fatality rates and fresh stillbirth rates (intrapartum fetal mortality) across different African communities.

2. To design and develop this programme so that it is sustainable, scalable, cost effective and transferrable to other sub-Saharan African locations and ultimately to other emerging economies.

To deliver the primary objectives, the strands will be developed by means of 5 work packages which optimise the expertise of European and African partners in this project:

Work Package 1 -	***Developing the workforce by training Non-Physician Clinicians in more advanced obstetric care.***
Work Package 2 -	***Developing improved clinical guidelines and pathways for the local African context and evaluation.***
Work Package 3 -	***Clinical education, leadership training and creation of a professional support network.***
Work Package 4 -	***Dissemination and outreach.***
Work Package 5 -	***Project Management.***

1.2 Progress beyond the state-of-the-art

Participants in this project and Work Package Leaders have pioneered working with healthcare systems in Africa to champion the role of the Non-Physician Clinician and extend their role (1,6,11,12,13). In many countries this is supported and encouraged by governments and their agencies (1,6).

To develop to their maximum potential this workforce needs a professional framework for training, assessment and continuing professional development and to have increasing recognition and status in the societies they work in.

This project will combine what has already been achieved by the Karolinska group and Tanzanian partners with the state-of-the-art educational models developed in Warwick to provide in Africa a relevant advanced leader and distance learning training methodology to support existing NPCs. The model will be designed to cope with the large scale training that is needed. Warwick has an international reputation leading large scale professional training in healthcare and engineering (15,16,17).

The Institute of Clinical Education at Warwick working with the Department of Public Health at Karolinska will together create a unique support network for Non-Physician Clinicians working in Africa. The adaptation of distance learning technologies to involve both local African obstetricians and neonatal paediatricians, as well as their European counterparts in real-time support provision is an exciting development. Not only will the clinician on the spot have better support, but active involvement in African feto-maternal scenarios will do much to enhance the clinical experience of European physicians.

GE Healthcare is a world leader in developing state of the art technology for healthcare and is committed to finding and funding the development of African solutions for African healthcare challenges. GE Healthcare has been working collaboratively with the healthcare organisations and government departments of Malawi and Tanzania where Karolinska Department of Public Health also has long-term relationships. We see it as progress beyond the state-of-the-art that we are building a collaboration between European and African academics working in partnership with policy-makers and clinicians at all levels and in conjunction with a leader in global health technology to deliver all the ingredients necessary to impact on maternal and fetal mortality and morbidity. Crucial to the success of this project will be the professional contacts and working relationships built over years and essential for local effectiveness and for the sustainability of any healthcare advantages that this project brings.

1.3 S/T Methodology and Work Plan

1.3.1 Overall Strategy of the work plan

We will design and develop methods that test the effectiveness of the complex multi-factorial interventions in rural and urban communities of sub-Saharan Africa. We aim to use a flexible and staged design that follows the UK's Medical Research Council framework recommended for complex interventions in randomised controlled trials (7,9). In the first phase of the research project, health service improvement methodologies will be deployed locally and training programmes will be developed. During this time up-to-date baseline data on maternal and neonatal events in the communities will be collected. This will establish robust figures on local birth rates, maternal mortality, neonatal mortality and complications of pregnancy in these communities. These data will inform the design of and the power calculations for, future studies of effectiveness and cost-effectiveness of our intervention.

We anticipate that the primary endpoints will be morbidity specific maternal case fatality rates and intrapartum fetal mortality (stillbirth rates). Secondary end points will include major obstetric complication (e.g. eclamptic fits, ruptured uterus, fistula, and maternal shock), operative mortality rates, surgical complications, and the cultural acceptability to all stakeholders and patients and the cost-effectiveness of the interventions. At this time it is not possible to decide on the appropriate study design to confirm effectiveness and cost-effectiveness. Possible methods include a classic cluster randomised trial that has been used successfully for public health in intervention in sub-Saharan Africa. Other possibilities including a step-wedge design of interrupted time series which may have ethical, logistic, political and scientific advantages in the evaluation of service improvements (7,9). All support will be premised on developing research capacity and infrastructure working with the collaborating universities and medical faculties in Tanzania and Malawi.

GE Healthcare has strong links and has collaborated in each of these countries and with all of these university partners. A track record in working successfully with government agencies and in supporting healthcare provision in rural and urban settings in Africa will be an important attribute in ensuring goals and targets are achieved and that the research and developments have appropriate impact.

All collaborators in the research train and supervise research fellows and the advanced leaders selected from the non-physician clinicians will educate in the workforce and local communities. Local health economies will contribute to and benefit from the application of clinical service improvement methodologies. The collaborations are designed to deliver a sustainable research framework that brings together health professionals and trains the future leaders for sustained future local development.

The 5 Work Packages identified to deliver the above strategy will consist of:

1. Developing the workforce by training Non-Physician Clinicians in more advanced obstetric care.
2. Developing improved clinical guidelines and pathways for the local African context and evaluation.
3. Clinical education, leadership management training and creation of a professional support network.
4. Dissemination and outreach.
5. Management.

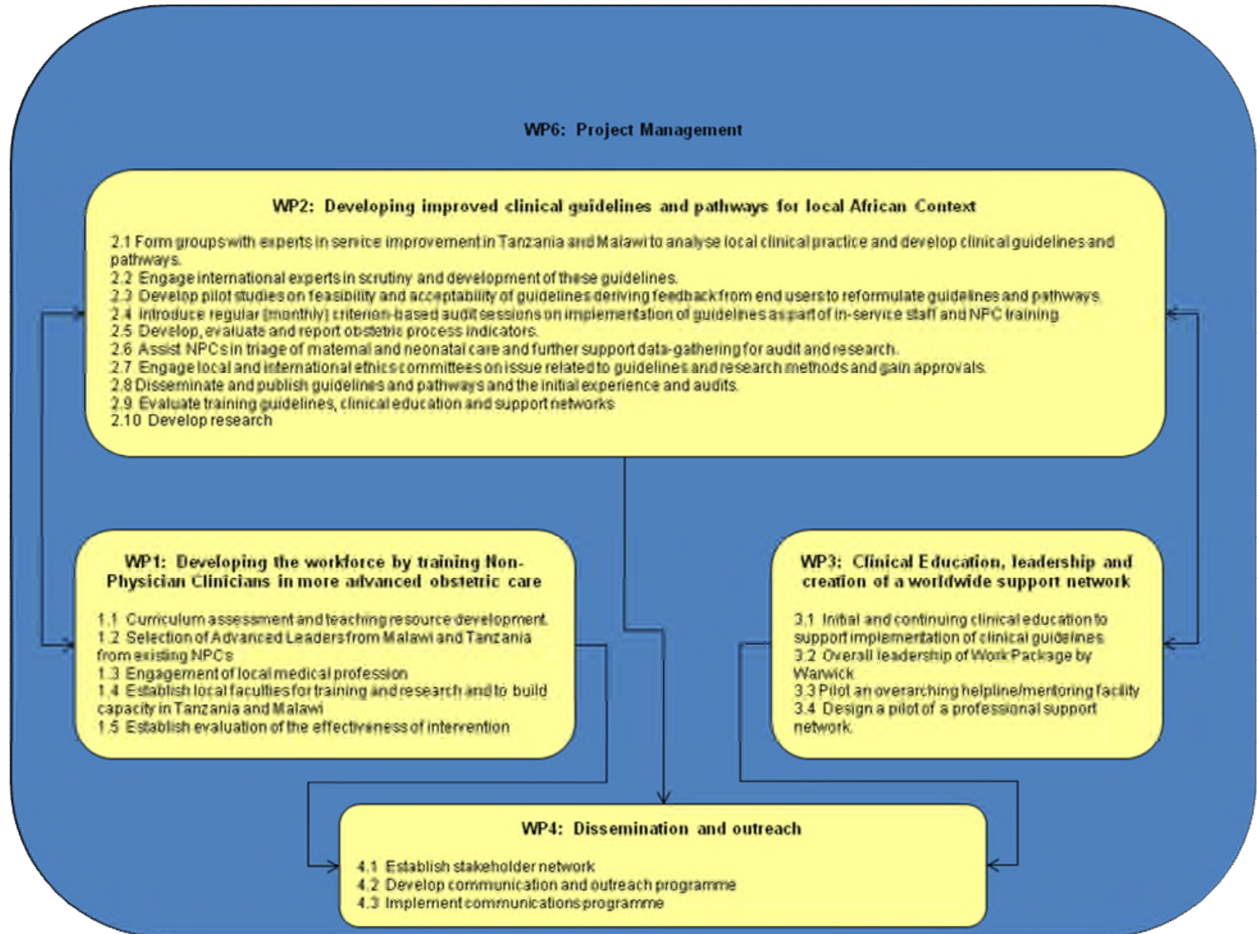
1.3.2 Timing of Work Packages and their components (months)

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42
Work package 1: Developing the workforce by training Non-Physician Clinicians in more advanced obstetric care																																										
1.1 Curriculum assessment and teaching resource development	■	■	■	■	■	■	■	■	■	■	■	■																														
1.2 Selection of Advanced Leaders from Malawi and Tanzania from existing NPCs	■	■	■	■	■	■	■	■	■	■	■	■																														
1.3 Engagement of local medical profession	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■																		
1.4 Establish local faculties for training and research and to build capacity in Tanzania and Malawi	■	■	■	■	■	■	■	■																																		
1.5 Establish evaluation of the effectiveness of intervention														■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Work package 2: Developing improved clinical guidelines and pathways for the local African context																																										
2.1 Form groups with experts in service improvement in Tanzania and Malawi to analyse local clinical practice and develop clinical guidelines and pathways.	■	■	■	■	■	■	■																																			
2.2 Engage international experts in scrutiny and development of these guidelines			■	■	■	■	■	■																																		
2.3 Develop pilot studies on feasibility and acceptability of guidelines deriving feedback from end users to reformulate guidelines and pathways			■	■	■	■	■	■	■	■																																
2.4 Introduce regular (monthly) criterion-based audit sessions on implementation of guidelines as part of in-service staff and NPC training.								■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
2.5 Develop, evaluate and report obstetric process indicators								■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
2.6 Assist NPCs in triage of maternal and neonatal care and further support data-gathering for audit and research.			■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■																								

Activity
2.7 Engage local and international ethics committees on issue related to guidelines and research methods and gain approvals
2.8 Disseminate and publish guidelines and pathways and the initial experience and audits
2.9 Evaluate training guidelines, clinical education and support networks
2.10 Develop research
Work package 3: Clinical Education, leadership and creation of a worldwide support network
3.1 Initial and continuing clinical education to support implementation of clinical guidelines
3.2 Overall leadership of Work Package by Warwick
3.3 Pilot an overarching helpline/mentoring facility
3.4 Design a pilot of a professional support network
Work package 4: Dissemination and outreach
4.1 Establish stakeholder network
4.2 Develop communication and outreach programme
4.3 Communications programme
Work package 5: Project Management
5.1 Steering Committee
5.2 Quality Management
5.3 Ethics
5.4 Professional and administrative support

This chart shows the estimated timing of each activity. However detailed planning will be undertaken by the Project Manager as part of WP5. The timescales shown above are subject to alteration.

1.3.3 Graphical presentation of the components showing their interdependencies.



1.3.4 Significant risks and contingency plan

Risks and contingencies relate to the interface this project will need with local healthcare workers at all levels and national and local government agencies. Initiatives that seem to arrive from Europe run the risk of indifference or rejection in Africa if co-ownership is not perceived. This risk will and has been met by involving partners with strong working relationships in training and research of Non-Physician Clinician that has been highly productive in the past, involves mentors and mutual respect. This ethos from the partners will be part of the professional ethic that embeds health service staff at all levels and this philosophy will be part of the contingency against any breakdown in working relations. Considerable effort and time will be spent developing the good relations and contacts that both GE Healthcare and Karolinska have been building in Tanzania and Malawi among health workers and managers over years. The participation of the University of Malawi College of Medicine, will enhance the academic credentials of the training and its professional ethic.
A more specific risk would be the alienation of the medical profession away from the concept of the value of Non-Physician Clinicians through a climate of fear or threat from a government sponsored development such as NPCs. This does exist in some parts of Africa. Contingency planning for this possibility is built into the proposal by actively engaging the local medical specialists in the training as part of faculty and supervision and mentoring of Non-Physician Clinicians. We will enhance training in leadership, the meaning of professionalism, clinical service improvement and management to enhance the status of the medical profession at the same time as task shifting skills to Non-Physician Clinicians. European and African partners with charismatic distinguished leaders of the profession (SB, PW, EP, GM, CM) who have gained respect and credibility in Africa will act as a contingency to protect against this risk. It is also anticipated that direct support from the University of Malawi College of Medicine will do much to mitigate this risk.

The project is spread over 4 centres in 2 continents and the geography imposes a risk to implementation. Distance learning technologies and the ability to scale up the delivery using Advanced Leaders should offset this risk when combined with the technical knowhow and back-up of GE Healthcare in communications technology.

Political unrest and violence is a risk in countries with a young political heritage but Tanzania and Malawi are chosen for their relative stability. If problems arise in one partner, the project functions could be developed on a larger scale in the other.

2. Implementation

2.1 Management Structure and Procedures

The project management structure has been devised to ensure that each partner institution is integrated equally into decision-making and processes of the Consortium. The project organisation diagram (Figure 1) shows the detailed structure.

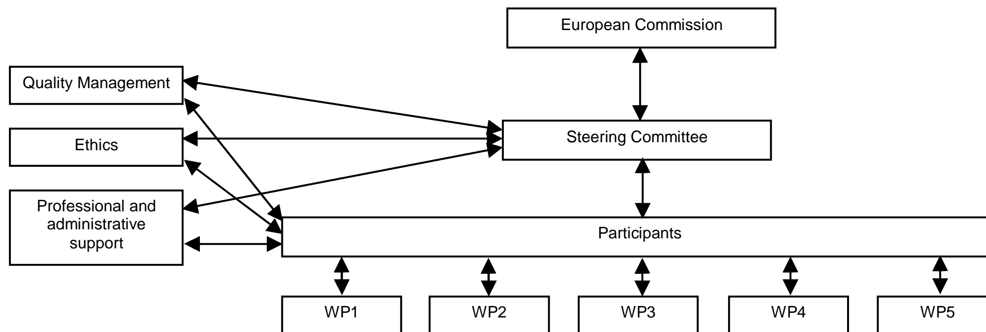


Figure 1: ETATMBA project management structure

The aim of the project management structure is to ensure that project objectives are fully achieved. Special attention will be paid to making sure that the project remains sensitive to the needs of the NPCs and the results of medical interventions, especially in terms of education and support. Other priority areas will include the management of financial resources, communications and intellectual property. A more detailed description of the overall structure and its various component elements is set out below.

Steering Committee (SC)

The Steering Committee (SC), chaired by the Project Co-ordinator (PC) consists of representatives of the partners, the Quality Assurance Co-ordinator, the Senior Clinical Research Fellow (SCRF), Work Package Leaders (WPL) and the Project Manager (PM). The SC has overall responsibility for the effective management of the project and the achievement of the project objectives, project finances and compliance with the European Commission's (EC) contractual terms. Decisions will be made by consensus or by majority vote where consensus is not achievable. In the case of tied votes, the Project Co-ordinator will have the casting vote. Each member of the SC will have one vote.

The SC plans, manages and controls the project. It will define research goals and ensure the smooth integration of the work packages. The progress of the project will be monitored by periodic reviews. The SC will decide on priorities, ethics issues, problem resolution, work plan corrections and variations in the partnership.

Project Co-ordinator (PC)

Professor Peter Winstanley from Warwick will serve as Project Coordinator and chair the Steering Committee. The PC will continuously monitor the progress of the project and will ensure that milestones are reached, and that the criteria for their evaluation are met. The Co-ordinator is responsible for reporting to, and communicating with, the EC as well as for the marketing of the project.

Quality Assurance Co-ordinator (QAC)

Dr Paul O'Hare (Warwick) will assist the PC in the delivery and quality assurance of the education and training and the assurance of research quality. He will assist the Co-ordinator and Work Package Leaders in the delivery of the project.

Senior Clinical Research Fellow (SCRF)

A key component of the project will be the role of two senior researchers working in Africa and jointly appointed between partners. This will involve the day-to-day management of the clinical issues arising out of the project, including clinical ethics; day-to-day oversight of the trial components and the co-ordination between them; maintaining liaison between the partners on clinical and associated technological matters; and advising the Co-ordinators on clinical issues. The researcher with the SCRF will deal with day-to-day issues of research governance and collaborate with the Clinical Trials Unit Staff in Warwick. Together the Project Manager and the SCRF will manage academic and clinical issues in developing and sustaining and evaluating the training programmes.

Project Manager (PM)

The Project Manager (PM) will ensure that the project is carried out according to plan, particularly in terms of time, cost, and quality. The responsibilities of the PM include all planning, steering and controlling activities, problem solving and associated administrative work. The PM is the contact point for project partners, Work Package Leaders (WPLs), external stakeholders and collaborators and in respect of day-to-day administrative issues. The PM will also develop and maintain the project website and will ensure effective communications between the partners. The PM will, thus, be the focal point for communication within the project and will support the PC and Quality Assurance Co-ordinator (QAC) in external communications.

The PM will work closely with the PC and QAC and will be crucial to the development of a positive and motivational atmosphere for all project partners.

Work Package Leaders (WPLs)

Work Package Leaders (WPLs) will build the interface between the scientific work in their corresponding Work Package to the other work packages as well as to the PC and the QAC. The role of the WPLs will comprise the following:

- the design, co-ordination and supervision of research and training developments in their Work Package
- implementation of the tasks allotted to their Work Package
- the monitoring of the achievement of the research and training objectives, deliverables and making recommendations to the SC in a timely fashion, should changes in circumstance arise.
- reporting to the SC and ensuring that the progress of their Work Package is consistent with the overall progress of other project components
- participation in Consortium meetings and organising meetings with partners from the other work packages.

External Advisory Board (EAB)

This committee will meet 6 monthly in the first year and then annually to provide advice from internationally and nationally renowned experts in training healthcare delivery and appropriate technologies to the Steering Committee.

Other Support

The Consortium will also be supported by a variety of support units at the partner institutions.

At the Project Co-ordinator's institution, the following support will be available:

- ***contract negotiation:*** Research Support Services will carry out the negotiations between the partners and the EC over a Consortium Agreement, between the Project Co-ordinator and the other partners and between the Consortium and sub-contractors.
- ***post award administration:*** specialist personnel in Research Support Services will provide advice and support to the PM in relation to financial management. They will also organise audits and liaise with auditors as necessary
- ***legal matters:*** the University Legal Officer is available to provide advice as appropriate
- ***communications:*** staff in the Communications Office will be available to provide advice and support to the PM in relation to the project website and other matters relating to the internal and external communications plans for the project.

Other administrative support from partners in the project includes:
African partner organisations will provide local administration for the project.
GE Healthcare will support the management leadership and technology training.
Karolinska Institute will support the administration of Gotland educational initiative for NPC education and the transfer to 'Gotland-in-Africa' education initiatives.

Quality Management Committee (QMC)
The Quality Management Committee (QMC) will monitor the quality of the research with a particular emphasis on the efficacy of both the education and support provided for non-clinical physicians and on the technological solutions tested. The QMC will advise and support the WPLs, who are responsible for the quality of their work. The QMC will be led by Dr Paul O'Hare and members will be elected at the first Consortium meeting.

Ethics Advisory Committee (EAC)
The Ethics Advisory Committee (EAC) will monitor the ethics issues arising from the project. The EAC will advise and support the WPLs, who are responsible for the implementation of appropriate ethical standards in their work. The EAC be chaired by Dr Anne-Marie Slowther (Warwick). Other members will be elected at the first Consortium meeting.

2.2 Individual Participants

Participant 1 – University of Warwick, UK

Main tasks attributed in the project

The team at Warwick will provide co-ordination for ETATMBA and Work Package Leaders (WPLs) for Work Package 3, 4 and 5 and with considerable involvement in WP 1-5. Peter Winstanley will be the Project Coordinator and will be assisted by Paul O'Hare who will quality assure all educational, assessment and research milestones and communication and marketing of the project. Neil Johnson, Paul O'Hare, Frances Griffiths and David Davies will lead and deliver WP3.

There are challenging capacity issues, and an expanded role for Warwick will facilitate the design, development and delivery of the training courses in Malawi. Warwick will also be training the local faculty, who will then sustain the delivery of the programme.

Summary of experience relevant to project

Warwick's Institute of Clinical Education has a track record of providing leadership in E-learning (D Davies), distance delivery (J Dale), large scale education to health service professionals in the UK and across the world and provide this expertise, knowledge and enthusiasm under the leadership of Professors Johnson and Peile. Martin Underwood and Frances Griffiths will play major leadership and advisory roles in the design and delivery of the research assisted by Warwick's research support services.

Professor Peter Winstanley, Dean of Warwick Medical School, is a leading researcher in Global Health and Malaria. Paul O'Hare, Director of Quality Assurance developed the strategy for the development of Postgraduate Education to health professionals at Warwick Medical School and is an international authority on healthcare delivery to ethnic minorities. Neil Johnson and Ed Peile are Professors of Medical Education and experts in curriculum design, development, delivery and assessment in health across the undergraduate and postgraduate spectrum. David Davies, Associate Clinical Professor in e-learning is one of the UK's academic experts on innovative approaches to education delivery. Martin Underwood and Frances Griffiths have extensive clinical trials experience and qualitative research in healthcare and will lead for the Warwick Clinical Trials Unit, the UK's fastest growing development in this area of translational research. Siobhan Quenby, Professor of Obstetrics is an authority on healthcare problems in pregnancy in ethnic groups and will be involved in WP1-3.

Relevant Publications

1. Tang A-W, Alfirevic Z, Turner M, Drury J, *Quenby* S Prednisolone Trial: Study protocol for a randomised controlled trial of prednisolone for women with idiopathic recurrent miscarriage and raised levels of uterine natural killer (uNK) cells in the endometrium . BMC Trials (2009), 10:102
2. *Quenby S*, Zhang Z, Bricker L, Wray S. Poor Uterine Contractility in Obese Women (2007) BJOG 114,343-348
3. **Peile E**, How can experts and novices learn together? BMJ 2004; 329: 902
4. Hernshaw H, Hughes N, **Dale J**, Jones G, Lindenmyer A. (2006). Warwick Certificate in Diabetes Care; an evaluation. Diabetes and Primary Care, 7(4), 197-204 (1466-8955).
5. Bellary S‡, **O'Hare JP**‡, Raymond NT, Gumber A, Mughal S, Szczepura A, Kumar S, Barnett AH for UKADS study groups. Enhanced diabetes care to patients of South Asian ethnic origin (the United Kingdom Asian Diabetes Study): a cluster randomised controlled trial. Lancet. 2008 May 24; 371(9626): 1769-76. (I.F. 28)
   ‡ Joint first authors

Participant 2 – Karolinska Institute, Sweden

Main tasks attributed in the project

The team at Karolinska led by Professor Staffan Bergström in the Division of Global Health will continue to pioneer the development of NPCs and act as Work Package Leader (WPL) for WP2 and have major involvements in WP1, 3. Staffan Bergström will be responsible for all aspects of the design delivery and achievement of milestones in WP2 working in collaboration with partners in Tanzania and Malawi. Dr Caetano Pereira, another senior obstetrician and research fellow at Karolinska will assist in the design, development and delivery of the project.

Summary of experience relevant to project

Karolinska's Division of Global Health/IHCAR has a vision and has played a sustained internationally renowned role over many years in contributing to Global Health through excellence in Research, Education and Information with a focus on poverty and inequity in Africa, Asia and Latin-America. Professor Bergström and colleagues have widespread experience of multidisciplinary collaborative research in Europe and Africa and the Global Health Division acts as a resource centre at Karolinska Institute. Extensive networks of collaboration exist within Karolinska Institute and the division is an active stakeholder in the Karolinska International Research and Training (KIRT) Programme and the Centre for Global Health (KICGH).

The Global Health Division research groups address 7 major health problems in low and middle income countries: Epidemiology and health systems, health policy, HIV/Aids, Medicines, Injuries Social Aetiology, Sexual and Reproductive Health and Rights, and Adolescent Sexual and Reproductive Health (including child health) Educational Programmes.

The division has well developed education programmes in Global Health at undergraduate, Master's and doctoral level. A research school in Global Health is organised together with Umeå University. In addition, the division collaborates closely with Gapminder Foundation for developing evidence-based information.

Relevant Publications

1. **Bergström S**. Who will do the caesareans when there is no doctor? Finding creative solutions to the human resource crisis. Brit J Obst Gyn 2005; 112:1168-9
2. McCord C, **Mbaruku G, Pereira C**, Nzabuhakwa C, and **Bergström S**.
   The quality of Emergency Obstetrical Surgery by Assistant Medical Officers in Tanzanian District Hospitals. Health Affairs 28, no. 5 (2009): W876 – 885.
2. **Pereira C**, Cumbi A, Vaz F, McCord C, Bacci A, **Bergstrom S**. Meeting the need for emergency obstetrical care in Mozambique: Work performance and work histories of medical doctors and assistant medical officers trained for surgery,
   Brit J Obst Gyn 2007: 114: 1530-33.
3. Chilopora GC, **Pereira C**, Kamwendo F, Chimbiri A, Malunga E, Malewezi J, **Bergstrom S**, Postoperative outcome of caesarean sections and other major emergency obstetric surgery by clinical officers and medical officers in Malawi.
   Human Resources for Health 2007; 5:17-23.
4. **Pereira C**, Bugalho A, **Bergstrom S**, Vaz F, Cotiro M. A comparative study of caesarean deliveries by assistant medical officers and obstetricians in Mozambique. Brit J Obst Gyn 1996: 103: 508-512.

Participant 3 – Ministry of Health, Malawi

Main tasks attributed in the project

The Ministry of Health will work with Ifakara, Karolinska and Warwick to translate the project objectives in the development of Non-Physician Clinicians into reality in the African setting. Dr Chisale Mhango, who was Director of the Reproductive Health Unit in the Ministry, has now left the Ministry and will contribute via his affiliation with the University of Malawi College of Medicine. However, the team that he formerly led will continue to contribute substantially to the local delivery to Work Package 1, and have major inputs to Work Package 2, and 3. Dr Francis Kamwendo of the University of Malawi's reproductive department will lead on implementation and evaluation of guidelines in Malawi (WP2). Dr Kamwendo will be the academic lead and be involved in the design and delivery of research in Malawi (WP2 and 3). Malawi's Ministry of Health have a proven track record of working with partners on the development and research into medical equipment. Any successful intervention will need to be sustained and the Ministry of Health has a proven track record of sustained community health programmes.

Summary of experience relevant to project

Dr Mhango and his team have long-standing experience working on the design and delivery of health care supporting maternal and perinatal survival in Malawi. They have the full support of the Ministry of Health, where maternal and child health is an important priority.

While at the Ministry of Health, Dr Mhango built up a network of professional colleagues and stakeholders through the country as part of his key role in providing strategic planning and management of the national reproductive health services. He has held senior positions with the United Nations and is advisor to the Health Ministers of Malawi. Hiskey links to the clinical academics in the Medical School in Blantyre where he previously held an academic post as Senior Lecturer in obstetrics, make Dr Mhango's return there a natural progression. Dr Mhango and his team have extensive experience in public health in undertaking evaluation exercises in Reproductive Health Programmes for WHO, World Bank, UNFPA and USAID. He and his team in Malawi have been involved in organising training and developing customised educational material such as training manuals. Malawi represents an enormous challenge in innovation and task shifting of roles and skills in healthcare. There is one doctor for every 70,000 people and one trained nurse for every 3,000. Non-Physician Clinicians struggle to improve reproductive healthcare but need expansion training and support. The Ministry of Health believes that providing essential health care at community level is the best strategy to improve the health of individuals, families and communities.

Relevant Publications

1. Chilopora GC, **Pereira C**, **Kamwendo F**, Chimiri A, Malunga E, Malewezi J, **Bergstrom S,** Postoperative outcome of caesarean sections and other major emergency obstetric surgery by clinical officers and medical officers in Malawi.
   Human Resources for Health 2007; 5:17-23.

Participant 4 – Ifakara Health Institute, Tanzania

Main tasks attributed in the project

The team at Ifakara Health Institute (IHI) will work with Karolinska and Warwick to translate the project objectives into reality in the African setting. The Deputy Director, Dr Godfrey Mbaruku will lead on Work Package 1, and have major inputs to Work Package 2 and, 3. He will co-supervise the Senior Clinical Research Fellow who will be based in Africa and will be responsible for the day to day management of clinical issues and co-ordination of the intervention studies and evaluations. He will be involved in WP3 in curriculum design and content.

Summary of experience relevant to project

Ifakara Health Institute for 50 years has been a beacon of excellence of international repute that is independent and provides a non-profit district based research and resource centre of 600 staff and 100 research scientists. In health research it leads on public health policy, translational research and teaching and training. It has a network across Tanzania of surveillance systems in 27 districts collecting routinely data on demographic, socio-economic and health from health facilities and households.

This pre-existing research infrastructure resource will be extremely valuable in achieving the objectives of ETATMBA. It has scientists capable of leading evaluations into applied technologies and working with GE and Warwick engineers. Dr Godfrey Mbaruku, a senior clinician in obstetrics, clinical researcher and teacher, plays a leadership role in organising and delivering appropriate teaching courses on clinical skills for mid-level health workers coming from across sub-Saharan Africa working in partnership with Karolinska. He is developing managerial and leadership courses. Research into 'on the job' training for mid-level providers (Assistant Medical Officers and Nurses) in surgical and anaesthesia skills is already underway and enhancing this provision will form the basis for the project. IHI has residential accommodation and state-of-the-art training facilities.

Relevant Publications

1. McCord C, **Mbaruku G, Pereira C**, Nzabuhakwa C, **Bergström S**. (2009). The quality of emergency obstetrical surgery by assistant medical officers in Tanzanian district hospitals. Journal of Health Affairs 28:876-885.
2. **Mbaruku G**, Msambichaka B, Galea S, Rockers PC, Kruk ME. (2009). Dissatisfaction with traditional birth attendants in rural Tanzania, International Journal of Gynaecology and Obstetrics doi:10.1016/j.ijgo 2009.05.008.
3. **Mbaruku G**, van Roosmalen J, Kimondo I, Bilango F, **Bergström S**. (2009). Perinatal audit using the 3-delays model in western Tanzania. International Journal of Gynaecology and Obstetrics. 106, 85-88.
4. Kruk ME, **Mbaruku G**, McCord CW, Moran M, Rockers PC, Galea S. (2009). Bypassing primary care facilities for childbirths; a population based study in rural Tanzania. Health Policy and Planning, 24, 279-288.
5. Rockers PC, Wilson ML, **Mbaruku G**, Kruk ME. (2008). Source of antenatal care influences facility delivery in rural Tanzania: a population-based study. Journal of Maternal and Child Health, doi 10.1007/3 10995-008-04127.

Participant 5 – GE Healthcare

Main tasks attributed in the project

The team at GE Healthcare will work with Warwick and African partners to realise the objectives particularly in the development of NPCs and the use of existing appropriate technologies for the African setting. Alan Davies, UK Medical Director will be responsible and will lead for GE Healthcare. GE Healthcare will also have major inputs into the organisational, managerial and leadership training aspects of WP3 and have training inputs in WP1 and WP2 GE Healthcare is assisting with the staffing and organisational costs for these courses as their contribution. Dr Alan Davies will co-ordinate GE Healthcare activity and is Chief Medical Officer for the European and African Region of GE Healthcare. He has over 50 peer reviewed publications and over 30 years experience in clinical research study design and analysis. He has worked extensively with government, leading universities and pharmaceutical and device companies on healthcare research, drug and device development.

Summary of experience relevant to project

GE Healthcare is a $17 billion unit of the General Electric Company and employs 46,000 people globally, headquartered in the United Kingdom. GE spends more than one third of its R&D efforts across Europe. It provides transformational medical technologies and services that are shaping a new age of patient care.

GE Healthcare is a world leader in developing state-of-the-art technology for healthcare and is committed to funding the development of low-cost solutions for rural healthcare challenges in low-income countries. This represents a massive underserved population of three billion people. GE Healthcares core expertise lies in technical R&D, medical device innovation, and quality/regulatory assurance.

GE Healthcare is committed to training for the technologies in clinical use, maintenance and hospital administration with African partners.

Participant 6 – University of Malawi, College of Medicine

Main tasks attributed in the project

The addition of the University of Malawi College of Medicine to the consortium will provide further support and professional esteem for the NPCs. The College will also assist with the training of NPCs in Malawi, a development further facilitated by Dr Chisale Mhango who has recently transferred from the Ministry of Health to the College of Medicine. Dr Mhango will continue to deliver training as before, but his primary connection to the project will be via the College of Medicine rather than the Ministry of Health. He is an experienced obstetric specialist who has practiced in Europe and in many countries in sub-Saharan Africa.

The College will continue to build additional, sustainable training into a framework that will lead to further qualifications, and will be a vital partner in developing this. The development of professional culture and ethos will form a significant aspect of the College's contribution due to the knowledge and reputation of the institution. It is therefore anticipated that the College of Medicine will contribute to Work Packages 1, 2 and 3.

The team at the College of Medicine will work with the other members of the consortium to implement the objectives of the Work Packages. Dr Francis Kamwendo will contribute his expertise to the training of the NPCs and will assume the role of one of the Senior Clinical Research Fellows to be appointed on the project. He will assist with the supervision of the PhD students and will be the contact for queries about the practicalities and management of the project. Additional research support capacity in Malawi will be provided by joint supervision with Warwick, lead by Senior Clinical Research Fellow Dr David Ellard. Dr Chisale Mhango will contribute to the training sessions and to the logistics of the project, where his considerable experience will inform both teaching and assessment strategies. Both Dr Kamwendo and Dr Mhango will have major input to Work Packages 1, 2 and 3.

Summary of experience relevant to project

The College of Medicine was established in 1991 as a constituent college within the University of Malawi, and remains the only medical school in Malawi. Its growth from an initial intake of 10-15 students per year to an average of 60 per year is testament to its success under the strong academic leadership of Prof Ken Maleta, with a faculty numbering 110 academics and clinicians, 67% of whom are Malawians. Academic achievements include the award of a number of international prizes for an innovative undergraduate teaching programme.
Since its establishment, the College and its collaborators have generated high quality health research findings which have been published in reputable local and international journals and presented at high profile scientific conferences. Some of the findings have enabled Malawi to improve the management of health-related conditions and to formulate relevant health programs and policies.
Research at the College hosted in different departments is coordinated by the Research Support Centre, and this strong infrastructure has been instrumental in the decision to request the College to manage the majority of the funding for the ETATMBA project.

Relevant Publications

Chilopora GC, Pereira C, **Kamwendo F**, Chimiri A, Malunga E, Malewezi J, Bergstrom S. Postoperative outcome of caesarean secrtions and other major emergency obstetric surgery by clinical officers and medical officers in Malawi. Human Resources for Health 2007; 5:17-23.

2.3 Consortium as a whole

ETATMBA brings together the leading European advocate and researcher for the role and development of NPCs (Karolinska) with one of Europe's leading centres for developing large scale education for health professionals (Warwick) in a project to develop the training and professionalism within their health sectors of NPCs in sub-Saharan Africa. Both African partners have the support of their local and government health agencies and are recognised as leading centres in their countries. The consortium brings together partners with the objective of articulating training and technology and developing with healthcare workers in Africa from NPCs to leading consultant specialists an ethos of mutual respect and professionalism to produce more effective and sustainable healthcare for mothers and their newborn. The academic interchange should lead to capacity building in teaching, assessment, leadership, management skills, research and enhance professionalism for all partners and groups across the consortium.
The project will develop frameworks for clinical service improvement and enhanced training for NPCs and the medical profession in Africa as trainers in two sub-Saharan countries. The model developed, educational resources derived and learning and professional culture engendered will be transferable across Africa and to low-income countries throughout the world.

Participants 1, 2, 3, 4 and 6 will sub-contract to external auditors for their Certificate on Financial Statements. An external organization will need to carry out this work in order to comply with FP7 regulations, since the requested EC contribution for these participants is greater than €375,000 Participant 5 will not require an external CFS because their requested EC contribution is less than the threshold. An estimate of the costs is provided in the detailed budget breakdown in section 2.4.

Table 2.3 Expertise of participants

Participant	Main Expertise	Contribution to Work Package
1. Warwick	Training/Clinical Education Management training Research design	WP3, 1, 2
2. Karolinska	Workforce development Training Clinical research Guidelines and protocols	WP1, 2, 3, 4
3. Tanzania	Training/teaching Translational research Guidelines	WP1, 2, 3
4. Malawi MoH	Training/teaching Translational research Guidelines and protocols	WP1, 2, 3
5. GE Healthcare	Management training Technology training	WP1, 2, 34
6. University of Malawi	Training/teaching Translational research Guidelines and protocols	WP1, 2, 3

2.4 Resources to be committed

In view of the importance of enhancing human resources and articulating appropriate technologies for maternal and perinatal survival in sub-Saharan Africa, the partnership for this project is committing a considerable amount of its own resources to the proposed project but requests additional financial support from the European Union in order to meet all the costs involved. Table 2.4.1 below summarises the estimated total budget for the project, showing separately the amounts requested from the European Union and estimates of the value of those resources that can be committed by the partners.

Participant	Own staff	Own equipment	Own consumables	Own resources total	Requested EU budget
1 Warwick	**€141,800**	**€40,000**	**€30,000**	**€211,800**	**€683,743**
2 KI	**€90,000**	**€56,000**	**€60,000**	**€206,000**	**€491,000**
3 MMOH	€12,800	**€3,200**	**€3,200**	**€19,200**	**€99,752**
4 IHI	**€80,000**	**€20,000**	**€20,000**	**€120,000**	**€809,497**
5 GE	**€100,000**	**€20,000**	**€30,000**	**€150,000**	**€10,000**
6. UOM	**€67,200**	**€16,800**	**€16,800**	**€100,800**	**€505,964**
TOTAL	**€491,800**	**€156,000**	**€160,000**	**€807,800**	**€2,599,957**

Table 2.4.1: Total resources committed to ETATMBA project (€)

Personnel

The ETATMBA consortium requests 380 person months to be funded by the EU, to cover leading expertise in all the technical fields relevant to successful delivery of the proposed project, including clinical and leadership training at all relevant levels within the health sector in sub-Saharan Africa; curriculum design, distance design and delivery; clinical trial design and delivery; clinical practice in obstetrics and neonatal care.

The Senior Clinical Research Fellows, for which EU funding is requested, will be based in Africa and play a key role in ensuring successful project delivery as well as providing a capacity-building opportunity.

GE Healthcare will contribute free-of-charge staffing costs of management and leadership training..

In addition, through the partners' institutions, considerable additional staff support can be accessed for project management including contract negotiation, post award administration and legal matters; project delivery; and appropriate dissemination and communication to multiple stakeholder groups. At IHI, for example, some 20 additional staff (Financial controller, Medical officers, Anaesthetist, Ward Incharges, Laboratory technicians, Theatre Room Incharges, and Auxiliary staff) will support the project.

Many of the partners have already worked together successfully on other research and implementation and so have a proven track record of delivery.

Other direct costs (Travel, equipment, facilities and materials)

Approximately 40% of the total requested budget is to cover the significant direct travel, technical and training costs associated with this project. Much of this budget will reside in the Malawi and Tanzanian budgets but if additional support staff travel/accommodation or educational materials are required it has been agreed that at the direction of the Management Board, and with the approval of the EC where required, movement of funds can occur. However, all the partner institutions are well-equipped to deliver a project of this nature and can provide significant additional support free of charge. Warwick is one of the UK's leading research-intensive Universities with impressive facilities supporting the delivery of medical research and training. KI is fully equipped with the

computers and field equipment (projectors, educational material, etc) as well as teaching and meeting facilities necessary to deliver its components of the project. The African partners are adequately resourced with computers (desk and laptops), printers, microscopes, clinical equipment (in the operating rooms, wards, outpatient department, pharmacy), and laboratory equipment (various for diagnosis and training). In addition, they have access to the Laboratories, Classrooms and Lecture theatre space, and Training Materials necessary to deliver a project of this scale, and the Consultant hospital at Ifakara and District hospital at Bagamoyo (mainly for Paediatrics and Laboratory).

The direct cost budget will be broken down across the whole project as follows:

PARTICIPANT Other Direct Costs	**1**	**1**	**2**	**3**	**4**	**5**	**6**	**Total**
	WAR	**WAR MGT**	**KI**	**MMOH**	**IHI**	**GE**	**UOM**	
PhD stipends and fees	€ 0	€ 0	€ 0	€ 31,974	€ 63,947	€ 0	€ 31,974	€ 127,895
Travel and accommodation	€ 131,684	€ 0	€ 64,138	€ 13,250	€ 76,329	€ 7,083	€ 160,298	€ 452,782
IT (where not provided from Participants' own resources)	€ 0	€ 1,740	€ 3,100	€ 0	€ 1,500	€ 0	€ 1,500	€ 7,840
Communication (mobiles, international calls)	€ 0	€ 2,000	€ 1,950	€ 200	€ 702	€ 0	€ 502	€ 5,354
Consumables (materials for course delivery, printing etc)	€ 2,900		€ 2,500	€ 0	€ 1,937	€ 2,500	€ 1,937	€ 11,774
Staff recruitment	€ 0	€ 2,000	€ 0	€ 0	€ 1,173	€ 0	€ 1,173	€ 4,346
Dissemination (publication costs, publicity for the initiative etc)	€ 1,776	€ 10,658	€ 0	€ 0	€ 6,602	€ 0	€ 6,602	€ 25,638
Facilities (eg room hire not provided out of Participants' own resources)	€ 0	€ 0	€ 0	€ 100	€ 600	€ 0	€ 500	€ 1,200
Tuition	€ 0	€ 0	€ 0	0	€ 102,194	€ 7,084	€ 102,194	€ 211,472
Total	**€ 136,360**	**€ 16,398**	**€ 71,688**	**€ 45,524**	**€ 254,984**	**€ 16,667**	**€ 306,680**	**€ 848,301**

Subcontracts for Certificate on Financial Statements (auditing)

	1	**1**	**2**	**3**	**4**	**5**	**6**	**Total**
	WAR	**WAR MGT**	**KI**	**MMOH**	**IHI**	**GE**	**UOM**	
	€ 0	€ 2,726	€ 3,500	€ 2,588	€ 2,588	€ 0	€ 2,588	€ 13,990
Total	**€ 0**	**€ 2,726**	**€ 3,500**	**€ 2,588**	**€ 2,588**	**€ 0**	**€ 2,588**	**€ 13,990**

Justification of costs classified as "Other" or "Management":

The direct costs classified under "Other" are for dissemination activities. Participants 3 and 4 will require €6,602 for international travel for the purpose of dissemination. Participant 1 will require €12,434 to pay for publication costs (including open access fees) and publicity for the initiative aimed at engaging a wide range of stakeholders. A further €2,000 is allocated to Participant 1's budget under "Management" in order to pay for the recruitment of a dedicated Project Manager.

All the staff costs classified under “Management” (€183,926 of Participant 1’s budget) are accounted for by the salary of the Project Manager. This individual will be a key part of the Management team described in section 2.1, and will be essential to the delivery of the project.

The Project Manager will also spend a total of six months over the duration of the project on dissemination activities (accounting for €52,653 of Participant 1’s staff budget) and a lead member of academic staff at Participant 1 will spend one month on dissemination activities (accounting for a further €2,842 of staff costs). These costs are classified as “Other”.

3. Impact

3.1 Expected Impacts listed in the work programme

Situating the project in the objectives of the work programme "Health 2010" 3.4.-2 Feasibility and community effectiveness of innovative intervention packages for maternal and new-born health in Africa. FLY - CALL – FOR – AFRICA – 2010", the ETATMBA project addresses the objective to develop research that is impact-orientated to promote the health of mothers and babies through strategies to educate and train the workforce. We aim to develop the use of NPCs and workers to provide structured education and training that is professionally recognised and resourced and will sustain and develop these key retainable resources. A major healthcare industrial partner will work with leading university healthcare and engineering faculties to develop, to train and sustain a new role for NPCs as advanced leaders and this advanced training cascaded down across Malawi and Tanzania should allow an impact on maternal and neonatal mortality in remote communities in sub-Saharan Africa. The project will provide an educational intervention that will be tied to local clinical services improvements that will design protocols and guidelines based on relevant and practical evidence based practice that will be applicable in the local socioeconomic and cultural context.
A major theme of the project is to provide research that demonstrates the effectiveness and ability of the training to translate and be sustainable in support of maternal and perinatal survival in sub-Saharan Africa. The project will research its overall effectiveness to ultimately improve maternal and newborn health and contribute to Millennium Development Goals 5 (maternal health) and 4 (child health)
The research will be guided by the involvement of a patient and trainee user group and involve local and government health agencies in two sub-Saharan African countries. This will ensure it is delivered and has the potential to be sustainable as a public health initiative across sub-Saharan Africa. The high profile of the international collaborators will ensure widespread media coverage. We will utilize the model in the development of the international focus in the partner universities. The project will be a catalyst and resource for research and teaching development in the partner African institutes. The research will maximise impact through publication in high impact journals, presentations at high-level international conferences and the development of special interest groups for education and the professional training of healthcare workers.

3.1.1 Impact on EU concerns related to population growth and healthcare needs in Africa

In 2010 the billionth African will be born and this population explosion is a major challenge to global health and economic development. The increase in population from 110 million in 1850 to 1 billion in 2010 has been at a rate that exceeds the most Malthusian predictions (22). The population in Africa has doubled in the last 27 years. Whereas in 1950 there were two Europeans for every African, by 2050 there will be two Africans for every European. Women in Africa still bear more children than woman in other regions. The average woman worldwide has 2.6 children, in sub-Saharan Africa the figure is 6.5 (23). Poverty and poor economic circumstances do not diminish population growth but low-life expectation and inadequate maternal and neonatal and infant healthcare are major drivers and fertility is high in societies where mortality is high. Underdevelopment of reproductive health services, poverty and limited education are major challenges for the emerging societies and governments in Africa. These are aggravated by the increasing and socially chaotic drive of urbanization with shifting populations and great demands on local healthcare provision.

Improving maternal and neonatal survival and health would have an immediate impact on health and allow sustainable economic development as has already been demonstrated in China and India. This will lead to a reduction in the overall population explosion. The EU and other world partners are committed to assisting Africa to become an economically viable and stable community facing its

health, urbanization and ecological challenges. Investment in solutions to improve reproductive healthcare are vital to Africa and the EU.
To provide high quality sustainable healthcare, systems are required to train, retain and sustain the professionals that will lead service provision. For maternal and neonatal health, the consequences of a lack of access to trained health professionals is a major contribution to the extremely high maternal and neonatal mortality. In the modern world this tragedy is unacceptable and largely preventable. Education and training for health professionals is the key to improving healthcare in Africa. It needs to be evidence-based and comprehensive but able to be delivered within the community, applicable to local needs. It needs to be sustainable yet scalable to cover the needs of the African mother in all areas of a vast continent. It also needs to be based on what works for Africa. To develop and sustain this provision, it must be extended to involve leaders (local health professionals and clinical research) to provide an ethos of continuing support, recognition and evaluation.

3.1.2 Innovations around workforce training and educational research

To address the shortage of qualified medical doctors and experienced nurses and midwives in sub-Saharan Africa, the use of Non-Physician Clinicians has been developed and supported by governments as an affordable solution. Their role has been supported and championed by local and international authorities (1,10,11,12,13). These workers are seen as key innovators in the development of effective healthcare provision but as an emerging profession they need, not only further expansion, but structure in the form of high quality training, structured assessments and systems of Continuing Professional Development (CPD). The practice must be evidence based and any clinical systems developed to improve healthcare at the community level need to be fully evaluated using clear research methodology. The relationship and tensions between the small numbers of fully medically qualified practitioners and the new types of professionals needs to be addressed and resolved. This is vital for the effective use of resources and to ensure that these healthcare systems are to sustain as development grows.

Developing research and educational capacity and research leadership that sustains in Africa is the key component and development objective of our bid. Our research programme aims to develop and deliver educational interventions targeting human resources. These new strategies around maternal and perinatal health will develop protocols and practices based on the application of clinical service improvement to improve patient safety and quality of care. These strategies will be highly relevant and applicable in the local socioeconomic and cultural context. Two specific African partner countries are involved at this stage, but the models and evaluation that will be developed will be applicable and the research evidence produced will be applicable across sub-Saharan Africa.

3.1.3 Added value of a European consortium working with partner institutions to capacity build in Africa

The project cannot be carried out by a single institution working with a selected area in Africa. The project will take the healthcare training expertise and leadership from Karolinska and Warwick and harness this to deliver through the existing carefully refined delivery structures in the partner institutes in Africa. The model will be researched in two countries to show that it is robust, scalable and transferrable across sub-Saharan Africa. Much of the initial phase of the project will be development and training but then research capacity will be developed and delivered. Integration of the project into the local healthcare system and ensuring the active collaboration of local and national government will be a major factor in producing sustainability and developing the model as a beacon for educational development across the sub-continent.

3.2 Dissemination and exploitation of project results and management of joint credentialing and intellectual property

All participants agree to and are aware of the importance that results are disseminated widely and at the earliest stage. The academic community, the public (including researchparticipants) and the media will be engaged. Interaction with the medical profession throughout Africa will ensure that the evidence base and efficiency measures and the academic debate lead to the development of a healthcare system where mutual trust and respect exists for all levels of workers. Working with governments, industry and academic figures in Africa will allow this important goal to be achieved.
The contribution of the European Union will be highlighted throughout the project.
To ensure that the proposed measures are implemented, all dissemination and exploitation activities will be co-ordinated by the Quality Assurance group working with work package leaders and advising the Steering Committee (SC)

Activities that will be employed to ensure an efficient flow of information include:

- Steering Committee meetings every 6 months involving all collaborators and key researchers. During this meeting the general progress of the project will be discussed. Focus will be on progress and deliverables. Video conference techniques will be used to allow regular contact and effective communication on a global basis.
- Research output for scientific/educational meetings will be approved by Steering Board and delivered at local, national and international meetings.
- By 24 months, a Pan-African international conference on educational development and training will be organised and delivered. This will be the basis for discussion of the later phases. The network of professionals interested and active in the medical education of healthcare workers in Africa will allow dissemination and feedback.
- Regular press and media communications will ensure public engagement. The Communications Department of Warwick Medical School will co-ordinate communication to implement a comprehensive strategy.
- The involvement of an industrial partner, GE Healthcare, with experience of African infrastructure will allow transfer of knowledge into marketable products.
- International exchange of research scientists and increased scientific capacity in partner institutions will improve the dissemination of technology and the transfer of knowledge. Building research and education capacity in Africa is a major deliverable.
- It is in the interests of collaborators to inform the scientific and academic community via publications of research results and abstracts in international peer reviewed journals. The Steering Board will ensure that publication is not delayed and is in open access journals.
- The scientific and medical education community will be informed through workshops, conferences and national and international scientific meetings.
- A specific public website will be created which will make protocols, guidelines, published papers and research progress available. In addition, the website will contain general information on the project, participants, background, press releases and progress reports. There will be an interactive element to allow public participation with comments and ideas. A separate forum will exist for the user-involvement group who will scrutinize and comment on research design, ethics and management. A website manager will maintain the website and regularly update it.
- In each country, participants and their teams will engage in public awareness using workshops in schools, public debates, institutions open days, and engaging in the curricula of their institutions.

The intellectual property will be shared between partners on the understanding that education materials are available to other emerging countries in Africa at minimal cost. In the case of funding, a consortium agreement will be prepared to clarify the rights and duties for the members with

regards to intellectual property issues and in accordance with the Grant Agreement on ownership, transfer protection, use and dissemination of foreground. This consortium agreement will clarify that as the project evolves partners will be flexible in using resources to deliver all the essential components of the work packages.

4. Ethical Issues

All participants will obey the charter of fundamental rights of the European Union (2000/C364701, dec 7, 2000).

Studies evaluating training and support

All research within the ETATMBA consortium will be conducted according to the latest version of the declaration of Helsinki. All mothers involved in our studies will give informed consent prior to participating in the clinical protocols and only volunteers will participate.

The training and educational interventions will involve evaluations that are part of enhanced clinical practice and all data collected will be anonymised for any analysis to protect the rights of individual patients. Full data protection and privacy rights will be respected across all five partner institutions and in health service facilities that are involved in collecting research data.

All research plans and consent forms will be reviewed by the ethics committee of the co-ordinating university (Warwick) and by the local ethics committees in Sweden, Tanzania and Malawi. Consent forms and patient information sheets will be provided in appropriate language and for mothers who cannot read interpreters and DVD consent information will be used at recruitment. Approval will be obtained prior to the studies and all academic partners have access to Medical Ethical Committees. GE Healthcare will provide insurance for all applied technology devices that will be made available according to local/national ethical board requirements to cover potential liabilities as a consequence of participation in the studies. Academic partner institutes will provide insurance for all other aspects of the research.

Protection of personal data

All data collected in this research will be subject to the UK Data Protection Act 1998 with regard to the collection, storage, processing and disclosure of personal information and will also follow recommendation N.R. (97) 5 of the committee of Ministers to Member States on the Protection of Medical Data. Data from medical records and data collected as part of consortium work will be used. Data stored on computers or shared between researchers involved in the project will be anonymised and will not refer to the person by name but will use a code. The identity of the person carrying a given code will be stored in secure files. Data will not be published in a form that enables the subjects to be indentified unless they have given their consent for the publication and publication is permitted by domestic law. Unnecessary collections and use of data will be avoided. Volunteers who later decide to withdraw consent can request destruction of their data.

Safety issues

All participants and institutions particularly in the areas of development and assessment of medical devices and technologies will comply fully with EU and national regulations for health and safety in the work place.

ETHICAL ISSUES TABLE

(Note: Research involving activities marked with an asterisk * in the left column in the table below will be referred automatically to Ethical Review)

	Research on Human Embryo/ Foetus	YES	PAGE
*	Does the proposed research involve human Embryos?		
*	Does the proposed research involve human Foetal Tissues/ Cells?		
*	Does the proposed research involve human Embryonic Stem Cells (hESCs)?		
*	Does the proposed research on human Embryonic Stem Cells involve cells in culture?		
*	Does the proposed research on Human Embryonic Stem Cells involve the derivation of cells from Embryos?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	X	

	Research on Humans	YES	PAGE
*	Does the proposed research involve children?	X	5-7, 18-19
*	Does the proposed research involve patients?	X	5-7, 18-19
*	Does the proposed research involve persons not able to give consent?		
*	Does the proposed research involve adult healthy volunteers?	X	5-7, 18-19
	Does the proposed research involve Human genetic material?		
	Does the proposed research involve Human biological samples?	X	
	Does the proposed research involve Human data collection?	X	5-7, 18-19
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Privacy	YES	PAGE
	Does the proposed research involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	X	5-7, 18-19
	Does the proposed research involve tracking the location or observation of people?	X	5-7, 18-19
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Research on Animals	YES	PAGE
	Does the proposed research involve research on animals?		
	Are those animals transgenic small laboratory animals?		
	Are those animals transgenic farm animals?		
*	Are those animals non-human primates?		
	Are those animals cloned farm animals?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	X	

	Research Involving Developing Countries	YES	PAGE
	Does the proposed research involve the use of local resources (genetic, animal, plant, etc)?	X	5-7, 18-19
	Is the proposed research of benefit to local communities (e.g. capacity building, access to healthcare, education, etc)?	X	5-7, 14-19
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Dual Use	YES	PAGE
	Research having direct military use		
	Research having the potential for terrorist abuse		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	X	

5. Consideration of gender aspects

This project is about enhancing effective human resources to help women and babies in sub-Saharan Africa and as such it addresses a major global tragedy of the inequity of healthcare that denies women in Africa of a basic human right.
Access to higher healthcare education can be limited by economic and cultural factors and the recruitment of NPCs should allow a gender balance that is more appropriate than traditional medical school selection. Providing more status and a professional training structure should encourage more women to become NPCs and to become advance leaders and to progress to senior managerial and clinical roles.

We aim to empower this group as professionals who in their own right will lead healthcare in their communities acting as beacons to stamp-out gender stereotypes and encouraging further professional roles in teaching research and healthcare management.

Safer childbirth in Africa coupled to improving economic development will ultimately relieve women from the burden of a high fertility rate while allowing them to have infants that will survive. This will restore for many women a fundamental human right.

In Europe and Africa in the field of obstetric care and pediatrics, there are increasing numbers of women in clinical leadership and academic roles. We will increase this number in our recruitment of staff in Europe, Tanzania and Malawi whilst following the ethics of equal opportunity.

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