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# BMJ Open

## Informing prevention of stillbirth and preterm birth in Malawi: development of a minimum dataset for health facilities participating in the DIPLOMATIC collaboration

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## ABSTRACT

### Objective

The global research group, DIPLOMATIC (Using evidence, Implementation science, and a clinical trial Platform to Optimise MATernal and newborn health in low Income Countries), aims to reduce stillbirths and preterm births and optimise outcomes for babies born preterm. Minimum datasets for routine data collection in healthcare facilities participating in DIPLOMATIC (initially in Malawi) were designed, to assist understanding of baseline maternal and neonatal care processes and outcomes, and facilitate evaluation of improvement interventions and pragmatic clinical trials.

Design  
Published and grey literature was reviewed alongside extensive in-country consultation to define relevant clinical best practice guidance, and the existing local data and reporting infrastructure, to identify requirements for the minimum datasets. Data elements were subjected to iterative rounds of consultation with topic experts in Malawi and Scotland, the relevant Malawian professional bodies, and the Ministry of Health in Malawi to ensure relevance, validity, and feasibility.

### Setting

Antenatal, maternity and specialist neonatal care in Malawi.

### Results

The resulting three minimum datasets cover the maternal and neonatal healthcare journey for antenatal, maternity and specialist neonatal care, with provision for effective linkage of records for mother/baby pairs. They can facilitate consistent, precise recording of relevant outcomes (stillbirths, preterm births, neonatal deaths), risk factors and key care processes.

### Conclusions

Poor quality routine data on care processes and outcomes constrains healthcare system improvement. The datasets developed for implementation in DIPLOMATIC partner facilities reflect, and hence support delivery of, internationally agreed best practice for maternal and newborn care in low income settings. Informed by extensive consultation, they are designed to integrate with existing local data infrastructure and reporting as well as meeting research data needs. This work provides a transferable example of strengthening data infrastructure to underpin a learning healthcare system approach in low income settings.

DIPLOMATIC is funded by the UK National Institute for Health Research.

### STRENGTH AND LIMITATIONS OF THIS STUDY

- In line with recommended practice, the datasets were designed using a multimodal approach, combining an in depth review of the contextual information and published and grey literature with expert input.
- Delphi methods to gain expert consensus were considered, but deemed unsuitable due to the large number of variables, many of which form interconnected constructs and could thus not be changed independently of each other.
- Instead of a Delphi survey, iterative rounds of consultation with DIPLOMATIC collaborators and other stakeholders in Malawi were undertaken, which were essential to facilitate Malawian ownership, increasing the likelihood that study recommendations can be implemented and scaled up to increase impact.
- One limitation of this inclusive approach is that the datasets are more extensive than other exemplars of national minimum datasets.
- However the approach ensures that the datasets can integrate with existing systems and meet local data requirements, and also have the capacity to evaluate other Ministry of Health initiatives, rather than addressing research requirements only.



## INTRODUCTION

The global burden of stillbirths and preterm births remains significant. According to recent global estimates, 2.6 million babies were stillborn at 28 completed weeks gestation or over in 2015.[1] Half of stillborn babies died during labour.[1] Complications of preterm birth (defined as delivery before 37 completed weeks gestation) accounted for nearly one fifth of deaths in under five year old children globally (18%) in 2016.[2] Babies born preterm, who survive, remain at risk of developmental delay,[3] and long term physical morbidities.[4]

## DIPLOMATIC

DIPLOMATIC (Using evidence, Implementation science, and a clinical trial Platform to Optimise MATernal and newborn health in low Income Countries) is a National Institute of Health Research (NIHR) funded global research group with partners in Malawi, Zambia and the United Kingdom (UK), which aims to reduce stillbirth and preterm birth, and optimise outcomes for babies born preterm. In Malawi and Zambia, an estimated 14,000 and 13,000 stillbirths occur every year (21.8 and 20.9 stillbirths per 1000 total births respectively).[1] An estimated 68,000 and 76,000 babies per year are born preterm, accounting for 10.5% of births in Malawi and 12% in Zambia.[5] Ranked by increasing rates, Malawi and Zambia were 160th and 155th out of 194 countries for rates of stillbirth in 2015 and 123rd and 127th out of 183 countries for rates of preterm birth in 2014, respectively.[1, 5] DIPLOMATIC aims to develop pragmatic clinical trials to test the effectiveness of evidence based practices and how best to implement them in low income settings. Consistent and accurate data are required from participating healthcare facilities to efficiently monitor intervention implementation and outcomes and hence trial results.

Establishing parallel data collection for research projects, rather than integrating this with routine data collection, can lead to a disjointed approach which risks duplication of effort and waste of scarce resources. A learning health system approach has been identified in similar low income settings, as an effective means of combining data intelligence for quality improvement, with research on the implementation of new interventions and optimising their effectiveness. [6, 7] In this context, the learning health system was characterised by a strong stakeholder network, and facilitation of local application of data intelligence, to allow faster integration of evidence based interventions, and efficient use of the same data to drive research. [7]

### **Current perinatal data infrastructure in Malawi**

To ensure that the data collection for DIPLOMATIC would integrate with and strengthen existing systems, the collaboration undertook a baseline, in-depth review of the existing data infrastructure relating to perinatal health in Malawi.

Vital events registration in Malawi is mandated by the National Registration Act of 2010, but coverage of birth and death registration is still incomplete, though efforts to improve coverage are in progress.[8, 9]

Individuals hold their own medical records as 'health passports' (structured paper based records), which they present whenever accessing healthcare. For women of childbearing age, the health passport records a summary of medical and obstetric history, contraceptives, antenatal care (ANC), and the delivery record. Neonates receive their own passport at birth. Most district and central hospitals maintain paper based patient notes when providing inpatient perinatal care. For specialist neonatal care, a standardised admission form is available. A brief note is made in the patients' health passport at discharge,[10] which is usually the main source of information to clinicians on patients' history in case of readmission, as retrieval of patient notes held by healthcare facilities is difficult. Neonatal and maternal records are not routinely linked, and if the mother is not present or deceased, her information is not available for the care of the neonate. An electronic patient record system for ANC is available, but uptake is limited to date (24 out of 85 hospitals and 12 out of 542 health centres across Malawi, as of May 2019).[11] An application for immediate electronic data capture on neonatal admissions (NeoTree) was developed recently and tested in one hospital.[12] This application is designed as a decision support tool, to improve quality of care, and does not have any reporting functionality for integration with local data systems as yet.[12]

In addition to individual patient notes, healthcare facilities maintain 'registers' (individual level paper logs) for clinical care including ANC, maternity/birth record, neonatal resuscitation, and Kangaroo Mother Care (KMC), with partial overlap in data items recorded. Aggregate data on healthcare activity are regularly extracted from registers and reported to the Ministry of Health (MoH), via the District Health Information System.[10]

### **Importance of high quality data**

Stillbirths, and infant morbidity and mortality associated with preterm births are markers of maternal health and markers of access to high quality care in pregnancy, especially around the time of childbirth.[13, 14] However, global and national estimates of stillbirths and premature births are

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3 frequently constrained by data quality.[1, 5, 15] High quality data are required to measure the  
4 burden of stillbirths and premature births, to assess effectiveness of interventions, and to monitor  
5 the benefits of investment to implement evidence based interventions (or the adverse  
6 consequences of a lack of investment). The importance of improving medical records and healthcare  
7 information systems, in order to allow monitoring and evaluation, and to improve performance and  
8 ultimately outcomes, has also been highlighted as the second of eight WHO standards for improving  
9 the quality of maternal and newborn care in health facilities.[16]  
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### 15 16 **Aim of this work**

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18 The aim of this work was to design a minimum dataset, which can be piloted and implemented  
19 across all healthcare facilities participating in DIPLOMATIC, to enable electronic collection of  
20 consistent and accurate data on perinatal outcomes, risk factors and the coverage of key care  
21 processes and treatments. Whilst the DIPLOMATIC collaboration spans both Zambia and Malawi, this  
22 initial work focused on Malawi, with a view to transferring the equivalent data collection, adapted to  
23 the Zambian context, in a second stage.  
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### 30 31 **METHODS**

32 The minimum datasets were drawn up using a multimodal approach, building on review of the  
33 literature and existing data infrastructure for identification of data requirements, followed by  
34 consultation with project collaborators and wider local stakeholders in Malawi.[17, 18]  
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#### 38 **Identification of data requirements**

39 Health passports, neonatal admission forms, and standard registers and the corresponding  
40 aggregate data returns to the MoH were reviewed. Variables required for the standard registers and  
41 to fulfil aggregate reporting requirements to the MoH were identified for inclusion in the datasets.  
42 The resulting list of variables was compared to relevant WHO guidance on ANC,[19] maternal health  
43 ,[20] and newborn health,[21] to ensure that the proposed datasets could be used to assess  
44 coverage of recommended clinical best practice. Finally, agreed quality indicators for maternity and  
45 neonatal services,[16, 22, 23] and existing minimum datasets,[24, 25] were reviewed to identify  
46 additional relevant variables. Wherever possible, international norms and standards were used to  
47 underpin definitions.[26]  
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## Consultation

Identification of the data requirements was followed by iterative rounds of consultation to refine the datasets based on critical evaluation by DIPLOMATIC collaborators and wider stakeholders in Malawi, who provided topic expertise and insights on Malawian health data structure and management:

DIPLOMATIC collaborators were consulted on the appropriateness and feasibility of the draft datasets. In addition to requesting electronic feedback from all collaborators, phone, skype and e-mail conversations with relevant Malawi based experts amongst the collaborators ensured detailed input from obstetricians, paediatricians, midwives, epidemiologists and data scientists. Feedback was recorded against the relevant variables. Where conflicting comments were received, alignment with existing data infrastructure was prioritised, to ensure the data would meet local requirements. The datasets were updated accordingly and shared again with collaborators and discussed at the DIPLOMATIC management group. The draft datasets were shared with relevant professional bodies in Malawi (Nurses and Midwives Council, Association of Obstetricians and Gynaecologists, Association of Paediatricians) facilitated by DIPLOMATIC collaborators who are members of the respective bodies. The draft datasets were also shared with colleagues from the MoH Directorate of Reproductive Health and Directorate of Quality Management and Digital Health. Finally, the datasets were presented to the Safe Motherhood Technical Working Group, for endorsement by the MoH. The Technical Working Group has multi-sectoral membership including representation from the MoH and the health sector as well as the third sector and academia, and acts as a platform for policy dialogue and coordination of work.

## Patient and Public involvement

Patients were not involved in the development of the datasets, but as set out in the DIPLOMATIC stakeholder engagement plan, the extensive experience of local host institutions for the DIPLOMATIC project (University of Malawi College of Medicine; Malawi Liverpool Wellcome Trust, Malawi Epidemiology and Intervention Research Unit) will be used to develop a program for public awareness of the interventions to be implemented (and to be evaluated using the datasets as described here), which will be supported by the Science Communication team at Malawi Liverpool Wellcome Trust. This will involve consultation with Community Groups, Women's Groups, Patients and Healthcare Workers and will involve multimedia platforms and local meetings.

## RESULTS

### Minimum dataset

Three minimum datasets were drafted to cover ANC, inpatient maternity care (including delivery and care of neonates in maternity settings, and care for miscarriages or complications of miscarriages), and specialist neonatal care. Figure 1 provides a flowchart summarising the datasets design process. Personal identifiers and demographic variables were included in each of the three datasets to ensure individuals can be uniquely identified and their records linked for care across different settings and at different facilities (horizontal linkage for the same individual during a single pregnancy and subsequent pregnancies, and vertical linkage for mothers and their babies). Malawi is in the process of implementing a unique health identification (UHID) system. Generation of a UHID will be facilitated through registration at the point of care, based on verification of identity using the recently introduced national ID (or birth certification). Use of a Quick Response (QR) code on health records for ease and speed of identification of the patient is being considered by the MoH. Each of the three DIPLOMATIC datasets allows recording of the local health record identifier, and this will be used to record the UHID as it embeds into health care record use in Malawi. Consistent use of the UHID across records of care will greatly support data linkage and may eventually allow automated imports of demographic details into the patient record, thus reducing data entry effort. However experience from Scotland shows that linkage of maternal and neonatal health records can remain challenging, even when a unique health identifier is well established. The demographic and ID section of each of the three DIPLOMATIC datasets, is designed to facilitate data linkage, even in the absence of or in the event of a failure of linkage through a UHID.

**Figure 1: Flowchart summarising the datasets design process** [submitted as separate file]

To mitigate the risk of incomplete information due to patients receiving some elements of their care in facilities not participating in DIPLOMATIC, the datasets were designed for a hybrid approach between contemporaneous and retrospective data collection. Data would ideally be collected in each of the settings as care is completed (ANC and maternity and neonatal inpatient). However, the datasets also provide the option to capture retrospective summary information if the relevant data was not captured at the time the care was delivered. The maternity dataset thus includes a summary section on ANC, and the specialist neonatal care dataset allows retrospective recording of summary

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3 of maternity/delivery care, if required (Figure 2). If the relevant data is captured electronically at the  
4 point of care, these retrospective summary sections can be auto-populated.  
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9 **Figure 2: DIPLOMATIC datasets structure [submitted as separate file]** (horizontal lines between the  
10 three ID/demography elements highlight that these facilitate the linkage of the different datasets for  
11 the same individual and/or mother baby pairings; different shading within the maternal discharge  
12 and the specialist neonatal care datasets show the retrospective summary sections).  
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18 The three datasets (summarised in Tables 1-3, available in full on Open Science Framework[17])  
19 included variables to record:  
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- 22 • the main outcomes of interest to the collaboration (stillbirths, preterm births and neonatal  
23 deaths), including variables to record estimated date of delivery (EDD), and pregnancy  
24 outcome, and ICD10 coding for cause of death for stillbirths and neonatal deaths where  
25 available.  
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- 28 • key clinical data on potential risk factors and mediators for these outcomes (factors on the  
29 causal pathway), including the required variables on obstetric history to derive the Robson  
30 criteria (which classify women undergoing caesarean sections into groups defined by a  
31 global standard, for comparison of caesarean rates between and within healthcare facilities),  
32 underlying maternal conditions of relevance to the current pregnancy, and neonatal  
33 observations and underlying conditions.  
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- 36 • process measures for key aspects of routine healthcare as potential modifiers for these  
37 outcomes (factors increasing/ reducing risk of adverse outcomes), for ANC, delivery and  
38 immediate care of the newborn (including emergency interventions), and specialist neonatal  
39 care.  
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**Table 1: Antenatal care (ANC) dataset structure and summary of included variables**

when recorded	group	variable	comment
Booking contact* (cross check ID at each contact)	unique ID	maternal unique ID	record linkage
	ID& demography	maternal names (incl parents' names), date of birth, district & neighbourhood	record linkage failsafe (building on experience of requirements to uniquely identify individuals from Karonga HDSS**)
		maternal education	measure of socioeconomic status
		maternal local ID & local file numbers	cross-reference local files
All ANC contacts	ANC episode details	facility, level of ANC and care provider	level of care
	contact date	contact date	
	observations & tests	fetal heart rate, symphysis fundal height, any ultrasound scan (USS), maternal haemoglobin, blood pressure, urine protein, infections (syphilis, HIV and Hep B status)	for any USS after booking reason is recorded, many of these observations & tests are required for mandatory reporting to MoH
	care & treatment	tetanus toxoid vaccine doses, malaria prophylaxis, iron and folic acid tablets, preventive anthelmintic, For HIV positive women: drugs for prevention of mother to child transmission (PMTCT)	many of these process measures are required for mandatory reporting to MoH
	high risk pregnancy indicator	indicator of whether woman meets any of the WHO high risk criteria	
Booking contact	EDD (and method of estimation)	EDD; USS before or at booking; LMP	EDD is recorded at booking alongside methods used for the estimate (USS, LMP, symphysis fundal height), EDD can subsequently only be altered once - and only on the basis of additional information provided by a first USS occurring after the booking visit
	obstetric, medical & behavioural history	obstetric history (previous pregnancies, deliveries and c-sections) medical history (weight, height, blood group, HIV status, tetanus vaccination history) behaviour (smoking, alcohol, drugs)	allows derivation of Robson criteria

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3 \*Booking contact: First (booking) visit as captured in the ANC Register, at which a full history is taken and, initial screening for medical, psychological and social risk factors  
4 takes places. Estimated date of delivery will also be recorded at the booking visit, although this may subsequently be amended if the first ultrasound scan for the pregnancy  
5 takes place after the booking visit.  
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8 \*\*Karonga Health and Demographic Health Surveillance System (HDSS)[27]  
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10 Abbreviations used in table 1: Antenatal care (ANC), caesarean section (c-section), estimated date of delivery (EDD), human immunodeficiency virus (HIV), Hepatitis B (Hep  
11 B), identifier (ID), International Classification of Diseases version 10 (ICD10), last menstrual period (LMP), Ministry of Health (MoH), prevention of mother to child  
12 transmission (PMTCT), ultrasound scan (USS), World Health Organization (WHO)  
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**Table 2: Maternal discharge dataset (including delivery record) structure and summary of included variables**

when recorded	group	variable	comments
All discharges	maternal unique ID	maternal unique ID	record linkage
	ID& demography	maternal names (incl parents' names), date of birth, district & neighbourhood	record linkage failsafe (building on experience of requirements to uniquely identify individuals from Karonga HDSS*)
		maternal education	measure of socioeconomic status
		maternal local ID & local file numbers	cross-reference local files
All discharges	episode dates & details	admission and discharge dates, facility, admission from, discharge to delivery and miscarriage episodes only: care provider staff group	
	condition & outcome	reason for admission (category and cause coded in ICD10), condition on discharge	condition on discharge indicates the outcome i.e. miscarriage, delivered or is still pregnant at the end of the care episode
Delivery and miscarriage episodes	ANC summary	obstetric, medical & behavioural history summary	to be autofilled if ANC took place in DIPLOMATIC participating facility, to be manually recorded retrospectively if ANC took place in facility not participating in DIPLOMATIC
		date of booking contact**	
		care & treatment summary	
		high risk pregnancy indicator, multiple pregnancy	
		EDD (and methods of estimation) summary	
Delivery record mother	outcome & details	number of babies, outcome of pregnancy, birth order, date, time, place, presentation, mode, indications for assisted delivery,	
	observation & tests	partograph used; HIV test, duration of stages of labour,	many of these observations & tests are required for mandatory reporting to MoH
	care & treatments	<u>preventive / routine</u> : antenatal steroids, magnesium sulfate, labour induction, augmentation of labour, analgesia, uterotonic for active management third stage of labour, episiotomy, companion present; <u>emergency</u> : uterotonic, anticonvulsive, antibiotic, blood transfusion, manual removal of placenta	many of these process measures are required for mandatory reporting to MoH

	discharge record	iron and folic acid tablets, preventive anthelminthic, contraception	
Delivery record baby	unique ID	baby unique ID	
	observations	<u>all</u> : sex, weight; <u>livebirths</u> : Apgar score, crown-heel length, head circumference	
	care & treatment	<u>routine</u> : dried & wrapped, delayed cord clamping, cord cut with sterile blade, skin to skin contact initiated, breastfeeding initiated, Vitamin K given, tetracycline eye ointment, BCG & OPV vaccine, PMTCT initiated (if mother HIV positive); <u>emergency/supportive</u> : resuscitation at birth, systemic antibiotics, kangaroo mother care (KMC) details, other thermal support	many of these process measures are required for mandatory reporting to MoH
	condition	congenital malformations, other perinatal complications	
	discharge record	date, feeding at discharge (mode & content), on KMC at discharge, discharge provider	
Miscarriages	miscarriage type & management	miscarriage type & management	
Stillbirths & Neonatal deaths	cause of death	immediate & underlying cause of death (coded in ICD10)	

\*Karonga Health and Demographic Health Surveillance System (HDSS)[27]

\*\*Booking contact: First (booking) visit as captured in the ANC Register, at which a full history is taken and, initial screening for medical, psychological and social risk factors takes places. Estimated date of delivery will also be recorded at the booking visit, although this may subsequently be amended if the first ultrasound scan for the pregnancy takes place after the booking visit.

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Abbreviations used in table 2: Antenatal care (ANC), Bacillus Calmette–Guérin tuberculosis vaccine (BCG), identifier (ID), estimated date of delivery (EDD), International Classification of Diseases version 10 (ICD10), kangaroo mother care (KMC), Ministry of Health (MoH), Oral Polio Vaccine (OPV), prevention of mother to child transmission (PMTCT)

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**Table 3: Specialist neonatal care dataset structure and summary of included variables**

when recorded	group	variable	use
All discharges	baby unique ID	baby unique ID	record linkage
	baby ID& demography	baby names, date of birth, sex, district & neighbourhood	record linkage failsafe
		baby local ID & local file numbers	cross-reference local files
	maternal unique ID	maternal unique ID	record linkage
maternal ID& demography		maternal names (incl parents' names), date of birth, district & neighbourhood	record linkage failsafe (building on experience of requirements to uniquely identify individuals from Karonga HDSS*)
		maternal education	measure of socioeconomic status
		maternal local ID & local file numbers	cross-reference local files
All discharges	episode dates & details condition observations care & treatment discharge record	admission and discharge dates, facility, admission from, discharge to	
		reason for admission (category and cause coded in ICD10),	
		temperature & weight at admission <u>emergency/supportive</u> : major invasive or therapeutic procedures, kangaroo mother care (KMC) details, other thermal support, respiratory support	many of these observations & tests are required for mandatory reporting to MoH
		date, weight at discharge, feeding at discharge (mode & content), on KMC at discharge, discharge provider	
All discharges	Delivery record mother summary	EDD	to be autofilled if delivery took place in DIPLOMATIC participating facility, to be manually recorded retrospectively if delivery took place in facility not participating in DIPLOMATIC
		outcome & details observation & tests care & treatments	
	Delivery record baby summary	observations care & treatments	
Neonatal deaths	cause of death	immediate & underlying cause of death (coded in ICD10)	

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\*Karonga Health and Demographic Health Surveillance System (HDSS)[27]

Abbreviations used in table 3: Antenatal care (ANC), identifier (ID), estimated date of delivery (EDD), International Classification of Diseases version 10 (ICD10), kangaroo mother care (KMC), Ministry of Health (MoH), prevention of mother to child transmission (PMTCT)

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4 All variables and response options were supported by clear definitions, using internationally  
5 recognised norms where possible.[26] Validation cross-checks at data entry were built in to support  
6 data quality by design. The datasets were designed to include all required variables to replicate the  
7 standard registers used in the respective settings [ANC , maternity, helping babies breathe (neonatal  
8 resuscitation), KMC ] and to allow generation of the respective mandatory reports for the MoH via  
9 the District Health Information System .  
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14 Consultation with the DIPLOMATIC collaborators, and wider stakeholders and professional bodies in  
15 Malawi resulted in refinement of a number of variables, including additional personal identifiers to  
16 create a failsafe for record linkage (based on local experience[27]), and the combination of variables  
17 that allow recording of the EDD and the method of estimation. Consultation input also ensured that  
18 the response options for all process measures were appropriate for the Malawian healthcare  
19 context, including response options to record that items were out of stock. The datasets were  
20 endorsed by the MoH through approval by the Safe Motherhood Technical Working Group.  
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## 28 **DISCUSSION**

29 The DIPLOMATIC minimum datasets were designed to cover the maternal and neonatal healthcare  
30 journey from ANC to specialist neonatal care. The datasets encompass the required elements to  
31 allow precise recording of the relevant outcomes (stillbirths, preterm births and neonatal deaths), as  
32 well as risk factors and key care processes. The datasets are aligned with international standards and  
33 definitions to ensure comparability of the results, and will enable DIPLOMATIC and the MoH to  
34 evaluate implementation and effectiveness of interventions (including care in line with existing  
35 policies). They were designed to integrate with and strengthen local data systems and meet  
36 reporting requirements, and to meet data needs to support decision making and learning for quality  
37 improvement in line with the WHO standards for improving the quality of maternal and newborn  
38 care in health facilities.[16] Consultation and refinement will need to continue during pilots in the  
39 DIPLOMATIC partner facilities, planned to commence in autumn 2020, to ensure the datasets remain  
40 aligned with MoH reporting requirements and to enable synergies with projects in the fast moving  
41 field of electronic medical record (EMR) developments, such as an eRegisters platform currently  
42 being piloted. In recent discussions the Quality Management and Digital Health (QMDH) Directorate  
43 under Malawi's MoH have provided their support to integrate the DIPLOMATIC minimum datasets  
44 into this eRegister platform.  
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3 Data collection on preterm births and stillbirths is reliant on accurate information on gestation,  
4 which underpins the definitions of both concepts. WHO recommends the integration of an  
5 ultrasound scan before 24 weeks of gestation into routine ANC, as the most accurate method of  
6 determining gestation.[19] At present, ultrasound scans are not part of routine ANC in Malawi, but  
7 this was identified as a key evidence-based priority and one of the interventions to be implemented  
8 in the healthcare facilities participating in DIPLOMATIC.  
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13 The methods of assessment of gestational age not only determine the precision of estimates for  
14 individual pregnancies, but can also lead to systematic differences in population level estimates of  
15 prematurity rates,[5] (as exemplified by changes in reporting in the United States [28]). However,  
16 most data sources contributing to recent global, regional and national estimates of premature birth  
17 rates reported insufficient details on the methods to determine gestational age, to allow the  
18 estimates to take this parameter into account.[5] In contrast, the DIPLOMATIC datasets include the  
19 relevant parameters to allow recording of whether and when an ultrasound scan was carried out to  
20 date the pregnancy, or which other method were used (last menstrual period, symphysis fundal  
21 height), alone or in combination to estimate gestation. These datasets thus allow estimates of  
22 preterm birth rates to be adjusted for the methods used to estimate gestational age. The datasets  
23 will also allow other important factors to be taken into account, such as multiplicity, and onset of  
24 delivery (spontaneous or provider initiated) for analysing both live and total births,[15] and maternal  
25 risk factors such as body mass index (BMI) and hypertensive conditions.[29]  
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36 The datasets include process measures on different elements of routine care. These elements serve  
37 to meet local reporting requirements, and by recording uptake of evidence based antenatal,  
38 maternal and neonatal care as recommended by WHO,[19-21] they facilitate monitoring of  
39 improvements in quality of care. However, each of these data elements also include response  
40 options to reflect that specific care in line with the protocols could not be carried out for example  
41 due to stock out of the relevant drugs, in recognition that resource limitations pose important  
42 barriers to implementation of care in line with these guidelines. Malawi has adopted the 'Every  
43 Newborn Action Plan',[22,30] and is one of the countries participating in the 'Network for Improving  
44 Quality of Care for Maternal, Newborn and Child Health', which aims to halve newborn and maternal  
45 deaths, and intrapartum stillbirths in participating countries over five years.[31] The process  
46 measures which will be captured in the DIPLOMATIC datasets are closely aligned to the WHO  
47 framework for improving quality of maternal and newborn care in healthcare settings,[16] and will  
48 facilitate reporting against a large proportion of the stipulated quality measures. The datasets allow  
49 facility based reporting against 73% (8/11) of core indicators for the framework, and 88% (32/36) of  
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3 outcome indicators and 77% (44/57) of process/output indicators under the first strategic area of  
4 the framework which relates to evidence based practices for routine care and management of  
5 complications.  
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9 DIPLOMATIC is staying abreast of the changing electronic health records landscape in Malawi, and is  
10 proactively engaging with the Quality Management and Digital Health Directorate under the MoH  
11 which is taking the lead to guide the systems to be development and supported. The collaboration  
12 also benefits from the insight of experts, who successfully implemented an electronic data-collection  
13 tool in the tertiary care hospital in Blantyre (Surveillance Programme of IN-patients and  
14 Epidemiology –SPINE). [32] However, paper records are currently still an important part of recording  
15 and sharing health care data in Malawi, and the technical implementation of the DIPLOMATIC  
16 minimum datasets will take this into account. The DIPLOMATIC minimum datasets will ideally feed  
17 off structured patient records that include the variables of interest, but these may be paper based or  
18 electronic, using real-time or retrospective methods of data collection depending on system  
19 functionality. Engagement with staff in the participating sites, to discuss advantages of different  
20 ways of data capture, to optimise ease of data recording, and to establish how this can be supported  
21 through existing clerking staff, will be essential to address the challenges of consistent data  
22 recording, in the face of pressures on clinical staff time.  
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33 Supporting staff to facilitate optimal use of the data will be an important part of piloting and  
34 implementation of the datasets. Electronic data can significantly reduce the work required to extract  
35 data for audits and patient reviews (compared to extraction from paper records). Experiencing  
36 benefits from the data will enhance ownership and buy in from clinical staff, and will be a  
37 prerequisite to ensuring sustainability of the datasets. High quality data providing continuous  
38 feedback on quality and safety of care and patient outcomes to healthcare providers can underpin a  
39 'learning health system', which allows data intelligence to foster learning and inform decisions.[33]  
40 Data linkage plays an important part in this when transfer of patients across facilities is common.  
41 Learning health system approaches have been shown to result in improved data and care quality in  
42 limited-resource settings similar to Malawi.[6,7] The DIPLOMATIC datasets have the potential to  
43 facilitate a learning health system approach.  
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### 52 **Strengths and limitations**

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54 In line with recommended practice, the datasets were designed using a multimodal approach,  
55 combining an in depth review of the contextual information and published as well as grey literature  
56 with expert input.[34] Delphi methods to gain expert consensus were considered, but deemed  
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3 unsuitable due to the large number of variables, many of which form interconnected constructs and  
4 could thus not be changed independently of each other. Instead of a Delphi survey, iterative rounds  
5 of consultation with DIPLOMATIC collaborators and other stakeholders in Malawi were undertaken.  
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8 Group discussions were helpful to find agreement on complex constructs, e.g. recording of EDD and  
9 methods used for its estimation. Whilst this process also took considerable time to complete, partly  
10 due to competing demands for the time of all of the relevant experts, it facilitated agreement on the  
11 variables to be prioritised for inclusion in the datasets. Sharing the draft datasets with professional  
12 associations and the relevant directorates of the MoH Malawi, and gaining approval by the Safe  
13 Motherhood Technical Working Group, was important to ensure there were no objections to the  
14 datasets, and to strengthen Malawian ownership, increasing the likelihood that any  
15 recommendations arising from future study findings can be implemented and scaled up to increase  
16 impact.  
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24 One limitation of the DIPLOMATIC datasets is that they are more extensive than other exemplars of  
25 national minimum datasets on maternal and neonatal health.[24, 25] This poses a challenge for  
26 implementation of these datasets in the context of stretched clinical staff, a background of  
27 predominantly paper based data recording and mixed success of electronic data systems.[10]  
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29 However it was deemed essential to ensure that the datasets incorporate all data items required for  
30 standard registers and can fulfil the Malawian national reporting obligations to the MoH, so the  
31 datasets can be embedded in existing systems and strengthen these (in line with the 'record once,  
32 use often' principle). This approach avoided creation of parallel datasets specific only to the research  
33 data needs, which would have been smaller, but would have overlapped to a large extent with  
34 existing paper based registers, leading to duplication of effort and no benefit to the existing system.  
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41 The DIPLOMATIC collaboration is focussed on health care interventions, and the minimum datasets  
42 can only capture maternal and newborn care in health facilities. Home births and complications  
43 associated with these, or stillbirths out with health facilities, would only be capture if aftercare was  
44 received in a health facility, or if recorded as part of a subsequent health care episode.  
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## 50 CONCLUSIONS

51 By combining contextual work with expert input, it was possible to design datasets, which build on  
52 existing structures, and can support local reporting requirements, as well as meeting the research  
53 data needs of DIPLOMATIC. The work to design the datasets highlights the need for a collaborative  
54 approach to ensure synergies and to strengthen existing systems, and avoid duplication of data and  
55 effort. Consultation on data collection is also essential to ensure local ownership of the data and any  
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3 findings arising from it. The datasets have the potential to underpin a ‘learning health system’  
4 approach, and their piloting and implementation will be aimed at supporting quality of care to  
5 improve outcomes. Implementation of these datasets could thus contribute to fulfilling the aims of  
6 the Network for Improving Quality of Care for Maternal, Newborn and Child Health, in particular to  
7 strengthening of the health information system, ‘to enable early, appropriate action to improve the  
8 care of every woman and newborn’ (Standard 2).[16] The datasets may also serve beyond the use  
9 by facilities participating in DIPLOMATIC, most immediately as an exemplar on how to incorporate  
10 methods of gestation estimates into routine data collection, in settings where access to early  
11 pregnancy ultrasound is limited and different methods are likely to be in use. In a wider context they  
12 also serve as a transferable example of strengthening data infrastructure and use of robust data, to  
13 underpin a learning healthcare system approach in low income settings.  
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### 23 **DATA SHARING STATEMENT**

24 The full specifications of the datasets, the development of which is described in this manuscript, are  
25 available on Open Science Framework: von Wissmann B, Gadama L, Dube Q, et al. The DIPLOMATIC  
26 Collaboration, Work Package 2: Core datasets. 2020. <https://osf.io/d3s7j> [17].  
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32 This work would not have been possible without consultation with stakeholders from the Ministry of  
33 Health Malawi, the Malawian Nurses and Midwives Council, the Malawian Association of  
34 Obstetricians and Gynaecologists, and the Malawian Association of Paediatricians.  
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39 We would like to thank Jakub Adamów for producing the graphic for this paper.  
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### 43 **CONTRIBUTORS**

44 BvW and RW designed the protocol for the development of the datasets and drafted the first version  
45 of the datasets. BvW wrote the first draft of the manuscript. BvW, EW, DW and RW synthesised the  
46 information needed to identify the dataset requirements. LAG, QD, CM, EC provided expert input on  
47 the dataset requirements, and current data infrastructure and management in Malawi. LAG, QD and  
48 EC led on engagement with the professional bodies. All authors (BvW, EW, DW, LAG, QD, CM, EC,  
49 SJS, RMR, JN, EM, BF, HC, JEN, RW) provided significant intellectual input to the iterative  
50 development of the datasets. All authors (BvW, EW, DW, LAG, QD, CM, EC, SJS, RMR, JN, EM, BF,  
51 HC, JEN, RW) provided input to drafting the manuscript.  
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### Competing interests

SJS reports grants from NIHR HTA, non-financial support from HOLOGIC, non-financial support from PARSAGEN, non-financial support from MEDIX BIOCHEMICA, during the conduct of the study; and SJS declares being a member of the HTA General committee.

JN reports membership of the following NIHR boards: Commissioning Priority Review Decision-making committee (2015); Health Technology Assessment (HTA) Commissioning Board (2010-2016); HTA Commissioning Sub-Board (Expression of Interest) (2014); HTA Funding Boards Policy Group (2016-2019); HTA General Board (2016-2019); HTA Post-Board funding teleconference (2016-2019); NIHR Clinical Trials Unit Standing Advisory Committee (2018-present); NIHR HTA and Efficacy and Mechanism Evaluation Editorial Board (2014-2019); Pre-exposure Prophylaxis Impact Review Panel (2017).

JEN reports being named as Principal Investigator on government and charitable research grants to her institution which aim to improve pregnancy outcome. In the last three years she has provided consultancy to Pharma companies GSK and Dilafor: her institution was remunerated for this. Her institution has received travel and subsistence expenses from Merck to facilitate her speaking at a Merck sponsored symposium on metformin. She is on Subpanel A1 for REF, and on a Wellcome Trust Science interview panel, and receive personal remuneration for each.

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**Jul-Sep 2018: Review of datasets and guidance documents**

**WHO guidance on clinical care**

- WHO recommendations on antenatal care for a positive pregnancy experience
- WHO recommendations on maternal health
- WHO recommendations on newborn health

**Existing data infrastructure in Malawi:**

- Health passports
- ANC register & monthly return
- Maternity register & monthly return
- Helping babies breathe register & monthly return
- Kangaroo mother care (KMC) register & monthly return
- Neonatal admissions form
- Postnatal monthly return
- HMIS15 (composite) quarterly return

**Relevant Scottish datasets**

- Scottish Morbidity Record 02 (maternity discharge)
- Scottish Birth Record
- Scottish Neonatal minimum dataset (draft)

**Sep-Oct 2018: Dataset drafted**

- ID and demography (for each dataset): 11 variables (6 ID variables, 5 demographic variables)
- ANC: 40 variables (14 only to be recorded at first/booking visit, 26 at all visits)
- Maternity discharge: 63 variables maternal discharge, 36 variables neonatal discharge
- Specialist neonatal: 37 variable (+ 9 maternal ID)

**Nov-Dec 2018: Consultation with all DIPLOMATIC collaborators, including one-to-one discussions with Malawi based obstetrician, paediatrician, midwife, epidemiologist and data scientist**

- ID & demography: 2 variables dropped
- Maternity discharge: 2 maternal discharge variables & 1 neonatal discharge variable dropped

- ID & demography: 7 variables added
- ANC: 4 variables added
- Maternity discharge: 2 maternal variables & 5 neonatal variables added
- Specialist neonatal: 8 variables added

**Dec 2018: Group discussion with 5 DIPLOMATIC collaborators, focussed on estimated date of deliver and gestation**

- ANC: 5 variables dropped
- Maternity discharge: 4 maternal discharge variables dropped

- ANC: 8 variables added
- Maternity discharge: 3 variables added
- Response options updated across all three datasets, to include options for care processes not being carried out

**Dec 2018: Datasets agreed with DIPLOMATIC collaborators**

- ID and demography (for each dataset): 16 variables (45% increase on first draft)
- ANC: 47 variables (18% increase on first draft)
- Maternity discharge: 62 variables maternal discharge, 40 variables neonatal discharge (3% increase on first draft)
- Specialist neonatal: 45 (+ 9 maternal ID) (22% increase on first draft)

**Dec – Mar 2018: Dataset shared with professional bodies**

- no further changes

**Mar – May 2019: Dataset shared with Ministry of Health**

- no further changes

**November 2019: Dataset presented to and approved by Safe Motherhood Initiative technical working group**

## Antenatal Care (ANC)

## Maternal discharge (incl. delivery record)

## Specialist neonatal care

maternal unique ID:  
ID & demography

maternal unique ID:  
ID & demography

maternal & baby unique ID:  
ID & demography

**All ANC contacts:** ANC episode details, contact date, observation & tests, care & treatment, high risk pregnancy indicator

**Booking contact:** obstetric, medical & behavioural history, EDD (and methods of estimation)

**All discharges:** episode dates & details, condition & outcome

**Delivery & miscarriages:** ANC summary

**Delivery record mother:** outcome & details, observations & tests, care & treatments, mat. discharge record

**Delivery record baby:** unique ID, observations, care & treatments, condition, discharge record

**Miscarriages:** type and management

**Stillbirths & neonatal deaths:** cause of death


**All discharges:** episode dates & details, condition, observations, care & treatments, discharge record

**All discharges:** Delivery record mother summary & Delivery record baby summary

**Neonatal deaths:** cause of death

Abbreviations used in Figure 1:

**ANC** Antenatal care  
**EDD** estimated date of delivery  
**ID** identifier

 retrospective summary sections



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4 **Informing prevention of stillbirth and preterm birth in Malawi: development of a minimum**  
5 **dataset for health facilities participating in the DIPLOMATIC collaboration**  
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8 Word count: 33544119  
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## ABSTRACT

### BackgroundObjective

The global research group, DIPLOMATIC (Using evidence, Implementation science, and a clinical trial Platform to Optimise MATernal and newborn health in low Income Countries), aims to reduce stillbirths and preterm births and optimise outcomes for babies born preterm. ~~An early objective was to design m~~Minimum datasets for routine data collection in healthcare facilities participating in DIPLOMATIC (initially in Malawi) were designed, to ~~improve-assist~~ understanding of baseline maternal and neonatal care processes and outcomes, and facilitate ~~the~~ evaluation of improvement interventions and pragmatic clinical trials.

### MethodsDesign

Published and grey literature was reviewed alongside extensive in-country consultation to define relevant clinical best practice guidance, and the existing local data and reporting infrastructure ~~and reporting requirements, to identify requirements for the minimum datasets~~. ~~Identified data item requirements~~Data elements were subjected to iterative rounds of consultation with topic experts in Malawi and Scotland, the relevant Malawian professional bodies, and the Ministry of Health in Malawi to ensure relevance, validity, and feasibility.

### Setting

Antenatal, maternity and specialist neonatal care in Malawi.

### Results

The resulting three minimum datasets cover the maternal and neonatal healthcare journey ~~from-for~~ antenatal, maternity and ~~to~~ specialist neonatal care, with provision for effective linkage of records ~~relating-to-for the same~~ mother/baby pairs. They can facilitate consistent, ~~and~~ precise recording of relevant outcomes (stillbirths, preterm births, ~~and~~ neonatal deaths), risk factors and key care processes.

### Conclusions

Poor quality routine data on care processes and outcomes constrains healthcare system improvement. The datasets developed for implementation in DIPLOMATIC partner facilities reflect, and hence support delivery of, internationally agreed best practice for maternal and newborn care in low income settings. ~~They have been-in~~formed by extensive consultation, ~~and-they~~ are designed to integrate with ~~and-strengthen~~ existing local data infrastructure structures and reporting processes. ~~Implementation will meet both local reporting requirements and~~ as well as meeting research data

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3 needs. This work ~~thus~~ provides a transferable example of strengthening data infrastructure to  
4 underpin a learning healthcare system approach in low income settings.  
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7 DIPLOMATIC is funded by the UK National Institute for Health Research.  
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### 13 **STRENGTH AND LIMITATIONS OF THIS STUDY**

- 14 • In line with recommended practice, the datasets were designed using a multimodal  
15 approach, combining an in depth review of the contextual information and published and  
16 grey literature with expert input.
- 17 • Delphi methods to gain expert consensus were considered, but deemed unsuitable due to  
18 the large number of variables, many of which form interconnected constructs and could thus  
19 not be changed independently of each other.
- 20 • Instead of a Delphi survey, iterative rounds of consultation with DIPLOMATIC collaborators  
21 and other stakeholders in Malawi were undertaken, which were essential to facilitate  
22 Malawian ownership, increasing the likelihood that study recommendations can be  
23 implemented and scaled up to increase impact.
- 24 • One limitation of this inclusive approach is that the datasets are more extensive than other  
25 exemplars of national minimum datasets.
- 26 • However the approach ensures that the datasets can integrate with existing systems and  
27 meet local data requirements, and also have the capacity to evaluate other Ministry of  
28 Health initiatives, rather than addressing research requirements only.
- 29 •
- 30 • ~~The three interlinking perinatal datasets, developed for the DIPLOMATIC collaboration,~~  
31 ~~collectively cover the maternal and neonatal healthcare journey from antenatal care to~~  
32 ~~neonatal care.~~
- 33 • ~~This integration of data elements along the perinatal care continuum has not previously~~  
34 ~~been implemented in Malawi for the purpose of routine health data collection at primary~~  
35 ~~health centre level.~~
- 36 • ~~The datasets are based on, and can therefore support delivery of, internationally agreed~~  
37 ~~best practice for maternal and newborn care in low income settings.~~
- 38 • ~~The datasets are more extensive than other exemplars of national minimum datasets, but~~  
39 ~~inclusion of additional variables ensures they can integrate with existing systems and meet~~  
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8 ~~Malawi were essential to facilitate Malawian ownership, increasing the likelihood that study~~  
9 ~~recommendations can be implemented and scaled up to increase impact.~~  
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## INTRODUCTION

The global burden of stillbirths and preterm births remains significant. According to recent global estimates, 2.6 million babies were stillborn at 28 completed weeks gestation or over in 2015.[1] Half of stillborn babies died during labour.[1] Complications of preterm birth (defined as delivery before 37 completed weeks gestation) accounted for nearly one fifth of deaths in under five year old children globally (18%) in 2016.[2] Babies born preterm, who survive, remain at risk of developmental delay,[3] and long term physical morbidities.[4]

## DIPLOMATIC

DIPLOMATIC (Using evidence, Implementation science, and a clinical trial Platform to Optimise MATernal and newborn health in low Income Countries) is a National Institute of Health Research (NIHR) funded global research group with partners in Malawi, Zambia and the United Kingdom (UK), which aims to reduce stillbirth and preterm birth, and optimise outcomes for babies born preterm. In Malawi and Zambia, an estimated 14,000 and 13,000 stillbirths occur every year (21.8 and 20.9 stillbirths per 1000 total births respectively).[1] An estimated 68,000 and 76,000 babies per year are born preterm, accounting for 10.5% of births in Malawi and 12% in Zambia.[5] Ranked by increasing rates, Malawi and Zambia were 160th and 155th out of 194 countries for rates of stillbirth in 2015 and 123rd and 127th out of 183 countries for rates of preterm birth in 2014, respectively.[1, 5] DIPLOMATIC aims to develop pragmatic clinical trials to test the effectiveness of evidence based practices and how best to implement them in low income settings. Consistent and accurate data are required from participating healthcare facilities to efficiently monitor intervention implementation and outcomes and hence trial results.

Establishing parallel data collection for research projects, rather than integrating this with routine data collection, can lead to a disjointed approach which risks duplication of effort and waste of scarce resources. A learning health system approach has been identified in similar low income settings, as an effective means of combining data intelligence for quality improvement, with research on the implementation of new interventions and optimising their effectiveness. [6, 7] In this context, the learning health system was characterised by a strong stakeholder network, and facilitation of local application of data intelligence, to allow faster integration of evidence based interventions, and efficient use of the same data to drive research. [7]

### Current perinatal data infrastructure in Malawi

To ensure that the data collection for DIPLOMATIC would integrate with and strengthen existing systems, the collaboration undertook a baseline, in-depth review of the existing data infrastructure relating to perinatal health in Malawi.

Vital events registration in Malawi is mandated by the National Registration Act of 2010, but coverage of birth and death registration is still incomplete, though efforts to improve coverage are in progress.<sup>[6, 78, 9]</sup>

Individuals hold their own medical records as 'health passports' (structured paper based records), which they present whenever accessing healthcare. For women of childbearing age, the health passport records a summary of medical and obstetric history, contraceptives, antenatal care (ANC), and the delivery record. Neonates receive their own passport at birth. Most district and central hospitals maintain paper based patient notes when providing inpatient perinatal care. For specialist neonatal care, a standardised admission form is available. A brief note is made in the patients' health passport at discharge,<sup>[810]</sup> which is usually the main source of information to clinicians on patients' history in case of readmission, as retrieval of patient notes held by healthcare facilities is difficult. Neonatal and maternal records are not routinely linked, and if the mother is not present or deceased, her information is not available for the care of the neonate. An electronic patient record system for ANC is available, but uptake is limited to date (24 out of 85 hospitals and 12 out of 542 health centres across Malawi, as of May 2019).<sup>[911]</sup> An application for immediate electronic data capture on neonatal admissions (NeoTree) was developed recently and tested in one hospital.<sup>[1012]</sup> This application is designed as a decision support tool, to improve quality of care, and does not have any reporting functionality for integration with local data systems as yet.<sup>[1012]</sup>

In addition to individual patient notes, healthcare facilities maintain 'registers' (individual level paper logs) for clinical care including ANC, maternity/birth record, neonatal resuscitation, and Kangaroo Mother Care (KMC), with partial overlap in data items recorded. Aggregate data on healthcare activity are regularly extracted from registers and reported to the Ministry of Health (MoH), via the District Health Information System.<sup>[810]</sup>

### Importance of high quality data

Stillbirths, and infant morbidity and mortality associated with preterm births are markers of maternal health and markers of access to high quality care in pregnancy, especially around the time of childbirth.<sup>[11, 1213, 14]</sup> However, global and national estimates of stillbirths and premature

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births are frequently constrained by data quality.[1, 5, 1315] High quality data are required to measure the burden of stillbirths and premature births, to assess effectiveness of interventions, and to monitor the benefits of investment to implement evidence based interventions (or the adverse consequences of a lack of investment). The importance of improving medical records and healthcare information systems, in order to allow monitoring and evaluation, and to improve performance and ultimately outcomes, has also been highlighted as the second of eight WHO standards for improving the quality of maternal and newborn care in health facilities.[1416]

### **Aim of this work**

The aim of this work was to design a minimum dataset, which can be piloted and implemented across all healthcare facilities participating in DIPLOMATIC, to enable electronic collection of consistent and accurate data on perinatal outcomes, risk factors and the coverage of key care processes and treatments. Whilst the DIPLOMATIC collaboration spans both Zambia and Malawi, this initial work focused on Malawi, with a view to transferring the equivalent data collection, adapted to the Zambian context, in a second stage.

### **METHODS**

The minimum datasets were drawn up using a multimodal approach, building on review of the literature and existing data infrastructure for identification of data requirements, followed by consultation with project collaborators and wider local stakeholders in Malawi.[15, 1617, 18]

#### **Identification of data requirements**

Health passports, neonatal admission forms, and standard registers and the corresponding aggregate data returns to the MoH were reviewed. Variables required for the standard registers and to fulfil aggregate reporting requirements to the MoH were identified for inclusion in the datasets. The resulting list of variables was compared to relevant WHO guidance on ANC,[1719] maternal health ,[1820] and newborn health,[1921] to ensure that the proposed datasets could be used to assess coverage of recommended clinical best practice. Finally, agreed quality indicators for maternity and neonatal services,[14, 20, 2116, 22, 23] and existing minimum datasets,[22, 2324, 25] were reviewed to identify additional relevant variables. Wherever possible, international norms and standards were used to underpin definitions.[2426]



## Consultation

Identification of the data requirements was followed by iterative rounds of consultation to refine the datasets based on critical evaluation by DIPLOMATIC collaborators and wider stakeholders in Malawi, who provided topic expertise and insights on Malawian health data structure and management:

DIPLOMATIC collaborators were consulted on the appropriateness and feasibility of the draft datasets. In addition to requesting electronic feedback from all collaborators, phone, skype and e-mail conversations with relevant Malawi based experts amongst the collaborators ensured detailed input from obstetricians, paediatricians, midwives, epidemiologists and data scientists. Feedback was recorded against the relevant variables. Where conflicting comments were received, alignment with existing data infrastructure was prioritised, to ensure the data would meet local requirements. The datasets were updated accordingly and shared again with collaborators and discussed at the DIPLOMATIC management group. The draft datasets were shared with relevant professional bodies in Malawi (Nurses and Midwives Council, Association of Obstetricians and Gynaecologists, Association of Paediatricians) facilitated by DIPLOMATIC collaborators who are members of the respective bodies. The draft datasets were also shared with colleagues from the MoH Directorate of Reproductive Health and Directorate of Quality Management and Digital [StrategyHealth](#). Finally, the datasets were presented to the Safe Motherhood Technical Working Group, for endorsement by the MoH. The Technical Working Group has multi-sectoral membership including representation from the MoH and the health sector as well as the third sector and academia, and acts as a platform for policy dialogue and coordination of work.

## Patient and Public involvement

Patients were not involved in the development of the datasets, but as set out in the DIPLOMATIC stakeholder engagement plan, the extensive experience of local host institutions for the DIPLOMATIC project (University of Malawi College of Medicine; Malawi Liverpool Wellcome Trust, Malawi Epidemiology and Intervention Research Unit) will be used to develop a program for public ~~sensitisation-awareness around of~~ the interventions to be implemented (and to be evaluated using the datasets as described here), which will be supported by the Science Communication team at Malawi Liverpool Wellcome Trust. This will involve consultation with Community Groups, Women's Groups, Patients and Healthcare Workers and will involve multimedia platforms and local meetings.

## RESULTS

### Minimum dataset

Three minimum datasets were drafted to cover ANC, inpatient maternity care (including delivery and care of neonates in maternity settings, and care for miscarriages or complications of miscarriages), and specialist neonatal care. [Figure 1 provides a flowchart summarising the datasets design process.](#) Personal identifiers and demographic variables were included in each of the three datasets to ensure individuals can be uniquely identified and their records linked for care across different settings and at different facilities (horizontal linkage for the same individual during a single pregnancy and subsequent pregnancies, and vertical linkage for mothers and their babies). [Malawi is in the process of implementing a unique health identification \(UHID\) system. Generation of a UHID will be facilitated through registration at the point of care, based on verification of identity using the recently introduced national ID \(or birth certification\). Use of a Quick Response \(QR\) code on health records for ease and speed of identification of the patient is being considered by the MoH. Each of the three DIPLOMATIC datasets allows recording of the local health record identifier, and this will be used to record the UHID as it embeds into health care record use in Malawi. Consistent use of the UHID across records of care will greatly support data linkage and may eventually allow automated imports of demographic details into the patient record, thus reducing data entry effort. However experience from Scotland shows that linkage of maternal and neonatal health records can remain challenging, even when a unique health identifier is well established. The demographic and ID section of each of the three DIPLOMATIC datasets, is designed to facilitate data linkage, even in the absence of or in the event of a failure of linkage through a UHID.](#)

**[Figure 1: Flowchart summarising the datasets design process \[submitted as separate file\]](#)**

To mitigate the risk of incomplete information due to patients receiving some elements of their care in facilities not participating in DIPLOMATIC, the datasets were designed for a hybrid approach between contemporaneous and retrospective data collection. Data would ideally be collected ~~contemporaneously~~ in each of the settings [as care is completed](#) (ANC and maternity and neonatal inpatient) ~~as care is completed~~. However, ~~there~~ [the datasets also provide](#) is the option to capture retrospective summary information [if the relevant data was not captured at the time the care was delivered. on ANC within the maternity dataset thus includes a summary section on ANC, and the specialist neonatal care dataset allows retrospective recording of summary of,](#) and on

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3 maternity/delivery care ~~within the neonatal care dataset~~, if required (Figure 12). If the relevant data  
4 is captured electronically at the point of care, these retrospective summary sections can be auto-  
5 populated.  
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11 **Figure 21: DIPLOMATIC datasets structure [submitted as separate file]** (horizontal lines between  
12 the three ID/demography elements highlight that these facilitate the linkage of the different  
13 datasets for the same individual and/or mother baby pairings; different shading within the maternal  
14 discharge and the specialist neonatal care datasets show the retrospective summary sections).  
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20 The three datasets (summarised in Tables 1-3, available in full on Open Science Framework[1517])  
21 included variables to record:  
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- 24 • the main outcomes of interest to the collaboration (stillbirths, preterm births and neonatal  
25 deaths), including variables to record estimated date of delivery (EDD), and pregnancy  
26 outcome, and ICD10 coding for cause of death for stillbirths and neonatal deaths where  
27 available.  
28
- 29 • key clinical data on potential risk factors and mediators for these outcomes (factors on the  
30 causal pathway), including the required variables on obstetric history to derive the Robson  
31 criteria (which classify women undergoing caesarean sections into groups defined by a  
32 global standard, for comparison of caesarean rates between and within healthcare facilities),  
33 underlying maternal conditions of relevance to the current pregnancy, and neonatal  
34 observations and underlying conditions.  
35
- 36 • process measures for key aspects of routine healthcare as potential modifiers for these  
37 outcomes (factors increasing/ reducing risk of adverse outcomes), for ANC, delivery and  
38 immediate care of the newborn (including emergency interventions), and specialist neonatal  
39 care.  
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**Table 1: Antenatal care (ANC) dataset structure and summary of included variables**

when recorded	group	variable	comment
Booking contact* (cross check ID at each contact)	unique ID	maternal unique ID	record linkage
	ID& demography	maternal names (incl parents' names), date of birth, district & neighbourhood	record linkage failsafe (building on experience of requirements to uniquely identify individuals from Karonga <u>HDDHSS**</u> )
		maternal education	measure of socioeconomic status
		maternal local ID & local file numbers	cross-reference local files
All ANC contacts	ANC episode details	facility, level of ANC and care provider	level of care
	contact date	contact date	
	observations & tests	fetal heart rate, symphysis fundal height, any ultrasound scan (USS), maternal haemoglobin, blood pressure, urine protein, infections (syphilis, HIV and Hep B status)	for any USS after booking reason is recorded, many of these observations & tests are required for mandatory reporting to MoH
	care & treatment	tetanus toxoid vaccine doses, malaria prophylaxis, iron and folic acid tablets, preventive anthelmintic, For HIV positive women: drugs for prevention of mother to child transmission (PMTCT)	many of these process measures are required for mandatory reporting to MoH
	high risk pregnancy indicator	indicator of whether woman meets any of the WHO high risk criteria	
Booking contact	EDD (and method of estimation)	EDD; USS before or at booking; LMP	EDD is recorded at booking alongside methods used for the estimate (USS, LMP, symphysis fundal height), EDD can subsequently only be altered once - and only on the basis of additional information provided by a first USS occurring after the booking visit
	obstetric, medical & behavioural history	obstetric history (previous pregnancies, deliveries and c-sections) medical history (weight, height, blood group, HIV status, tetanus vaccination history) behaviour (smoking, alcohol, drugs)	allows derivation of Robson criteria

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3 \*Booking contact: First (booking) visit as captured in the ANC Register, at which a full history is taken and, initial screening for medical, psychological and social risk factors  
4 takes places. Estimated date of delivery will also be recorded at the booking visit, although this may subsequently be amended if the first ultrasound scan for the pregnancy  
5 takes place after the booking visit.  
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8 \*\*Karonga Health and Demographic Health Surveillance System (HDSS)[2527]  
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10 Abbreviations used in table 1: Antenatal care (ANC), caesarean section (c-section), estimated date of delivery (EDD), human immunodeficiency virus (HIV), Hepatitis B (Hep  
11 B), identifier (ID), International Classification of Diseases version 10 (ICD10), last menstrual period (LMP), Ministry of Health (MoH), prevention of mother to child  
12 transmission (PMTCT), ultrasound scan (USS), World Health Organization (WHO)  
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**Table 2: Maternal discharge dataset (including delivery record) structure and summary of included variables**

when recorded	group	variable	comments
All discharges	maternal unique ID	maternal unique ID	record linkage
	ID& demography	maternal names (incl parents' names), date of birth, district & neighbourhood	record linkage failsafe (building on experience of requirements to uniquely identify individuals from Karonga HDSS+HDSS*)
		maternal education	measure of socioeconomic status
		maternal local ID & local file numbers	cross-reference local files
All discharges	episode dates & details	admission and discharge dates, facility, admission from, discharge to delivery and miscarriage episodes only: care provider staff group	
	condition & outcome	reason for admission (category and cause coded in ICD10), condition on discharge	condition on discharge indicates the outcome i.e. miscarriage, delivered or is still pregnant at the end of the care episode
Delivery and miscarriage episodes	ANC summary	obstetric, medical & behavioural history summary	to be autofilled if ANC took place in DIPLOMATIC participating facility, to be manually recorded retrospectively if ANC took place in facility not participating in DIPLOMATIC
		date of booking contact**	
		care & treatment summary	
		high risk pregnancy indicator, multiple pregnancy	
		EDD (and methods of estimation) summary	
Delivery record mother	outcome & details	number of babies, outcome of pregnancy, birth order, date, time, place, presentation, mode, indications for assisted delivery,	
	observation & tests	partograph used; HIV test, duration of stages of labour,	many of these observations & tests are required for mandatory reporting to MoH
	care & treatments	<u>preventive / routine</u> : antenatal steroids, magnesium sulfate, labour induction, augmentation of labour, analgesia, uterotonic for active management third stage of labour, episiotomy, companion present; <u>emergency</u> : uterotonic, anticonvulsive, antibiotic, blood transfusion, manual removal of placenta	many of these process measures are required for mandatory reporting to MoH

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	discharge record	iron and folic acid tablets, preventive anthelminthic, contraception	
Delivery record baby	unique ID	baby unique ID	
	observations	<u>all</u> : sex, weight; <u>livebirths</u> : Apgar score, crown-heel length, head circumference	
	care & treatment	<u>routine</u> : dried & wrapped, delayed cord clamping, cord cut with sterile blade, skin to skin contact initiated, breastfeeding initiated, Vitamin K given, tetracycline eye ointment, BCG & OPV vaccine, PMTCT initiated (if mother HIV positive); <u>emergency/supportive</u> : resuscitation at birth, systemic antibiotics, kangaroo mother care (KMC) details, other thermal support	many of these process measures are required for mandatory reporting to MoH
	condition	congenital malformations, other perinatal complications	
	discharge record	date, feeding at discharge (mode & content), on KMC at discharge, discharge provider	
Miscarriages	miscarriage type & management	miscarriage type & management	
Stillbirths & Neonatal deaths	cause of death	immediate & underlying cause of death (coded in ICD10)	

\*Karonga Health and Demographic Health Surveillance System (HDSS)[2527]

\*\*Booking contact: First (booking) visit as captured in the ANC Register, at which a full history is taken and, initial screening for medical, psychological and social risk factors takes places. Estimated date of delivery will also be recorded at the booking visit, although this may subsequently be amended if the first ultrasound scan for the pregnancy takes place after the booking visit.

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3 Abbreviations used in table 2: Antenatal care (ANC), Bacillus Calmette–Guérin tuberculosis vaccine (BCG), identifier (ID), estimated date of delivery (EDD), International  
4 Classification of Diseases version 10 (ICD10), kangaroo mother care (KMC), Ministry of Health (MoH), Oral Polio Vaccine (OPV), prevention of mother to child transmission  
5 (PMTCT)  
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**Table 3: Specialist neonatal care dataset structure and summary of included variables**

when recorded	group	variable	use
All discharges	baby unique ID	baby unique ID	record linkage
	baby ID& demography	baby names, date of birth, sex, district & neighbourhood	record linkage failsafe
		baby local ID & local file numbers	cross-reference local files
	maternal unique ID	maternal unique ID	record linkage
All discharges	maternal ID& demography	maternal names (incl parents' names), date of birth, district & neighbourhood	record linkage failsafe (building on experience of requirements to uniquely identify individuals from Karonga HDSS+HDSS*)
		maternal education	measure of socioeconomic status
		maternal local ID & local file numbers	cross-reference local files
		admission and discharge dates, facility, admission from, discharge to	
All discharges	episode dates & details	condition	reason for admission (category and cause coded in ICD10),
		observations	temperature & weight at admission
		care & treatment	<u>emergency/supportive</u> : major invasive or therapeutic procedures, kangaroo mother care (KMC) details, other thermal support, respiratory support
		discharge record	date, weight at discharge, feeding at discharge (mode & content), on KMC at discharge, discharge provider
All discharges	Delivery record mother summary	<del>final</del> EDD	to be autofilled if delivery took place in DIPLOMATIC participating facility, to be manually recorded retrospectively if delivery took place in facility not participating in DIPLOMATIC
		outcome & details observation & tests care & treatments	
All discharges	Delivery record baby summary	observations	
		care & treatments	
Neonatal deaths	cause of death	immediate & underlying cause of death (coded in ICD10)	

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3 \*Karonga Health and Demographic Health Surveillance System (HDSS)[[2527](#)]  
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5 Abbreviations used in table 3: Antenatal care (ANC), identifier (ID), estimated date of delivery (EDD), International Classification of Diseases version 10 (ICD10), kangaroo  
6 mother care (KMC), Ministry of Health (MoH), prevention of mother to child transmission (PMTCT)  
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4 All variables and response options were supported by clear definitions, using internationally  
5 recognised norms where possible.<sup>[2426]</sup> Validation cross-checks at data entry were built in to  
6 support data quality by design. The datasets were designed to include all required variables to  
7 replicate the standard registers used in the respective settings [ANC , maternity, helping babies  
8 breathe (neonatal resuscitation), KMC ] and to allow generation of the respective mandatory reports  
9 for the MoH via the District Health Information System .  
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14 Consultation with the DIPLOMATIC collaborators, and wider stakeholders and professional bodies in  
15 Malawi resulted in refinement of a number of variables, including additional personal identifiers to  
16 create a failsafe for record linkage (based on local experience<sup>[2527]</sup>), and the combination of  
17 variables that allow recording of the EDD and the method of estimation. Consultation input also  
18 ensured that the response options for all process measures were appropriate for the Malawian  
19 healthcare context, including response options to record that items were out of stock. The datasets  
20 were endorsed by the MoH through approval by the Safe Motherhood Technical Working Group.  
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## 28 DISCUSSION

29 The DIPLOMATIC minimum datasets were designed to cover the maternal and neonatal healthcare  
30 journey from ANC to specialist neonatal care. The datasets encompass the required elements to  
31 allow precise recording of the relevant outcomes (stillbirths, preterm births and neonatal deaths), as  
32 well as risk factors and key care processes. The datasets are aligned with international standards and  
33 definitions to ensure comparability of the results, and will enable DIPLOMATIC and the MoH  
34 to evaluate implementation and effectiveness of interventions (including care in line with existing  
35 policies). They were designed to integrate with and strengthen local data systems and meet  
36 reporting requirements, and to meet data needs to support decision making and learning for quality  
37 improvement in line with the WHO standards for improving the quality of maternal and newborn  
38 care in health facilities.<sup>[1416]</sup> Consultation and refinement will need to continue during pilots ~~and~~  
39 ~~implementation~~ in the DIPLOMATIC partner facilities, planned to commence in autumn 2020, to  
40 ensure the datasets remain aligned with MoH reporting requirements and to enable synergies with  
41 projects in the fast moving field of electronic medical record (EMR) developments, such as an  
42 eRegisters platform currently being piloted. In recent discussions the Quality Management and  
43 Digital Health (QMDH) Directorate under Malawi's MoH have provided their support to integrate the  
44 DIPLOMATIC minimum datasets into this eRegister platform.  
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3 Data collection on preterm births and stillbirths is reliant on accurate information on gestation,  
4 which underpins the definitions of both concepts. WHO recommends the integration of an  
5 ultrasound scan before 24 weeks of gestation into routine ANC, as the most accurate method of  
6 determining gestation.[1719] At present, ultrasound scans are not part of routine ANC in Malawi,  
7 but this was identified as a key evidence-based priority and one of the interventions to be  
8 implemented in the healthcare facilities participating in DIPLOMATIC.  
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11 The methods of assessment of gestational age not only determine the precision of estimates for  
12 individual pregnancies, but can also lead to systematic differences in population level estimates of  
13 prematurity rates,[5] (as exemplified by changes in reporting in the United States [2628]). However,  
14 most data sources contributing to recent global, regional and national estimates of premature birth  
15 rates reported insufficient details on the methods to determine gestational age, to allow the  
16 estimates to take this parameter into account.[5] In contrast, the DIPLOMATIC datasets include the  
17 relevant parameters to allow recording of whether and when an ultrasound scan was carried out to  
18 date the pregnancy, or which other method were used (last menstrual period, symphysis fundal  
19 height), alone or in combination to estimate gestation. These datasets thus allow estimates of  
20 preterm birth rates to be adjusted for the methods used to estimate gestational age. The datasets  
21 will also allow other important factors to be taken into account, such as multiplicity, and onset of  
22 delivery (spontaneous or provider initiated) for analysing both live and total births,[1315] and  
23 maternal risk factors such as body mass index (BMI) and hypertensive conditions.[2729]  
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26 The datasets include process measures on different elements of routine care. These elements serve  
27 to meet local reporting requirements, and by recording uptake of evidence based antenatal,  
28 maternal and neonatal care as recommended by WHO,[17-1919-21] they facilitate monitoring of  
29 improvements in quality of care. However, each of these data elements also include response  
30 options to reflect that specific care in line with the protocols could not be carried out for example  
31 due to stock out of the relevant drugs, in recognition that resource limitations pose important  
32 barriers to implementation of care in line with these guidelines. Malawi has adopted the 'Every  
33 Newborn Action Plan',[20,2822,30] and is one of the countries participating in the 'Network for  
34 Improving Quality of Care for Maternal, Newborn and Child Health', which aims to halve newborn  
35 and maternal deaths, and intrapartum stillbirths in participating countries over five years.[2931] The  
36 process measures which will be captured in the DIPLOMATIC datasets are closely aligned to the  
37 WHO standards framework for improving quality of maternal and newborn care in healthcare  
38 settings,[1416] and will facilitate reporting against a large proportion of the stipulated quality  
39 measures. The datasets allow facility based reporting -against 73% (8/11) of core indicators for the  
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3 framework, and 88% (32/36) of outcome indicators and 77% (44/57) of process/output indicators  
4 under the first strategic area of the framework which relates to evidence based practices for routine  
5 care and management of complications.

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8 DIPLOMATIC is staying abreast of the changing electronic health records landscape in Malawi, and is  
9 proactively engaging with the Quality Management and Digital Health Directorate under the MoH  
10 which is taking the lead to guide the systems to be development and supported. The collaboration  
11 also benefits from the insight of experts, who successfully implemented an electronic data-collection  
12 tool in the tertiary care hospital in Blantyre (Surveillance Programme of IN-patients and  
13 Epidemiology –SPINE). [32] However, paper records are currently still an important part of recording  
14 and sharing health care data in Malawi, and the technical implementation of the DIPLOMATIC  
15 minimum datasets will take this into account. The DIPLOMATIC minimum datasets will ideally feed  
16 off structured patient records that include the variables of interest, but these may be paper based or  
17 electronic, using real-time or retrospective methods of data collection depending on system  
18 functionality. Engagement with staff in the participating sites, to discuss advantages of different  
19 ways of data capture, to optimise ease of data recording, and to establish how this can be supported  
20 through existing clerking staff, will be essential to address the challenges of consistent data  
21 recording, in the face of pressures on clinical staff time.

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33 Supporting staff to facilitate optimal use of the data will be an important part of piloting and  
34 implementation of the datasets. Electronic data can significantly reduce the work required to extract  
35 data for audits and patient reviews (compared to extraction from paper records). Experiencing  
36 benefits from the data will enhance ownership and buy in from clinical staff, and will be a  
37 prerequisite to ensuring sustainability of the datasets. High quality data providing continuous  
38 feedback on quality and safety of care and patient outcomes to healthcare providers can underpin a  
39 'learning health system', which allows data intelligence to foster learning and inform  
40 decisions.[3033] Data linkage plays an important part in this when transfer of patients across  
41 facilities is common. Learning health system approaches have been shown to result in improved data  
42 and care quality in limited-resource settings similar to Malawi.[316,7] The DIPLOMATIC datasets  
43 have the potential to facilitate a learning health system approach.

### 51 **Strengths and limitations**

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54 In line with recommended practice, the datasets were designed using a multimodal approach,  
55 combining a systematic in depth review of ~~the literature and~~ the contextual information and  
56 published as well as grey literature with expert input.[3234] Delphi methods to gain expert  
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3 consensus were considered, but deemed unsuitable due to the large number of variables, many of  
4 which form interconnected constructs and could thus not be changed independently of each other.  
5 Instead of a Delphi survey, iterative rounds of consultation with DIPLOMATIC collaborators and  
6 other stakeholders in Malawi were undertaken. Group discussions were helpful to find agreement  
7 on complex constructs, e.g. recording of EDD and methods used for its estimation. Whilst this  
8 process also took considerable time to complete, partly due to competing demands for the time of  
9 all of the relevant experts, it facilitated agreement on the variables to be prioritised for inclusion in  
10 the datasets. Sharing the draft datasets with professional associations and the relevant directorates  
11 of the MoH Malawi, and gaining approval by the Safe Motherhood Technical Working Group, was  
12 important to ensure there were no objections to the datasets, and to strengthen Malawian  
13 ownership, increasing the likelihood that any recommendations arising from future study findings  
14 can be implemented and scaled up to increase impact.

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24 One limitation of the DIPLOMATIC datasets is that they are more extensive than other exemplars of  
25 national minimum datasets on maternal and neonatal health.<sup>[22, 23, 24, 25]</sup> This poses a challenge  
26 for implementation of these datasets in the context of stretched clinical staff, a background of  
27 predominantly paper based data recording and mixed success of electronic data systems.<sup>[8, 10]</sup>  
28 However it was deemed essential to ensure that the datasets incorporate all data items required for  
29 standard registers and can fulfil the Malawian national reporting obligations to the MoH, so the  
30 datasets can be embedded in existing systems and strengthen these (in line with the 'record once,  
31 use often' principle). This approach avoided creation of parallel datasets specific only to the research  
32 data needs, which would have been smaller, but would have overlapped to a large extent with  
33 existing paper based registers, leading to duplication of effort and no benefit to the existing system.

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35 The DIPLOMATIC collaboration is focussed on health care interventions, and the minimum datasets  
36 can only capture maternal and newborn care in health facilities. Home births and complications  
37 associated with these, or stillbirths out with health facilities, would only be capture if aftercare was  
38 received in a health facility, or if recorded as part of a subsequent health care episode.

## 49 CONCLUSIONS

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51 By combining contextual work with expert input, it was possible to design datasets, which build on  
52 existing structures, and can support local reporting requirements, as well as meeting the research  
53 data needs of DIPLOMATIC. The work to design the datasets highlights the need for a collaborative  
54 approach to ensure synergies and to strengthen existing systems, and avoid duplication of data and  
55 effort. Consultation on data collection is also essential to ensure local ownership of the data and any  
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3 findings arising from it. The datasets have the potential to underpin a 'learning health system'  
4 approach, and their piloting and implementation will be aimed at supporting quality of care to  
5 improve outcomes. Implementation of these datasets could thus contribute to fulfilling the aims of  
6 the Network for Improving Quality of Care for Maternal, Newborn and Child Health, in particular to  
7 strengthening of the health information system, 'to enable early, appropriate action to improve the  
8 care of every woman and newborn' (Standard 2).<sup>[1416]</sup> The datasets may also serve beyond the use  
9 by facilities participating in DIPLOMATIC, most immediately as an exemplar on how to incorporate  
10 methods of gestation estimates into routine data collection, in settings where access to early  
11 pregnancy ultrasound is limited and different methods are likely to be in use. In a wider context they  
12 also serve as a transferable example of strengthening data infrastructure and use of robust data, to  
13 underpin a learning healthcare system approach in low income settings.  
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### 23 **DATA SHARING STATEMENT**

24 The full specifications of the datasets, the development of which is described in this manuscript, are  
25 available on Open Science Framework: von Wissmann B, Gadama L, Dube Q, et al. The DIPLOMATIC  
26 Collaboration, Work Package 2: Core datasets. 2020. <https://osf.io/d3s7j> <sup>[1517]</sup>.  
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### 31 **ACKNOWLEDGEMENTS**

32 This work would not have been possible without consultation with stakeholders from the Ministry of  
33 Health Malawi, the Malawian Nurses and Midwives Council, the Malawian Association of  
34 Obstetricians and Gynaecologists, and the Malawian Association of Paediatricians.  
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39 We would like to thank Jakub Adamów for producing the graphic for this paper.  
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### 43 **CONTRIBUTORS**

44 BvW and RW designed the protocol for the development of the datasets and drafted the first version  
45 of the datasets. BvW wrote the first draft of the manuscript. BvW, EW, DW and RW synthesised the  
46 information needed to identify the dataset requirements. LAG, QD, CM, EC provided expert input on  
47 the dataset requirements, and current data infrastructure and management in Malawi. LAG, QD and  
48 EC led on engagement with the professional bodies. All authors (BvW, EW, DW, LAG, QD, CM, EC,  
49 SJS, RMR, JN, EM, BF, HC, JEN, RW) provided significant intellectual input to the iterative  
50 development of the datasets. All authors (BvW, EW, DW, LAG, QD, CM, EC, SJS, RMR, JN, EM,  
51 BF, HC, JEN, RW) provided input to drafting the manuscript.  
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## COMPETING INTERESTS

SJS reports grants from NIHR HTA, non-financial support from HOLOGIC, non-financial support from PARSAGEN, non-financial support from MEDIX BIOCHEMICA, during the conduct of the study; and SJS declares being a member of the HTA General committee.

JN reports membership of the following NIHR boards: Commissioning Priority Review Decision-making committee (2015); Health Technology Assessment (HTA) Commissioning Board (2010-2016); HTA Commissioning Sub-Board (Expression of Interest) (2014); HTA Funding Boards Policy Group (2016-2019); HTA General Board (2016-2019); HTA Post-Board funding teleconference (2016-2019); NIHR Clinical Trials Unit Standing Advisory Committee (2018-present); NIHR HTA and Efficacy and Mechanism Evaluation Editorial Board (2014-2019); Pre-exposure Prophylaxis Impact Review Panel (2017).

JEN reports being named as Principal Investigator on government and charitable research grants to her institution which aim to improve pregnancy outcome. In the last three years she has provided consultancy to Pharma companies GSK and Dilafor: her institution was remunerated for this. Her institution has received travel and subsistence expenses from Merck to facilitate her speaking at a Merck sponsored symposium on metformin. She is on Subpanel A1 for REF, and on a Wellcome Trust Science interview panel, and receive personal remuneration for each.

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