Belgian Analysis system for Maternal Mortality

Study protocol

Version 1.1 dd 26/11/2020

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SUMMARY

Study title and specifics

Title: BAMM: Belgian Analysis system for Maternal Mortality
B6702020000865 / BC-08725

Study type

National surveillance system
Multicentre epidemiological study

Aim of the study

Evaluation of obstetrical care in Belgium and international comparison of obstetrical care, by the registration and analysis of individual cases of maternal mortality in Belgium, to improve maternal care and decrease maternal mortality and severe maternal morbidity.

Primary objectives

- To investigate the incidence of maternal mortality in Belgium
- To analyse cases of maternal mortality in a structured manner on the local and national level
- To identify causes of maternal deaths, risk factors and contributing factors

Secondary objectives

- To formulate recommendations to improve obstetrical care
- International comparison of obstetrical care

Patient population

All women in Belgium who died during pregnancy or within 1 year after end of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

We estimate a number of 12 cases per year.

Study duration

The BAMM registry is a pilot project with funding from the Federal Public Service of Health, currently up till June 2021. The project will start in January 2021 and the aim is to consolidate the project into a long-term registry.

The study of each case will start promptly after the case is reported. The local and national analysis of each case will take maximum 1 year to finalisation.

INTRODUCTION

In high-income countries like Belgium, most women have a successful pregnancy without complications. A small number of women will have minor complications during pregnancy or childbirth. And on a rare occasion a woman will suffer a serious complication that requires an emergency intervention to save her and/or her baby's life.
The rarity of those serious complications makes them difficult to investigate. As a result, evidence on how frequent they occur, on strategies to prevent or the best way to manage these complications, is restricted. By registering all cases of these complications that occurred in a larger region - Belgium in this case - and by analysing the details of these cases, we can improve our knowledge. Better knowledge in turn will improve the information we can provide to our mothers and will further improve our quality of care. The United Kingdom was a pioneer in this area with the United Kingdom Obstetric Surveillance System (UKOSS) started up in 2005 (1). They demonstrated that UKOSS-studies contributed efficaciously to improved care for pregnant women and their babies (2).

The Belgian Obstetric Surveillance System (B.OSS) was launched in 2012 as a registration system for serious maternal morbidity in Belgium (3). with the support of the College of physicians of the Mother and Newborn, an institute of the Federal Public Service of Health.
Busy clinicians, gynaecologists and midwives, in nearly all Belgian maternities participate in the B.OSS registry on a voluntary basis. Their dedication demonstrates that there is a need for knowledge about serious obstetric complications in our own country.
Meanwhile, B.OSS has proved its effectiveness through national and international publications reporting on incidence and risk factors (4-7), through comparative studies with other INOSS countries (8-9) and through the development of national guidelines (e.g. a national guideline on the delivery with a scarred uterus). B.OSS has become a respectable partner within the International Network of Obstetric Survey Systems (INOSS) (10) .

However, Belgium is an exception when it comes to maternal mortality. Unlike our neighbouring countries, we do not have an enhanced maternal mortality registration system. Currently our knowledge of maternal mortality in Belgium is restricted to the data of STATBEL based on the analysis of death certificates. It is known however that vital statistics underestimate the true number of maternal deaths up to 50% (11-12) and are inaccurate in identifying the cause of death (13). Further, the information on maternal mortality retrieved from the perinatal registries is limited to the number of mothers who gave birth to a child of at least 22 weeks together with a (tentative) cause of death (14) in Flanders (Studiecentrum voor Perinatale Epidemiologie, SPE in Flanders). In Brussels and Wallonia, the 'Centre d'Epidémiologie Périnatale' (CEpiP) does not currently record data on maternal deaths.

The most accurate way of charting maternal mortality is an enhanced registration and analysis system. The United Kingdom has the longest tradition of a highly developed system since over fifty years: the well-known Confidential Enquiries into Maternal Deaths (CEMD), currently known as MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK) (15). Analogues of these Confidential Enquiries were developed in the Netherlands, France, Italy, Finland, Slovenia, and even in several African countries.

Being aware that the analysis of cases of maternal deaths reveals 'substandard care' in half of the cases even in high-income countries, emphasises the need for a Belgian system for the registration and analysis of maternal mortality.
We can no longer lag behind.

Appendix 1 gives a summary of the enhanced registration systems for maternal death in 3 neighbouring countries.

AIM of BAMM

BAMM aims to **evaluate obstetrical care** in Belgium by the registration and in-depth analysis of cases of maternal deaths.
BAMM aims to **improve the quality of obstetrical care** in Belgium by the recommendations, formulated by experts based on the analysis of individual deaths, serving as key guidance for policy makers. Implementations of recommendations may lead to a further reduction in maternal morbidity (near-miss events) and mortality.
BAMM aims to be of help for the committed doctors, midwives and health departments in Belgium, by providing a supportive and structured system to perform a retrospective incident analysis in the rare case of a maternal death.

STUDY OBJECTIVES

Primary objectives

- To investigate the incidence of maternal mortality in Belgium in a prospective way, and thereby produce a more accurate estimate of the Maternal Mortality Ratio (MMR) in Belgium, a number that is communicated to international instances, such as Europeristat, WHO.
- To analyse the cases of maternal mortality in detail in a structured way, firstly on a local level (hospital), secondly on a national level (multidisciplinary team of experts).
- To identify the causes of maternal deaths, risk factors and contributing factors.

Secondary objectives

- To formulate recommendations to improve obstetrical care, management and outcomes, e.g. by developing national guidelines.
- To compare obstetrical care in Belgium with outer countries, based on the maternal mortality registration and analysis.

STUDY POPULATION

Inclusion criteria

Maternal deaths in Belgium, including late maternal deaths, in line with the ICD-10 definition:

A maternal death is the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

Maternal deaths are subdivided into two groups:

- Direct obstetric deaths are those resulting from obstetric complications of the pregnancy state (pregnancy, labour and the puerperium), from interventions, omissions, incorrect treatment, or from a chain of events resulting from any of the above.
- Indirect obstetric deaths are those resulting from previous existing disease or disease that developed during pregnancy and which was not due to direct obstetric causes, but which was aggravated by physiologic effects of pregnancy.

Late maternal death

A late maternal death is the death of a woman from direct or indirect causes more than 42 days but less than one year after termination of pregnancy.

Exclusion criteria

Maternal deaths from accidental or incidental causes.

STUDY DESIGN

Type of study

BAMM is

- an epidemiological study
- a nationwide multicentre study
- a national surveillance system
- an enhanced registration and analysis system of cases of maternal death
- a study on assignment for the Federal Public Service of Health

Study period

The BAMM registry is a pilot project with funding from the Federal Public Service of Health, currently up till June 2021.

A try-out of the BAMM registry will start in November 2020. The project will start officially from January 2021. Aim is to consolidate the project into a long-term registry.

The study of each case will start promptly after the cases is reported. The local and national analysis of each cases will take maximum 1 year until finalisation.

Methodology

The methodology of BAMM is illustrated by the timeline shown in **Figure 1**.

i. Notification of a case

A case of maternal death can be notified to BAMM:

1. via the monthly reporting form of B.OSS, send automatically by mail to the B.OSS contact person in each hospital asking for complications in the previous month.
2. Spontaneously: gynaecologists, midwives, family doctors, psychiatrists, IC specialists, etc. can report a case directly to the BAMM team via contact details presented on the website.

Information requested on the monthly reporting form is limited to

- the date of maternal death
- contact details of the care provider involved in the case, who may be contacted for further instructions

ii. Local analysis

The BAMM officer will contact the person who reported the case and will ask permission to participate in the local analysis of the case.

A maternal death is a serious event that should result in a 'retrospective incident analysis' organised by the hospital, more specifically by the quality coordinator of the department or the hospital.

In case the hospital did not already take initiative to organise a local analysis, the BAMM officer will give instructions to organise a structured retrospective incident analysis on a short term.

People involved in this local analysis should be:

- the quality coordinator (takes the lead of the meeting)
- medical team: all the clinicians that were involved in the case, together with their supervisors (head of department, senior midwife, etc.)
- the BAMM officer

An in-depth and well-executed retrospective incident analysis by the medical team involved in the case, is of major importance for the success of the further BAMM analysis. At this local analysis, detailed information needs to be gathered from every team member and from every link in the chain of events. This is an important task for the local quality coordinator, together with the BAMM officer.

The output of this local analysis, requested for the BAMM analysis is:

- Surveillance form (**Appendix 2**): asking general information on the woman's personal, family, obstetric history and current pregnancy.
- Summarising report of the local analysis: this is a detailed narrative, a meticulous reconstruction of the event.
- Local clinician reports (**Appendix 3**): summary on the care provided to the patient and possible failure factors (what went wrong) completed by every clinician involved in the case.
- Local BAMM analysis form (**Appendix 4**): set of 45 statements asking for contributing factors.
- Anonymised copy of the relevant case notes: these will be printed out and anonymised manually by the local team.

Appendix 5 is a checklist of the requested documentation for BAMM and a guidance for anonymising, that will be provided to the team.
The BAMM officer will gather all requested documentation (cfr supra), scan and immediately upload the information to the BAMM platform, a secured system localised on the servers of Nestor, described in detail in iii. Safe data transfer.
The paper documentation is not taken along by the BAMM officer, but will be returned to the local team at the hospital.

Important note: it is not the BAMM officer who will explore the patient files to collect the relevant documents. The documents will be handed to the BAMM officer by the local team.

iii. Safe data transfer

The BAMM platform is developed by Nestor.

The decision to work with Nestor is broadly supported by the DPO UGhent, DPO Ghent University Hospital, ICT head of department Ghent University Hospital, IT Security Officer UGhent, Legal Service Ghent University Hospital, following presentation and discussion on 23/10/2019 and 2/09/2020.

Nestor is a cvba, with whom there is a good and ongoing cooperation since 2013 for the B.OSS project https://nestor.coop/ .

Appendix 6 gives a detailed description of the BAMM platform by Nestor.

The BAMM platform consists of two components

a. Viewing of unstructured data.
   The documentation gathered at the local analysis (cfr supra) under the form of PDF-files is stored per case.
   Access to these data will be restricted
   - To the BAMM team.
   - To national experts: when invited to analyse a case, experts will be able to access the data through a login and pass-word, and access will be restricted by IP-addresses. This access will be specific per expert and per case; and will be limited in time: access will be disabled manually once the analysis is finalised or automatically after 6 months.

b. Analysing the case, leading to structured data per case.
   An expert invited to analyse a case, will be asked to complete a number of questions, explained in detail below (iv. National analysis).

iv. National analysis

Following the local analysis, a multidisciplinary team of experts will be invited to examine the case.
This national team of experts consists of

- core experts (4 gynaecologists, 4 midwifes and 2 anaesthetists) and
- specialist experts based on the specific case (cardiologists, infectiologists, psychiatrists, haematologists, anaesthetists).

Their initial assessment will be online, going through three rounds.

1. First, after consulting the documentation provided by the local team, they may formulate critical questions asking for further details that according to them is lacking.
   These questions will be listed and offered to the clinical team involved.

Responses to these questions will then be uploaded to the BAMM platform, for further assessment.

2. Secondly, experts are asked to respond to a number of questions:
   I. **The cause of death**, presented as a chain of events
      Disease or condition leading directly to death …
      Due to or as a consequence of …
      Due to or as a consequence of …
      Due to or as a consequence of …
      Filling in codes selected out of a list of ICD-MM codes.
   II. **Contributing factors** are interrogated through a list of 45 statements asking for failure factors in 4 categories (organisational, technical, patient-related and human). This list should be responded by every expert using a 4-point Likert scale from 'fully disagree' to 'fully agree' and further options 'not applicable for this case' and 'unable to respond to this question adequately'. The Delphi methodology is used to evaluate consensus between the experts. Consensus is reached when the I-CVI (=item content validity index) is 0.78 or higher. (see Statistics)
   III. The experts will then formulate **recommendations**, based on the contributing factors that came forward in previous assessment, to improve obstetrical care.
      Recommendations for the specific hospital setting and recommendations for obstetrical care in general.
3. Thirdly, the experts will be asked to go through a second online round.
   The BAMM team will analyse the responses on i. ii. iii. of the previous round, will summarise these responses and reformulate a cause of death chain of events (i), reformulate statements in which there was no consensus (ii), and reformulate a list of recommendations (iii). Experts will be asked for their opinion on the above in this second online round.

v. <u>Life meeting</u>

Two times per year the BAMM team will organise a life meeting with all national expert team members around the table, to discuss cases without consensus and summarise cases of the previous six months.

vi. <u>National BAMM report</u>

After finalisation of local and national analysis, each case will be drawn up in a national BAMM report with a resume of the cause of death, the contributing factors and the recommendations.
This national BAMM report will be stored by the BAMM team and will not include patient or hospital identifiable data.
This national BAMM report will not be shared with the local hospital team. If the hospital or the medical team involved in the case, explicitly requested feedback from the national BAMM analysis, this information will be provided orally to the team during a visit at the hospital.
This national BAMM report will not be shared with family members of the deceased mother.

vii. <u>Publication of BAMM results</u>

Depending on the number of cases, the BAMM analysis will publish their results in a 5 or 10 yearly BAMM publication. This publication will include recommendations for improvement of obstetric care, besides a summary of the reported cases during those 5 or 10 years. One or more obstetric morbidities can be highlighted if these are found to be more frequent or if trends are observed.

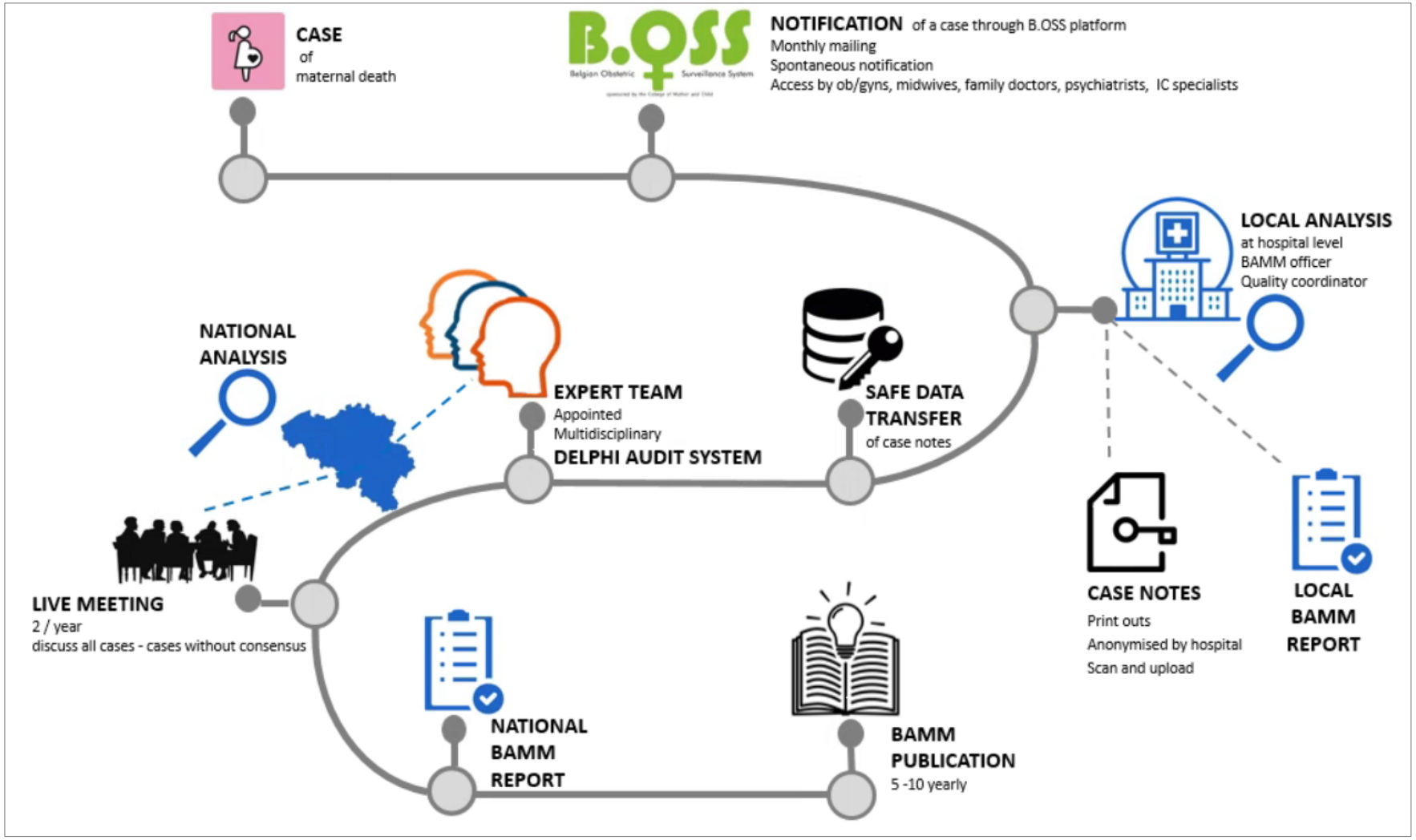

Figure 1: Timeline of the BAMM progress in case of a maternal death.

STRUCTURE OF BAMM

Funder

Federal Public Service (FPS) Public Health

The B.OSS study was established in 2011 as an initiative of the College of Physicians for Mother and Newborn, an agency of the FPS Public Health.
Mieke Walraevens, in name of Minister Maggie De Block, approved funding for the maintenance of B.OSS and the development of BAMM in 2019 as a pilot project for 18 months. This funding allowed the recruitment of a national coordinator for B.OSS and BAMM, by means of a B-4 contract at the Ghent University Hospital. The pilot project started in January 2020.
Aim is to consolidate both B.OSS and BAMM into long-term national registration systems.

Working group

In 2018 a working group was gathered consisting of people with different expertise and with special interest into maternal mortality registration.
The working group helped in the design of the BAMM methodology, in the recruitment of experts and in the campaign to make family doctors, midwives, gynaecologists and other specialists aware of the BAMM reporting system.

- Gynaecologists: Julie Belhomme; Caroline Daelemans, Griet Vandenberghe, Hilde Logghe
- Gynaecologist with master in public health: Elena Costa
- Midwives: Annick Bogaerts, Sarah Michel
- Anaesthetists: Marc Coppens, Fabienne Roelants
- Statbel: Michel Willems (now retired), Gisèle Vandervelpen
- B.OSS / BAMM officer: Karolien Benoit

Scientific committee of B.OSS and BAMM (alphabetical order)

- Anne Clercx – FPS Health, Collge Mother and Newborn
- Caroline Daelemans – Erasme ULB, CEpiP
- Charlotte Leroy – CEpiP
- Frédéric Chantraine – CEpiP, CHU Liège
- Frédéric Debiève – CEpiP, College Mother and Newborn
- Griet Vandenberghe – UZ Gent, B.OSS, BAMM
- Ilse Peeters – Sciensano
- Kristien Roelens – UZ Gent, College Mother and Newborn, SPE, B.OSS, BAMM
- Laura Cornelissen – Sciensano
- Leen Verleye – KCE
- Monika Laubach – UZ Brussel, SPE
- Régine Goemaes – SPE
- Roland Devlieger – UZ Leuven, SPE
- Sophie Quoilin – Sciensano
- Virginie Van Leeuw – CEpiP

Supervisory committee

The supervisory committee stands for the follow-up and evaluation of the project and exists of:

- Mieke Walraevens as representative of Minister Maggie De Block, the current Minister of Public Health (until October 2020)
- Isabelle Van Der Brempt as representative of the FPS Health, Food chain safety and Environment
- Margareta Haelterman as representative of the FPS Health, Food chain safety and Environment (retired since April 2020)
- Omer Vanhaute as representative of the Ghent University Hospital
- Frédéric Debième as representative of CEpiP and the College of Mother and Newborn
- Roland Devlieger as representative of SPE and the College of Mother and Newborn
- Kristien Roelens as representative of the Ghent University Hospital, SPE and the College of Mother and Newborn
- Julie Belhomme as representative of the BAMM working group and the College of Mother and Newborn

BAMM-team for daily work

- BAMM officer: Karolien Benoit – FPS / Ghent University Hospital (B4-contract)
- BAMM team:
  Caroline Daelemans, Erasme, ULB
  Julie Belhomme, CHU St Pierre
  Hilde Logghe, AZ St Lucas
  Griet Vandenberghe, UZ Ghent

Local investigators

The BAMM project will take benefit of the performance of the B.OSS project since 2012. The B.OSS contact person in every Belgian maternity unit (this is a gynaecologist in most cases, a senior midwife or an administrative person) receives a monthly call for cases through mail.
From November 2020 onwards, this monthly reporting form will also ask for cases of maternal death in the previous month.

National Expert Team

This multidisciplinary team of experts is involved in the assessment of maternal deaths.
The national expert team exists of:

- Core experts: 4 gynaecologists, 4 midwifes, 2 anaesthetists
- Extra experts specific per case: cardiologists, infectiologists, psychiatrists, haematologists

They are nominated, mostly from a national association in their discipline, for a period of 3 years.
Their participation will be on a voluntary basis.
Per discipline, back-up persons are available in the case an expert is involved in the mortality case.

Appendix 7 presents a list of the 28 experts that are recruited for the launch of the BAMM project in 2020-2021.

DATA MANAGEMENT

Data collection

The following data / documents are collected by the BAMM research team for every case of maternal death:

1. Notification of a case: B.OSS reporting form: this will only include a date of the event and contact details of the person reporting the cases. No person-identifiable information will be asked.

2. Local analysis:
   - Surveillance form (Appendix 2) (unstructured data)
   - Summarising report of the local analysis (unstructured data)
   - Local clinician reports (Appendix 3) (unstructured data)
   - Local BAMM analysis form (Appendix 4) (structured data)
   - Anonymised copy of the relevant case notes: printed out and anonymised manually by the local team. (unstructured data)
   - Checklist of the requested documentation (Appendix 5)

3. National analysis: (structured data)
   - List of additional questions by the BAMM national expert team
   - Responses to the additional questions by the medical team involved (unstructured data)
   - BAMM analysis form completed by each expert on the online BAMM platform in the first round, consisting of
     i. cause of death (chain of events),
     ii. response to 45 statements in a Likert scale
     iii. recommendations formulated by the expert
   - Analysis and summary of the first round by the BAMM team
   - BAMM analysis form completed by each expert on the online BAMM platform in the second round, consisting of a Likert scale on
     i. cause of death (chain of events) formulated by BAMM team
     ii. reformulated statements in a Likert scale
     iii. recommendations formulated by the BAMM team
   - Analysis and summary of the second round by the BAMM team

4. Live meeting
   Meeting notes by the national BAMM coordinator.

5. National BAMM report
   Conclusion of the national expert analysis, based on the online assessment and the live meeting, consisting of i. ii. iii (cfr supra).

All data summarised above is considered **structured data**, with exception of the a) anonymised copy of the relevant case notes, b) the summarising report of the local analysis, c) the completed surveillance form, d) the local clinician reports, and e) the responses to the questions of the national expert team, which is considered **unstructured data**.

Data anonymisation

- A BAMM code will be assigned to every maternal death.
  The BAMM team will hold track for every BAMM code of the date of notification and the person notifying the maternal death.
- The copy of the relevant case notes will be printed out and anonymised at the hospital by the local medical team / quality coordinator. Appendix 5 is a checklist of the requested documentation for BAMM and a guidance for anonymising, that will be provided to the team.
- All documents gathered at the local analysis will be anonymised:
  They will not contain information that can lead to identification of the patient, the healthcare providers of the medical team involved, or the hospital where the maternal death occurred.
- All documents gathered at the local analysis will be scanned and uploaded, locally at the hospital, to the BAMM platform. The uploaded files will be coded using the BAMM code and will be stored on the BAMM platform in a specific section named with this BAMM code.
- The information provided to the experts of the national analysis will only contain the BAMM code (cfr supra). The analysis of each expert in each round will also be stored on the BAMM platform in this specific section named with the BAMM code.
- The national BAMM report will contain the BAMM code only.
- See section Methodology, section vi. and vii.
  The national BAMM report will not be shared with the local hospital or medical team, nor with the family of the deceased mother.
  The results of the BAMM analysis will be published in a 5 to 10 yearly publication, depending on the number of cases, to be able to guarantee the confidentiality of the cases.

Data storage

Data gathered from the local and national analysis will be saved **electronically on the secure servers of Nestor**.
Appendix 6 gives a detailed description of the BAMM platform by Nestor.

> The decision to work with Nestor is broadly supported by the DPO UGhent, DPO Ghent University Hospital, ICT head of department Ghent University Hospital, IT Security Officer UGhent, Legal Service Ghent University Hospital, following presentation and discussion on 23/10/2019 and 2/09/2020. A data processing agreement is set up between UZ Gent and Nestor (see **appendix 8**)
> Nestor is a cvba, with whom there is a good and ongoing cooperation since 2013 for the B.OSS project https://nestor.coop/ .

After finalising a national BAMM report of the maternal death case, all structured and unstructured data from the cases will be removed from the servers of Nestor.
The anonymised case notes will be removed permanently from the servers of Nestor and will not be archived any longer.

Archiving data

The national BAMM report and other structured data resulting from the local and national analysis, will be archived on the secure servers of the University Hospital of Ghent, for 20 years.
The anonymised case notes are not archived, but are removed permanently after finalising the national BAMM report.

The other anonymous unstructured data resulting from the local analysis report, will be archived on the secure servers of the University Hospital of Ghent, for 20 years (the summarising report of the local analysis, the completed surveillance form, the local clinician reports, the responses to the questions of the national expert team).

Access to data

The access to the data of BAMM is severely **restricted**:

- Access to unstructured data (summarised above) stored on the BAMM platform
  - Restricted to **national experts** invited to analyse the case
  - Restricted by a Login and Password
  - Restricted by an IP-address
  - Restricted in time (up till 6 months or the time necessary to finalise the analysis)
- Access to structured data (summarised above) on the BAMM platform
  - Restricted to the BAMM team
  - On the BAMM platform (as long as the analysis is ongoing)
  - On the servers of Ghent University Hospital once the analysis is completed

Data control

1. Data collected per case of maternal death:
   - Forms collected at the time of the local analysis:
     - Checklist of requested documentation
     - Check for completeness by the BAMM officer (surveillance form, local clinician report, local BAMM analysis form)
     - The national expert team will have the opportunity to ask for further information, when they judge that information is missing based on the documentation provided.
   - Data collected at the time of the national analysis:
     - Analysis and summary of the data by the BAMM officer / BAMM team
     - Live meeting 2x/ year: to discuss cases without consensus, to go through the summary of all cases of the previous 6 months

2. Accurateness of the number of cases of maternal death registered by BAMM:

   Two pathways to control for missing cases in the BAMM registry
   (especially cases of late maternal death)

   - Triangulation (data-linkage) of 3 federal databases by the national registry number

     1) STATBEL: vital statistics

     2) RHM/MZG: Minimal Hospital Data (Résumé Hospitalier Minimum/Minimale Ziekenhuis Gegevens)

     3) IMA/AIM: Inter Mutualistic Agency (Agence InterMutualiste/ InterMutualistisch Agentschap

   This project is set-up parallel with the development of the BAMM system, by Dr Elena Costa (Master in Public Health, and Obstetrician/gynaecologist) and will start with a retrospective study from 2009 to 2019.

   This system will be probably more efficient, in the first phases, than the BAMM-system to detect late maternal deaths, which may happen far from the obstetrical environment such as suicides and domestic abuse related deaths.

- The Study Centre for Perinatal Epidemiology (SPE) in Flanders will continue to register maternal deaths, limited to mothers who gave birth to an infant of more than 22weeks. Data are available the following year.
  The Centre d'Épidémiologie Périnatale (CEpiP) is planning to start the registration of maternal mortality, in line with SPE.

Data property

The anonymised data gathered during the local analysis becomes property of the BAMM team once uploaded on the BAMM platform.
The national analysis by the experts on the BAMM platform and the final national BAMM report of every maternal death, is property of the BAMM-team.

Property of the BAMM-team implies property of the Federal Public Service of Health.

Use of data

The principal investigator and BAMM-team have the right to use the data for

- scientific purposes, by drawing up a BAMM-report for publication every 5 to 10 yearly.
- epidemiological purposes, by providing data to national instances (such as STATBEL, SPE, CEpiP) and international instances (such as Europeristat, WHO).
- quality improvement purposes, by formulating recommendations based on recommendations out of the national and local analysis. Recommendations can lead to the development of guidelines, to (proposals of) policy changes.
- international comparison, e.g. initiatives to compare maternal mortality within the International Network of Obstetric Survey System (INOSS). International comparison can contribute to better insight in a country's quality of (obstetric) care.

STATISTICS

- The Delphi methodology
  Used to evaluate consensus between the experts in the national analysis.
  Consensus is reached when the I-CVI (=item content validity index) is 0.78 or higher.
  The I-CVI is the number of experts giving a rate 3 or 4 to a statement divided by the total number of experts rating that item. (Lynn 1986, Polit & Beck 2016).

- The 5-10 yearly BAMM report
  Statistics will be limited to descriptive statistics merely.

ETHICS & LEGAL ASPECTS

Ethics Committee approval

Ethics committee approval for the BAMM project (B6702020000865 / BC-08725) was obtained from the EC of Ghent University Hospital dd 18/11/2020.

An amendment for expanding this study to a multicentre study is requested to the EC of Ghent University Hospital as central EC of this multicentre registry, in analogy with the B.OSS project.
The EC of all participating Belgian maternities will be informed by the central EC,
of approval of the study protocol
of approval of any changes to the original study protocol requested by amendment
The EC of each participating maternity will confirm participation to the central EC.

In case of a late maternal death, notified by a family doctor, psychiatrists or others care-provider, the approval of the central EC is valid.

Good Clinical Practice

The study is conducted in accordance with the guidelines of good clinical practice (ICH/GCP) and the Helsinki Declaration, written to protect those involved in clinical studies.

The NO-BLAME approach is of paramount importance for the BAMM project to succeed in its main goal: identifying risk factors and contributing factors in the rare cases of maternal death, to enable the formulation of recommendations, the development of guidelines, the proposal of policy changes, to improve obstetrical care in Belgium.

The national experts and BAMM officer follow a 4-hour training in retrospective incident analysis, by Mrs Evelien Raman (trainer of quality coordinators of the FPS Health). Aim of this training is to support them in performing an objective and thorough analysis of each case, with focus on contributing factors, not focus on persons.

Confidentiality & data protection

The collection of medical data will be limited to those data necessary to fulfil the objectives of the BAMM-project: a full analysis of the case to identify risk factors and factors contributing to the maternal death.
All data will be collected and processed with adequate precautions to ensure the utmost confidentiality of the deceased patient, the health care providers and hospitals.

Experts and instances approached for (legal) advice in the development of the BAMM project:

- Tom Balthazar, professor at the faculty of Law and criminology and faculty of Medicine and Health Science at the University of Ghent
- Legal service of Ghent University Hospital (Mevr E. Vandermeersch)
- DPO of the Ghent University Hospital and the University of Ghent
- Orde der Artsen / Ordre des médecins

Regulation (EU) 2016/679 of the European Parliament and of the Council, the European Union's General Data Protection Regulation (GDPR), regulates the processing by an individual, a company or an organisation of personal data relating to individuals in the EU.

GDPR does not apply to the processing of personal data of deceased persons.

Informed consent for the use of medical data in case of a deceased person:

An informed consent must **not** be obtained for the use of the medical data. This also applies in the exceptional situation of a maternal death of a mother under the age of 18.

The health-care providers involved in the maternal death, participate in the local analysis and provide a copy of the medical case notes to the BAMM-project at this moment; in this way they indirectly consent with the use of their notes and medical data.

Feedback to the hospital / to the health-care providers involved

The results of the BAMM-analysis must not be provided to the local hospital team in an officially written report.

If the hospital or the medical team involved in the case, explicitly requested feedback from the national BAMM analysis, this information can be provided directly to the team during a visit at the hospital.

Feedback to the partner / the family of the deceased mother

The results of the BAMM-analysis must not be provided to the partner or the family by the BAMM research team.

The health-care providers involved, have the responsibility to inform the partner/ family of the deceased mother, of the fact that a structured analysis by a national team will take place besides the local analysis at the hospital. Only the health-care providers involved, have the authority to communicate the results of the local and national BAMM analysis.

The national BAMM report will not be shared with family members of the deceased mother.

We cite Prof Marian Knight (responsible for MBRRACE-UK): “Confidentiality is the key for the system to succeed. If you plan to communicate results to the family of the mother, you will find no health-care provider willing to cooperate in this system.”

Obligation to communicate in case the national analysis reveals a ‘serious concern’

Or what is called in the MBRRACE-UK system ‘Cases of concern’ when meeting one of the following criteria:

1. *Death (child or adult) attributable to abuse or neglect, in any setting, but no indication of cross agency involvement (i.e. no mention of safeguarding, social services, police or LSCB).*

2. Staff member displaying:

- *Abusive behaviour (including allegations of sexual assault)*
- *Serious professional misconduct*
- *Dangerous lack of competency*

But not clear if incident has been reported to senior staff.

3. Standards in care that indicate a dysfunctional or dangerous department or organisation, or grossly inadequate service provision.

The communication of ‘serious concerns’ revealed during a national BAMM analysis, is contrary to the NO-BLAME approach and guarantee of confidentiality for which the BAMM project stands. The BAMM project can impossibly gain the confidence of health-care providers without the guarantee of no-blame and confidentiality.

Therefore, a serious concern revealed during the national BAMM analysis by the national expert, will not be communicated to the Medical Director of the hospital, or to other instances.

Moreover, a serious concern should be identified at the moment of the local analysis by the hospital team involved. It is the responsibility and the authority of the local team, together with the quality coordinator to handle such a concern appropriately.

Following additional appropriate technical and organizational measures are taken, to guarantee confidentiality of data, to protect the personal data against unauthorized disclosures or access, accidental or unlawful destruction, or accidental loss or alteration:

- Anonymisation of case notes: 'Document checklist and guidance' (Appendix 5) describes for the local health care providers how to anonymise the case notes by hand and how to handle these documents to the national BAMM coordinator. The coordinator will scan the anonymised notes to the BAMM platform. The research team has no access to the original case notes, only to the anonymised notes. No personal identifiers are accessible for the research team.
- Development of a safe BAMM platform (see Appendix 6) with a data processing agreement between UZ Gent and Nestor, the provider of the platform (see Appendix 8).
- Data access to the safe BAMM platform and the servers of UZ Ghent: restricted in time and restricted to individuals (see 'Acces to data'). These individuals only have access if they have signed:
  - **The statement of confidentiality** (**Appendix 9**)
  - **The declaration of potential conflict of interest** (**Appendix 10**)
- Access will only be possible with authentication (username and password) and via IP address after receiving an invitation to consult the data of a single case in which they need to conduct an analysis.
- For each expertise, a backup expert is provided, in case of involvement of one of the experts.
- After finalising each case with a national BAMM report, the anonymised case notes are removed permanently. No future use of these data will be possible.
- The report itself is completely anonymised and will be kept onto the secure servers of UZ Gent, only accessible for BAMM research team.

Remuneration

There are no remunerations for participation or contribution to the study. All collaborators and experts cooperate on a voluntary basis.

Insurance

Insurance for participants in the BAMM project is provided by the Ghent University Hospital:: Allianz Global Corporate & Specialty - Policy Number: BEL000862 (Appendix 11)
The Ghent University Hospital is involved in the BAMM project through the B-4 contract by the FPS of Public Health (see structure of BAMM, funding) and as the central Ethical Committee.

PUBLICATION RULES

- Publication of the detailed results of the BAMM analysis will be limited by the number of cases, to guarantee confidentiality to the maximum possible extent, and therefore published only after 5 or even 10 years.
- Feedback of the aggregated results and leading recommendations will be provided to the funder (Federal Public Service (FPS) Public Health) on a yearly basis. To demonstrate the effectiveness and importance of the system, to motivate the continuation of funding and to convert recommendations into real measures.
- This feedback will also be revealed to the target-group of clinicians (obstetricians, midwifes, anesthetists, …) by means of an infographic and presentations on national conferences.

- Authorship of the publications of the BAMM results will be discussed and agreed within the BAMM scientific committee and the FPS supervisory committee, before initiation of the writing process. Authors should comply with the ICMJE authorship rules based on the following 4 criteria:

    - Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
    - Drafting the work or revising it critically for important intellectual content; AND
    - Final approval of the version to be published; AND
    - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

REFERENCES

1. Marian Knight, Jennifer J. Kurinczuk, Derek Tuffnell and Peter Brocklehurst. The UK Obstetric Surveillance System for rare disorders of pregnancy. BJOG: an International Journal of Obstetrics and Gynaecology. 2005; 112(3):263-5. (https://doi.org/10.1111/j.1471-0528.2005.00609.x)
2. Knight M, Lindquist A. The UK Obstetric Surveillance System: impact on patient safety. Best Pract Res Clin Obstet Gynaecol 2013;27(4):621-30.
3. Vandenberghe G, Roelens K, Van Leeuw V, Englert Y, Hanssens M, Verstraelen H. The Belgian Obstetric Surveillance System to monitor severe maternal morbidity. Facts Views Vis Obgyn. 2017 Dec;9(4):181-8.
4. Vandenberghe G, De Blaere M, Van Leeuw V, Roelens K, Englert Y, Hanssens M, et al. Nationwide population-based cohort study of uterine rupture in Belgium: results from the Belgian Obstetric Surveillance System. BMJ open. 2016;6(5):e010415.
5. Vandenberghe G, Guisset M, Janssens I, et al. A nationwide population-based cohort study of peripartum hysterectomy and arterial embolisation in Belgium: results from the Belgian Obstetric Surveillance System. BMJ open 2017;7(11):e016208.
6. Langedock A, Vandenberghe G, Van Leeuw V, Leroy C, Englert Y, Debiève F, Hanssens M, Van Calsteren K, Roelens K. Eclampsie in België: resultaten van het Belgian Obstetric Surveillance System. Gunaïkeia. 2019 Nov; 24 (4): 6-12.
7. Vandenberghe G, De Blaere M, Verstraelen H, Van Leeuw V, Leroy C, Englert Y, Hanssens M, Roelens K. Uterusruptuur in België: resultaten van de Belgian Obstetric Surveillance System. Gunaïkeia. 2019 Sept; 24 (5): 5-10.
8. Vandenberghe G, Bloemenkamp K, Berlage S, Colmorn L, Deneux-Tharaux C, Gissler M, Knight M, Langhoff-Roos J, Lindqvist PG, Oberaigner W, Van Roosmalen J, Zwart J, Roelens K; INOSS (the International Network of Obstetric Survey Systems). The International Network of Obstetric Survey Systems study of uterine rupture: a descriptive multi-country population-based study. BJOG. 2019 Feb;126(3):370-381. doi: 10.1111/1471-0528.15271. Epub 2018 Jun 12.
9. Athanasios F. Kallianidis, Alice Maraschini, Jakub Danis, Lotte B. Colmorn, Catherine Deneux-Tharaux, Serena Donati, Mika Gissler, Maija Jakobsson, Marian Knight, Alexandra Kristufkova, Pelle G. Lindqvist, Griet Vandenberghe, homas Van Den Akker, on behalf of INOSS (the International Network of Obstetric Survey Systems). Epidemiological analysis of peripartum hysterectomy across nine European countries. Acta Obstetrica et Gynecologica Scandinavica 2020 May, doi: https://doi.org/10.1111/aogs.13892
10. Knight M. The International Network of Obstetric Survey Systems (INOSS): benefits of multi-country studies of severe and uncommon maternal morbidities. Acta obstetricia et gynecologica Scandinavica. 2014;93(2):127-31.
11. Alkema L, Chou D, Hogan D, Zhang S, Moller AB, Gemmill A, et al. Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group. Lancet 2016 Jan;387(10017):462-74.
12. Donati S, Senatore S, Ronconi A, group Rmmw. Maternal mortality in Italy: a record-linkage study. BJOG 2011 Jun;118(7):872-9.
13. Euro-Peristat. European Perinatal Health Report. Health and Care of Pregnant Women and Babies in Europe in 2010 2010 [cited 2017 July 6]. Available from: http://www.europeristat.com/images/doc/EPHR2010_w_disclaimer.pdf.
14. Roelens K. Vandenberghe G. Temmerman M. Maternale Sterfte. PERINATALE ACTIVITEITEN IN VLAANDEREN : SPE. 2011;14:89-97

15. Knight M TD, Kenyon S, Shakespear J, Gray R, Kurinczuk JJ (Eds.) on behalf of MBRRACE-UK. Saving Lives, Improving Mother's Care - Surveillance of maternal deaths in the UK 2011-13 and lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009-13. 2015.

APPENDICES

Appendix 1: Background information
A summary of the enhanced registration systems for maternal death in 3 neighbouring countries.

Appendix 2: BAMM surveillance form
Completed by the medical team involved at the time of the local analysis, asking general information on the woman's personal, family, obstetric history and current pregnancy.

Appendix 3: BAMM Local clinician report
Completed by every clinician involved at the time of the local analysis, asking for failure factors.

Appendix 4: Local BAMM analysis form
Set of 45 statements asking for failure factors based on a Likert scale.
This form will be completed by the medical team involved at the time of the local analysis.
This form will not be visible for the national team of experts.

Appendix 5: Checklist and guidance for anonymising

Appendix 6: Description of the BAMM platform by Nestor

Appendix 7: List of the 28 experts recruited for the launch of BAMM in 2020-2021

Appendix 8: Data processing agreement

Appendix 9: The statement of confidentiality (NL & Fr)

Appendix 10: The declaration of potential conflict of interest (NL & Fr)

Appendix 11: Insurance document