**RODOLFO DE CARVALHO PACAGNELLA**

# Morbidade Materna Grave: explorando o papel das demoras no cuidado obstétrico

**Tese de Doutorado**

**ORIENTADOR: Prof. Dr. JOSÉ GUILHERME CECATTI**

**UNICAMP**
**2011**

UNIVERSIDADE ESTADUAL DE CAMPINAS
Faculdade De Ciências Médicas

# Morbidade Materna Grave: explorando o papel das demoras no cuidado obstétrico

**RODOLFO DE CARVALHO PACAGNELLA**

Tese de Doutorado apresentada ao Programa de Pós-Graduação em Tocoginecologia da Faculdade de Ciências Médicas da Universidade Estadual de Campinas para obtenção do Título de Doutor em Ciências da Saúde, área de concentração em Saúde Materna e Perinatal, sob orientação do Prof. Dr. José Guilherme Cecatti.

**UNICAMP**
**2011**

FICHA CATALOGRÁFICA ELABORADA POR
ROSANA EVANGELISTA PODEROSO – CRB8/6652
BIBLIOTECA DA FACULDADE DE CIÊNCIAS MÉDICAS
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P113m

Pacagnella, Rodolfo de Carvalho, 1974 -
Morbidade materna grave: explorando o papel das demoras no cuidado obstétrico. / Rodolfo de Carvalho Pacagnella. -- Campinas, SP : [s.n.], 2011.

Orientador: José Guilherme Cecatti
Tese (Doutorado) - Universidade Estadual de Campinas, Faculdade de Ciências Médicas.

1. Mortalidade materna. 2. Gravidez - complicações e sequelas. 3. Assistência perinatal. I. Cecatti, José Guilherme. II. Universidade Estadual de Campinas. Faculdade de Ciências Médicas. III. Título.

Informações para Biblioteca Digital

**Título em inglês:** Severe maternal morbidity: exploring the role of delays in obstetrical care
**Palavra-chave em inglês:**
Maternal mortality
Pregnancy complications
Perinatal care
**Área de concentração:** Saúde Materna e Perinatal
**Titulação:** Doutor em Ciências da Saúde
**Banca examinadora:**
José Guilherme Cecatti [Orientador]
Renato Passini Junior
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Rossana Pulcineli Vieira Francisco
Maria do Carmo Leal
**Data da defesa:** 04-11-2011
**Programa de Pós-Graduação:** Tocoginecologia

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**Data: 04/11/2011**

# Dedicatória

*Como realização pessoal,*

*dedico este trabalho às mulheres da minha vida (em ordem de aparecimento): Silvia, minha mãe, pelo empenho, dedicação e amor tão intensamente devotados; Raquel, minha irmã, companheira e torcedora fiel do meu trabalho; Carina, minha esposa e generosa amiga, com quem aprendo muito e com quem partilho as mais ousadas conquistas; Olívia, minha filha, mais novo e intenso sopro de amor.*

*E a meu pai, José Carlos (in memorian), que sempre quis ter um "doutor" na família e me deu condições para isso.*

*Como realização profissional,*

*dedico esta tese ao meu orientador, Dr. Guilherme, pelo amor com que faz seu trabalho. Com ele aprendi a dar valor ao que é caro e, fundamentalmente, a trabalhar em equipe.*

# Agradecimentos

*Primeiramente gostaria de agradecer ao meu amigo João Paulo Dias de Souza, companheiro de longa data e exemplo de sucesso que almejo alcançar, pela ajuda e incentivo.*

*E agradeço também ao meu novo grande amigo Rodrigo Camargo, sempre disposto e alegre, com quem aprendo a levar a vida de forma mais "leve".*

*Às minhas amigas, amigos e cúmplices na jornada da pesquisa: Carla, Laura, Samira, Dra. Fernanda Surita, Dra. Mary Parpinelli, Maria Helena, Elias, Ricardo Tedesco, Lúcio, Dulce, Fernando e Edilberto (companheiros de república): "Porque várias cabeças pensam melhor que uma só!"*

*Aos colegas e amigos da Rede Brasileira de Estudos em Saúde Materna e Perinatal pela realização desse projeto.*

*Ao meu irmão, Rafael, meu grande apoiador, e à minha família ampliada (avós, tios e primos) pela base sólida e porto seguro. Obrigado!*

# Sumário

# Símbolos, Siglas e Abreviaturas

| | |
|---|---|
| **AVC** | Acidente vascular cerebral |
| **BJOG** | *British Journal of Obstetrics and Gynaecology* |
| **CAISM** | Centro de Atenção Integral à Saúde da Mulher |
| **CI 95%** | 95% *Confidence interval* |
| **CNPq** | Conselho Nacional de Pesquisa |
| **CONEP** | Conselho Nacional de Ética em Pesquisa com Seres Humanos |
| **CPAV** | Condições potencialmente ameaçadoras da vida |
| **DECIT** | Departamento de ciência e tecnologia do Ministério da Saúde |
| **EmOC** | *Emergency obstetric care* |
| **FCM** | Faculdade de Ciências Médicas |
| **GIS** | *Geographic information system* |
| **HELLP** | Hemolytic anemia; Elevated Liver enzymes; Low Platelet count; |
| **IC95%** | Intervalo de confiança 95% |
| **ICU** | *Intensive care unit* |
| **LTC** | *Life threatening conditions* |
| **MCH** | *Maternal and Child Health* |
| **MD** | *Maternal deaths* |
| **mHealth** | *Mobile technology in ealth* |
| **MM** | Morte Materna |
| **MMG** | Morbidade materna grave |
| **MMR** | *Maternal mortality ratio* |

| | |
|---|---|
| **MNM** | *Maternal Near-miss* |
| **NGO** | *Non-governmental organization* |
| **NMM** | *Near-miss* Materno |
| **OM** | Óbito Materno |
| **OMS** | Organização Mundial de Saúde |
| **PR** | *Prevalence Ratio* |
| **RBESRP** | Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal |
| **RP** | Razão de prevalência |
| **SMM** | *Severe Maternal Morbidity* |
| **UNDP** | *United Nation Development Program* |
| **UNFPA** | *United Nation Population Fund* |
| **UNICAMP** | Universidade Estadual de Campinas |
| **UTI** | Unidade de tratamento intensivo |
| **VHF** | *Very high frequency* |
| **WHO** | *World Health Organization* |

# Resumo

**Introdução:** Embora a maioria das causas das mortes maternas seja evitável, não podem ser previstas, mesmo nos melhores contextos, mesmo onde haja pré-natal adequado, educação adequada e bom suporte nutricional. Contudo, embora as complicações no parto e puerpério não sejam previsíveis e nem preveníveis, os indicadores de mortalidade materna são extremamente sensíveis à instituição de cuidados obstétricos adequados e o tempo na obtenção de cuidados adequados é o fator mais importante relacionado às mortes maternas. A partir dessa observação um modelo "three delays" que avalia as demoras na assistência obstétrica tem sido amplamente utilizado como referencial teórico para a pesquisa sobre mortalidade materna. Seu uso tem sido intensificado a partir da utilização do conceito de *near-miss* materno, uma alternativa à mortalidade materna.

**Objetivos**: Avaliar a associação entre demoras na obtenção de cuidados obstétricos adequados e diferentes desfechos maternos segundo o modelo "three delays".

**Método**: foi realizada ampla revisão bibliográfica e elaboração de um ensaio abordando o marco conceitual sobre o tema e um estudo de corte transversal multicêntrico para vigilância prospectiva e coleta de dados para a identificação

dos casos com morbidade materna grave (MMG) e condições potencialmente ameaçadoras da vida (CPAV) segundo critérios previamente definidos pela OMS. Dados sobre as demora foram colhidos dos prontuários médicos e por informações com a equipe assistente.

**Resultados**: Os dados da literatura permitiram inferir que o uso da análise de demoras na assistência obstétrica com o modelo “three delays” pode ser extremamente útil na avaliação dos determinantes da mortalidade materna, especialmente se associada à investigação do near-miss materno. Os dados obtidos no estudo transversal permitiram a comparação entre diferentes desfechos maternos e com isso observou-se uma associação crescente entre a identificação de alguma demora no atendimento obstétrico e desfechos maternos adversos extremos (near-miss materno e óbito). Observou-se 54% de demoras em geral, 52% de demoras nas mulheres apenas com condições potencialmente ameaçadoras da vida, 68,4% no grupo de near-miss materno e 84,1% no grupo de com óbito materno.

**Conclusão**: O modelo “Three delays” é um importante referencial teórico para o estudo dos casos de near-miss materno. A freqüência de demoras na assistência obstétrica está diretamente relacionada ao pior desfecho materno.

**Palavras-chave:** Morbidade materna grave. *Near-miss* materno. Assistência obstétrica. Demoras. Three delays

# Abstract

**Introduction**: Although the majority of causes of maternal deaths are preventable they cannot be predicted, even in the best settings, where there is adequate antenatal care, education and good nutritional support. However, maternal mortality indicators are extremely sensitive to the adequate obstetric care and time in getting appropriate care is the most important factor related to maternal deaths. Considering this, the “three delays model”, which evaluates the delays in obstetric care, has been widely used as a theoretical framework for research on maternal mortality. Its use has been intensified since the use of the concept of maternal near-miss, a proxy of maternal mortality.

**Objectives**: To evaluate the association between delays in obtaining adequate obstetric care and different maternal outcomes according to the "three delays model".

**Methods**: We performed an extensive literature review and preparation of an essay addressing the conceptual framework on the issue and a multicenter cross-sectional study for prospective surveillance and data collection of cases with maternal near-miss (MNM) and potentially life threatening conditions (PLTC) according to previously defined criteria by WHO. Data on delay were collected from medical records and interviews with the staff.

**Results**: The literature data allowed inferring that the use of the analysis of delays in obstetric care using the "three delays model" can be extremely useful in assessing the determinants of maternal mortality, especially if associated with the investigation of maternal near-miss. The data provided by the cross-sectional study allowed comparison between different maternal outcomes and it was observed that there was a growing association between the identification of some delay in obstetric care and extreme maternal adverse outcomes (near-miss and maternal death). In general, there was a frequency of 54% delays, 52% of delays in women only with potentially life-threatening conditions, 68.4% in the maternal near-miss group and 84.1% in the group with maternal death.

**Conclusion**: The "Three Delays model" is an important theoretical framework for the study of near-miss cases. The frequency of delays in obstetric care is directly related to worse maternal outcome.

**Key words:** severe maternal morbidity; maternal n*ear-miss*; obstetric care; delays; three delays model.

# Lista de quadros

# 1. Introdução

A mortalidade materna talvez seja o indicador que mais reflita as enormes diferenças e disparidades no desenvolvimento humano entre os países (Maine, 1991). Representa um indicador do *status* da mulher, considerando seu acesso à assistência à saúde e a adequação do sistema de assistência à saúde em responder às suas necessidades (World Health Organization. Maternal Health and Safe Motherhood Programme. e Unicef., 1996).

No entanto, em termos absolutos, é um evento raro (Hogan, Foreman *et al.*, 2010). É a principal causa evitável de mortes de mulheres em idade reprodutiva no mundo e sua natureza é diferente de outras estatísticas de mortalidade, não apenas pelas causas, mas até mesmo pela potencial solução (Rosenfield e Maine, 1985). Por exemplo, enquanto a mortalidade materna não se reduz apenas com a melhoria nas condições sócio-econômicas da população, as taxas de mortalidade infantil melhoram sensivelmente com a instituição dessas medidas (Loudon, 1986). De fato, há uma clara diferença entre a velocidade do declínio da mortalidade materna e da mortalidade entre menores de 5 anos (Lozano *et al.*, 2011) que pode ser explicada pelas diferenças nas

estratégias e ações necessárias para se tratar das duas condições. Mas isso também pode ser explicado pela falta de investimentos no cuidado à saúde da mulher gestante.

Somente a partir da metade da década de 1980, com um argumento fornecido por Rosenfield e Maine (Rosenfield e Maine, 1985), que a mortalidade materna ganhou espaço e importância na pesquisa e na política. Depois disso um movimento de conscientização para a redução da mortalidade materna levou à Iniciativa Maternidade Segura da OMS (Maine, 1991). Desde então, nos últimos 25 anos, a saúde materna tem melhorado em muitos países. Todavia, a maioria das melhorias necessárias para a redução da mortalidade materna ainda não ocorreu.

Embora a incidência de complicações que podem levar à morte pode eventualmente ser semelhante em todo o mundo, existem diferenças substanciais no manejo destas complicações. Como conseqüência, 99% das mortes maternas acontecem nos países de baixa renda e continuam a ser as mesmas de antes do advento da obstetrícia moderna, sendo a maioria delas devida a causas obstétricas diretas (hemorragia, sepse, complicações do aborto, distúrbios hipertensivos, parto obstruído, rotura uterina e gravidez ectópica) (Lozano *et al.,* 2011).

As diferenças observadas hoje em dia nos indicadores de mortalidade materna entre os países de alta e de baixa renda são geralmente devidas a diferenças na oferta de cuidados obstétricos adequados. Embora as causas das mortes maternas sejam evitáveis, não podem ser previstas, mesmo nos melhores contextos, mesmo onde haja pré-natal adequado, educação adequada e bom suporte nutricional (Maine, 1991). Alguns estudos não encontraram associação entre complicações obstétricas e

características demográficas reconhecidas, fatores de risco comportamentais ou mesmo complicações no pré-natal (Rooks *et al.,* 1989). Outros, observaram que nenhum tipo de triagem pré-natal influencia na detecção de mulheres que vão precisar de cuidados médicos de emergência próximos ao parto (Kaunitz *et al.,* 1984).

Isto implica que, enquanto muitas mulheres que desenvolvem complicações têm um ou mais fatores de risco detectáveis, a maioria das mulheres com tais fatores de risco não terá problemas durante o parto. Além disso, em números absolutos, as complicações durante o parto ocorrem mesmo nas melhores condições de vida e uma grande proporção de complicações graves ocorre em mulheres sem fatores de risco reconhecidos (Rosenfield e Maine, 1985).

Contudo, embora as complicações no parto e puerpério não sejam previsíveis e nem preveníveis, as taxas de mortalidade materna são extremamente sensíveis à instituição de cuidados obstétricos adequados (Loudon, 1986). Assim sendo, a Atenção Primária à Saúde essencialmente não é capaz de reduzir a mortalidade materna e ações que visem à redução da mortalidade materna devem ser dirigidas e concebidas sob o conceito de prevenção secundária (Leavell e Clark, 1965).

Mas para reduzir a mortalidade materna não basta melhorar a assistência médica para emergências obstétricas nas instituições de referência (Paxton *et al.*, 2003; Paxton, Maine *et al.*, 2005). Ao revisar estudos sobre morte materna e sobre a utilização de serviços de saúde, Thaddeus e Maine no início da década de 1990 observaram que muitas gestantes que faleciam devido a complicações da gravidez chegavam às instituições de referência em condições de saúde tão graves que dificilmente poderiam

ser salvas (Thaddeus e Maine, 1990). As autoras afirmam que o tempo na obtenção de cuidados adequados é o fator mais importante relacionado às mortes maternas.

Essa talvez tenha sido a primeira grande mudança estratégica na abordagem da mortalidade materna. Thaddeus e Maine (Thaddeus e Maine, 1990) propuseram um modelo teórico de três demoras conhecido como "three delays model", como um referencial teórico para estudar as mortes maternas. Desde então essa proposta tem sido usada na abordagem de mortalidade materna.

As autoras ofereceram um ponto de vista singular a partir do qual as mortes maternas podem ser gerenciáveis, abordando-se o tempo ocorrido a partir do início de uma complicação até seu resultado. Estima-se que o intervalo médio entre o início de uma complicação obstétrica até a morte seja algo entre 2 a 5,7 horas para hemorragia pós-parto de 3,4 a 6 dias, devido a infecções (Maine, 1991; Ganatra, Coyaji, Rao, 1998). Portanto os fatores que interfiram na busca pelo cuidado médico adequado determinam as chances de vida e morte.

Considerando a mortalidade materna uma combinação de fatores inter-relacionados, Thaddeus e Maine entendem que as demoras entre o início de uma complicação e seu tratamento adequado ou resultado podem ocorrer em três fases: fase I - demora na decisão de procurar cuidados pelo indivíduo e / ou família; fase II - demora no alcance uma unidade de cuidados adequados de saúde; e fase III - demora em receber os cuidados adequados na instituição de referência. No entanto, todas as demoras são inter-relacionadas, visto que a maioria das mortes maternas não pode ser atribuída a uma demora única, sendo mais comumente uma combinação de fatores.

Esse conceito unifica fatores diversos (como a autonomia das mulheres, a distância geográfica, e a assistência médica) de diversas áreas do conhecimento (antropologia, ciências sociais, geografia) e fornece um referencial teórico claro para o estudo das mortes maternas, uma vez que destaca a seqüência causal, social e comportamental, relacionada à família, comunidade e sistema de saúde em um referencial teórico único (Kalter *et al* 2011.).

No entanto, essa abordagem tem sido usada com dificuldades metodológicas. Estudos utilizando a morte como variável de desfecho geralmente enfrentam um desafio em relação ao baixo número absoluto dos casos (Paxton *et al.*, 2005). Isso mudou desde os anos 1990 quando, principalmente devido a melhorias no cuidado obstétrico nos países desenvolvidos, um grupo diferente de mulheres surgiu das unidades de tratamento intensivo (UTI). Essa condição, conhecida como *near-miss* materno, compartilha muitas características com as situações de morte materna (Say *et al.*, 2004) e constitui um modelo para o estudo do óbito materno, com as vantagens de que seu estudo tem melhor aceitação que as mortes maternas, o modelo fornece um maior número de casos para análise e podem ser obtidas informações das próprias mulheres após o evento (Cecatti *et al.*, 2007; Souza *et al.*, 2009; Amaral *et al.*, 2011).

A entrevista da mulher que se apresentou como *near-miss* é uma forma singular de se obter informações, pois proporciona meios para tornar acessíveis as vozes e experiências de pessoas que passaram pelas mesmas circunstâncias que as mulheres que morreram, complementando as informações constantes nos registros médicos (Filippi *et al.*, 2009). Alguns autores sugerem que a coleta de informações sobre *near-*

*miss* materno seria uma pedra chave para avaliar a qualidade dos serviços de atenção obstétrica (Roost, Jonsson *et al*., 2009; Lori e Starke, 2011).

Assim sendo, atualmente vários autores têm investigado as demoras na obtenção do adequado cuidado obstétrico associadas com o *near-miss* (Filippi, 2005; Okong *et al,* 2006.; Adisasmita *et al*., 2008; Filippi, Richard *et al*., 2009; Souza, Cecatti *et al*., 2009; Amaral, Souza *et al*., 2011; Hirose *et al*, 2010.; Lori e Starke, 2011), (Ronsmans, 2009; Rööst, Altamirano *et al.,* 2009; Kaye *et al*., 2011; Morse *et al*, 2011.), (Oladapo *et al*., 2007). Em geral os resultados mostram que as mulheres classificadas posteriormente ao evento como *near-miss* materno têm percursos semelhantes às mulheres que morreram.

Essas mulheres observam as mesmas dificuldades que as mulheres que morreram em conseqüência de uma complicação obstétrica em relação aos custos de transporte, tratamento e manejo clínico, o que afeta as demoras em todas as suas fases. No entanto, poucos desses estudos oferecem uma abordagem analítica adequada, tendo a maioria deles problemas metodológicos especialmente com relação à falta de um grupo de comparação e ao pequeno número de casos (Hirose *et al.,* 2011).

Esse tipo de abordagem, combinando o modelo teórico da análise de demoras fornecido por Thaddeus e Maine (Thaddeus e Maine, 1990) com a abordagem do "*near-miss*" materno, é de extrema relevância para o estudo e redução da mortalidade materna, especialmente no Brasil e em outros países de renda média onde tem havido uma redução no ritmo de declínio da mortalidade materna nos últimos 10 anos (Lozano *et al.* 2011). Essa abordagem pode fornecer informações e ideias sobre como ir além do patamar atingido ao identificar as lacunas para se obter a tempo uma assistência obstétrica adequada.

# 2. Objetivos

## 2.1. Objetivo geral

Avaliar a associação entre demoras na obtenção de cuidados obstétricos adequados e diferentes desfechos maternos segundo o modelo “three delays model”.

## 2.2. Objetivos específicos

- Identificar o referencial teórico mais adequado à análise de demoras na assistência obstétrica e aprofundar a discussão conceitual sobre sua importância e utilização.
- Identificar a freqüência, características e fatores associados às demoras na obtenção do adequado cuidado obstétrico entre mulheres com condições potencialmente ameaçadoras da vida, com *near-miss* materno e óbito materno.

# 3. Método

## 3.1. Desenho do estudo

O estudo foi desenvolvido segundo um corte transversal multicêntrico, implantado em 27 unidades obstétricas de referência nas diversas regiões geográficas do Brasil. Durante um período de doze meses foi realizada vigilância prospectiva e coleta de dados para a identificação dos casos com morbidade materna grave (MMG) e condições potencialmente ameaçadoras da vida (CPAV) segundo critérios previamente definidos (Quadro 1).

A lista com as unidades participantes bem como os procedimentos para a coleta de informações e a definição de variáveis estão descritos no Anexo 3.

## 3.2. Procedimentos

Inicialmente e posteriormente à coleta dos dados foi realizada uma ampla revisão da literatura sobre demoras na assistência obstétrica nas bases de dados Pubmed, ISI, Scielo, EMBASE e Google acadêmico, além da biblioteca WHOLIS da Organização Mundial de Saúde. Os resultados obtidos serviram de base para a elaboração de um ensaio abordando o marco conceitual sobre o tema e auxiliaram na análise dos resultados. Seguindo o projeto original (Cecatti *et al.*, 2007), a coleta de dados foi

realizada de forma prospectiva durante o período de um ano nos vinte e sete centros participantes.

**Quadro 1 - Condições Potencialmente Ameaçadoras da Vida (CPAV)**

| COMPLICAÇÕES HEMORRÁGICAS | |
|---|---|
| Descolamento prematuro de placenta | Hemorragia pós parto |
| Placenta prévia / acreta/increta/percreta | Atonia |
| Prenhez ectópica | Retenção placentária |
| Rotura uterina | Lacerações de trajeto |
| Hemorragia grave por aborto | Coagulopatia |
| **COMPLICAÇÕES HIPERTENSIVAS** | |
| Pré-eclampsia grave | Hipertensão grave |
| Eclâmpsia | HELLP síndrome |
| **OUTRAS COMPLICAÇÕES** | |
| Edema pulmonar | Choque |
| Convulsões | Insuficiência respiratória aguda |
| Sepse grave | Acidose |
| Endometrite pós parto | Cardiopatia |
| Endometrite pós aborto | AVC |
| Foco urinário | Distúrbios de coagulação |
| Foco pulmonar | Tromboembolismo |
| Trombocitopenia < 100 mil | Cetoacidose diabética |
| Crise tireotoxica | Icterícia / disfunção hepática |
| | Meningite |
| | Insuficiência Renal Aguda |
| **INDICADORES DE MANEJO DE GRAVIDADE** | |
| Transfusão de hemoderivados | Intubação não relacionada à anestesia |
| Acesso venoso central | Retorno à sala cirúrgica |
| Admissão em UTI | Intervenção cirúrgica maior (histerectomia, laparotomia) |
| Hospitalização prolongada (>7dias) | Uso de sulfato de magnésio |

Uma vez identificados os casos durante a internação, uma filipeta ou ficha identificadora era anexada ao prontuário médico de forma a identificar o mesmo para futura revisão (Anexo 4). Após a identificação dos casos, os prontuários médicos de mulheres que apresentaram os critérios de inclusão eram revisados logo após alta

hospitalar da mulher ou óbito materno para coleta de dados. Para cada caso incluído, foram coletados dados sobre as características demográficas e obstétricas, diagnósticos clínicos prévios à gestação, condições potencialmente ameaçadoras da vida, ocorrência de indicadores de *near-miss* materno em qualquer momento da internação hospitalar, indicadores de desfecho perinatal e condições de alta da mulher.

Os dados faltantes nos prontuários foram procurados adicionalmente em outras fontes, como o banco de dados do hospital, cartões de pré-natal, documentos de transferência, etc. Além disso, informações não disponíveis no prontuário, mas de interesse para a pesquisa, foram obtidas junto à equipe assistente. Para todos os sujeitos incluídos, o médico responsável pelo acompanhamento horizontal do caso ou o investigador principal local responderam as perguntas referentes à adequação da assistência e à ocorrência de demoras.

Os formulários manualmente preenchidos foram posteriormente arquivados para verificação e controle de qualidade. Além disso, o número total de partos e o número total de mortes maternas (MM) por centro colaborador no período de estudo foram também coletados.

**Procedimentos para coleta de informações sobre demoras**

A seção específica do estudo sobre demoras no atendimento foi realizada de maneira um pouco diferente do preenchimento das demais seções, pois considerou não somente a obtenção de dados do prontuário das mulheres. Os pesquisadores foram orientados a fazer uma análise subjetiva da cadeia de cuidados prestados, com base nas informações existentes no prontuário, para definir a possível ocorrência de demoras

relacionadas ao serviço de saúde, ao paciente e/ou familiares ou aos profissionais de saúde.

Além disso, após o preenchimento de todas as variáveis, os dados de cada sujeito foram reanalisados pelos pesquisadores principais e procedimentos-padrão para classificação de demoras foram tomados para todos os casos de todos os conglomerados, como parte do procedimento de verificação de consistência do banco de dados.

Nesse contexto, todos os itens da ficha de coleta de dados direta ou indiretamente correlacionados a demoras do atendimento, foram considerados:

- Quando estava assinalado “pré-natal ausente” no campo de dados obstétricos da ficha de coleta, foi considerada demora referente ao paciente e marcada a questão específica: “pré-natal ausente ou inadequado”. Isto pode ser controverso, mas para a realidade de todos os centros envolvidos, houve um consenso que os serviços de pré-natal facilmente eram facilmente disponíveis para praticamente todas as mulheres grávidas. Se o número de visitas pré-natal foi abaixo do mínimo recomendado pelo Ministério da Saúde para a idade gestacional, o pré-natal foi considerado "inadequado".

- Quando assinalado “transferência inter hospitalar não programada” no campo de dados pessoais da ficha de coleta de dados, foi considerada demora referente ao sistema de saúde. De modo geral, no Brasil a transferência de uma mulher grávida para um hospital de referência terciário terceiro deve ser feita com a assistência de um centro regulador do sistema. Esse sistema verifica diariamente o número de leitos disponíveis nessas unidades e decide, de acordo com

localização geográfica e recursos disponíveis, para onde transferir o caso específico que necessita cuidados médicos mais adequados.

- Nos casos de pré-eclâmpsia grave assinalada no campo de CPAV da ficha de coleta de dados, foi verificada a administração de sulfato de magnésio como condição de manejo e todos os casos sem uso desta medicação foram questionados, através de e-mails aos centros responsáveis, quanto ao critério utilizado para a definição da pré-eclâmpsia como grave e sobre a possibilidade de demora relacionada aos profissionais de saúde. Após obtenção das respostas, os pesquisadores principais puderam preencher de maneira adequada os campos correspondentes.

- Quando assinalado “alta a pedido” ou “evasão” no campo de desfecho materno, foi considerada demora relacionada ao paciente e familiares, especificamente “recusa ao tratamento”;

- Por fim, todos os dados digitados no espaço determinado para comentários, inserido no campo de desfecho materno da ficha de coleta de dados (campo aberto/livre), foram avaliados pelos pesquisadores principais e muitas vezes, através das explicações fornecidas, foi possível compreender e definir demoras no atendimento.

Este rígido processo de verificação de consistência e análise sistemática de cada caso permitiu que os dados com relação às demoras fossem sólidos e de certa forma menos sujeitos à subjetividade de diferentes pesquisadores.

## 3.3. Tamanho amostral

Originalmente o estudo foi desenvolvido com poder necessário para avaliar o uso dos novos critérios de *near-miss* estabelecidos pela Organização Mundial de Saúde em 2009 (Say, Souza *et al.*). Para se determinar o número de centros colaboradores, o cálculo do tamanho da amostra levou em consideração o número de partos que teriam de ser monitorados para se identificar casos de *near-miss* e morte materna (Cecatti, Souza *et al.*, 2009).

Assim, para realizar a análise permitindo avaliar o nível de complexidade da unidade de saúde, faixa etária e causas específicas de morbidade estimou-se que um total de aproximadamente 75.000 partos teriam de ser monitorados fim de identificar cerca de 100 mortes maternas e 600 casos *near-miss* materno a partir de uma incidência estimada de *near-miss* materno de cerca de 8 casos por 1.000 partos (Souza, Cecatti *et al.*, 2007).

## 3.4. População de estudo

A população de estudo foi formada por todas as mulheres internadas nos hospitais participantes durante o período de estudo que apresentarem alguma das condições potencialmente ameaçadoras da vida (CPAV) (Quadro 1), *near-miss* materno (NMM) (Quadro 2), que faleceram ou foram transferidas para outros serviços de saúde.

## 3.5. Variáveis

As variáveis de desfecho: condição potencialmente ameaçadora da vida e *near-miss* materno foram estabelecidas segundo os critérios apresentados nos quadros 1 e 2.

Quadro 2 - Critérios de identificação de *Near-miss* Materno

| **A presença de qualquer uma das condições abaixo descritas classifica o caso como *near-miss* materno** | | | |
|---|---|---|---|
| Sistema disfuncional | Quadro Clinico | Quadro Laboratorial | Condições de Manejo |
| Cardiovascular | Choque<br>Falência cardíaca | pH<7.1<br>Lactato >5 mEq/ml | Uso continuo de drogas vasoativas<br>Resusssitação cárdio-pulmonar |
| Respiratório | Cianoses aguda<br>Respiração ofegante<br>Respiração >40bpm, <6bpm | Sat. $O_2$ <90% por >60 minutos<br>$PaO_2$ / $FiO_2$<200 mmHg | Intubação e ventilação não relacionada a anestesia |
| Renal | Oligúria não responsiva a reposição volêmica e diurético | Creatinina ≥300µmol/l ou ≥3,5 mg/dL | Diálise para insuficiência renal aguda |
| Coag/hemat. | Distúrbio de coagulação | Trombocitopenia agura grave <50,000 plaquetas/ml | Transfusão de >5 concentrados de hemácias |
| Hepático | Icterícia na presença de pré-eclâmpsia | Bilirubina>100 µmol/l ou > 6,0 mg/dL | |
| Neurológico | Peda de consciência ≥12 h<br>Perda de consciência E falta de batimentos cardíacos<br>Acidente Vascular Cerebral<br>Mal epilético e Paralisia | | |
| Endócrino | | Perda de consciência E a presença de glicose e ácidos cetônicos na urina | |
| Uterino | | | Histerectomia seguida de hemorragia ou infecção |

Os casos de morte materna foram definidos segundo a orientação da OMS como:

> a "morte de uma mulher durante a gestação ou no período de 42 dias após o término da gestação, independentemente da duração ou da localização da gravidez, devido a qualquer causa relacionada com ou agravada pela gestação ou por medidas tomadas em relação a ela, porém não devidas a causas acidentais ou incidentais" (World Health Organization., 2009)

Demoras na assistência obstétrica foram definidas como possíveis fatores evitáveis responsáveis pela ocorrência do evento. Foram classificados como:

a) relacionados à infra-estrutura: incluem os casos onde dificuldades na obtenção de suprimentos ou medicações, transporte, comunicação, hemoderivados ou para monitorização e tratamento de pacientes graves possam ter levado a um cuidado sub-ótimo;

b) relacionados ao paciente: incluem aqueles gerados pelo paciente, ou seus familiares, sejam na demora para buscar atenção de um profissional de saúde ou recusa de tratamento;

c) relacionados à equipe de saúde: incluem a demora na definição do diagnóstico apropriado e/ou ocorrência de manejo inapropriado.

As variáveis sócio-demográficas e obstétricas foram definidas segundo consta no anexo 3 - Artigo referente ao projeto da Rede Brasileira de Vigilância de Morbidade Materna Grave

## 3.6. Instrumentos para coleta de dados

Os dados foram coletados manualmente em uma ficha de coleta de dados (Anexo 1) e então digitados em formulários eletrônicos abrigados na plataforma eletrônica da web OpenClinica® (Anexo 3). O link para o site do OpenClinica® era acessível pelo website do Centro de Atenção Integral à Saúde da Mulher (CAISM) (www.caism.unicamp.br).

## 3.7. Processamento e análise dos dados

Os resultados foram analisados através do software EpiInfo ® e SPSS ®. Inicialmente, a ocorrência de todos os tipos de demoras foi descrita de acordo com os

níveis de atenção e desfecho materno. Na análise bivariada testes $\chi 2$ ou exato de Fisher foram usados para comparar os grupos, considerando a influência do conglomerado na análise. Para avaliar o papel de algumas variáveis sociodemográficas e obstétricas e relacionadas à assistência pré-natal como preditores para a ocorrência de demoras, foram estimadas razões de prevalência (RP) e seus respectivos intervalos de confiança IC95% ajustados para o efeito do conglomerado. Finalmente a análise multivariada através de regressão múltipla de Poisson foi utilizada para identificar os fatores independentemente associados à ocorrência de qualquer demora. foram considerados como estatisticamente significativos p-valores <0,05.

## 3.8. Controle de qualidade

Para controle de qualidade foram adotados procedimentos como revisão dos formulários preenchidos manualmente, checagem da digitação, nova coleta de dados de prontuários selecionados e utilização do manual de operações. Além disso, os investigadores locais foram orientados a manter um registro de problemas ocorridos durante o estudo e possíveis dúvidas para posterior discussão com a coordenação nacional do projeto.

Um primeiro controle de qualidade da coleta de dados foi realizado pelo investigador local, antes e durante a digitação eletrônica das fichas, para identificação de possíveis incongruências nos dados. Posteriormente um segundo controle de qualidade foi feito por ocasião das visitas às instituições participantes, realizadas por um dos pesquisadores principais. Nessas visitas, foi verificada a compatibilidade entre os

registros físicos arquivados e os dados contidos nos formulários eletrônicos bem como foi realizada a avaliação aleatória de prontuários.

## 3.9. Considerações éticas

O estudo foi aprovado pelo Conselho Nacional de Ética em Pesquisa com Seres Humanos (CONEP) e também foi aprovado pelo Conselho de Ética em Pesquisa com Seres Humanos de cada centro participante (Anexo 2).

Considerando que, especialmente para os casos de morte materna, informações importantes poderiam ser perdidas caso houvesse necessidade de consentimento da pessoa ou da família, assim os dados de cada paciente foram colhidos apenas após a alta das mesmas não sendo necessário, assim, um termo de consentimento a participação dos sujeitos.

# 4. Publicações

- **Objetivo específico 1:** Identificar o referencial teórico mais adequado à análise de demoras na assistência obstétrica e aprofundar a discussão conceitual sobre sua importância e utilização.

**Artigo 1:**

Pacagnella RC, Cecatti JG. Exploring the conceptual framework on the role of delays for severe maternal morbidity and mortality. *Reprod Health Matters* 2011 (submitted).

- **Objetivo específico 2:** Identificar a freqüência, características e fatores associados às demoras na obtenção do adequado cuidado obstétrico entre mulheres com condições potencialmente ameaçadoras da vida, com *near-miss* materno e óbito materno.

**Artigo 2:**

Pacagnella RC, Cecatti JG, Parpinelli MA, Sousa MH, Haddad SM, Costa ML, Souza JP, Pattinson RC, for the Brazilian Network for the Surveillance of Severe Maternal Morbidity Group. Delays in receiving obstetrical care are associated with the occurrence of maternal near-miss and maternal death. *BJOG*, 2011 (submitted).

## 4.1. Artigo 1.

**Exploring the conceptual framework on the role of delays for severe maternal morbidity and mortality**

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**Abstract**

Maternal mortality has gained space and importance in research and policy since the middle 1980s. The recognition of the associated factors and determinants of maternal deaths has been offered latter by Thaddeus and Maine which may be the first shift in maternal mortality approach. By this view, maternal deaths can be definitively avoidable by timely adequate treatment and thus, in obstetrical care, time is the major factor. Considering this, a three phases framework has been proposed to understand the gaps in access adequate management for obstetrical emergencies: phase I – delay in deciding to seek care by the individual and/or family; phase II – delay in reach an adequate health care facility; and phase III – delay in receiving adequate care at the facility. Recently there has been an increasing interest in the use of this model in part as a result of another shift in maternal mortality approach: the maternal near miss concept. This strategy may offer a unique source of information by interviewing the women who survived a critical event surrounding childbirth. A comprehensive search in the literature was performed to review the use of this concept on recent research on maternal mortality and morbidity. The results suggest that the use of analysis of delays in obstetric care can be extremely useful in assessing the determinants of maternal mortality. Especially if associated with the investigation of maternal near-miss and the combined use of methods of gathering information (audit of medical records, geospatial assessment and interview with the patients), this approach can be a powerful tool for politicians and health managers to point out the weaknesses of systems and health services in obstetric care. However, for a prospective approach as in surveillance system to identify and manage factors before the outcome, the "three delays model" needs to be rethought.

**Keywords**: three delays model; severe maternal morbidity; maternal near-miss; obstetrical care assessment

## Introduction

In the middle 1980s, with an argument provided by Rosenfield and Maine [1] maternal mortality has gained space and importance in research and policy. The authors called attention to the fact that while the major avoidable cause of deaths for women in reproductive age, maternal mortality had received little attention from health professionals, policy makers and politicians. After that an advocacy movement for the reduction of maternal mortality led to the WHO Safe Motherhood Initiative [2].

This initiative was a worldwide effort launched in a conference held in Nairobi in 1987 to draw the world's attention to women's well-being and to deaths occurring during motherhood. Since then, over the last 25 years, maternal health had been improved in many countries. However, most needed improvements have not yet occurred. Today, considering global statistics [3-5], the major causes of maternal death in developing countries remain the same as 100 years ago and the vast majority of them are due to direct obstetric causes (haemorrhage, sepsis, complications of abortion, hypertensive disorders, obstructed labour, ruptured uterus and ectopic pregnancy).

Although the causes of most maternal deaths are at least theoretically avoidable, they cannot be completely prevented even in the best contexts [2]. Maternal mortality however is extremely sensitive to standards of obstetric care [6]. Reviewing studies on maternal deaths and on health services utilization, Thaddeus and Maine observed that many dead pregnant women reached health facilities in a such poor condition that they could not be saved anymore [7]. These authors have stated that time in getting adequate care is the overwhelming factor related to maternal death and since then this proposal has been used in maternal mortality approach and have reached to a "three delays model" as a framework to study maternal deaths.

The differences seen nowadays in maternal mortality ratio (MMR) between high and low-income countries are usually due to the different time management of obstetrical complications. Reducing maternal deaths needs not only improving medical assistance for obstetric emergencies in facilities [8, 9], but also to reduce the interval between the onset of a complication and its management in all settings. However, facing the absolute relatively low number of cases of maternal deaths, this approach had been used with methodological difficulties.

This has shifted since a group of women who escaped death by luck or by receiving timely and appropriate care after a severe complication of pregnancy, known as a ''maternal near-miss'', has

been defined and studied [10, 11]. Recently, this issue has been addressed regarding the study of delays. This article presents a review and a conceptual discussion of the "three delays" framework according to the recent methodological approaches of maternal morbidity and mortality.

**The conceptual framework**

The recognition of the associated factors and determinants of maternal deaths offered by Thaddeus and Maine in 1990 [7] can be viewed as the first shift in maternal mortality approach. They offered a singular point of view from which maternal deaths can be manageable by addressing time from the onset of a complication to its final outcome. Even considering maternal mortality a combination of interrelated factors the authors have emphasized an apparent paradox in public health investments until then, whereas there is no well-known primary prevention for most maternal complication leading to death and primary health care is not able to reduce maternal mortality in essence.

This was deeply discussed further in the Safe Motherhood Initiative program [2]. The argument emerges from studies that found no association between obstetric emergency complications and recognized demographic characteristics, behavioural risk factors or antenatal complications [12]. Others found that no amount of screening will influence on detecting women who will need emergency medical care nearby childbirth [13, 14] or that there is no decrease in maternal mortality while increasing life conditions [6]. Thus, action in reducing maternal mortality should be driven and designed under the concept of secondary prevention [15].

While many women who develop complications have one or more detectable risk factors, the majority of women who share these risk factors do not go on to have serious problems at all. Moreover, in absolute numbers, complications during pregnancy and labour may occur even in the best conditions and a large proportion of serious complications do occur among women with no recognizable risk factors [1].

Considering this, as quickly as the identification of the problem and the treatment occurred, bigger are the chances of stopping the natural history of the disease. Likewise, when dealing with maternal mortality, deaths can be definitively avoidable by timely adequate treatment [16]. Indeed, in obstetrical care, time is a major factor. The average interval from onset of a major obstetric complication to death is anywhere between 2-5.7 hours for postpartum haemorrhage to 3.4-6 days due to infections [2, 17].

Thaddeus and Maine have used “delays” as time postponed between the onset of a complication and its adequate treatment and outcome. This concept can join as diverse factors as distance, women’s autonomy and medical assistance from different knowledge fields (anthropology, social sciences, geography). This model has provided a clear framework for the study of maternal deaths as it highlighted the social and behavioural causal sequence relating the household, community, and health system in a unique framework [18].

It has been proposed chronologically (for didactic purpose) as having three phases: phase I – delay in deciding to seek care by the individual and/or family; phase II – delay in reach an adequate health care facility; and phase III – delay in receiving adequate care at the facility. However, all the delays are interrelated as most maternal deaths cannot be attributed to a single delay, being more commonly a combination of factors each one addressing only partially the woman's pathway to death.

***Phase I delay – User factors***

This delay is usually addressed as barriers or constraints to healthcare services utilization. It is often affected by all factors involved in the next delays as factors associated to the user’s behaviour related to healthcare utilization. For the authors: “factors commonly examined include barriers in the socio-cultural milieu that shapes values, beliefs and attitudes; in the socioeconomic conditions that shape access to money and information; in the geographical setting that shapes physical accessibility; in the financial environment that determines the cost of services; and in the institutional context that shapes the scope and organization of medical services and the quality of care” [7].

Seeking healthcare and healthcare utilization is the most prevalent delay in many contexts and counts for the greater proportion of women reaching facilities in poor clinical conditions [19-22]. It may be the more complex event in the obstetrical care chain and it is not simply matter of availability of health services. Therefore it is one of the most difficult problems to be defined and sought after because it involves the concept of access and a behaviour phenomenon [23].

Several recent studies have reaffirmed that barriers most related to seeking healthcare behaviour are economic status [21], distance to the facility [24], educational level [25], women’s autonomy [25, 26], recognition of disease [21, 27], aetiology [24], severity of symptoms [19, 23, 26, 28] and knowledge and attitudes about utilization of health system [22, 29-31]. Decision making is,

thereafter, a complex behaviour related to health needs perception which requires a broad approach in gathering information. Some authors have used a theoretical framework that assumes social aspects as a crucial factor for the definition of the care seeking behaviour [23]. However, the use of antenatal care seems to enhance the utilization of emergency obstetric care the same way that lack of antenatal access is associated with poor maternal outcomes through delays [32, 33].

Recently some authors have proposed different approaches for this delay. Some of them suggested that the recognition of the problem is the first event followed by the decision to seek care [34]. Others proposed that after the decision to seek care women would need to make decisions on departure to seek for obstetrical care [24]. Therefore, the delay phase I may be subdivided in three components: recognition, decision and departure delay.

***Phase II delay – Service accessibility***

Once deciding to seek care, the obstacles to reach a facility may postpone the adequate care. This acts as a disincentive to decision to seek care and, then, contribute to not reach timely care. Even when the women decide to seek care in an appropriate time, they may face barriers due to lack of transportation or to the uneven distribution of facilities [27].

Usually, phase II delay is a matter of accessibility and access to health services depends on several factors as financial, organizational and social or cultural barriers that control the utilization of services [35]. Thereby it will be influenced by distribution of health facilities, travel distances, transportation and costs. Usually, in cases of poor maternal outcome women travel greater distances, passing through greater number of facilities and taking longer to reach an adequate facility [17]. While in some contexts this issue does not constitute a problem or a cause of additional delay, these factors have been confirmed by many authors as associated to the phase II delay.

A structural factor accounting for this delay is regarding the distribution of and distance to health facilities. A protective effect has been documented for women residing not away from village [17], and living in remote villages with no transportation available has an association with the phase II delay [30]. Even in developed countries with no problems with transport geographical inaccessibility is associated with more frequent negative pregnancy outcomes [36].

However, some authors discuss the ‘‘urban advantage’’ as, despite the proximity to services, the urban poor do not have better access to health services than the rural poor [37]. Indeed it seems that cost and poverty may play a central role in reaching a facility [19]. Many women, due to lack of autonomy or to economic disadvantages, have difficulty to find money for transportation when deciding to seek care [25, 30, 38].

Even when they have money for transport there may be no transport means available [25] or they do run on unsafe roads when seeking assistance during the night [30]. A sort of different ways of transport are used by women seeking healthcare including walking, taxis, market trucks or even wheel barrows or hammocks on poles to carry the woman [25, 30]. This lack of readily available emergency transport increases the risk of dying as it increases the time spent to reach facilities [17]. Some authors indeed have addressed time in this framework.

Reaching an appropriate facility may take too long, ranging from 10 minutes to one full day [30], but usually taking more than one hour for the majority of the patients to reach a facility [21]. A study found that when women reach hospital within 4 hours from the decision to seek care, they have a greater chance of a good outcome and when it happened within 8 hours the odds of dying are bigger [25]. Differences can be found in time to reach adequate care when considering the place where the seeking for further care has started. The time required to reach a facility is greater among the women who were referred from home than from delivery centre [21, 39].

This is a big problem when the majority of users of hospital based childbirth, especially in African countries, are not referred by a healthcare provider but ‘‘self referrals’’ [30, 40]. In part this reflects lack of confidence in lower level of care and results in congestion of hospitals [40]. However, even when referred from another facility (both a rural clinic or facility without EmOC capabilities), women arrive in severe clinical conditions [30]. Reasons for this include structure and process deficiencies (delayed referral, the high cost of emergency obstetric care, lack of public transport) [41].

The flaws in referral system lead to patients being shunted from one facility to another [17, 40] due to the inability health facilities to deal with obstetric complications [42]. The number of referrals that the woman undergoes before reaching an appropriate health facility impact on time to reach adequate care and is crucial for survival. Therefore, referral guidelines and protocols for the referrer and for the receiving facility needs to be implemented in order to diminish disparity between the theoretical hierarchical ‘‘referral pyramid’’ and the real gaps [40].

Other authors suggest further factors contributing to delays in reaching a facility as supportive social network [24, 38], which includes relatives, friends and community [17, 20, 26]. But fundamentally, it seems that the real problem in accessing health services is inequity [37].

***Phase III – Quality of medical care***

The additive characteristic of the previous delays highly contributes in an intertwined way to the number of women reaching facilities in severe condition [30, 41, 43]. Many of them, although referred due to emergency condition, will never reach the hospital [26, 40]. But reaching the facility does not mean the end of the journey.

Rosenfield and Maine have claimed that the solution for maternal mortality would not be just better transportation and referral because many hospitals have chronic shortages of trained staff and essential supplies [1]. Indeed, even at the present time this has been documented by many authors in several contexts.

Not rarely studies identify that the interval between decision to proceed and the emergency obstetric surgery exceeded 30 minutes [44, 45]. Other delays occur in initiating adequate treatment when the woman had already reached the health care service [42]. The reasons for it generally include costs which lead to shortage of supplies, blood products and lack of trained staff [that lack technical support and have poor attitudes to the patients) [20, 22, 29, 38], but these reasons are multiple and complex. Facilities with comprehensive Emergency obstetric Care (EmOC) usually have huge case load with severe conditions and there is not any clear policy towards adequate treatment for life-threatening emergencies [44].

In low income countries, in general, the poor quality of care found even in tertiary facilities [46, 47] contributes to maternal mortality both directly (using suboptimal standard of emergency care) and indirectly (deterring health service utilization) [48]. The poor quality of services motivates women in decision making processes and mitigate timely care [21].

**Maternal morbidity and near miss approach**

The study, once published as a booklet, was after published as a newsletter [49] and then in article format at Social Science & Medicine in 1994. Since then, the “Three Delays Model” has been very useful to recognize and study the leading causes of maternal mortality since the onset of a complication. A brief analysis of publications citing Thaddeus and Maine [16] indexed at ISI Web

of knowledge (Figure 1] shows a rapidly increasing use of this conceptual framework especially since 2004-5. Additionally, during the same period there seems to be a similar increase on the number of publications on severe maternal morbidity and maternal near-miss. By this qualitative analysis, it seems that more recently there is a revival on using this conceptual framework for explaining and understanding a series of conditions and adverse maternal outcomes.

This increasing interest in the use the "Three Delays Model" may be in part a result of another shift in maternal mortality approach. Studies using death as the outcome variable usually face a challenge regarding the low absolute number of the events [9]. Since the 1990s, especially due to improvements in obstetrical care in developed countries a different group of women arose from intensive care unit (ICU). These women, who had escaped death due to luck or by receiving timely and appropriate care after a severe complication of pregnancy, shared many characteristics with women who have died due to an obstetric complication and became known as a ''maternal near-miss'' [50, 51].

Further studies have defined this clinical condition as an outcome due to organic failure and WHO have provided an operational definition in 2009 [11]. Today these women constitute a proxy model for maternal death with the advantage of a larger number of cases for analysis and better acceptability by individuals and institutions than maternal deaths [10, 11, 20]. Another great advantage over maternal deaths is that they may provide information after the event including the difficulties they have faced to reach timely obstetric treatment [22].

Studying maternal deaths, there may not be possible to know, even by family interview, if the care offered was delayed. However, interviewing maternal near-miss women is an unique source of information as it provides means to make accessible the voices and experiences of those experiencing the same threats as women who died, supplementing medical records [19, 22, 52]. Some authors suggest that gathering information on maternal near-miss events would be a key stone to access quality care [23, 30].

Thus, many authors have been investigating delays associated with near miss event [19, 20, 22-24, 30, 32, 41, 42, 45, 46, 53-55]. Generally the findings point that women considered as obstetrical near miss have similar pathways as maternal deaths and experience the same difficulties regarding costs of care, transportation and management of care affecting delays in all the three phases.

It is of interest that, concerning the high number of women arriving in poor clinical conditions at the referral facility [23, 41], while these women may be considered as an indicator of the effectiveness of emergency referrals, women classified as near miss by developing severe conditions at the facility may potentially be a tool for monitoring the performance of obstetric services [41].

**Data collection**

Methods for addressing information on delays have ranged from verbal autopsies, in depth review of a small number of cases to a more systematic audit of cases. Audit process is the major method chosen to study maternal deaths but the recent use of near miss approach has been offering the opportunity to use in-depth interview as a potential instrument for collecting data on delays, especially if focused in the survivors from severe maternal morbidity.

Broader investigations may either aim at identifying avoidable and other substandard care factors or at assessing the quality of care [45]. The use of a different method will depend on the goals of the investigation. Depending on a suitable design it may be possible to analyze the barriers to the primary and secondary preventions [55].

***Verbal and social autopsy***

Verbal and social autopsies are different but complementary instruments that may be useful in settings with poor vital data register [18]. Verbal autopsy consistes of standardized techniques of structured checklist of medical symptoms and the timing of their occurrence [56]. Although different, the social autopsy is a powerful tool for raising awareness of maternal death and may gather information on events leading to death [18], helping understanding the therapeutic itineraries that lead to the "road to death" [57].

Verbal and social autopsies are usually conducted with relatives (parents, especially mothers, husbands, sisters) and social autopsies may use to interview friends, neighbours, traditional birth attendants, physicians and clinic personnel to be interviewed [29]. Although verbal autopsy may not be as robust, it can gather information where otherwise there would be none but users should be aware of its suboptimal performance relative to other methods [58]. Moreover, community participation in death analysis may act as an intervention, increasing care seeking by raising awareness and motivating communities to take action [18]

***Audit***

Audit and feedback is a well known tool to improve clinical practice and the audit of critical incidents (as maternal death) or a sentinel event (as a near miss case) is a recognized part of obstetric care [59, 60]. Audits are not only a description of ‘‘problems’’ but, as feedback is their intrinsic component, they lead to direct actions and solutions along with hospital teams. Clinical audits are a sort of systematic evaluation of care received by women who have died or presented life threatening conditions. They can be performed in many ways such as clinical audits, which involve structured peer review, criterion-based clinical audits, that can be effectuated by non-medically qualified audit and in-depth case reviews and confidential enquiries [19, 48].

Also, audits of maternal mortality can be performed at different levels of care [59]. They are useful methods for quality of care evaluation, especially on the process component, as it provides information about the deficiencies in clinical practice [48]. Additionally, with the collection of clinical, organizational, and patient-centred data by hospital staff themselves, this audit and feedback can be effective in improving professional practice.

In cases of severe maternal morbidity the audit process has several advantages in particular because the large number of cases that allow for a more comprehensive review of factors contributing to substandard care [45]. It may permit a local diagnosis of the causes of delay [10] and can be useful assessing the multiple dimensions of the quality of obstetric care and increasing the systems' responsiveness [41]. Audits are being used frequently as a complement to the reviews of maternal death [10]. Now there is little doubt that audits of near miss cases are extremely useful for studying maternal deaths [45].

***Interview***

In-depth interview with the women that has experienced a critical event has been recently applied in the study of delays regarding maternal deaths due to the recognition that the near miss is a proxy for maternal death. Therefore, listening to the woman's story is a powerful tool to identify constraints to medical assistance. Yet, it is the only method able to further understand how women experience the obstetric care they receive at the facilities [22, 45].

Considering that in many settings medical records are of poor quality, interviewing women who survived a near-miss event is a unique source of information [20]. Besides, to study the first and

second delay, data collected during interviews are of best quality [24]. However there are some disadvantages in interviewing a near miss woman as they may not recognize a flaw in medical assistance or they may be reluctant to revive the experience they have survived or do it in a superficial way [19].

Other methods of interview are being less used as focus discussion groups [38], but a combination of several methods, especially audits with in-depth interviews is a potential tool to aggregate information with the best of the two methods. This enhances the ability of the audit team to identify whereas the delays are most important [19].

## Potentials for use and research

This "three delays model" can be addressed as potential tool to identify factors underlying maternal deaths even in clinical/epidemiological practice as in research field. Following we present some of its potentialities.

### *Improvements in recognition of symptoms*

As discussed above, some studies have stated that poor recognition of clinical conditions especially in obstetrical care is one of the factors that leads to delay in seek care. And this may happen even in a health care facility where the health workers may not be able to provide adequate diagnosis and timely referral. Hence, some authors have proposed appropriate health education for communities and family to recognize pregnancy-danger signs, in particular life-threatening conditions, such as antepartum haemorrhage, postpartum haemorrhage, and eclampsia [17, 21].

For health professionals others have found that medical education as well as audit and feedback may contribute to improve medical staff ability to deal with emergencies in obstetrical care. Additionally, new insights on signs and symptoms to proper and quickly recognize severe conditions are being discussed.

### *Theoretical approaches*

New theoretical approaches may be of value by integrating the quality of care assessment framework and "The Three delays model" [48]. Although quality of care is a multifaceted construct, the model proposed by Donabedian [61] may serve as the basis for this approximation

as Thaddeus and Maine's model may be considered as a quality of care assessment tool. Other authors have discussed the theoretical proximity of the "three delays model" to the Pathway to Survival, considering they are useful for organizing the care-seeking process for severe child and maternal illnesses [18]. But fundamentally, the "three delays model" refers to three main concepts that need to be more fully addressed: health needs, access to healthcare and quality of care assessment.

***Financial incentives***

As mentioned above, many authors have found cost as one key factor in determining the phase I, phase II and phase II delays. Yet, the structure of decision-making power is a cultural factor but influenced by economic issues and woman who rely on their husbands for financial support may not make referral decisions without other's permission [20, 38]. Additionally, costs of transportation and of direct obstetric care supplies [44, 45] play an important role in maternal deaths.

Therefore it is of great importance that further studies can address this with operational researches. Authors have already investigated the 'money to transport' experience [62] while others suggested the possibility of implementing fee-exemption policy for pregnant women [38]. Recently Brazil's government has improved the income transfer programs to address pregnancy and lactation [63], but operational researches are needed to evaluate the strategy.

***Task shifting strategy***

Although strong evidence suggests that initiatives to reduce maternal mortality need skilled providers in treating obstetric disorders [64], task shifting strategy has been proposed in some contexts [65]. But some programs using this strategy as those implemented in Mozambique, Tanzania, Malawi and in India need further evaluation for potential scale-up [64]. Recently a study using task shifting policy suggested that non-physician clinicians performed a significant proportion of emergency obstetric procedures with similar postoperative outcomes than the achieved by physicians [66]. However to provide good quality obstetric care, training cannot occur in a vacuum and requires a functional health system [65].

***Mobile phones***

The urgency of many obstetric emergencies implies that communication needs to be enhanced. Some initiatives have reduced the average transport delays using radio-telephones or solarpowered VHF radio communication system. Recently mobile phones have been widely available even in low income settings and the use of this technology in health (mHealth) is receiving attention. The potential of mobile phone technology in maternal health is to improve communication throughout different levels of the health system. This can be available for health workers, as traditional birth attendants and general practitioners improving the capacity of lesser trained health workers, as well as for women increasing communication between patients and health services and access to information. However, there is still a need for evidence on the use of this technology [67].

***Geographic information system***

Another technological issue that has been used regarding maternal death reduction is geographic information system (GIS). This is a system designed to work with all types of geographically referenced data and can be used to trace geographical difficulties in reaching obstetrical care. For some authors, geographic access to emergency obstetric care is a key factor to explore the absence of good quality obstetric care [68]. This technology has great potential for future research as they may be useful to access emergency obstetric care facilities use and availability [69].

***Fourth delay***

Sometimes, surviving a critical condition may lead to other complications or negative consequences. In some setting, near miss event itself may lead women to perpetuate poverty due to direct and indirect financial costs of its management. There also is a higher chance of developing additional severe clinical conditions and even death after the event [70-72]. However, in practice, the repercussions of pregnancy complications have not been thoroughly explored and postponing the recognition and treatment of these complications after the childbirth may be considered as another delay. Further work is needed to better understand this clinical condition beyond birth [45].

***Referral system***

Considering this as an important factor contributing to phase I and II delay, the provision of adequate access to EmOC, transport and timely referral decisions need to be implemented [73]. Some authors advocate solutions as maternity waiting homes [74] and the creation of ‘‘functional splits’’ within the referral hospitals themselves [40] and some broad intervention to improve the referral system has been implemented in different settings at regional and national level [75]. However operational research is needed to evaluate the global impact of an adequate referral system in maternal mortality.

**Limitations and final considerations**

Consideration must be made on limitations and difficulties for the use of this framework. Although this is a very popular model and has been used widely in maternal deaths studies, it refers to emergency obstetrical care and do not address missed opportunities in primary prevention or in early detection of pregnancy complication that can be implemented with an adequate antenatal care [19, 76]. Although not enough, the role of preventive programmes is very important on avoiding maternal deaths [1].

Nevertheless this model improves the recognition of fields that need more attention. This is of great importance considering that inequalities between countries and within them are increasing. This can be a reality even for middle-income countries where there have been a reduced speed of decline in maternal mortality in the past 10 years [3] and where the maternal mortality combine two burdens of disease: the death from lack of appropriate technology and from inappropriate use of medical technology [77].

This is the essence of this theoretical framework: to draw attention to gaps in reaching obstetrical care. However, this is not a linear model and works in a retrospective way which cannot interfere in the ongoing process. For a prospective approach as in surveillance system to identify and manage factors before the outcome, the “three delays model” needs to be rethought.

To reduce maternal mortality and maternal near miss efforts must reduce the likelihood of pregnancy, the likelihood that a pregnant woman will suffer a severe complication of pregnancy or childbirth and improve the outcomes for women once complications do appear [57]. But nowadays there has been a clearly difference in the decline of maternal deaths and under-5 mortality [3] which may be due to both lack of investments and differences in treatment of the two conditions.

It seems that there is something missing in between these figures. Maybe Thaddeus and Maine's model can help us on that. The framework provides a powerful tool to examine the inconsistencies in obstetrical care offered and highlights the delays regarding care seeking behaviour, healthcare availability and quality of care. But still then another missing point is the political action towards maternal near miss and mortality reduction.

Only recently maternal mortality has been considered by the Office of the High Commissioner for Human Rights of the United Nations as a result of violations of key human rights principles including accountability, equality, non-discrimination and meaningful participation [78]. This may be a reflection of the advocacy movement started more than 20 years ago [1, 2]. And, according to a NGO website [79], which acknowledges a call for operational guidance on implementing the human rights-based approach to preventing maternal death and disability occurred in Geneva in September 2011, the practical application of the resolution is currently inconsistent, inadequate and even accidental.

This may reflect the low value of "women and girls` lives as well as the limited attention that it is paid to women's priorities in public policy" [79]. Maternal mortality and morbidity is a gender based issue [80] and without focusing this aspect when assessing the subject, unfortunately we will still need to ask where is the M in the MCH [64].

## Conflict of interests

The authors declare that there are no conflicts of interests.

## Authors' contributions

The idea for the study arose in discussion among the authors. The first version of the manuscript was drafted by RCP, and then complemented with suggestions and amendments from JGC who supervised the entire process.

## Acknowledgements

The authors acknowledge the financial support of CNPq/DECIT (The National Research Council and the Department of Science and Technology of the Brazilian Ministry of Health), grant number

402702/2008-5, which sponsored the Brazilian Network for the Surveillance of Severe Maternal Morbidity study. The current theoretical approach was developed under the umbrella of this study.

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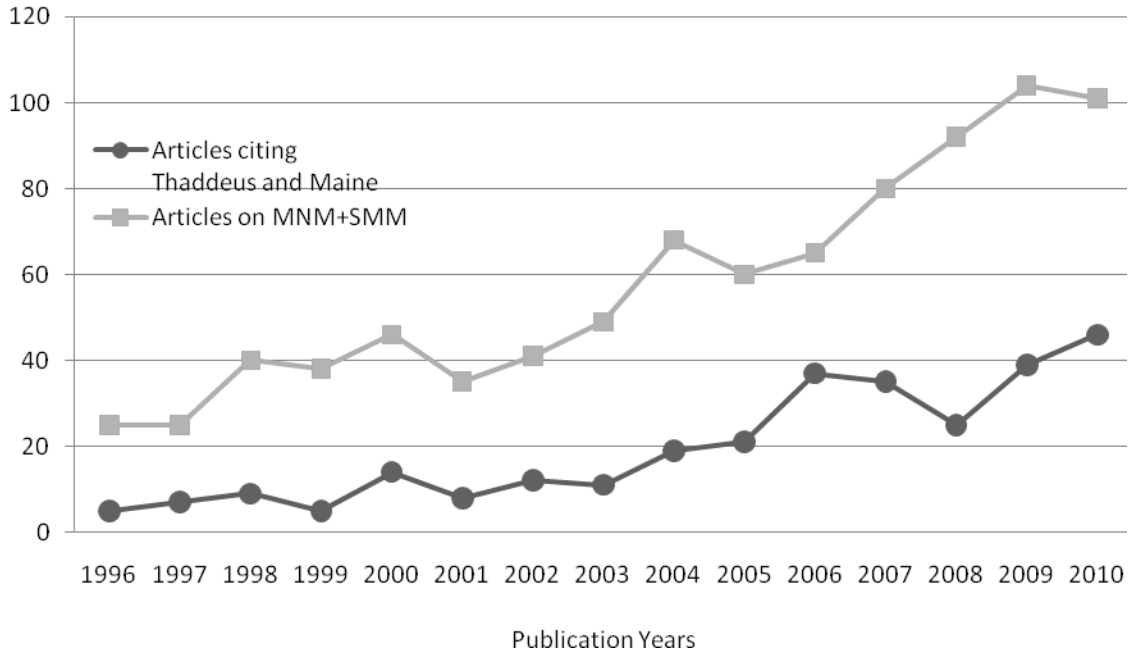


Figure 1 - Publications citing Thaddeus and Maine (16) and publications on severe maternal morbidity and near miss indexed at ISI Web of knowledge from 1996 to 2010

## 4.2. Artigo 2.

# Delays in receiving obstetrical care are associated with the occurrence of maternal near-miss and maternal death

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**Running title:** delay in obstetrical care and severe maternal morbidity

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## Abstract

Objective: The vast majority of maternal deaths in developing countries are preventable. Delays in getting access to appropriate care are amongst the most common areas where improvement can be made. This study aimed to explore the association between delays in the provision of health care and severe maternal morbidity and death.

Design: A multicenter cross-sectional study

Setting: 27 referral obstetric facilities in all regions of Brazil

Population: 9,555 cases of maternal death (MD), maternal near-miss (MNM) and cases classified as potentially life-threatening conditions (PLTC) according to the new WHO criteria.

Method: Data on delays were collected upon medical records examination and interview with medical staff. The prevalence of different types of delays was estimated according to the level of care and outcome of the complication. For factors possibly associated with any delay, PR and 95%CI controlled for cluster design were estimated.

Main outcome measures: frequency of delays related to the patient, to health service/system and to health professionals

Results: 82,144 live births were screened with 9,555 cases having PLTC, MMN or MD prospectively identified. Overall, any type of delay was observed in 54% of cases; delay related to patient was observed in 39%, followed by 17% of delays related to health professionals and 15% related to the health system. Presence of any delay was associated with increasing severity of maternal outcome: 84% in MD, 68% in MNM and 53% in PLTC.

Conclusion: There is an association with increasing delays and poorer outcomes confirming that timely proper management impacts on survival.

**Keywords**: severe maternal morbidity; maternal mortality; maternal near-miss; delays for obstetrical care; emergency obstetric care.

## Introduction

Maternal mortality is a robust indicator of human development 1. However, in absolute terms, it is a relatively rare event 2. In many developing countries deaths related to pregnancy are the leading cause of death for women in reproductive age, although they are supposed to be mostly avoided by timely and adequate treatment 3. Complications in pregnancy can occur in all circumstances, even in the best conditions available for nutrition, education and antenatal care; thus not be preventable even in the best contexts 4. Maternal mortality is closely associated with the levels of socioeconomic deprivation which are difficult to alter, but preventing maternal deaths is extremely sensitive to standards of obstetric care 5.

Although the incidence of maternal complications that can lead to death may possibly be similar around the world, there are substantial differences in how to manage them. As consequence, 99% of all maternal deaths occur in the developing world mainly due to direct obstetric causes (hemorrhage, sepsis, complications of abortion, hypertensive disorders, obstructed labor, ruptured uterus and ectopic pregnancy) [4].

In order to improve care of obstetric emergencies, the timing of receiving the appropriate care is important [1]. Providing timely treatment for obstetrical emergencies is the key to reduce maternal mortality [4]. Thaddeus and Maine [3] developed the three delays model to evaluate the circumstances surrounding access to appropriate emergency care. They described the three delays as phase I – delay in deciding to seek care by the individual and/or family; phase II – delay in reaching an adequate health care facility; and phase III – delay in receiving adequate care at the facility.

Since then, the "three delays model" has been very useful to recognize and study maternal mortality since the onset of a complication. However, studies using death as the outcome variable usually face a challenge regarding the low absolute number of events [4]. This has shifted since the 1990s when a group of women who escaped death by luck or by receiving timely appropriate care after a severe complication of pregnancy, known as a ''maternal near-miss'', has been studied. These women constitute a proxy model for maternal death with the advantage that they may provide information after the event; there is a larger number of cases for analysis and better acceptability of individuals and institutions than for maternal deaths [6-8].

Recently, some authors have investigated delays regarding near-miss event [7-14], however few provided an analytic approach and most had methodological problems [9]. This study aimed to

explore the occurrence of delays in the provision of health care among pregnant women with severe maternal morbidity in Brazil.

**Method**

This is an analysis of the Brazilian Network for Surveillance of Severe Maternal Morbidity study, a cross-sectional multicenter study, implemented in 27 obstetric reference facilities in all geographic regions of Brazil. From July 2009 to June 2010, a prospective surveillance of all women admitted was performed to identify cases of maternal death (MD), maternal near-miss (MNM) and potentially life-threatening conditions (PLTC) according to the new WHO criteria 15. The study design involved an in depth analysis of medical records of all women with severe maternal morbidity conditions immediately after the hospital discharge. The study was approved by the National Council on Ethics in Human Research and has also been approved by local Institutional Review Boards of each participating center.

Data on demographic and economic characteristics, obstetric history, antenatal care status, previous pathological conditions during pregnancy was collected using an online questionnaire at OpenClínica® platform; criteria for the classification of severe maternal morbidity [15], maternal and neonatal outcomes, as well as information on the presence of delays for obstetric care were collected. Additional methodological details on the research proposal and its implementation are already published elsewhere [16].

For all cases data on possible delays that could be responsible for or contribute to the occurrence of PLTC, MNM or MD according to the Thaddeus and Maine's "Three delays model" [3] were sought. These delays were classified as: a) delay related to the service and/or health system included cases whose difficulties were in obtaining medical supplies or equipment which may lead to a substandard care; b) delay related to health professionals included delays in determining the appropriate diagnosis and providing appropriate treatment for the case which could lead to improper management or difficult timely referral; and c) delay related to the women and/or their families included delay in identifying the condition, and seeking for medical care or even refusing offered treatment.

The local research investigator and coordinator were oriented to pursuit evidence of delays regarding health system, health professionals and woman and/or family in a comprehensive way. Medical records scrutinized for data on timely diagnosis, medication and blood products provided

for that specific medical condition, information on referral, improper management and refusal to treatment by the women or the family themselves by the local researchers. Additionally the local research coordinator was encouraged to interview medical staff to find more information on the sequence of care offered for each woman. Neither the women nor their family were interviewed.

The local researchers were asked to consider delay whenever there was a positive impression by researchers or when there were reports on the occurrence of delay in medical records. When any delay related to service / health system and health professionals could be identified, the level of care where it has occurred (primary, secondary or tertiary) was specified. The cases were reanalyzed by the researchers from the coordinating center. Standard procedures for classification of delays were taken for all cases of all centers, as part of the procedures to verify the database consistency. Items from the data collection form directly or indirectly related to delays were considered as follow:

- When "absent antenatal care" was present, the researchers considered delay related to the woman and marked the specific delay "absent or inadequate antenatal care". Prenatal services were readily available for virtually all pregnant women. If the number of prenatal visits was below the minimum for that specific gestational age as recommended by the Brazilian Ministry of Health prenatal care was considered “inadequate”.
- When “inter-hospital transfer unscheduled” was checked, researchers considered delay related to health system. Generally speaking, in Brazil the transfer of a pregnant woman to a tertiary referral hospital is done with the assistance of a public call center which regulates the system, daily checking the number of available beds in these units and deciding, according to geographical location and resources available, to where transfer the specific case needing higher medical care.
- In cases of severe preeclampsia/eclampsia, researchers looked for the administration of magnesium sulfate as a management criterion. For all cases not receiving magnesium sulfate, the local researchers were asked to identify the criterion used to classify preeclampsia as severe and the possibility of delay related to health care professionals. With this information, a decision on delay could be adequately taken and the database was corrected accordingly.
- When "discharge asked by the patient" or "evasion" was identified, the delay "refused treatment" related to patients and/or families was considered.
- Finally, all data entered into the comments form (open field) were evaluated by researchers at

the coordinating center and often, through the explanations provided, it was possible to understand and set specific delays in care.

The results were analyzed using the software EpiInfo® and SPSS®. Initially the occurrence of all types of delays was described according to the levels of care and to the maternal outcome. In the bivariate analysis $\chi 2$ or Fisher's exact tests was used to compare groups controlling the influence of cluster in the analysis. For assessing the role of some sociodemographic, antenatal and obstetrical variables as predictors for the occurrence of delays, prevalence ratios (PR) and their respective 95%CI adjusted for the effect of cluster design were estimated. Finally multivariate analysis using multiple Poisson regression was used to identify the factors independently associated the occurrence of any delay. P-values $<0.05$ were considered as statistically significant.

**Results**

During the 12 months period, 82,144 live births occurred with 9,555 cases of PLTC, MMN or MD prospectively identified. There was missing information on delays for 839 cases. Maternal deaths were a rare event occurring in 140 (0.17%) and maternal near-miss in 770 (0.94%) of live births from all centers.

In general, any form of delay was observed in 54% of cases (Table 1). The delay related to patient and/or family was the most frequently observed (39%) followed by delays related to health professionals (17%) and delay related to the service/health system in 15% of the records. In the service/health care system difficulty of communication was the most common. The inappropriate management of the case was the most prevalent delay among health professionals (13%). In general, delays in secondary care level were identified in 8% of cases from healthcare service, especially due to difficulty of communication between the hospital and regulation system and the difficulty of monitoring patients. The tertiary level care was more commonly identified in delays from health professionals.

There was a positive association between the presence of any delay and the severity of maternal outcome as showed in Table 2. Any delay was present in 84% of MD, in 68% of MNM and in 53% of cases classified as PLTC, showing a significant and clear increase of delay with the severity of outcome. Figure 1 shows this trend. For delays related to service/health system there has been an increase from 13% among PLTC cases to 51% in cases of MD. Excepting the difficult in access to antenatal care, all other delays related to the health service were significantly

associated with severity of maternal outcome. All delays by health professionals were also associated with maternal outcome. However, the delay on seeking health care was the only one related to patient/family significantly associated with the severity of the outcome.

The presence of any delay was significantly more prevalent among adolescents, non-white low schooling status women, whose stay in hospital was publicly funded (Table 3). When antenatal care was performed at the same facility and privately sponsored, the prevalence of any delay was significantly lower. In addition, if any transfer was necessary for women having access to the facility, the risk of any delay was also higher (Table 4).

Table 5 shows the obstetric characteristics associated with any delays. They were multiparity, lower gestational ages at admission and pregnancy termination, postpartum admission, and induced and unsafe abortion. There was no difference in the frequency of delays with respect to mode of delivery and the presence of pre-existing health problems. In the multivariate analysis (Table 6) any delay was independently associated with hospitalization publicly sponsored, gestational age below term at pregnancy termination or still pregnant, to be non-white, with antenatal care in another health facility, with previous abortions, low schooling and public insurance for prenatal care.

**Discussion**

This is one of the very few studies to address the occurrence of delays in obstetrical care among women presenting severe maternal morbidity. Other studies analysed only maternal deaths or near-miss cases. The current data enabled the comparison of delays observed in these groups of extremely bad outcome and a group of women with less severe conditions. There was a positive association between delay in obstetrical care and severity of adverse maternal outcome. Overall any delay was identified in almost 54% of all cases. There were 52% with at least one delay among women with PLTC, 68% in MNM group and 84% in MD group. Although these figures were expected, to the best of our knowledge this is the first time that this gradient of increasing delay associated with severity of maternal outcomes has been demonstrated.

Many authors have found association between delays in obstetrical care and maternal outcomes, mainly MD [12, 17]. Recently, studies on MNM outcome have also addressed information on delays [7-12]. Substandard care and delay phase I could be identified in more than half the cases of severe maternal morbidity in an audit study [8]. Reviewing clinical and administrative data from

another Brazilian study identified some delay in 34% of cases of MD and MNM [13]. Delay in receiving care was found in 20%, seeking care took longer than expected in 14% and reaching care delay was found in 4%. Another study using maternal near-miss audit surveys found 9% of cases with more than one delay in reaching the referral facility [14]. Studies on MNM found that the majority of cases arrived at the facility in a severe clinical condition suggesting that women need to overcome a sort of obstacles to reach the facility able to provide the necessary adequate care [7, 9, 18, 19].

In this study, delays related to patients and/or their family predominate especially absent or inadequate antenatal care. However, although the phase one delay is a matter of importance in many studies [7, 12, 14, 20], in this study there was no association between most types of this delay and maternal outcomes, except for delay in seeking health services, which was 2.5 times more frequent for MNM and 6 times for MD group than for PLTC. This is a relatively common finding. According to Thaddeus and Maine [3], phase 1 delay is often discussed as barrier or constraint to the utilization of health services, a process dependent on the sociocultural and economic context, resulting from interaction between infrastructure, distance to maternal health facilities, the cost of maternal care, and the quality of care [3, 18].

There is some evidence that duration of seeking care behavior differs significantly across types of complications [9]. Women may look for care only after recognizing their condition as potentially life threatening, although there are studies suggesting the possibility of an inability for such a judgment [8, 12, 18, 20, 21]. There is also evidence suggesting that providers do not sufficiently attempt to explain to women how to recognize the severity of obstetrical problems and how to deal with them [17]. There is a need to educate the community for early recognition of symptoms and make timely decisions [20], and this is one of the purposes for prenatal care. The high proportion of women in this study with absent or inadequate antenatal care does not concur with that found in the general pregnant population of the country. In Brazil, the use of antenatal services is high; nowadays, less than 3% of all pregnant women deliver without any antenatal care [22].

Similar findings have already been published [23]. The quality of antenatal care is determinant for health education and facilitates the use of emergency obstetric care [24]. Emergency care utilization is a key point for obstetric care. In the present study, when considering delays related to the healthcare system, communication between the facilities and difficulties with transportation

were more common than the absence of equipment or medication (third delay). These data shows that difficulties and problems in the referral and transfer process are the major barriers to reach adequate emergency obstetrical care and it occurs mostly in secondary level.

The Brazilian healthcare system is supposed to guarantee health care appropriate to the level required [25]. It is estimated that 15% of all pregnant women will develop pregnancy related complications which require access to upper referral level care [26]. Structural and process deficiencies such as low access to health facilities, lack of infrastructure for transportation and the distribution of health facilities produce delays that may compromise the maternal outcome [3]. Many studies found that a significant proportion of MNM or MD cases reached the facility already in a severe clinical condition [7, 11, 14, 27-29] and that important delays were encountered for reaching the facility. This will require adequate structure and processes organization to manage such emergencies [11].

Our data on access to the referral hospital also showed association with "any delay". This suggests referral system failures and deficiencies. Maternal deaths in the community are rare in Brazil. The frequency of institutional births is now almost a hundred percent of all deliveries in Brazil [30]. The barriers encountered by the women when trying to get assistance once a complication has been recognized compromises timely access to obstetrical emergency care [29]. The recognition of these conditions and their management, including appropriate emergency referral procedures, are key skills required for obstetric care providers [27].

In the present study the most important delays were related to case management by health professionals and were more commonly observed in the tertiary level. Studies in Africa points that in many hospitals and in different contexts there are no emergency drugs immediately available in the services making heavier the burden of an obstetric complication [11].

The successful management of physical illness often requires the management of cognitive in addition to other psychological, and social factors [31]. This is a matter of concern in health care facilities. In interviewing near-miss women after discharge, some of them felt the absence of appropriate care by health professionals of not looking at them or listening to them, suggesting a substandard care [7]. Fortunately, for the majority of women, due to luck or merit, the medical system works properly, even for those with PLTC [17]. But obviously this is not true for all women, the reason why we found more than 80% of MD with at least one delay identified.

As the study design proposed neither the women nor their family were interviewed. This did

now allow exploring one of the most interesting characteristic of near-miss cases: the possibility to talk to the women after the event when more information should be available [7, 11, 23]. Therefore we were not able to address qualitative information on reasons and times for delays. In most facilities the research coordinator and investigator were part of the staff. This could represent a bias while they could avoid recognizing a delay due to the improper management of the case. However, all cases went in a rigid process of consistency checking which allowed this data to be less prone to subjectivity of different investigators.

As we have collected data on different outcomes, we were able to provide a risk estimate for delays. This analytical approach and the large sample size gave this study the power to deal with the topic. As far as we know this was the first time this data have been prospectively and systematically collected using the new WHO definition and criteria [15] which would allow further comparison.

## Conclusion

We confirmed the Three Delays Model proposed by Thaddeus and Maine 3 as we found association between maternal deaths and maternal near-misses with the presence of delays. Furthermore we identified a gradient of delays as the outcomes worsen confirming that despite the prevalence of clinical complication in pregnancy, life and death are a matter of timely proper management.

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**Disclosure of interests**
The authors declare that there are no conflicts of interests.

**Contribution to authorship**
The idea for the study and this specific analytic approach arose in a group discussion among all the authors. The analyses were planned and performed by RCP, JGC and MHS. The first version of the manuscript was drafted by and RCP, and then complemented with suggestions of all the others. JGC supervised the entire process. All authors contributed to the development of the study protocol and approved the final version of the manuscript.

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**Acknowledgements**
The authors acknowledge the financial support of CNPq/DECIT (The National Research Council and the Department of Science and Technology of the Brazilian Ministry of Health), grant number 402702/2008-5 and also the involvement of the members of its Steering Committee and all the other investigators and coordinators from all the centers involved in the National Network for the Surveillance of Severe Maternal Morbidity.

**Table 1. Proportion of cases of obstetrical complications with delays identified for receiving care according to the level of health facility**

| Delays | n (%) | Level of service where delay was identified | | |
|---|---|---|---|---|
| | | Primary Health care | Secondary Health care | Tertiary Health care |
| **Delay related to the Service and / or health system [a]** | **1376 (15.6)** | **286 (3.2)** | **754 (8.5)** | **393 (4.4)** |
| Difficulty in accessing antenatal care | 126 (1.4) | 95 (1.1) | 27 (0.3) | 4 (<0.1) |
| Difficulties or problems with transportation city / hospital | 117 (1.3) | 33 (0.4) | 75 (0.8) | 9 (0.1) |
| Difficulty in communication between hospital and regulatory center | 779 (8.8) | 139 (1.6) | 425 (4.8) | 215 (2.4) |
| Lack of magnesium sulfate, ATB, vasoactive drugs, uterotonic | 117 (1.3) | 36 (0.4) | 56 (0.6) | 25 (0.3) |
| Absence of blood products | 57 (0.6) | 9 (0.1) | 41 (0.5) | 7 (0.1) |
| Difficulty in monitoring | 409 (4.6) | 21 (0.2) | 256 (2.9) | 132 (1.5) |
| Lack of trained staff | 271 (3.1) | 74 (0.8) | 144 (1.6) | 53 (0.6) |
| **Delay related to health professionals [b]** | **1548 (17.3)** | **164 (1.8)** | **539 (6.0)** | **1007 (11.3)** |
| Delay in referral / transfer the case | 292 (3.3) | 61 (0.7) | 179 (2.0) | 52 (0.6) |
| Delay in diagnosis | 487 (5.5) | 93 (1.0) | 266 (3.0) | 128 (1.4) |
| Delay in starting treatment | 602 (6.7) | 79 (0.9) | 315 (3.5) | 208 (2.3) |
| Improper management of the case | 1218 (13.6) | 69 (0.8) | 277 (3.1) | 872 (9.8) |
| **Delay related to the patient and/or their families [c]** | **3296 (39.3)** | | | |
| Delay in seeking health services | 442 (5.3) | | | |
| Refuse to treatment | 426 (5.1) | | | |
| Absent or inadequate antenatal care | 2692 (32.1) | | | |
| Unsafe abortion | 51 (0.6) | | | |
| Geographical difficult in accessing health service | 198 (2.4) | | | |
| **Any delay [d]** | **4687 (53.8)** | | | |

[a] Missing information on delays for 707 cases [b] Missing information on delays for 624 cases
[c] Missing information on delays for 1175 cases [d] Missing information on delays for 839 cases

**Table 2.** Proportion of cases of obstetrical complications with delays identified for receiving care according to maternal outcome

| Type of delay | PLTC | MNM | MD | p-value* |
|---|---|---|---|---|
| **Health service/system** [a] | **1101 (13.8)** | **210 (29.2)** | **65 (51.6)** | **<0.001** |
| Difficulties or problems with transportation city / hospital* | 83 (1.0) | 19 (2.6) | 15 (11.9) | **<0.0001** |
| Difficulty in communication between hospital and regulatory center | 647 (8.1) | 100 (13.9) | 32 (25.4) | **0.005** |
| Difficulty in accessing antenatal care* | 106 (1.3) | 16 (2.2) | 4 (3.2) | 0.191 |
| Lack of magnesium sulfate, antibiotics, vasoactive drugs, uterotonic* | 81 (1.0) | 26 (3.6) | 10 (7.9) | **<0.001** |
| Absence of blood products* | 28 (0.3) | 23 (3.2) | 6 (4.8) | **<0.0001** |
| Difficulty in monitoring | 270 (3.4) | 105 (14.6) | 34 (27.0) | **<0.0001** |
| Lack of trained staff* | 189 (2.4) | 59 (8.2) | 23 (18.3) | **<0.0001** |
| **Health professionals** [b] | **1269 (15.7)** | **218 (30.4)** | **61 (48.8)** | **<0.001** |
| Delay in referral / transfer the case* | 177 (2.2) | 82 (11.4) | 33 (26.4) | **<0.0001** |
| Delay in diagnosis | 340 (4.2) | 113 (15.7) | 34 (27.2) | **<0.0001** |
| Delay in starting treatment | 439 (5.4) | 120 (16.7) | 43 (34.4) | **<0.0001** |
| Improper management of the case | 1029 (12.7) | 145 (20.2) | 44 (35.2) | **0.003** |
| **Patients/relatives** [c] | **2955 (38.8)** | **281 (43.4)** | **61 (55.5)** | **0.007** |
| Delay in seeking health services | 339 (4.4) | 74 (11.4) | 29 (26.4) | **<0.001** |
| Refuse to treatment | 380 (5.0) | 36 (5.6) | 10 (9.1) | 0.333 |
| Absent or inadequate antenatal care | 2442 (32.0) | 211 (32.6) | 39 (35.5) | 0.713 |
| Unsafe abortion | 41 (0.5) | 8 (1.2) | 2 (1.8) | 0.285 |
| Geographical difficult in accessing health service | 172 (2.3) | 22 (3.4) | 4 (3.6) | 0.072 |
| **Any delay** [d] | **4107 (52.0)** | **474 (68.4)** | **106 (84.1)** | **<0.001** |

* Chi-squared test considering the cluster design [a] Missing information on delays for 707 cases
[b] Missing information on delays for 624 cases [c] Missing information on delays for 1175 cases
[d] Missing information on delays for 839 cases

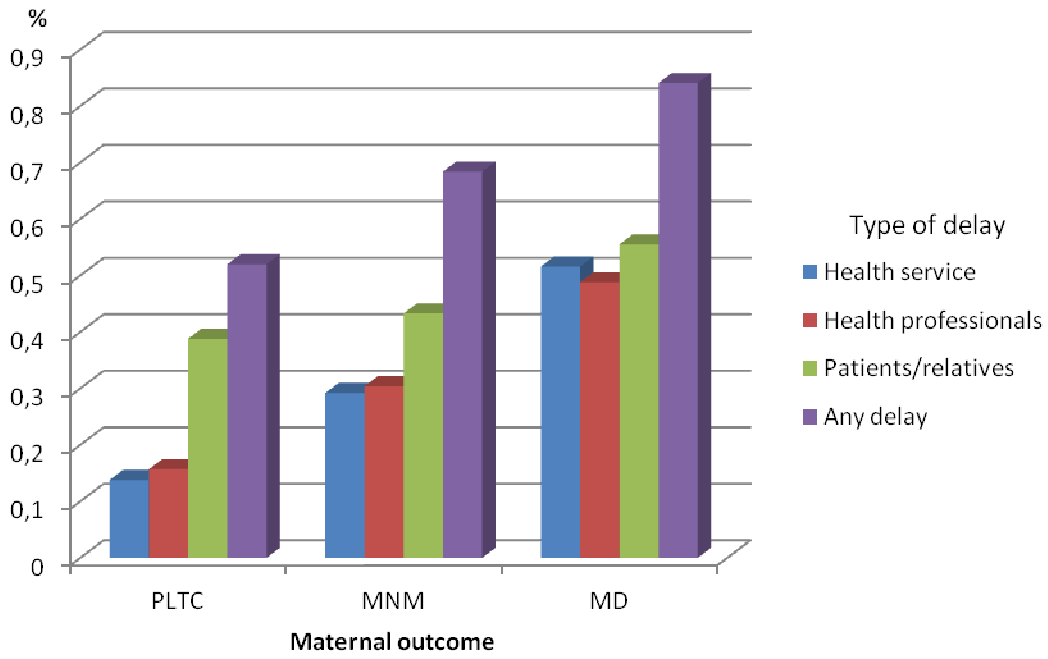


**Figure 1**. Rates of delays in getting care among women with obstetric complications related to health services, health professionals or to the patients and their relatives according to maternal outcome (PLTC: potentially life threatening condition, MNM: maternal near-miss, or MD: maternal death). * $p<0.0001$

**Table 3.** Estimated risks of any delay in obstetrical care according to some sociodemographic characteristics

| Characteristic | Health Service | Professionals | Patients | Any delay (%) | | PR | 95%CI ** |
|---|---|---|---|---|---|---|---|
| | % | % | % | Yes | No | | |
| **Age** | | | | | | | |
| < 19 | 19.5 | 17.2 | 19.3 | 19.1 | 16.3 | **1.09** | **1.02-1.15** |
| 20-29 | 47.5 | 46.9 | 47.3 | 47.3 | 48.4 | ref | |
| 30-39 | 28.9 | 31.5 | 27.8 | 28.5 | 30.7 | 0.98 | 0.92-1.03 |
| ≥40 | 4.1 | 4.5 | 5.6 | 5.1 | 4.6 | 1.06 | 0.96-1.16 |
| Total (n) | 1376 | 1548 | 3297 | 4687 | 4029 | | |
| p-value * | 0.317 | 0.512 | **<0.001** | **0.008** | | | |
| **Ethnicity** | | | | | | | |
| With | 29.5 | 42.1 | 37.0 | 38.1 | 48.0 | Ref | |
| Non-white | 70.5 | 57.9 | 63.0 | 61.9 | 52.0 | **1.22** | **1.07-1.39** |
| Total (n) | 1029 | 1155 | 2534 | 3550 | 3273 | | |
| p-value * | **0.038** | 0.862 | **0.003** | **0.006** | | | |
| **Educational level** | | | | | | | |
| Basic | 50.1 | 41.4 | 54.0 | 50.7 | 42.5 | **1.45** | **1.15-1.84** |
| High-school | 44.2 | 52.0 | 42.8 | 44.9 | 50.0 | **1.27** | **1.04-1.56** |
| College | 5.7 | 6.6 | 3.2 | 4.3 | 7.5 | ref | |
| Total (n) | 968 | 1002 | 2530 | 3415 | 3087 | | |
| p-value * | 0.306 | 0.235 | **<0.001** | **<0.001** | | | |
| **Marital status** | | | | | | | |
| Cohabitating | 56.9 | 60.1 | 48.9 | 52.1 | 55.7 | ref | |
| No cohabitating | 43.1 | 39.9 | 51.1 | 47.9 | 44.3 | 1.07 | 0.95-1.21 |
| Total (n) | 1129 | 1207 | 2801 | 3903 | 3578 | | |
| p-value * | 0.519 | 0.191 | **0.002** | 0.242 | | | |
| **Insurance for hospitalization** | | | | | | | |
| Public | 99.8 | 98.9 | 99.7 | 99.4 | 98.1 | **1.98** | **1.40-2.79** |
| Private/Insurance | 0.2 | 1.1 | 0.3 | 0.6 | 1.9 | ref | |
| Total (n) | 1374 | 1548 | 3293 | 4682 | 4026 | | |
| p-value * | **0.006** | 0.798 | **<0.001** | **<0.001** | | | |

* Chi-squared test considering the cluster design **95%CI considering the cluster design

**Table 4**. Estimated risks of any delay in obstetrical care according to some characteristics of antenatal care

| Characteristic | Health Service | Professionals | Patients | Any delay (%) | | PR | 95%CI ** |
|---|---|---|---|---|---|---|---|
| | % | % | % | Yes | No | | |
| **Antenatal care at the same facility** | | | | | | | |
| Yes | 8.9 | 20.6 | 20.7 | 18.9 | 28.3 | ref | |
| No | 87.0 | 74.7 | 69.8 | 73.6 | 68.3 | **1.28** | **1.06-1.53** |
| No antenatal care | 4.1 | 4.6 | 9.4 | 7.5 | 3.4 | **1.66** | **1.26-2.19** |
| Total (n) | 1231 | 1377 | 2995 | 4212 | 3692 | | |
| p-value * | **<0.001** | 0.675 | **<0.001** | **0.002** | | | |
| **Insurance for antenatal care** | | | | | | | |
| Public | 95.6 | 94.2 | 96.6 | 95.9 | 93.4 | **1.31** | **1.03-1.67** |
| Private/Insurance | 4.4 | 5.8 | 3.4 | 4.1 | 6.6 | ref | |
| Total (n) | 1023 | 1134 | 2429 | 3426 | 3227 | | |
| p-value * | 0.495 | 0.527 | **0.005** | **0.010** | | | |
| **Way of access to the hospital** | | | | | | | |
| Spontaneous demand | 15.5 | 40.4 | 48.8 | 42.0 | 55.2 | ref | |
| Transfer from Emergency Service | 2.1 | 2.7 | 2.4 | 2.2 | 1.2 | **1.45** | **1.18-1.78** |
| Scheduled Inter-hospital transfer | 25.1 | 19.3 | 22.4 | 22.2 | 18.7 | **1.24** | **1.03-1.49** |
| No-scheduled Inter-hospital transfer | 47.5 | 14.1 | 7.6 | 14.8 | 0.6 | **na** | **na** |
| Referral from another Health Service | 7.4 | 14.0 | 10.0 | 10.6 | 13.1 | 1.03 | 0.87-1.22 |
| Referral from the same Health Service | 2.4 | 9.6 | 8.8 | 8.1 | 11.2 | 0.97 | 0.88-1.07 |
| Total (n) | 1333 | 1411 | 3122 | 4401 | 3898 | | |
| p-value * | **<0.001** | **0.046** | 0.160 | **<0.001** | | | |

* Chi-squared test considering the cluster design **95%CI considering the cluster design
na: not applicable; this category was used for defining delay and therefore cannot be used as predictor

**Table 5**. Estimated risks of any delay in obstetrical care according to some obstetrical characteristics

| Characteristic | Health Service | Professionals | Patients | Any delay (%) | | PR | 95%CI ** |
|---|---|---|---|---|---|---|---|
| | % | % | % | Yes | No | | |
| **Number of pregnancies** | | | | | | | |
| 1 | 43.3 | 42.4 | 37.8 | 40.6 | 42.8 | ref | |
| 2 to 3 | 36.5 | 38.4 | 36.9 | 36.8 | 40.4 | 0.98 | 0.93-1.04 |
| ≥4 | 20.2 | 19.2 | 25.3 | 22.6 | 16.9 | **1.16** | **1.06-1.28** |
| Total (n) | 1367 | 1531 | 3281 | 4658 | 4021 | | |
| p-value * | 0.414 | 0.768 | **<0.001** | **<0.001** | | | |
| **Number of previous births** | | | | | | | |
| 0 | 48.4 | 49.6 | 43.3 | 46.3 | 49.7 | ref | |
| 1 to 2 | 37.2 | 37.4 | 38.2 | 37.6 | 39.8 | 1.01 | 0.95-1.06 |
| ≥3 | 14.3 | 12.9 | 18.5 | 16.1 | 10.5 | **1.23** | **1.10-1.38** |
| Total (n) | 1367 | 1531 | 3281 | 4658 | 4021 | | |
| p-value * | 0.478 | 0.372 | **<0.001** | **<0.001** | | | |
| **Number of previous C-sections** | | | | | | | |
| 0 | 76.6 | 75.2 | 73.5 | 74.6 | 76.7 | ref | |
| 1 | 17.0 | 17.3 | 18.0 | 17.4 | 16.9 | 1.03 | 0.96-1.09 |
| ≥2 | 6.5 | 7.5 | 8.5 | 7.9 | 6.4 | 1.11 | 1.00-1.24 |
| Total (n) | 1331 | 1477 | 3218 | 4570 | 4003 | | |
| p-value * | 0.643 | 0.845 | **0.002** | 0.065 | | | |
| **Number of abortions** | | | | | | | |
| 0 | 80.0 | 76.6 | 75.9 | 76.9 | 78.2 | ref | |
| ≥1 | 20.0 | 23.4 | 24.1 | 23.1 | 21.8 | 1.04 | 0.97-1.10 |
| Total (n) | 1367 | 1531 | 3280 | 4657 | 4020 | | |
| p-value * | **0.049** | 0.696 | **0.038** | 0.268 | | | |
| **Gestational age at admission** | | | | | | | |
| <22 | 4.5 | 5.9 | 6.0 | 5.5 | 5.9 | 1.10 | 0.88-1.39 |
| 22 a 27 | 6.9 | 6.2 | 6.3 | 6.2 | 5.0 | **1.27** | **1.05-1.52** |
| 28 a 33 | 26.1 | 23.7 | 20.0 | 21.5 | 16.1 | **1.30** | **1.12-1.51** |
| 34 a 36 | 21.9 | 20.1 | 21.6 | 21.4 | 17.4 | **1.26** | **1.11-1.42** |
| ≥37 | 29.4 | 34.1 | 42.2 | 39.4 | 52.1 | ref | |
| postpartum/ postabortion | 11.2 | 10.0 | 4.0 | 6.0 | 3.4 | **1.43** | **1.14-1.80** |
| Total | 1340 | 1518 | 3203 | 4558 | 3924 | | |
| p-value * | **<0.001** | **0.009** | 0.051 | **<0.001** | | | |
| **Gestational age at pregnancy termination** | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| <22 | 3.4 | 4.5 | 3.9 | 3.7 | 3.4 | 1.16 | 0.95-1.41 |
| 22 to 27 | 3.7 | 3.2 | 3.2 | 3.3 | 2.7 | **1.23** | **1.03-1.46** |
| 28 to 33 | 23.1 | 21.0 | 15.9 | 17.6 | 12.5 | **1.29** | **1.12-1.49** |
| 34 to 36 | 24.5 | 22.3 | 21.3 | 22.0 | 16.5 | **1.27** | **1.13-1.43** |
| ≥37 | 37.2 | 42.1 | 47.7 | 45.8 | 57.5 | ref | |
| still pregnant | 8.1 | 6.9 | 8.1 | 7.6 | 7.4 | 1.13 | 0.91-1.40 |
| Total | 1253 | 1430 | 3135 | 4408 | 3840 | | |
| p-value * | **0.001** | **0.036** | 0.063 | **<0.001** | | | |
| **Onset of abortion** | | | | | | | |
| Spontaneous | 54.2 | 51.9 | 48.9 | 51.3 | 76.1 | ref | |
| Induced | 45.8 | 48.1 | 51.1 | 48.7 | 23.9 | **1.55** | **1.18-2.03** |
| Total (n) | 24 | 27 | 94 | 117 | 88 | | |
| p-value * | 0.239 | 0.243 | **0.003** | **<0.001** | | | |
| **Safety of Abortion** | | | | | | | |
| Safe | 75.0 | 65.4 | 46.1 | 55.1 | 96.6 | ref | |
| Unsafe | 25.0 | 34.6 | 53.9 | 44.9 | 3.4 | **2.28** | **1.72-3.03** |
| Total (n) | 20 | 26 | 89 | 107 | 87 | | |
| p-value * | 0.905 | 0.521 | **<0.001** | **<0.001** | | | |
| **Preexisting health conditions** | | | | | | | |
| Yes | 42.0 | 53.0 | 50.5 | 49.0 | 49.3 | 0.99 | 0.88-1.13 |
| No | 58.0 | 47.0 | 49.5 | 51.0 | 50.7 | ref | |
| Total (n) | 1100 | 1248 | 2933 | 4019 | 3815 | | |
| p-value * | 0.222 | 0.358 | 0.330 | 0.928 | | | |
| **Mode of delivery** | | | | | | | |
| Vaginal | 15.4 | 19.3 | 24.0 | 21.8 | 24.4 | ref | |
| C-section | 71.5 | 68.3 | 62.9 | 65.7 | 62.4 | 1.08 | 0.96-1.22 |
| Abortion/ectopic | 5.5 | 6.0 | 5.3 | 5.4 | 6.0 | 1.00 | 0.75-1.33 |
| Still pregnant | 7.5 | 6.4 | 7.7 | 7.2 | 7.1 | 1.06 | 0.84-1.34 |
| Total (n) | 1367 | 1543 | 3290 | 4674 | 4018 | | |
| p-value * | 0.091 | 0.516 | 0.599 | 0.539 | | | |

* Chi-squared test considering the cluster design **95%CI considering the cluster design

**Table 6.** Factors independently associated with any delay identified for receiving care among women with obstetrical complication (multiple analysis by Poisson regression*; n=4.794)

| **Variable** | **$PR_{adj}$** | **95%CI *** | p |
|---|---|---|---|
| - Insurance for hospitalization (Public) | 1.96 | 1.47–2.60 | <0.001 |
| - Gestational age at pregnancy termination (Still pregnant or <37 weeks) | 1.32 | 1.13–1.55 | <0.002 |
| - Ethnicity (Non-white) | 1.26 | 1.10–1.46 | 0.002 |
| - Antenatal care at the same facility (No/no PN) | 1.30 | 1.10–1.53 | 0.003 |
| - Number of previous abortions (≥1) | 1.07 | 1.02–1.13 | 0.011 |
| - Schooling (up to high school) | 1.27 | 1.03–1.57 | 0.025 |
| - Insurance for prenatal care (Public) | 0.87 | 0.76–0.99 | 0.043 |

*Analysis considering the cluster design (center)

Predictors included in the multivariate model: age, ethnicity, educational level, marital status, insurance for hospitalization, antenatal care at the same facility, insurance for antenatal care, way of access to hospital, number of pregnancies, number of previous births, number of previous C-sections, number of abortions, gestational age at admission, gestational age at pregnancy termination, preexisting health conditions and mode of delivery.

# 5. Discussão Geral

Os resultados apresentados sugerem que o uso da análise de demoras na assistência obstétrica conforme proposto por Thaddeus e Maine (Thaddeus e Maine, 1990) pode ser extremamente útil na avaliação dos determinantes da mortalidade materna. Especialmente se associada à investigação do *near-miss* materno como variável de desfecho e à utilização combinada de métodos de coleta de informações (auditoria de prontuários médicos, avaliação geoespacial e entrevista com as pacientes), essa abordagem pode ser um instrumento potente para os políticos e gestores de saúde ao apontar as lacunas dos sistemas e dos serviços de saúde no cuidado obstétrico.

Essa associação pode mesmo oferecer condições para uma verdadeira mudança na assistência obstétrica. Talvez para isso, novas abordagens teóricas possam vir a integrar os conceitos envolvidos na avaliação da qualidade dos serviços de saúde, como as propostas de Donabedian (Donabedian, 1966) e os conceitos de necessidade de saúde e acesso. Alguns autores têm proposto aproximações teóricas (Pirkle, Dumont, Zunzunegui, 2011; Kalter *et al.*, 2011; Behague *et al.*, 2008; Roost, Jonsson *et al.*, 2009), todavia o modelo “Three delays” parece ser robusto e suficiente para a avaliação das condições que circundam as mortes maternas.

De fato, muitos autores têm utilizado a abordagem do *near-miss* materno na investigação das demoras no cuidado obstétrico (Hirose *et al.,* 2011; Souza *et al.*, 2009; Adisasmita *et al.,* 2008; Filippi *et al.*, 2005; Filippi, *et al.*, 2009; Amaral, *et al.*, 2011; Lori e Starke, 2011; Kaye *et al.*, 2003; Kaye, *et al.*, 2011; Morse *et al., 2011;* Roost, Jonsson *et al.*, 2009; Oladapo *et al.*, 2007). Em geral os resultados apontam que as mulheres consideradas como *near-miss* materno têm percursos semelhantes às mulheres que morreram e experimentam as mesmas dificuldades em relação aos custos de transporte, tratamento e manejo clínico afetando as demoras em todas as três fases.

No entanto a maior parte desses estudos carece de uma abordagem analítica adequada, pois, em sua maioria, apresentam problemas metodológicos especialmente com relação à falta de um grupo de comparação e ao pequeno número de casos (Hirose *et al.*, 2011). Mas contrariamente a esses autores, os dados apresentados pelo segundo artigo oferecem uma condição de análise diferenciada, pois são oriundos de um grande número de observações e podem oferecer maior poder analítico uma vez que permite a comparação entre diferentes desfechos maternos.

Esse estudo pode ser um dos únicos a fornecer informações sobre a ocorrência de demoras na prestação de cuidados obstétricos em pacientes que apresentam condições clínicas potencialmente ameaçadoras da vida. Enquanto outros autores têm estudado somente as mortes maternas ou casos de *near-miss*, nossos dados oferecem a possibilidade de comparar os grupos com diferentes desfechos, podendo oferecer uma estimativa de risco.

Nossos dados mostram uma associação crescente entre a identificação de alguma demora no atendimento obstétrico e desfechos maternos adversos extremos (*Near-miss*

materno e óbito). Alguma demora foi identificada em quase 54% dos casos em geral e, não surpreendentemente, em mulheres com CPAV houve identificação de alguma demora em 52% dos casos, em 68,4% no grupo NMM e em 84,1% no grupo de MM. Essa é a primeira vez que esse crescente gradiente de demoras associado com o desfecho materno desfavorável é observado.

Além desse achado, foram mais evidentemente relacionadas aos piores desfechos as demoras relacionadas ao sistema de saúde. A disponibilidade adequada dos serviços obstétricos de urgência e uma rede de referência robusta parece ser mesmo um "Nó Górdio" da atenção obstétrica. No presente estudo, ao considerar as demoras relacionadas com o sistema de saúde, a comunicação entre os equipamentos de saúde e as dificuldades com o transporte (refletindo a fases II do modelo de demoras) foram mais comuns do que a ausência de equipamentos ou medicamentos para a assistência (fase III).

Além disso, deficiências na estrutura e no processo da assistência obstétrica, como os problemas relacionados com transporte e transferência do caso (ser admitida no hospital após o parto ou aborto, transferência inter-hospitalar não programada ou transferência a partir dos serviços de emergência) foram igualmente associados a piores desfechos maternos; ambos se referem às demoras fase 2 e ocorreram com mais freqüência nível secundário de assistência. Esses dados mostram que em relação à organização dos serviços de saúde, as dificuldades e problemas na referência e transferência dos casos são uma das maiores barreiras para se oferecer atendimento obstétrico adequado nas situações de emergência.

Embora saibamos que o sistema de saúde brasileiro é organizado de acordo com os níveis de complexidade do cuidado, de maneira a proporcionar atenção integral e universal através de redes de referência regional de prestadores de serviços complementares, existe uma grande fragilidade nessa rede com relação à assistência obstétrica, em especial na atenção secundária (Rosa e Hortale, 2000; 2002; Coutinho *et al.*, 2010; Silva *et al.*, 2010).

O fato de termos encontrado associação entre demoras e condições sociodemográficas, historicamente relacionadas à dificuldade de acesso aos serviços de saúde (idade precoce, baixa escolaridade e uso do sistema público de saúde), corrobora a necessidade de implementação da rede de assistência obstétrica. Há necessidade de uma comunicação formalizada e da disponibilidade de transporte porque existe uma premência temporal na assistência obstétrica às emergências obstétricas.

Na verdade, não é incomum que as mulheres busquem os serviços terciários de assistência espontaneamente, sem passar pela rede oficial de serviços de saúde (Nkyekyer, 2000; Souza *et al.*, 2009; Lori e Starke, 2011). Isso, de certa maneira, reflete a incapacidade das unidades de saúde de nível primário e secundário em fornecer cuidados adequados às complicações obstétricas (Ganatra *et al.*, 1998). Isso reflete ainda ineficiência do sistema de referência, que pode levar ao congestionamento de hospitais e subutilização dos níveis primário e secundário de atenção (Murray e Pearson, 2006).

O fato de muitas mulheres chegarem às instituições de referência reforça essa situação. Isso pode indicar possíveis demoras na tomada de decisões por profissionais de saúde, seja por dificuldades de diagnóstico seja por demora na decisão de transferir

o caso. O fato é que na região de Campinas quase metade dos casos de *near-miss* materno foi encaminhada aos serviços de referência (por outros municípios ou pelo sistema privado de saúde) (Amaral *et al.,* 2011). Isso reforça a necessidade de se organizar a rede de atenção perinatal, envolvendo gestores de saúde, maternidades e equipe médica. E mesmo nas unidades de referência há problemas evidentes, incluindo falta de suprimentos e inadequação a protocolos assistenciais (Amaral *et al.*, 2011).

Todavia, os dados apresentados não oferecem condições para se ir além dessas informações. Em decorrência do desenho retrospectivo do estudo, nem as mulheres nem seus familiares foram entrevistados, o que não permitiu explorar uma das características mais interessantes dos casos de *near-miss* que permitiria que mais informações fossem colhidas: a possibilidade de conversar com as mulheres após a o evento (Souza *et al.*, 2009; Filippi *et al.*, 2007). Por causa disso, não foi possível abordar informações qualitativas sobre os motivos e que geraram as demoras. Os dados obtidos, porém, são o mais consistente possível. Pois são oriundos de um rígido processo de verificação de inconsistências e de análise sistemática das informações que permitiu que os dados sobre as demoras fossem menos propensos a subjetividade dos diferentes investigadores.

Finalmente, outras considerações precisam ser feitas. Embora o modelo das três demoras seja um modelo muito popular e amplamente utilizado, ele se refere à atenção obstétrica na situação de emergência (Filippi *et al.*, 2009; Gabrysch e Campbell, 2009). Apesar de não ser suficiente para reduzir a mortalidade materna, o papel dos programas de prevenção é muito importante (Rosenfield e Maine, 1985) e deve ser considerado

nas abordagens mais amplas da questão da mortalidade materna (Gabrysch e Campbell, 2009).

Além disso, é fundamental considerar que a questão da mortalidade materna está imersa em um contexto político desafiador que por vezes impede e dificulta mudanças (Rosenfield e Maine, 1985; Maine, 2007). Apenas recentemente, em 2009, o Conselho de Direitos Humanos das Nações Unidas reconheceu que a prevenção da mortalidade materna é uma questão de direitos humanos. Essa resolução histórica em que os governos signatários expressam grande preocupação sobre as taxas inaceitavelmente elevadas de morbidade e mortalidade materna e se comprometem a aumentar esforços a nível nacional e internacional para proteger as vidas de mulheres e meninas em todo o mundo, talvez seja um reflexo tardio do movimento iniciado ao menos 20 anos antes (Rosenfield e Maine, 1985; Maine, 1991).

Todavia o percurso ainda parece ser longo e cheio de descaminhos, mas iniciativas oportunas podem dar fôlego às metas de desenvolvimento do milênio (Rosenfield, Maine, Freedman, 2006; Maine, 2007). Estudos oriundos de iniciativas governamentais, como a reorganização dos sistemas na Malásia, Sri-Lanka e Honduras (Maine, 2007), programas de transferência de renda específicos como os do Brasil (Brasil, 2011) e Índia (De Costa, Patil *et al.*) mostram que tais iniciativas têm potencial transformador.

Contudo o que ainda se vê é o paradoxo da falta de melhora substancial nas taxas de mortalidade materna nos últimos 20 anos no mundo ao passo que melhoraram quase todos os outros indicadores da saúde materna e das mulheres, bem como o acesso aos serviços de saúde (Diniz, 2009; Lozano *et al.*, 2011; Victora *et al.*, 2011). Em especial

nos países de renda média, observa-se o uso cada vez mais intenso da tecnologia, sem contudo, melhores resultados, como a estagnação do declínio das taxas de mortalidade materna no Brasil. (Diniz, 2009; Lozano *et al.*, 2011).

Na assistência ao parto nesses contextos convive-se com o pior dos dois mundos: o problema da falta de tecnologia apropriada e o problema do excesso tecnologia inapropriada (Diniz 2009). Isso não pode ser tratado senão por uma perspectiva de gênero nas questões de saúde reprodutiva, que imobiliza as ações de redução da mortalidade materna assim como as mulheres no momento do parto. Para tanto talvez sejam mesmo necessários novos modelos paradigmáticos para que se vejam mudanças substanciais nas altas taxas de mortes anunciadas de mulheres grávidas.

# 6. Conclusões

1. O modelo “Three delays” é um importante referencial teórico para o estudo dos casos de *near-miss* materno e a análise de demoras na assistência obstétrica nos casos de *near-miss* materno pode fornecer dados precisos sobre os determinantes da mortalidade materna. Entretanto, ele precisa ser repensado se o objetivo é recomendar um sistema de vigilância prospectivo para a detecção e manejo adequado dos casos de morbidade materna grave.

2. A frequência de demoras na assistência obstétrica está diretamente relacionada ao pior desfecho materno. Elas são significativamente mais prevalentes entre as mulheres que tem um near miss materno e entre as que tiveram óbito materno, do que entre as que tiveram complicações potencialmente ameaçadoras da vida. Fatores sócio-demográficos adversos relacionam-se significativamente com a prevalência de demoras no recebimento do cuidado obstétrico adequado.

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# 8. Anexos

# 8.1. Anexo 1. Ficha de coleta de dados

**Rede Nacional de Vigilância de Morbidade Materna Grave - FORMULÁRIO DE COLETA MANUAL**

**IDENTIFICAÇÃO**

1. Centro do Estudo*: ☐☐
2. Subject ID*: _____
3. Person ID*: _____

Data de nascimento*: ☐☐ ☐☐ ☐☐

**DADOS PESSOAIS**

4. Idade em anos completos*: ☐☐
5. Cor: [ ] 1 negra [ ] 2 branca [ ] 3 indígena [ ] 4 amarela [ ] 5 outro [ ] 8 não consta
6. Escolaridade: [ ] 1 analfabeta [ ] 2 Fundamental incompleto [ ] 3 Fundamental [ ] 4 Médio incompleto [ ] 5 Médio [ ] 6 Superior incompleto [ ] 7 Superior [ ] 8 não consta
7. Estado civil: [ ] 1 casada/amasiada [ ] 2 solteira [ ] 3 separada/divorciada [ ] 4 viúva [ ] 8 não consta
8. Peso em kg: _____
9. Altura em m: _____
10. Data da internação no centro*: ☐☐ ☐☐ ☐☐
11. A paciente fazia pré-natal no serviço?* [ ] 1 sim [ ] 2 não [ ] 3 sem pré-natal [ ] 8 não consta
12. Como foi o acesso da mulher ao centro?* [ ] 1 procura espontânea [ ] 6 encaminhamento da própria instituição [ ] 2 transferência por serviço de resgate/emergência [ ] 8 não consta [ ] 3 transferência inter hospitalar programada [ ] 4 transferência inter hospitalar não programada [ ] 5 encaminhamento de outro serviço
13. Qual cobertura financeira majoritária do pré-natal? [ ] 1 público [ ] 2 privado [ ] 3 seguro saúde/convênio [ ] 4 sem pré-natal [ ] 8 não consta
14. Qual cobertura financeira majoritária da internação?* [ ] 1 público [ ] 2 privado [ ] 3 seguro saúde/convênio [ ] 8 não consta

**DADOS OBSTÉTRICOS**

15. Número de gestações*: ☐☐
16. Número de partos*: ☐☐
17. Número de abortos*: ☐☐
18. Número de cesáreas prévias*: ☐☐
19. Número de nascidos vivos*: ☐☐
20. Anos desde o último parto: ☐☐
21. A mulher possui cirurgia uterina prévia? (excluindo cesárea seg. transv) [ ] 1 sim [ ] 2 não [ ] 8 não consta
22. Número de consultas de pré-natal*: ☐☐
23. A mulher estava grávida quando foi admitida?* [ ] 1 sim [ ] 2 não [ ] 8 não consta
24. Idade gestacional na internação*: ☐☐
25. Forma de início do trabalho de parto*: [ ] 1 espontâneo [ ] 2 induzido [ ] 3 sem trabalho de parto [ ] 4 aborto [ ] 5 continua grávida [ ] 8 não consta
26. Data da resolução da gestação: ☐☐ ☐☐ ☐☐
27. Idade gestacional na resolução*: ☐☐
28. Como foi ultimada a gestação?
[ ] 1 parto vaginal [ ] 5 aborto
[ ] 2 parto vaginal operatório [ ] 6 prenhez ectópica
[ ] 3 parto cesárea antes do início do trabalho de parto [ ] 7 continua grávida
[ ] 4 parto cesárea após o início do trabalho de parto [ ] 8 não consta

**ABORTO**

29. Como se iniciou o aborto? [ ] 1 espontâneo [ ] 2 induzido [ ] 8 não consta
30. O aborto foi mais provavelmente seguro ou inseguro? [ ] 1 seguro [ ] 2 inseguro [ ] 8 não consta
31. Quais procedimentos foram realizados?
[ ] 1 dilatação e/ou curetagem [ ] 2 ocitocina [ ] 3 vácuo aspiração
[ ] 4 prostaglandinas [ ] 5 outros [ ] 6 nenhum [ ] 8 não consta
32. Se outro procedimento, especifique: _____

**DADOS DO RN**

33. Número total de nascidos: ☐☐
34. Qual era a apresentação fetal ao nascimento? [ ] 1 cefálico [ ] 2 pélvico [ ] 3 outro [ ] 8 não consta
35. Sexo: [ ] 1 feminino [ ] 2 masculino [ ] 3 indeterminado [ ] 8 não consta
36. Condição do nascimento: [ ] 1 vivo [ ] 3 natimorto anteparto [ ] 2 natimorto intra-parto [ ] 8 não consta
37. Qual foi o Apgar de 1º. Minuto? ☐☐
38. Qual foi o Apgar de 5º. Minuto? ☐☐
39. Peso em gramas: ☐☐☐☐
40. Desfecho neonatal:
[ ] 1 alta [ ] 2 internado [ ] 3 óbito neonatal precoce (<7dias)
[ ] 4 óbito neonatal tardio (8-28 dias) [ ] 5 transferido [ ] 8 não consta
41. Se gemelar, informe os dados dos outros RN: _____
_____

**CONDIÇÕES MATERNAS PRÉ-EXISTENTES**

42. A mulher apresentava alguma condição patológica/ de risco prévios à gestação?* [ ] 1 sim [ ] 2 não [ ] 8 não consta
43. Quais condições estavam presentes?
[ ] 1 hipertensão arterial crônica [ ] 9 anemia falciforme-talassemia
[ ] 2 obesidade [ ] 10 HIV/AIDS
[ ] 3 baixo peso [ ] 11 tireoidopatias
[ ] 4 diabetes mellitus [ ] 12 doenças neurológicas / epilepsia
[ ] 5 tabagismo [ ] 13 colagenoses
[ ] 6 doenças cardíacas [ ] 14 neoplasias
[ ] 7 doenças respiratórias [ ] 15 outro
[ ] 8 doenças renais [ ] 16 drogadição
44. Se outra condição patológica, especifique: _____

**CONDIÇÕES POTENCIALMENTE AMEAÇADORAS DA VIDA**

45. Houve alguma complicação hemorrágica?*[ ] 1 sim [ ] 2 não [ ] 8 não consta
46. Qual complicação hemorrágica ocorreu no período?*
[ ] 1 descolamento prematuro de placenta [ ] 5 hemorragia grave por aborto
[ ] 2 placenta prévia/acreta/increta/percreta [ ] 6 hemorragia pós parto
[ ] 3 prenhez ectópica complicada [ ] 7 outra hemorragia grave
[ ] 4 rotura uterina [ ] 8 não houve/não consta
47. Se HEMORRAGIA PÓS- PARTO, especifique:
[ ] 1 atonia [ ] 2 retenção placentária [ ] 3 lacerações de trajeto
[ ] 4 coagulopatia [ ] 5 inversão uterina [ ] 6 outra causa obstétrica

48. Houve alguma complicação hipertensiva?*[ ] 1 sim [ ] 2 não [ ] 8 não consta

49. Qual complicação hipertensiva ocorreu no período?*

[ ] 1 pré-eclâmpsia grave [ ] 2 eclâmpsia [ ] 3 hipertensão grave
[ ] 4 HELLP síndrome [ ] 5 fígado gorduroso [ ] 8 não houve / não consta

50. Houve alguma outra complicação?*[ ] 1 sim [ ] 2 não [ ] 8 não consta

51. Quais complicações?*

[ ] 1 edema pulmonar [ ] 2 convulsões [ ] 3 trombocitopenia < 100 mil
[ ] 4 crise tireotoxica [ ] 5 choque [ ] 6 insuf. respiratória aguda
[ ] 7 acidose [ ] 8 cardiopatia [ ] 9 AVC
[ ] 10 dist. de coagulação [ ] 11 CIVD [ ] 12 tromboembolismo
[ ] 13 cetoacidose diabética [ ] 14 icterícia/disf hepática [ ] 15 meningite
[ ] 16 sepse grave [ ] 17 IRA [ ] 88 não houve / não consta
[ ] 18 complicação associada à suspeita ou confirmação de Influenza A (H1N1)

52. Se SEPSE GRAVE, especifique o foco:

[ ] 1 endometrite pós-parto [ ] 2 endometrite pós aborto [ ] 3 foco pulmonar
[ ] 4 foco urinário [ ] 5 outro [ ] 8 não consta [ ] 9 ignorado

53. Se outro foco, especifique:_____

54. A mulher apresentou alguma das condições de manejo de gravidade?*
[ ] 1 sim [ ] 2 não [ ] 8 não consta

55. Quais condições estavam presentes?*

[ ] 1 transfusão de hemoderivados [ ] 6 retorno à sala cirúrgica
[ ] 2 acesso venoso central [ ] 7 histerectomia/laparotomia
[ ] 3 admissão em UTI [ ] 8 uso de sulfato de magnésio
[ ] 4 hospitalização prolongada (>7 dias) [ ] 9 outro proc. cirúrgico maior
[ ] 5 intubação não relacionada à anestesia [ ] 88 não houve/não consta

## CRITÉRIOS DE NEAR MISS MATERNO

56. A mulher apresentou algum dos critérios clínicos de near miss?*
[ ] 1 sim [ ] 2 não [ ] 8 não consta

57. Se SIM, indique quais*:

[ ] 1 cianose [ ] 9 acidente vascular cerebral
[ ] 2 gasping [ ] 10 convulsão não controlada – paralisia total
[ ] 3 FR > 40 ou < 6 [ ] 11 icterícia na presença de pré-eclâmpsia
[ ] 4 choque [ ] 88 não houve / não consta
[ ] 5 oligúria não responsiva a fluidos ou diuréticos
[ ] 6 distúrbios de coagulação
[ ] 7 perda da consciência durante 12 h ou mais
[ ] 8 ausência de consciência E ausência de pulso-batimento cardíaco

58. A mulher apresentou algum dos critérios laboratoriais de near miss?*
[ ] 1 sim [ ] 2 não [ ] 8 não consta

59. Se SIM, indique quais*:

[ ] 1 saturação de $O_2$ < 90% por > 60 min.
[ ] 2 $PaO_2/FiO_2$ < 200
[ ] 3 creatinina ≥300mmol/l ou ≥ 3,5 mg/dl
[ ] 4 bilirrubina ≥ 100 mmol/l ou ≥ 6 mg/dl
[ ] 5 pH < 7,1
[ ] 6 lactato > 5
[ ] 7 plaquetas < 50 mil
[ ] 8 ausência de consciência e presença de glicose e cetoácidos na urina
[ ] 88 não houve / não consta

60. A mulher apresentou algum dos critérios de manejo?*
[ ] 1 sim [ ] 2 não [ ] 8 não consta

61. Se SIM, indique quais*:

[ ] 1 uso de droga vasoativa contínua [ ] 6 R. Cardiopulm. (RCP)
[ ] 2 histerectomia por infecção ou hemorragia [ ] 88 não houve / não consta
[ ] 3 transfusão de ≥ 5 U de hemácias
[ ] 4 intubação e ventilação por ≥ 60 minutos não relacionada com anestesia
[ ] 5 diálise para insuficiência renal aguda

62. Alguma dessas condições já estava presente na admissão do sujeito?
[ ] 1 sim [ ] 2 não [ ] 3 não se aplica [ ] 8 não consta

## DESFECHO MATERNO

63. Data da alta, transferência ou óbito*: [ ][ ] [ ][ ] [ ][ ]

64. Qual foi a condição de alta da mulher?*

[ ] 1 alta médica [ ] 2 alta a pedido [ ] 3 transferência [ ] 4 óbito [ ] 5 evasão

65. Comentários ou observações referentes a dados incluídos e dados relativos à transferência do sujeito: _____
_____

## PESQUISA DE DEMORAS NO ATENDIMENTO

66. Durante o atendimento do caso, houve alguma demora relacionada ao serviço e/ou sistema de saúde?* [ ] 1 sim [ ] 2 não [ ] 9 ignorado

Se houve demora, especifique: (se NÃO houve, deixe em branco)
1 nível primário 2 nível secundário 3 nível terciário

67. Falta de medicação (sulfato, ATB, DVA, uterotônicos): [ ]
68. Dificuldade ou problemas com transporte municipal / hospitalar): [ ]
69. Dificuldade na comunicação (hospitalar/central reguladora): [ ]
70. Ausência de hemoderivados: [ ]
71. Dificuldade para monitorização (unidade de cuidados intensivos): [ ]
72. Falta de pessoal treinado: [ ]
73. Dificuldade de acesso ao pré-natal: [ ]

74. Houve alguma demora relacionada ao paciente e/ou seus familiares?*
[ ] 1 sim [ ] 2 não [ ] 9 ignorado

75. Se resposta SIM, especifique quais:

[ ] 1 demora na procura ao Serv. Saúde
[ ] 2 dificuldade geográfica ao acesso ao Serv. Saúde
[ ] 3 recusa ao tratamento
[ ] 4 Pré-natal ausente ou inadequado
[ ] 5 Aborto inseguro

76. Houve alguma demora na assistência relacionada aos profissionais de saúde?* [ ] 1 sim [ ] 2 não [ ] 9 ignorado

Se houve demora, especifique: (se NÃO houve, deixe em branco)
1 nível primário 2 nível secundário 3 nível terciário

77. Demora no diagnóstico: [ ]
78. Demora no início do tratamento: [ ]
79. Manejo inadequado do caso: [ ]
80. Demora na referência ou transferência do caso: [ ]

## 8.2. Anexo 2. Carta de aprovação do projeto pelo CEP

**FACULDADE DE CIÊNCIAS MÉDICAS**
**COMITÊ DE ÉTICA EM PESQUISA**

www.fcm.unicamp.br/pesquisa/etica/index.html

CEP, 05/03/09.
(Grupo III)

**PARECER CEP:** Nº 097/2009 (Este nº deve ser citado nas correspondências referente a este projeto)
**CAAE**: 0071.1.146.000-09

**I - IDENTIFICAÇÃO:**

PROJETO: **"REDE NACIONAL DE VIGILÂNCIA DA MORBIDADE MATERNA GRAVE: A GRAVIDEZ NA ADOLESCÊNCIAE O ABORTO COMO FATORES DE AGRAVO À SAÚDE".**
PESQUISADOR RESPONSÁVEL: José Guilherme Cecatti.
INSTITUIÇÃO: CAISM/UNICAMP
APRESENTAÇÃO AO CEP: 06/02/2009
**APRESENTAR RELATÓRIO EM: 05/03/10** (O formulário encontra-se no *site* acima)

**II - OBJETIVOS**

Desenvolver uma rede nacional de cooperação científica para vigilância da morbidade materna grave, com ênfase na adolescência e aborto.

**III - SUMÁRIO**

Estudo de corte transversal multicêntrico, a ser implementado com 25 unidades obstétricas de referência nas diversas regiões geográficas do Brasil. Durante um período de doze meses, os pesquisadores principais e os pesquisadores locais deverão realizar vigilância prospectiva de todas as mulheres internadas nessas unidades, para a identificação dos casos de near miss materno e morbidade materna grave não-near miss. Foi realizado cálculo do tamanho amostral, estimando-se que será necessária a vigilância de um total aproximado de 75.000 partos. Os dados serão coletados em ficha específica e enviados ao banco de dados central através de formulário eletrônico disponível no website do projeto. Análise de dados: A análise dos dados será feita por sub-grupos de acordo com a época da ocorrência do near miss ou morbidade materna grave (na adolescência e em outros momentos de sua vida reprodutiva) e causa determinante (aborto e outras causas), estimando-se as respectivas taxas, razões e riscos relativos para os respectivos preditores.

**IV - COMENTÁRIOS DOS RELATORES**

Após respostas às pendências, o projeto encontra-se adequadamente redigido e de acordo com a Resolução CNS/MS 196/96 e suas complementares, bem como a dispensa do Termo de Consentimento Livre e Esclarecido.

**V - PARECER DO CEP**

Comitê de Ética em Pesquisa - UNICAMP
Rua: Tessália Vieira de Camargo, 126
Caixa Postal 6111
13083-887 Campinas – SP

FONE (019) 3521-8936
FAX (019) 3521-7187
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O Comitê de Ética em Pesquisa da Faculdade de Ciências Médicas da UNICAMP, após acatar os pareceres dos membros-relatores previamente designados para o presente caso e atendendo todos os dispositivos das Resoluções 196/96 e complementares, resolve aprovar sem restrições o Protocolo de Pesquisa, bem como ter aprovado a dispensa do Termo do Consentimento Livre e Esclarecido, assim como todos os anexos incluídos na Pesquisa supracitada.

O conteúdo e as conclusões aqui apresentados são de responsabilidade exclusiva do CEP/FCM/UNICAMP e não representam a opinião da Universidade Estadual de Campinas nem a comprometem.

## VI - INFORMAÇÕES COMPLEMENTARES

O sujeito da pesquisa tem a liberdade de recusar-se a participar ou de retirar seu consentimento em qualquer fase da pesquisa, sem penalização alguma e sem prejuízo ao seu cuidado (Res. CNS 196/96 – Item IV.1.f) e deve receber uma cópia do Termo de Consentimento Livre e Esclarecido, na íntegra, por ele assinado (Item IV.2.d).

Pesquisador deve desenvolver a pesquisa conforme delineada no protocolo aprovado e descontinuar o estudo somente após análise das razões da descontinuidade pelo CEP que o aprovou (Res. CNS Item III.1.z), exceto quando perceber risco ou dano não previsto ao sujeito participante ou quando constatar a superioridade do regime oferecido a um dos grupos de pesquisa (Item V.3.).

O CEP deve ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo (Res. CNS Item V.4.). É papel do pesquisador assegurar medidas imediatas adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e enviar notificação ao CEP e à Agência Nacional de Vigilância Sanitária – ANVISA – junto com seu posicionamento.

Eventuais modificações ou emendas ao protocolo devem ser apresentadas ao CEP de forma clara e sucinta, identificando a parte do protocolo a ser modificada e suas justificativas. Em caso de projeto do Grupo I ou II apresentados anteriormente à ANVISA, o pesquisador ou patrocinador deve enviá-las também à mesma junto com o parecer aprovatório do CEP, para serem juntadas ao protocolo inicial (Res. 251/97, Item III.2.e)

Relatórios parciais e final devem ser apresentados ao CEP, de acordo com os prazos estabelecidos na Resolução CNS-MS 196/96.

## VI I- DATA DA REUNIÃO

Homologado na II Reunião Ordinária do CEP/FCM, em 17 de fevereiro de 2009.

***Profa. Dra. Carmen Silvia Bertuzzo***
PRESIDENTE DO COMITÊ DE ÉTICA EM PESQUISA
FCM/UNICAMP

Comitê de Ética em Pesquisa - UNICAMP
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## 8.3. Anexo 3. Artigo referente ao projeto da Rede

**Reproductive Health**

BioMed Central

Study protocol

Open Access

# Brazilian network for the surveillance of maternal potentially life threatening morbidity and maternal near-miss and a multidimensional evaluation of their long term consequences

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Published: 24 September 2009

*Reproductive Health* 2009, **6**:15 doi:10.1186/1742-4755-6-15

Received: 17 July 2009
Accepted: 24 September 2009

This article is available from: http://www.reproductive-health-journal.com/content/6/1/15

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**Abstract**

**Background:** It has been suggested that the study of women who survive life-threatening complications related to pregnancy (maternal near-miss cases) may represent a practical alternative to surveillance of maternal morbidity/mortality since the number of cases is higher and the woman herself is able to provide information on the difficulties she faced and the long-term repercussions of the event. These repercussions, which may include sexual dysfunction, postpartum depression and posttraumatic stress disorder, may persist for prolonged periods of time, affecting women's quality of life and resulting in adverse effects to them and their babies.

**Objective:** The aims of the present study are to create a nationwide network of scientific cooperation to carry out surveillance and estimate the frequency of maternal near-miss cases, to perform a multicenter investigation into the quality of care for women with severe complications of pregnancy, and to carry out a multidimensional evaluation of these women up to six months.

**Methods/Design:** This project has two components: a multicenter, cross-sectional study to be implemented in 27 referral obstetric units in different geographical regions of Brazil, and a concurrent cohort study of multidimensional analysis. Over 12 months, investigators will perform

prospective surveillance to identify all maternal complications. The population of the cross-sectional component will consist of all women surviving potentially life-threatening conditions (severe maternal complications) or life-threatening conditions (the maternal near miss criteria) and maternal deaths according to the new WHO definition and criteria. Data analysis will be performed in case subgroups according to the moment of occurrence and determining cause. Frequencies of near-miss and other severe maternal morbidity and the association between organ dysfunction and maternal death will be estimated. A proportion of cases identified in the cross-sectional study will comprise the cohort of women for the multidimensional analysis. Various aspects of the lives of women surviving severe maternal complications will be evaluated 3 and 6 months after the event and compared to a group of women who suffered no severe complications in pregnancy. Previously validated questionnaires will be used in the interviews to assess reproductive function, posttraumatic stress, functional capacity, quality of life, sexual function, postpartum depression and infant development.

## Background

Currently, more than half a million maternal deaths occur annually worldwide. Although an extremely rare event in developed countries, maternal mortality is higher in less developed countries. Better social conditions, better medical care in cases of severe complication and family planning are factors that contribute to reducing maternal mortality [1].

Nevertheless, quantifying maternal mortality in Brazil is a complex task. The Ministry of Health estimates the maternal death ratio at 75 maternal deaths per 100,000 live-born infants [2]. Reflecting the complexity of this estimate, other agencies, using different methods, have calculated maternal death ratios twice or even four times higher than the official figures [3,4].

Notwithstanding, the recorded cases of maternal deaths constitute a tiny proportion of the whole problem. Around the world, millions of women present severe maternal complications every year and the precise size of this specific population currently remains unknown. For this reason, women who have survived severe complications of pregnancy have in recent years sparked the attention of investigators and healthcare administrators. The World Health Organization (WHO) developed the maternal near-miss approach, a tool to uniformly identify near-miss cases and evaluate quality of care provided to women presenting severe complications. WHO defines a maternal near miss case as a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy [5].

Therefore, the study of maternal near-miss cases has been suggested as a practical alternative to the surveillance of maternal morbidity and mortality, mainly in view of the larger number of cases and because the woman herself is able to provide information on the event and on the difficulties she had to face. It is believed that auditing near-miss cases would enable even smaller services to evaluate how the determinants of severe maternal morbidity (and consequently the determinants of maternal death) affect their users and services [6,7].

In addition, little is known on the long-term repercussions of severe, life-threatening complications related to pregnancy. An acute stress disorder associated with the occurrence of severe maternal complications has been suggested, but further research is needed. [8]. The repercussions of these events may lead to adverse effects in the women and their children, may negatively affect their quality of life and may persist for extended periods of time after the event [9-12].

Among the possible repercussions, studies have been carried out to evaluate the psychological impact and occurrence of posttraumatic stress disorder (PTSD), postpartum depression and changes in sexual health following delivery [10,13-17]. Considering that other factors such as mode of delivery, medical interventions and obstetrical complications [9,18,19] negatively affect women's quality of life, it is probable that in dramatic situations such as near-misses such repercussions would be even more evident. According to some authors, evaluation of the state of health, quality of life and sexual function of patients who suffered severe complications is poorer in the immediate postpartum period [15,20-23].

Nevertheless, doubts remain with respect to the long-term health status of women who suffer severe acute maternal morbidity and near-miss. Investigation of various aspects related to mental health and quality of life may offer a valuable perspective on the effect of maternal morbidity on the life of these women.

Studying the occurrence of severe complications in pregnancy and the factors associated with this event will result in a greater understanding of the process that occurs in

these women taking them from a state of health to one of sickness. Further knowledge on this issue may collaborate towards improving public policies and the healthcare provided to women who develop severe acute maternal morbidity.

Therefore, the objective of the present project is to evaluate this issue using clear goals to differentiate it from previous studies. These goals include estimating the frequency of the occurrence of maternal near-miss using a uniform set of criteria, carrying out a multicenter investigation into the quality of care provided to women with severe complications of pregnancy and performing a longitudinal evaluation of the quality of life of these women following the event.

## Objectives and Hypothesis

The overall objective is to develop a nationwide network of scientific cooperation for the surveillance of severe maternal complications and maternal near-miss and their consequences.

### *Specific objectives*

- To determine the frequency of maternal near-miss in healthcare facilities of different levels of complexity situated in different regions of Brazil, using the World Health Organization (WHO)'s new set of criteria for near-miss [5];
- To determine the frequency of non-near-miss severe maternal morbidity in these facilities using specifically defined potentially life threatening conditions;
- To evaluate the association between the indicators of organ dysfunction used to define maternal near-miss and the risk of maternal death;
- To determine the frequency of near-miss and non-near-miss severe maternal morbidity according to age-group and specific causes;
- To examine the occurrence of avoidable factors and other factors associated with maternal near-miss;
- To investigate the repercussions of severe maternal morbidity and near-miss on the quality of life of survivors up to six months after the event;
- To investigate the presence of sexual dysfunction, posttraumatic stress disorder and postpartum depression, as well as women's perception of their functional status in routine activities in the six months following an occurrence of severe maternal morbidity.
- To investigate the immediate perinatal outcome and subsequent neuromotor and weight-height development in children born from pregnancies associated with severe maternal morbidity.

### *Main hypotheses*

In survivors of severe acute maternal morbidity:

- health and quality of life would be poorer;
- posttraumatic stress would be more common;
- postpartum depression would be more common;
- sexual function would have deteriorated and the woman's return to sexual activity would take longer;
- functional status in routine activities would be evaluated as poorer.

In the children born from a pregnancy associated with severe maternal morbidity:

- immediate perinatal outcome would be poorer;
- the occurrence of impaired neuromotor and weight-height development would be significantly higher.

## Methods/Design

This study has two components: a multicenter cross-sectional study and a concurrent cohort study.

The cross-sectional study will be implemented in 27 referral obstetric units in different geographical regions of Brazil, which have already joined the initiative for building a national network for studies on maternal and reproductive health. Over a 12-month period, the principal and local investigators will carry out prospective surveillance and will collect data for the identification of maternal near-miss and non-near-miss cases, severe maternal morbidity (potentially life threatening conditions) and maternal deaths. To determine the number of collaborating centers to be included in the present study, calculation of sample size took into consideration the number of deliveries that would have to be monitored to identify cases of near-miss and maternal deaths. Previous studies have estimated a maternal near miss incidence of approximately 8 cases per 1000 deliveries [24] and a Brazilian maternal mortality ratio of 140 per 100,000 LB. Therefore, a total of approximately 75,000 deliveries would have to be monitored in order to identify around 100 maternal deaths and 600 maternal near miss cases. These numbers are believed to be sufficient to evaluate the use of the new criteria for near-miss established by the World Health Organization

in 2009 [5] and to perform analysis allowing for level of complexity of health facility, age group and specific cause.

The study population will consist of all the women admitted to the participating hospitals during the study period in whom organ dysfunction is registered (maternal near-miss, Appendix 1), in whom one of the diagnoses defined as non-near-miss severe maternal morbidity is present (Appendix 2), and those who died or were transferred to another healthcare service because of their bad health condition.

For the multidimensional analysis of the repercussions of severe maternal morbidity, a concurrent cohort, specific population study will be carried out with an externally selected comparison group. The main exposure factor will be the occurrence of severe maternal morbidity (both maternal potentially life threatening or near miss conditions). During the second half of the cross-sectional study, a sample of women identified as having severe maternal morbidity will be selected and invited to participate in the longitudinal evaluation. There will be a comparison group composed of women who did not suffer severe maternal morbidity. These women will be randomly selected externally in a proportion of 1:1 from postpartum women in the rooming-in wards of the same maternity hospitals as the cases. Controls will be selected at random and balanced according to mode of delivery, maternal age and gestational age at the time of delivery.

### Main outcomes

*Maternal near-miss*

A woman who fulfills one of the clinical, laboratory or management criteria representing severity as defined by WHO [5] and who survives a complication occurring during pregnancy, childbirth or within 42 days postpartum.

*Maternal potentially life threatening condition*

A condition of severe morbidity found in women during pregnancy, childbirth or in the puerperium, classified as potentially life threatening conditions [5], including hemorrhagic or hypertensive disorders, other systemic disorders, and indicators of severe management (Appendix 2).

*Main cause of complication/death*

classification of the determinant main cause of the complication identified among cases and/or the main cause of death.

*Maternal death*

Death of a woman during pregnancy or within a 42-day period following the end of pregnancy irrespective of the duration or localization of the pregnancy, resulting from any cause related to or aggravated by the pregnancy or by measures taken with respect to it; however, not from accidental or incidental causes.

*Conditions at birth*

Vital status of the newborn infant as recorded on the medical chart, dichotomized into live or intrauterine death.

*Vitality of the newborn infant*

Evaluation of the newborn infant according to 1st and 5th minute Apgar scores as shown on the medical chart, classified from 0 to 10.

*Neonatal outcome*

Condition of the newborn infant at the time of data collection, identified from a review of the medical charts and classified as: discharged from hospital together with the mother, early neonatal death (<7 days) or late neonatal death (7-28 days).

*Quality of life*

The woman's perception of her position in life within the cultural context and value system in which she lives and in relation to her goals, expectations, health, standards and concerns (WHO); identified by the investigators using a standard SF-36 form.

*Posttraumatic stress*

Symptoms of intrusion, avoidance and hyperarousal following the occurrence of a pregnancy with severe complications; identified by the investigator using a standard questionnaire (PTSD - Checklist CV).

*Ideal number of children*

Number of children that the woman considered ideal prior to and following the index pregnancy.

*Return to sexual activity*

Time taken by the woman to recommence sexual activity after delivery and reason given for not recommencing sexual activity.

*Sexual function*

Sexual function and response; identified by the investigator using a standard questionnaire (*Female Sexual Function Index - FSFI*).

*Postpartum depression*

Depressive symptoms following the occurrence of a pregnancy with severe complications; identified by the investigator using a standard questionnaire (Edinburgh Postnatal Depression Scale - EPDS).

*Functional status*

Perception of the woman with respect to her functional status in six items related to her routine activities (understanding and communicating, getting around, self-care, getting along with people, life activities in the home/at work and participation in society), classified from 0 to 100 (from best to worst) [25].

*Neuromotor development in the child born from the index pregnancy*
Process of changes in motor behavior that involve both maturation of the central nervous system and interaction with the environment and stimuli given during the child's development; identified by the investigator using the Denver II - Revised Denver Developmental Screening Test [26].

*Weight-height development of the child born from the index pregnancy*
Process of weight and height increment during the child's development, weight measured in grams and height in centimeters, using scales and anthropometer, classified as adequate or inadequate for age, according to the standards of the World Health Organization [27].

*Control variables*
maternal age, marital status, place of residence, number of previous pregnancies, parity, previous abortions, previous Cesarean sections, number of children, mode of delivery, gestational age, birthweight, gender of neonate, condition of neonate at discharge, condition of mother at discharge.

### *Data Collection and Procedures*

*Cross-sectional component*
Research assistants, referred to as local coordinators, will review the charts of hospitalized patients on a daily basis in search of cases with one of the conditions identifying severity (Appendix 2). In cases found with these diagnoses, the relevant hospital records will be reviewed for data collection following the women's hospital discharge, death or transfer to another healthcare facility. Data unavailable on the chart but of interest to the study will be obtained from the attending medical team. For each case included, data will be collected on the demographic and obstetric characteristics of the patient, the primary determinant of maternal near-miss (the first complication to occur in the chain of events leading to severe maternal morbidity), the duration of hospitalization (prior to delivery, following delivery and total time), the occurrence of indicators of maternal near-miss at any time during hospitalization, indicators of perinatal outcome and conditions of the woman at discharge from hospital.

These data will be collected on a previously coded form developed specifically for this purpose. A central database will be constructed and the data will be included by the local investigators themselves using electronic forms. The manually completed forms will be filed and made available at technical visits for the purpose of quality control.

For the electronic inclusion of data, each center will have its own restricted area on the study website where password-protected access will be granted only to cases included at that center. An overview of all the cases included in the network will be provided in the form of monthly graphs and tables containing the number of cases included by each center. In addition, the reported diagnoses will be provided by the coordinating center on the main page of the website.

In cases of near-miss, data will be collected on avoidable factors responsible for their occurrence (delays). These factors will be classified into those related to infrastructure, the patient or the healthcare professionals. Avoidable factors related to infrastructure include cases in which difficulties in obtaining supplies or medication, transportation, communication, blood components or monitoring and treatment may have led to less than ideal care. Factors related to the patient include those generated by the patient herself or her family, either by delaying seeking professional care or by refusing treatment. Factors related to the healthcare team include delays in defining the correct diagnosis and/or inappropriate management.

The degree of complexity at each hospital will be evaluated using an adapted version of the hospital complexity index developed for the WHO Global Survey project [28]. Participating institutions will provide information on a monthly basis via the website on the total number of deliveries, live births and maternal deaths that occurred the previous month. These data will be confirmed by the principal local investigator after data collection is finished.

To minimize the number of uncertainties that research assistants may face during data collection, a manual of operation was produced containing all the necessary information on how to use the internet, how to complete the written and electronic forms and how to access the database of each individual center, as well as information regarding the standardization of diagnostic definitions.

A meeting will be held with the investigators and local coordinators of each center (two individuals from each center) at the study coordinating center immediately preceding initiation of data collection in order to provide adequate training and clarify any queries regarding the data collection process and use of the website. Sometime after the initiation of data collection, a meeting of the study's Steering Committee will also be held. A second meeting will take place involving only the local investigators after data collection has finished to discuss facts related to the previous process, disclosure of partial results, scheduling of the preliminary and final analyses, agreement on papers to be written on the results and assignment of responsibility regarding execution of each item in this process.

*Longitudinal component*

As in the cross-sectional component, women with one of the conditions indicative of severity will be selected as potential subjects for longitudinal evaluation. Once identified, research assistants who are not involved in the cross-sectional portion of the study will invite eligible women to participate in the longitudinal evaluation of the study. Women who agree to take part will be asked to sign an informed consent form and two CATI (computer assisted telephone interview) will be scheduled for 3 and 6 months postpartum plus a medical visit with the woman and the newborn infant six months following delivery.

For the control group, all women admitted to the hospital for obstetric care in the same facility on the same day on which a case has been identified and who have none of the conditions indicating severity will be eligible. Following a process of randomized selection balanced according to mode of delivery, maternal age and gestational age at the time of delivery, women in the control group will be invited to participate in the study by the research assistants in the same way as candidates to the study group. Three months after delivery, the study call center will contact the women to carry out the first step in data collection. At the time of this contact, the interviewers will again go over the objectives of the study and will apply standard questionnaires designed to investigate quality of life and postpartum depression. This interview is estimated to last around 20 minutes.

At six months postpartum, the study call center will contact the women again to carry out the second step in data collection. At this contact, the interviewers will go over the study objectives once again and apply the same standard questionnaires on quality of life and postpartum depression, lasting no more than 20 minutes. In the case of women who do not have a telephone, a reminder letter will be sent asking them to phone the study call center at the sixth month postpartum to enable the interview to take place.

At the end of the 6-month telephone interview, the interviewer will confirm the date, time and place of the visit that was previously scheduled when the women were still in hospital. The women will be reminded that they should bring the baby to the visit. Even if they do not authorize the participation of their infants in the study, the women will be invited to return to the hospital and answer the questionnaires. The interview will be carried out by a trained female interviewer, who will apply standard questionnaires to evaluate posttraumatic stress disorder, sexual function and the woman's perception of her functional status in routine activities, taking no more than 35 minutes for each woman. After the mothers have answered the questionnaires, the weight, height and neuro-psychomotor development of the infants will be evaluated by a specially trained pediatrician, taking around 20 minutes. Finally, the women will receive a token cash payment as a contribution towards their transportation and food costs while attending this visit.

The following instruments will be used for data collection:

*Posttraumatic Stress Disorder (PTSD) Checklist - Civilian Version (PCL-C)*

This questionnaire has been validated in Brazil to screen for the diagnosis of posttraumatic stress disorder. It contains 17 items in which women will indicate to what extent she has been disturbed by symptoms over the past month on a scale of 1-5 (ranging from not at all to a lot). A score ≥ 3 (a medium score) for any one of the items is considered indicative of a clinically significant symptom.

*Medical Outcomes Study 36-Item Short-Form Health Survey (SF36)*

This is a generic questionnaire for evaluating quality of life that has been validated for use in Brazil. It is multidimensional with 36 items in 8 scales: physical functioning, role-physical, body pain, general health, vitality, social functioning, role-emotional and mental health. Final scores vary from 0 to 100 (poorest to best).

*Female Sexual Function Index*

A multidimensional questionnaire used to evaluate female sexual function consisting of 19 questions in 6 domains: desire, arousal, lubrication, orgasm, satisfaction and pain. Final scores vary from 2 to 36, a cut-off point < 26 having been proposed as determinant of sexual dysfunction. This questionnaire has been culturally adapted for use in Brazil.

*Edinburgh Postnatal Depression Scale (EPDS)*

A questionnaire used to screen for symptoms of depression and anxiety in the postpartum period, containing 10 questions that may be self-administered. A final score ≥ 10 has been defined as the cut-off point of greatest sensitivity in screening. The tool has been validated for use in Brazil.

*The World Health Organization Disability Assessment Schedule II (WHODAS II)*

A 36-item questionnaire used to evaluate the individual's perception of herself and her functional status, consisting of six activity domains related to the woman's routine activities (understanding and communicating, getting around, self-care, getting along with people, life activities in the home/at work and participation in society), on a 6-level scale varying from (1) no difficulty to (6) extreme difficulty/cannot do. Final score varies from 0 to 100 (from best to worst) [25].

*Neuro-psychomotor development of the child*

The Denver Developmental Screening Test II consists of 125 tasks or items organized in the form of tests of 4 general functions: personal-social, fine motor-adaptive, language and gross motor. At the end, a behavior test is applied that helps the examiner subjectively observe the overall behavior of the child and obtain an impression on how the child uses his/her skills.

### *Quality control*

Quality control procedures will be adopted and include techniques such as reviewing completed forms, checking data entry, repeating data collection for selected medical charts and the use of a detailed manual of operation. Initial quality control of data collection will be performed by the local investigator prior to and during electronic data entry of the forms in order to identify any possible inconsistencies in the data.

A second quality control procedure will be carried out by one of the principal investigators, who will visit the participating centers. At this visit, consistency will be verified between the manual records on file and the data contained in the electronic forms. In addition, a random evaluation will be made of hospital records.

For the quality control of the longitudinal component, 10% of the records at each participating center will be randomly selected at the end of individual data collection and contact will once again be made with the patient in order to verify the data obtained at the first interview. The local investigators will maintain a record of any problems occurring during the study and any queries will be raised with the country coordinator of the project.

### *Data analysis*

Data analysis will be performed in sub-groups according to the time of occurrence of the near-miss or severe maternal morbidity (in adolescence, older ages or at another time in the woman's reproductive life) and determining cause (hypertension, hemorrhage, abortion or other causes). The rates of maternal near-miss will be calculated for each collaborating center using the WHO maternal near miss approach [5], and frequencies of non-near-miss severe maternal morbidity will be calculated using specific defined diagnoses. General estimates will be calculated together with their respective 95% confidence intervals. The association between organ dysfunction and maternal death will be estimated using odds ratios, likelihood ratio test and their respective 95% confidence intervals. In addition, relative risks will be calculated for sexual dysfunction, postpartum depression, posttraumatic stress disorder, deterioration in quality of life, deterioration in the woman's perception of her own functional status in routine activities, risk of adverse perinatal outcome and risk of impaired neuromotor and weight-height development in the children born from the pregnancy associated with severe maternal morbidity.

### *Results obtained from the preliminary project*

Initially, a meeting was held during the Brazilian national congress of Gynecology and Obstetrics in November, 2007, and attended by representatives of 35 healthcare facilities in Brazil. At this meeting, the main points featured in the initial concept of the project were presented and an invitation was made to institutions interested in participating in a Brazilian network on the topic. Those who were interested in participating filled out a registration form with the addresses and characteristics of their respective healthcare institutions. In December 2007, an electronic form was sent to them to be completed with specific information. In accordance with the data received, 27 of these candidate healthcare institutions were selected to participate in the network, taking regional characteristics, geographic distribution, level of complexity and the number of deliveries performed into consideration.

In August 2008, a meeting with representatives from all the centers was held at the coordinating center in Campinas. At this meeting, the proposal was presented and discussed in detail, and suggestions were incorporated into the final version of the protocol. Participating center representatives were identified, the operational issues involved in implementing the study and the theoretical concepts were discussed, and the final version of the research project was defined. Concurrently, a signed commitment was undertaken by each representative to participate in the Brazilian Network for the Surveillance of Severe Maternal Morbidity: the Brazilian Network of Studies in Reproductive and Perinatal Health was created. A Steering Committee was also designated for the study.

### *Ethical aspects*

The coordinating center has already obtained the approval of the local Institutional Review Board and of the National Council for Ethics in Research (CONEP) of the Brazilian Ministry of Health for both components of the project. The participation of the collaborating centers in this study will only be confirmed after the project has been approved by their respective Institutional Review Boards. Individual signed informed consent will not be requested from the women involved in the cross-sectional analysis, since this study does not involve any type of intervention that could adversely affect their treatment; the data of interest will be obtained retrospectively from the patient's charts and without identifying the woman. Therefore, a waiver of the requirement for signed informed consent was obtained. It is understood that there is no other way of obtaining concrete, reliable information on cases of severe maternal morbidity or death,

since these patients are unable to give their consent. However, informed consent will be obtained from the women involved in the longitudinal component of the study. All the principles regulating research in human beings will be respected.

Based on the questionnaires applied, women diagnosed with some type of pathological condition, who are not receiving medical care, will be referred to healthcare facilities equipped to provide them with follow-up care. Women who have already received a diagnosis of a pathological condition but are not being followed up by a physician will also be referred to an appropriate healthcare service.

#### *Technical and scientific contributions expected from the project*

Brazil is a country with very high proportion of births taking place in health facilities (around 97%). The results of the present study will permit a prospective evaluation of severe maternal morbidity and deaths nationwide through the participation of healthcare facilities with different regional characteristics. No multicenter collaborative studies of this dimension are currently being carried out in healthcare institutions in Brazil in the field of Reproductive Health, and no data thus obtained are currently available. In addition to the specific study of maternal health hazards, the organizational structure required by this project will guarantee continuity of the investigation into various conditions of interest to public health beyond the period in which this study will be conducted. The implementation of a collaborative network is essential for expanding the production of substantive research in the field of maternal and perinatal health in Brazil.

Certainly, the availability of resources for the implementation and development of the Brazilian Network for the Surveillance of Severe Maternal Morbidity will lead to new scientific findings relevant to Brazil and other countries. Concomitantly, this will permit the construction of an innovative technological base from which health data may be obtained on a continuous basis, providing the evidence required to institute a real and effective improvement in the quality of life and health of the population. This network is committed to participating in future collaborative studies in the areas of perinatal and women's healthcare. The implementation of a series of multicenter studies is anticipated in this area in a way never before achieved in this country. This fact gives greater power to the results, which will therefore be more representative of the country, a particularly interesting achievement bearing in mind the wide ethnic, cultural and social diversity of the Brazilian population.

We hope that this initiative contributes to the improvement of health care and for the reduction of maternal and perinatal morbidity and mortality.

## Competing interests

The authors declare that they have no competing interests.

## Authors' contributions

The idea for the study arose in a group discussion with all authors. The first version of the protocol was drafted by JPS and JGC, then complemented with the suggestions of the others. RCP and RSC were responsible for including the initial proposal for a multidimensional evaluation of consequences. SMH was responsible for the final, complete version of the protocol. JGC supervised the whole process. All authors contributed to the development of the study protocol and approved the final version of the manuscript.

## Appendix 1: Criteria defining Near-Miss (WHO)*

A woman who fulfills one of the following criteria and survives a complication during pregnancy, childbirth or in the 42 days postpartum should be considered a near-miss.

#### *Clinical Criteria*

Acute cyanosis

Breathing rate > 40 or < 6

Oliguria unresponsive to fluids or diuretics

Loss of consciousness for ≥ 12 hours

Unconscious, no pulse/heartbeat

Jaundice concomitantly with preeclampsia

Gasping

Shock

Coagulation disorders

Cerebrovascular accident

Total paralysis

#### *Laboratory Criteria*

Oxygen saturation <90% for > 60 minutes

Acute thrombocytopenia (<50,000 platelets)

Creatinine ≥ 300 μmol/l or ≥ 3.5 mg/dL

Bilirubin >100 μmol/l or > 6.0 mg/dL

Unconscious, presence of glucose and ketoacidosis in urine.

Lactate > 5PaO2/FiO2 < 200

pH < 7.1

***Management Criteria***
Use of continuous vasoactive drug

Dialysis for treatment of acute kidney failure

Puerperal hysterectomy due to infection or hemorrhage

Cardiopulmonary resuscitation (CPR)

Transfusion ≥ 5 units of red blood cell concentrate

Intubation and ventilation for a period ≥ 60 minutes, unrelated to anesthesia*

Modified from [5]

## Appendix 2: Indicators of non-near-miss severe maternal morbidity (potentially life-threatening conditions) *

***Hemorrhagic disorders***
Abruptio placentae

Placenta accreta/increta/percreta

Ectopic pregnancy

Antepartum hemorrhage

Postpartum hemorrhage

Ruptured uterus

Abortion with severe hemorrhage

***Hypertensive disorders***
Severe Preeclampsia

Eclampsia

Severe hypertension

Hypertensive encephalopathy

HELLP syndrome

***Other systemic disorders***
Endometritis

Pulmonary edema

Respiratory failure

Seizures

Sepsis

Thrombocytopenia <100,000

Thyroid crisis

***Management indicators of severity***
Blood transfusion

Central venous access

Hysterectomy

ICU admission

Prolonged hospital stay (>7 postpartum days)

Intubation not related to anaesthetic procedure

Return to operating room

Major surgical intervention

*Modified from [5]

## Acknowledgements

The first component of the study, the Brazilian Network for the Surveillance of Severe Maternal Morbidity, is being sponsored by the Brazilian National Research Council (CNPq) (Grant 402702/2008-5). We also acknowledge the other members of the Brazilian Network for the Surveillance of Severe Maternal Morbidity: Marilza V Rudge, Olímpio B Moraes Filho, Francisco E Feitosa, Ione R Brum, Carlos A Menezes, Everardo M Guanabara, Joaquim L Moreira, Frederico A Peret, Luiza E Schmaltz, Leila Katz, Antonio C Barbosa Lima, Melania M Amorim, Marilia G Martins, Fernando C Oliveira Jr, Roger D Rohloff, Sergio M Costa, Adriana G Luz, Gustavo L Azevedo, Eduardo Cordioli, Cláudio S Paiva, Jose Carlos Peraçoli, Nelson L Maia Filho, Silvana M Quintana, Fátima A Lotufo, Elvira A Zanette, Carla A Polido, Márcia M Aquino and Rosiane Mattar.

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## 8.4. Anexo 4. Ficha identificadora dos casos

**Rede Nacional de Vigilância de Morbidade Materna Grave**

Nome:_____ HC:_____Data da alta:_____

- Anexar este formulário aos prontuários de todas as pacientes obstétricas (gestantes ou puérperas) internadas no serviço.
- Identificar durante a internação ou na alta hospitalar se houve o diagnóstico de alguma das condições abaixo descritas.
- Para as que apresentarem qualquer uma das condições abaixo ("SIM"), o prontuário será separado para revisão antes do seu arquivamento.
- Para as que NÃO tiverem nenhum das condições, esta ficha deverá ser arquivada em pasta específica e o prontuário pode ser liberado para arquivamento pelo SAME

| **Complicações hemorrágicas** | **Sim** | **Não** |
|---|---|---|
| Descolamento prematuro de placenta | | |
| Placenta prévia / acreta/increta/percreta | | |
| Prenhez ectópica | | |
| Rotura uterina | | |
| Hemorragia grave por aborto | | |
| Hemorragia pós-parto | | |
| a) atonia | | |
| b) retenção placentária | | |
| c) lacerações de trajeto | | |
| d) coagulopatia | | |
| e) inversão uterina | | |
| **Complicações hipertensivas** | **Sim** | **Não** |
| Pré-eclampsia grave | | |
| Eclâmpsia | | |
| Hipertensão grave | | |
| HELLP síndrome | | |
| Fígado Gorduroso | | |
| **Outras complicações** | **Sim** | **Não** |
| Edema pulmonar | | |
| Convulsões | | |
| Sepse grave | | |
| Trombocitopenia < 100 mil | | |
| Crise tireotóxica | | |
| Choque | | |
| Insuficiência respiratória aguda | | |
| Acidose | | |
| Cardiopatia | | |
| AVC | | |
| Distúrbios de coagulação | | |
| Tromboembolismo | | |
| Cetoacidose diabética | | |
| Icterícia / disfunção hepática | | |
| Meningite | | |
| Insuficiência Renal Aguda | | |
| **Indicadores de manejo de gravidade** | **Sim** | **Não** |
| Transfusão de hemoderivados | | |
| Acesso venoso central | | |
| Admissão em UTI | | |
| Hospitalização prolongada (>7dias) | | |
| Intubação não relacionada à anestesia | | |
| Retorno à sala cirúrgica | | |
| Intervenção cirúrgica maior (histerectomia, laparotomia) | | |
| Uso de sulfato de magnésio | | |

RESUMO ☐ SIM ☐ NÃO

Resp. pelo preenchimento: _____

## 8.5. Anexo 5. Carta de recebimento do artigo 2 pela revista British Journal of Obstetrics and Gynaecology



ONLINE MANUSCRIPT SUBMISSION & PEER REVIEW
BJOG An International Journal of Obstetrics and Gynaecology

Home

**Detailed Status Information**

| | |
|---|---|
| **Manuscript #** | 2011-OG-10128 |
| **Current Revision #** | 0 |
| **Submission Date** | 27th September 11 18:48:52 |
| **Current Stage** | Initial Quality Check Started |
| **Title** | Delays in receiving obstetrical care are associated with the occurrence of maternal near miss and maternal death |
| **Running Title** | delay in obstetrical care and severe maternal morbidity |
| **Manuscript Type** | Main Research Article |
| **"Theme Issue"** | N/A |
| **Clinical Category** | General obstetrics |
| **Corresponding Author** | José Cecatti (Univesity of Campinas) |
| **Contributing Authors** | Rodolfo Pacagnella , Mary Parpinelli , Maria Sousa , Samira Haddad , Maria Costa , Joao Souza , Robert Pattinson , for the Brazilian Network for the Surveillance of Severe Maternal Morbidity Group |
| **Abstract** | Objective: The vast majority of maternal deaths in developing countries are preventable. Delays in getting access to appropriate care are amongst the most common areas where improvement can be made. This study aimed to explore the association between delays in the provision of health care and severe maternal morbidity and death. Design: A multicenter cross-sectional study Setting: 27 referral obstetric facilities in all regions of Brazil Population: 9,555 cases of maternal death (MD), maternal near-miss (MNM) and cases classified as potentially life-threatening conditions (PLTC) according to the new WHO criteria. Method: Data on delays were collected upon medical records examination and interview with medical staff. The prevalence of different types of delays was estimated according to the level of care and outcome of the complication. For factors possibly associated with any delay, PR and 95%CI controlled for cluster design were estimated. Main outcome measures: frequency of delays related to the patient, to health service/system and to health professionals Results: 82,144 live births were screened with 9,555 cases having PLTC, MMN or MD prospectively identified. Overall, any type of delay was observed in 54% of cases; delay related to patient was observed in 39%, followed by 17% of delays related to health professionals and 15% related to the health system. Presence of any delay was associated with increasing severity of maternal outcome: 84% in MD, 68% in MNM and 53% in PLTC. Conclusion: There is an association with increasing delays and poorer outcomes confirming that timely proper management impacts on survival. |
| **Keywords** | severe maternal morbidity, maternal mortality, maternal near miss, delays for obstetrical care, emergency obstetric care |
| **Methodology** | OBSERVATIONAL STUDIES (e.g. cohort, case-controlled, epidemiology) |
| **Disclosure of Interests** | No, there are no conflict of interests that I should disclose, having read the above statement. |

**Clinical Trial** No
**Section Verification** Yes

| Stage | Start Date |
|---|---|
| Sent to Editor | 27th September 11 20:39:40 |
| Files submitted for Quality Check | 27th September 11 20:39:40 |
| Waiting for Author Approval | 27th September 11 20:34:56 |
| Submission | 27th September 11 20:32:47 |
| Preliminary Data Submitted | 27th September 11 20:09:56 |

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