JOÃO PAULO DIAS DE SOUZA

Uma abordagem abrangente para o estudo populacional do near miss materno

Tese de Doutorado

ORIENTADOR: Prof. Dr. JOSÉ GUILHERME CECATTI

CO-ORIENTADORA: Profa. Dra. MARY ANGELA PARPINELLI

UNICAMP 2008

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Tese de Doutorado apresentada à Pós-Graduação da Faculdade de Ciências Médicas da Universidade Estadual de Campinas para obtenção do Título de Doutor em Tocoginecologia, área de Tocoginecologia.

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Dedicatória

Esta tese é dedicada às milhões de mulheres que, a cada ano, sofrem complicações graves durante a gravidez, parto e puerpério.

Aos meus pais e à Cynthia, pela paciência e continuado suporte.

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Símbolos, Siglas e Abreviaturas

ABEP Associação Brasileira de Empresas de Pesquisa

Ac Accuracy

APM Actual prevalence of morbidity

BMI Body mass index

CAISM Centro de Atenção Integral à Saúde da Mulher

CEP Comitê de Ética em Pesquisa

DP Desvio-padrão

DHS Demographic and Health Survey

DTG Departamento de Tocoginecologia

FAPESP Fundação de Amparo à Pesquisa do Estado de São Paulo

FCM Faculdade de Ciências Médicas

IBGE Instituto Brasileiro de Geografia e Estatística

ICU Intensive Care Unit

IPEA Instituto de Pesquisas Econômicas Aplicadas

IRB Institutional Review Board

IMM Índice de Mortalidade Materna

LB Live births

LR Likelihood ratio

NA Not available

NMR Near Miss Ratio

OMS Organização Mundial da Saúde

Significância estatística р

PNDS Pesquisa Nacional de Demografia e Saúde

PSRM Prevalence of self reported morbidity

PSU Primary Sampling Unit

PTSD Post traumatic stress disorder

SciELO Scientific electronic library online

Sens Sensitivity

SIH Sistema de Informações Hospitalares

SMM Severe maternal morbidity

Sp Specificity

UN **United Nations**

UNICAMP Universidade Estadual de Campinas

UNFPA United Nations Population Fund

USAID United States Agency for International Development

UTI Unidade de Terapia Intensiva

UTI Urinary tract infection

WHO World Health Organization

Resumo

Desde os anos 1990, um grupo especial de mulheres que sobrevivem a complicações graves da gestação tem despertado o interesse de pesquisadores e formuladores de políticas públicas. O melhor entendimento deste grupo, conhecido como "near miss", poderia contribuir para o desenvolvimento de políticas de saúde para a melhora da saúde materna. A presente tese de doutorado foi desenvolvida com a finalidade mais ampla de avaliar se o estudo do near miss materno seria factível através de inquéritos populacionais. Para este fim, foi desenvolvida uma série de projetos, implementados em três fases: preparação, desenvolvimento e validação de um instrumento para o inquérito populacional, e aplicação (através de uma pesquisa nacional de demografia e saúde). Na fase de preparação foram analisadas informações obtidas por inquéritos demográficos de saúde realizados na América Latina e Caribe sobre a morbidade materna. Durante a fase de desenvolvimento e validação do questionário, foi realizada uma revisão sistemática sobre o assunto, desenvolvida uma definição pragmática de near miss e avaliadas vivências da morbidade materna grave. A partir de achados das duas primeiras fases foi desenvolvido um instrumento para a realização de inquéritos populacionais, que foi submetido a um estudo de validação. A fase de aplicação se deu com a incorporação deste questionário na mais recente Pesquisa Nacional de Demografia e Saúde realizada no Brasil. Ao final deste processo, e utilizando-se uma definição pragmática, baseada na ocorrência de eclâmpsia, histerectomia, internação à UTI e transfusão de sangue, estimam-se a incidência anual de 54.000 casos de *near miss* materno no Brasil, com prevalência aproximada ao redor de 20 casos/1.000 nascidos vivos. Mulheres com mais de 40 anos ou de baixa escolaridade apresentam risco aumentado de desenvolver a condição. No conjunto, esta tese demonstra a versatilidade do conceito de near miss materno, cuja definição pode ser estrita ou pragmática, e utilizada para diversos fins, incluindo monitoramento, vigilância epidemiológica, controle de qualidade e para orientação do cuidado. A versatilidade do conceito, a maior freqüência dos casos e a possibilidade de entrevistar as mulheres suportam o propósito de se estudar o *near miss* materno para guiar os esforços locais na redução da mortalidade materna e da carga das complicações graves.

Palavras-chave: morbidade materna grave, near miss, complicações da gestação, mortalidade materna, cuidados internsivos, inquérito demográfico de sáude

Summary

Since the 1990s, a special group of women who survive severe complications of pregnancy has attracted the interest of researchers and public policymakers. A better understanding of this group, known as "near miss", could contribute to the development of health policies to improve maternal health. This doctoral thesis was developed with the wider aim of assessing whether the study of maternal near miss would be feasible through population surveys. To this end we developed a series of projects, implemented in three phases: preparation, development and validation of an instrument for the survey, and implementation (through a national survey of population and health). At the stage of preparation, information obtained by demographic health surveys conducted in Latin America and the Caribbean on maternal morbidity was analyzed. During the development and validation of the questionnaire, a systematic review was conducted and a pragmatic definition of near miss was developed. Women's experiences of severe maternal morbidity were evaluated. The findings from the first two phases supported the development of tool for population inquiries, which has undergone a validation study. The phase of implementation was possible due to the incorporation of this questionnaire in the most recent national Demographic and Health Survey held in Brazil (2006/07). At the end of this process, and using a pragmatic definition, based on the occurrence of eclampsia, hysterectomy, admission to the ICU and blood transfusion, it is estimated the annual incidence of 54,000 cases of maternal near miss in Brazil, with prevalence around 20 cases/1.000 live births. Women aged > 40 years or with low education are at increased risk of developing the condition. Overall, this thesis demonstrates the versatility of the concept of near miss, whose definition can be strict or pragmatic, and used for various purposes, including monitoring, surveillance, quality control and guidance of care. The versatility of the concept, the greater frequency of cases and the possibility of interviewing women support the purpose of studying the maternal near miss to guide local efforts in reducing maternal mortality and the burden of severe complications.

Key words: severe maternal morbidity, near miss, complications of pregnancy, maternal mortality, intensive care, demographic and health survey.

1. Introdução

A cada ano, meio milhão de mulheres perde suas vidas em decorrência de complicações relacionadas à gestação, parto e puerpério (WHO, 2007). Estas mortes poderiam ser evitadas em sua quase totalidade, constituindo um indicador da desigualdade ainda existente entre os gêneros. A ocorrência de mortes maternas está inversamente associada ao grau de desenvolvimento humano. Por este motivo, a redução do número de mortes maternas tornou-se um dos objetivos do milênio (UN, 2000).

Na realidade, as mortes maternas constituem apenas a ponta de um *iceberg* de morbidade grave relacionada à gestação, parto e puerpério. E, embora se estime em dez milhões o número de mulheres que apresenta complicações graves da gestação a cada ano, o tamanho exato deste todo de morbidade é ainda desconhecido. Entretanto, é este todo que deve ser enfrentado para que ocorra uma real melhora da saúde materna. A incidência de complicações agudas durante a gestação é semelhante, tanto nos países desenvolvidos quanto naqueles em desenvolvimento. Diferenças no modo como as complicações são percebidas e tratadas podem ser responsáveis

pelasenormes diferenças nas razões de morte materna (Filippi et al., 2006; Rosenfield et al., 2006).

Desde os anos 90, um grupo especial de mulheres que sobrevivem a complicações graves da gestação tem despertado o interesse de pesquisadores e formuladores de políticas públicas. Este grupo, conhecido como "*near miss*", seria aquele formado por mulheres que, após uma complicação aguda e grave da gestação, escapam da morte por sorte ou por terem recebido um cuidado apropriado e em tempo adequado (Say et al., 2004).

Neste contexto, o conceito de *near miss* foi bem estabelecido, mas uma definição comum para identificação dos casos foi apenas muito recentemente alcançada (WHO, 2008). A maioria dos estudos sobre o tema vinha adotando definições relacionadas à complexidade do manejo (por exemplo, admissão em unidades de terapia intensiva). Outros investigadores reconheceram a morbidade grave pela presença de entidades clínicas, disfunção orgânica ou através de critérios mistos. Nestes estudos, a taxa de relatada de morbidade grave variou de 0,3/1000 a 101,7/1000 partos, e a relação de caso:fatalidade variou de 2:1 a 223:1. Também foi observada tendência de maior incidência de morbidade grave nos estudos realizados em países em desenvolvimento (Say et al., 2004; Souza et al., 2006).

No Brasil, inicia-se a divulgação de dados sobre a ocorrência de morbidade materna grave. Existe ainda predomínio dos estudos de base hospitalar, embora estudos de base populacional já tenham sido realizados.

Através da identificação dos registros de mulheres com condições sugestivas de morbidade materna grave, utilizando o Sistema de Informação Hospitalar (SIH) do Ministério da Saúde, obteve-se a primeira estimativa nacional de morbidade materna grave (44,3/1000 nascidos vivos) (Sousa et al., 2008).

Porém, a abrangência destes sistemas informatizados é ainda parcial no Brasil, assim como em outros países em desenvolvimento. Nestes locais, onde sistemas integrados de informação epidemiológica não estão implantados, os inquéritos populacionais de saúde podem ser uma alternativa para o estudo da morbidade grave (Kalter, 1992; Stewart & Festin, 1995; Seoane et al., 1998; Filippi et al., 2000).

Uma das principais vantagens do estudo dos casos de near miss é a possibilidade de ouvir diretamente as experiências destas mulheres. Acredita-se que as mulheres que tenham sobrevivido a complicações potencialmente fatais possam informar adequadamente sobre os obstáculos e demoras enfrentados para sua sobrevivência. Estas características e o maior número de casos fazem com que o estudo da morbidade grave seja considerado favorável para a compreensão dos determinantes da mortalidade materna. Pode ser também utilizado como um indicador de processo e para o acompanhamento das intervenções visando o aperfeicoamento da assistência obstétrica (Pattinson & Hall, 2003).

A presente tese de doutorado foi desenvolvida com a finalidade mais ampla de avaliar se o estudo do *near miss* materno seria factível através de inquéritos

populacionais. Neste sentido, foram implementados diversos projetos a fim de bem fundamentar a avaliação populacional do *near miss* materno no Brasil.

Estes projetos foram implementados em três fases: preparação, desenvolvimento e validação de um instrumento para o inquérito populacional, e aplicação (através de uma pesquisa nacional de demografia e saúde). Na fase de preparação foram analisadas informações obtidas por inquéritos demográficos de saúde realizados na América Latina e Caribe sobre a morbidade materna. Os bancos de dados de sete inquéritos populacionais em diferentes países da América Latina foram analisados. Usando essa mesma abordagem, a situação brasileira foi avaliada por regiões geográficas em inquérito realizado em 1996. Durante a fase de desenvolvimento e validação do questionário, foi realizada uma revisão sistemática sobre o assunto. Como durante esta fase a definição de near miss materno era ainda controversa, foi desenvolvida uma definição pragmática, baseada nos resultados do estudo global da OMS em saúde materna e perinatal para a América Latina. A fim de melhorar o entendimento da vivência da morbidade materna grave e sua relação com a capacidade da mulher de recordar posteriormente estes eventos, foi desenvolvido um estudo qualitativo. A partir de achados das duas primeiras fases foi desenvolvido um instrumento para a realização de inquéritos populacionais, que foi submetido a um estudo de validação. A fase de aplicação se deu com a incorporação deste questionário na mais recente Pesquisa Nacional de Demografia e Saúde realizada no Brasil.

2. Objetivos

2.1. Objetivo geral

Desenvolver uma abordagem abrangente para o estudo populacional do near miss materno, utilizando distintos enfoques metodológicos, como parâmetro complementar ao estudo da mortalidade materna.

2.2. Objetivos específicos

- 1. Compilar, consolidar e analisar as informações obtidas por inquéritos populacionais sobre a assistência obstétrica e complicações da gestação na América Latina e Caribe;
- 2. Avaliar a informação coletada através da Pesquisa Nacional de Demografia e Saúde de 1996 sobre a ocorrência de complicações da gestação, parto e puerpério no Brasil;
- 3. Avaliar, através de uma revisão sistemática, a habilidade de inquéritos populacionais em estimar a ocorrência de complicações da gestação, parto e puerpério;

- 4. Determinar os elementos essenciais para a avaliação populacional do near miss materno, com os dados do Estudo Global da Organização Mundial da Saúde para a América Latina;
- 5. Investigar qualitativamente a vivência das mulheres com morbidade materna grave/near miss e explorar fatores que possam prejudicar a sua recordação;
- 6. Desenvolver e validar um questionário para avaliação populacional do near miss materno e das complicações relacionadas à gravidez;
- Determinar a prevalência do near miss materno no Brasil através de 7. um inquérito populacional e estudar seus fatores associados;
- 8. Consolidar de forma abrangente as iniciativas de múltiplas estratégias metodológicas para a avaliação da morbidade materna grave.

3. Publicações

Pelas caracterísiticas pouco comuns da presente Tese de Doutorado, algumas explicações adicionais se fazem necessárias. A presente sessão de Publicações corresponde aos resultados do projeto mais abrangente deste doutorado. Para os artigos 1 e 2 já publicados, foi feita uma análise secundária a partir dos dados das DHS para o Brasil e demais países da América Latina e Caribe, disponíveis por via eletrônica, sob solicitação, no site da Macro International. O Artigo 3, também já publicado, corresponde a uma análise sistemática sobre o uso de questionários para morbidade materna grave em inquéritos populacionais. O Artigo 4, já aceito para publicação, representa uma tentativa de definição mais pragmática dos critérios de gravidade de complicações maternas que poderiam ser utilizados para a conceituação do near miss materno, utilizando também uma análise secundária do banco de dados da OMS referente à pesquisa Global Survey para a América Latina, após a autorização da instituição.

O Artigo 5, também já aceito para publicação, representa uma incursão qualitativa ao universo da morbidade materna grave na perspectiva da mulher que vivencia essa condição, com a proposta inédita da caracterização de uma "síndrome do *near miss* materno", o que poderia ajudar a explicar muitas das dificuldades e controvérsias acerca das informações e caracterização do quadro. Esse foi um projeto regular, aprovado pelo CEP da FCM/UNICAMP (Anexo 1) e que contou com um auxílio pesquisa da FAPESP (Processo 2006/04491-5). Esse projeto ainda contempla outros elementos não apresentados nessa oportunidade, referentes ao manejo apropriado das mulheres com morbidade materna grave, sob o ponto de vista médico e psicológico, que serão objeto de publicações futuras já em fase de preparação.

Após a revisão sistemática realizada, um formulário padronizado para a coleta de informações sobre a ocorrência de morbidade materna grave foi proposto para ser utilizado em inquéritos populacionais, para que a própria mulher autoreferisse esas complicações. Assim, antes de sua implementação, outro estudo foi realizado para avaliar a validade desse questionário, através de entrevistas realizadas por telefone e conferidas com o padrão ouro da informação respectiva colhida dos prontuários médicos dessas mulheres. Esse é o conteúdo do Artigo 6, cujo projeto foi também aprovado pelo CEP da FCM/UNICAMP (Anexo 2) e que foi financiado por um auxílio à pesquisa da FAPESP (Processo 2007/00290-8). Este projeto também contempla outros aspectos não diretamente ligados ao tema principal desta abordagem, sobretudo os aspectos metodológicos de inquéritos populacionais na área de saúde reprodutiva feitos através de telepesquisa, enfocado em outro artigo.

Esse questionário simplificado foi utilizado na última Pesquisa Nacional de Demografia e Saúde (PNDS 2006) no Brasil (Anexo 3). Os resultados deste inquérito com relação à ocorrência de complicações graves relacionadas à gestação, parto e puerpério estão no Artigo 7 a ser logo submetido também a publicação, que também contempla os aspectos da validação do questionário previamente realizada.

Por último, o Artigo 8, também já publicado, explora um pouco mais filosoficamente, a abordagem ao estudo da morbidade materna grave ou *near miss* materno em um contexto de país em desenvolvimento como é o caso do Brasil, e o papel que os pesquisadores da área de saúde reprodutiva têm para avançar nessa área, atualmente considerada fundamental para a implementação de qualquer política pública com o objetivo da melhor qualidade das intervenções nesse período. Assim, todos os resultados desta abordagem mais abrangente estão contemplados nos seguintes objetivos e artigos:

Objetivo específico 1:

Artigo 1: Souza JP, Parpinelli MA, Amaral E, Cecatti JG. Assistência obstétrica e complicações graves da gestação na América Latina e Caribe: análise das informações obtidas a partir de inquéritos demográficos de saúde. Revista Panamericana de Salud Publica 2007; 21(6): 396-401.

Objetivo específico 2:

Artigo 2: Souza JP, Sousa MH, Parpinelli MA, Amaral E, Cecatti JG.
 Self-reported maternal morbidity and associated factors among Brazilian women. Revista da Associação Médica Brasileira 2007; 54(3):249-55.

Objetivo específico 3:

 Artigo 3: Souza JP, Parpinelli MA, Amaral E, Cecatti JG. Population surveys using validated questionnaires provided useful information on the prevalence of maternal morbidities. *Journal of Clinical Epidemiology* 2008; 61(2):169-76.

Objetivo específico 4:

• Artigo 4: Souza JP, Cecatti JG, Faúndes A, Morais SS, Villar J, Carroli G, Gulmezoglu AM, Wojdyla D, Zavaleta N, Donner A, Velazco A, Bataglia V, Valladares E, Kublickas M, Acosta A, for the World Health Organization 2005 Global Survey on Maternal and Perinatal Health Research Group. Severe maternal morbidity / near miss as a proxy for maternal mortality: the 2005 WHO global survey on maternal and perinatal health. Aceito para publicação no Bulletin of World Health Organization 2008. (Anexo 4)

Objetivo específico 5:

Artigo 5: Souza JP, Cecatti JG, Parpinelli MA, Krupa FG, Osis MJD. Near missed voices: narratives of women who almost died during pregnancy and childbirth - an emerging "maternal near miss syndrome". Artigo aceito para publicação no Birth 2008. (Anexo 5)

Objetivo específico 6:

Artigo 6: Souza JP, Cecatti JG, Giavarotti TM, Parpinelli MA, Sousa MH, Osis MJ. Women recalled more accurately process indicators than obstetric complications in a severe maternal morbidity survey. Artigo submetido a publicação no Journal of Clinical Epidemiology 2008. (Anexo 6)

Objetivo específico 7:

Artigo 7: Souza JP, Cecatti JG, Parpinelli MA, Sousa MH. The challenge of studying maternal near miss in the community: findings of the 2006/07 Brazilian Demographic Health Survey. Artigo a ser submetido a publicação no Journal of Clinical Epidemiology 2008.

Objetivo específico 8:

Artigo 8: Cecatti JG, Souza JP, Parpinelli MA, Sousa MH, Amaral E. Research on severe maternal morbidities and near misses: What we have learned. Reproductive Health Matters 2007; 15(30): 1-10.

3.1. Artigo 1

Revista Panamericana de Salud Pública

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INVESTIGACIÓN ORIGINAL ORIGINAL RESEARCH

Assistência obstétrica e complicações graves gestação na América Latina e Caribe: análise das informações obtidas a partir de inquéritos demográficos de saúde

Obstetric care and severe pregnancy complications in Latin America and the Caribbean: an analysis of information from demographic health surveys

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RESUMO

OBJETIVOS: Compilar, consolidar e analisar as informações obtidas por inquéritos do projeto MEASURE DHS acerca de assistência obstétrica e complicações da gestação na América Latina e Caribe.

MÉTODOS: O presente estudo exploratório incluiu sete inquéritos demográficos realizados na década de 1990 (Bolívia, Brasil, Colômbia, Guatemala, Nicarágua, Peru e República Dominicana). Além do levantamento das características das entrevistadas e da assistência obstétrica recebida, foi estimada a ocorrência de complicações (trabalho de parto prolongado e complicações hemorrágicas, hipertensivas e infecciosas).

RESULTADOS: A mediana do número de visitas de pré-natal oscilou entre 4,7 (Bolívia) e 6,6 (República Dominicana). Na Bolívia, Peru e Guatemala foram observadas altas taxas (>40%) de assistência ao parto por parteiras tradicionais, parentes e outras pessoas sem treinamento formal. República Dominicana e Brasil apresentaram as maiores taxas de parto em estabelecimento de saúde (>90%). Na Guatemala, Peru e Bolívia, mais de 45% dos partos foram domiciliares. A maior taxa de cesárea foi registrada no Brasil (36,4%); as menores taxas foram registradas no Peru e Guatemala (<12%). A taxa de complicações da gestação referidas pelas mulheres foi de 16,7% no Brasil, 17,9% na Guatemala, 42,1% na Colômbia, 42,5% na Nicarágua, 43,0% na República Dominicana, 51,7% na Bolívia e 51,8% no Peru.

CONCLUSÃO: A ocorrência relatada de complicações graves da gestação nos inquéritos avaliados está muito acima da taxa de 15% citada na literatura, podendo ter sido superestimada. A validação prévia dos questionários utilizados para coleta de dados nesse tipo de estudo é extremamente importante para gerar dados mais adequados.

Palavras-chave: Morbidade, complicações na gravidez, inquéritos de morbidade, América Latina, região do Caribe.

ABSTRACT

OBJECTIVE: To compile, consolidate, and analyze information obtained in surveys conducted by the MEASURE DHS [Demographic and Health Surveys] program, concerning obstetric care and pregnancy complications for women in Latin America and the Caribbean, in the five years before the survey.

METHODS: This exploratory study utilized data from demographic surveys carried out in the 1990s in seven countries of Latin America: Bolivia, Brazil, Colombia, the Dominican Republic, Guatemala, Nicaragua, and Peru. The study describes the characteristics of the women who were interviewed and of the obstetric care that they received in the five years before the respective survey, and it also estimates the occurrence of prolonged labor and of hemorrhagic, hypertensive, and infectious complications in those five years.

RESULTS: The median number of prenatal consultations ranged from 4.7 in Bolivia to 6.6 in the Dominican Republic. More than 40% of deliveries in Guatemala, Peru, and Bolivia were attended by traditional midwives, relatives, or other persons without formal training. The highest rates of deliveries performed in health care facilities (> 90%) were in the Dominican Republic and Brazil. In Guatemala, Peru, and Bolivia more than 45% of deliveries were at home. The highest rate of cesarean delivery was in Brazil (36.4%), and the lowest rates (< 12%) were in Peru and Guatemala. The rate of pregnancy complications reported by the women surveyed was 16.7% in Brazil, 17.9% in Guatemala, 42.1% in Colombia, 42.5% in Nicaragua, 43.0% in the Dominican Republic, 51.7% in Bolivia, and 51.8% in Peru. **CONCLUSION:** The reported occurrence of severe pregnancy complications in the surveys we examined was well above the 15% rate reported in other scientific literature, suggesting that these complications may have been overestimated in the MEASURE DHS surveys. Prior validation of the questionnaires used for data collection is extremely important in the generation of high-quality data.

Key words: Morbidity, pregnancy complications, health surveys, Latin America, Caribbean region.

No ano 2000, os estados-membros das Nações Unidas assinaram a Declaração do Milênio, que apresenta, como uma de suas metas, a redução em três quartos da razão de morte materna até 2015. A razão de morte materna, um dos principais indicadores da saúde da mulher, representa o número de mulheres que morrem em decorrência de complicações relacionadas à gestação por 100 000 nascidos vivos. Na América Latina e Caribe, estima-se que ocorram cerca de 22 000 mortes maternas por ano, e a razão de morte materna é estimada em 190 mortes por 100 000 nascidos vivos (1). Para o cumprimento das metas da Declaração do Milênio, foi proposta uma ampla gama de ações, atualmente em diferentes graus de implementação (2). Monitorar o impacto produzido por essas ações é um desafio em si, pois a obtenção de estimativas confiáveis de mortalidade materna é uma tarefa complexa e custosa (3, 4).

Nesse contexto, um grande esforço tem sido realizado para desenvolver e validar outros indicadores da qualidade da saúde materna, como os indicadores de processo e os indicadores indiretos da mortalidade (5). Entre essas abordagens, destaca-se o estudo da morbidade materna grave — por exemplo, os casos de eclâmpsia e hemorragia maciça, entre outros. Essas complicações agudas e graves relacionadas à gestação são mais freqüentes do que o óbito materno, compartilhando muito de seus determinantes. Mais além, as sobreviventes dessas condições (maternal near miss) podem informar diretamente sobre as dificuldades e os obstáculos que tiveram de superar para receber seu tratamento (6–8).

Por outro lado, ainda não foi desenvolvido um sistema de vigilância integrado, com base hospitalar e ampla cobertura geográfica, que monitore a ocorrência de morbidade materna grave. Mesmo nos países com elevadas taxas de institucionalização da atenção ao nascimento, não existe esse tipo de sistema. Nos locais onde a cobertura de serviços é baixa ou variável, e onde a integração de informações hospitalares é ainda incipiente, a realização de inquéritos populacionais pode ser a única maneira de se obter informações populacionais sobre a prevalência de complicações e morbidade materna grave (9).

Nos últimos 15 anos, uma série de estudos demográficos de saúde que abordam (entre outros aspectos) as complicações da gestação e do parto vêm sendo realizados na América Latina e Caribe (10). O programa MEASURE (*Monitoring and Evaluation to Assess and Use Results*, ou seja, monitoramento e avaliação para estimar e usar resultados), da Agência Norte-Americana para Desenvolvimento Internacional (USAID), reúne e disponibiliza esses dados para utilização científica. São inquéritos domiciliares com amostragem geralmente entre 5 000 e 30 000

domicílios, o que confere a eles representatividade nacional. Normalmente, são realizados a cada 5 anos nos países em desenvolvimento. Dessa forma, o presente estudo foi desenvolvido com o objetivo de compilar, consolidar e analisar as informações obtidas por esses inquéritos acerca de assistência obstétrica e complicações da gestação na América Latina e Caribe, de forma a contribuir para a reflexão sobre mortalidade materna nessa região.

MATERIAIS E MÉTODOS

O presente estudo exploratório consiste na análise secundária de inquéritos demográficos realizados na América Latina e Caribe na segunda metade da década de 1990.

Para fins de seleção, o conjunto de bancos de dados do projeto *MEASURE DHS* (10) foi consultado na busca de inquéritos demográficos de saúde realizados no continente americano com informações sobre complicações da gestação e parto. Os inquéritos demográficos que não abordavam temas relacionados com a ocorrência de complicações da gestação não foram incluídos nesta análise. Cada um dos 33 inquéritos inicialmente selecionados foi checado para a presença dos dados de interesse de forma manual e eletrônica.

As complicações estudadas nos inquéritos avaliados foram: trabalho de parto prolongado, complicações hemorrágicas, complicações hipertensivas e complicações infecciosas. Essas são as complicações normalmente avaliadas nos inquéritos demográficos, por serem as principais causas de morte materna nos países em desenvolvimento (9). Os dados sobre complicações foram obtidos diretamente das mulheres entrevistadas através da aplicação de um questionário estruturado e referem-se a gestações ocorridas nos 5 anos que precederam a realização do inquérito.

Foi acessado o inquérito mais recente realizado em cada país, obtendo-se os dados referentes às características das mulheres entrevistadas, da assistência obstétrica e das complicações referidas. A realização de metanálise ou outros procedimentos estatísticos foi considerada inapropriada devido à heterogeneidade entre os estudos e ao fato de que os estudos primários trazem dados oriundos de contextos específicos, com bases populacionais diferentes e estratégia variável de validação dos questionários utilizados. A consulta aos bancos de dados e o manejo das informações obtidas foram realizados através da ferramenta DHS STAT*compiler* e de planilhas geradas pelo *software* Excel.

A presente avaliação, por se tratar de análise secundária de banco de dados de mulheres não identificadas, segue todos os princípios de ética contidos na Declaração de Helsinque, preservando a confidencialidade das fontes de informação.

RESULTADOS

Foram examinados 33 inquéritos demográficos de saúde realizados pelo projeto *MEASURE DHS* na América Latina e Caribe em busca de informações referentes à ocorrência de complicações na gravidez. Desse total, oito estudos apresentavam informações sobre complicações da gestação e parto (11–18). Na Guatemala, no

período analisado, foram realizados dois inquéritos, tendo sido incluído na presente análise apenas o mais recente. Dessa forma, foram analisados sete inquéritos, realizados nos seguintes países: Bolívia, Brasil, Colômbia, Guatemala, Nicarágua, Peru e República Dominicana.

A tabela 1 apresenta as características gerais dos estudos demográficos de saúde incluídos, enquanto que a tabela 2 apresenta as características das mulheres entrevistadas. Observa-se uma alta taxa de resposta das mulheres, de maneira geral acima de 90%, exceto no estudo realizado no Brasil (86,5%) e na Guatemala (89,1%). A média de nascidos vivos foi superior a 3,0 por mulher, exceto no caso do Brasil e Colômbia, onde essa média foi menor (2,7 e 2,8, respectivamente).

TABELA 1. Características dos inquéritos demográficos de saúde por país, América Latina e Caribe, década de 1990

Características (n)	Bolívia, 1998	Brasil, 1996	Colômbia, 1995	República Dominicana, 1996	Guatemala, 1998/1999	Nicarágua, 1997/1998	Peru, 1996
Domicílios amostrados	13 136	16 451	12 142	10 534	6 652	12 783	33 498
Domicílios encontrados	12 281	14 252	11 297	9 026	5 972	11 726	28 805
Mulheres elegíveis	11 831	14 579	12 086	9 034	6 756	14 807	31 241
Mulheres entrevistadas	11 187	12 612	11 140	8 422	6 021	13 634	28 951
Taxa de resposta (%)	94,6	86,5	92,2	93,2	89,1	92,1	92,7
Nascidos vivos últimos 5 anos	6 893	4 782	5 050	4 379	4 545	7 992	15 639

Fonte: MEASURE DHS (10)

TABELA 2. Características das mulheres entrevistadas por paísª, inquéritos demográficos de saúde na América Latina e Caribe, década de 1990

Características (%)	Bolívia, 1998	Brasil, 1996	Colômbia, 1995	República Dominicana, 1996	Guatemala, 1998/1999	Nicarágua, 1997/1998	Peru, 1996
Idade							
15 a 19	22,3	19,5	19,4	21,4	22,1	24.3	21,2
20 a 29	32,8	30,4	33,7	35,4	34,6	33,6	34,0
30 a 39	26.6	28.9	27,2	26,4	25.5	26,1	26,8
40 a 49	18,3	21,1	19,7	16.8	17,7	16,0	17.9
Nascidos vivos (média)	3.7	2,7	2.8	3,0	3,9	3,5	3,4
Filhos vivos na entrevista (no.)	3.2	2,5	2.7	2,7	3,5	3.2	3,1
Situação conjugal							
Nunca foi casada	33,4	30,6	32,2	25,6	26,2	23,6	34.2
Casada	45.0	47,4	29,6	22,8	40.2	26.0	34.3
Mora junto	14,4	12,7	25,1	36,4	25,6	33.0	24,0
Vlúva	1,4	1,6	1,4	0,7	1,5	1,0	1,1
Divorciada	1,0	1,0	0.1	2,1	0.2	0.7	0,2
Não mora junto	4.7	6,7	11,5	12,5	6,3	15,7	6,1
Educação	22/50	32570	10/2/68		0000	80880	
Sem educação	8,1	5,2	3.8	7,0	25,3	15,5	6,2
Fundamental	34,3	32,9	36.5	49,4	49,3	40,4	29,3
Secundário/ superior	57,5	61,9	59,7	43,6	25,4	44,0	64,5
Estuda atualmente	20,5	19,7	17,7	21,0	9,8	15,5	17,3
Não trabalhou no ano anterior	41,6	38,6	40,5	49,5	62,2	55,6	38,2
Domicílio	10.00	550050	100000				1349013
Urbano	71.5	82,0	74.6	66,6	45.0	64,9	73,5
Aural	28,5	18,0	25,4	33,4	55,0	35,1	26.5

Fonte: MEASURE DHS (10).

Bilivia: n = 11 187; Brasil: n = 12 612; Colòmbia: n = 11 140; Guatemala: n = 6 021; Nicarágua: n = 13 634; Peru: n = 28 951; República Dominicana: n = 8 422.

As características da assistência obstétrica nos 5 anos que precederam os estudos são descritas na tabela 3. A mediana do número de visitas de pré-natal oscilou entre 4,7 e 6,6, sendo menor na Bolívia e maior na República Dominicana e no Brasil. A mediana do número de meses de gestação no momento da primeira visita de pré-natal ficou ao redor de 3,0. A assistência pré-natal esteve a cargo principalmente de profissionais médicos na Bolívia, Brasil e Colômbia, enquanto que na República Dominicana e Nicarágua esse papel esteve preponderantemente a cargo de outros profissionais de saúde. Excetuando-se a Guatemala, o papel desempenhado pelas parteiras foi pouco expressivo.

TABELA 3. Características da assistência obstétrica nas gestações que resultaram em nascidos vivosª nos 5 anos que precederam o inquérito, América Latina e Caribe, década de 1990

	República						
Características	Bolívia, 1998	Brasil, 1996	Colômbia, 1995	Dominicana, 1996	Guatemala, 1998/1999	Nicarágua, 1997/1998	Peru, 1996
Número de consultas de pré-natal	100,110,00	11000		222.2	2000		1000
(mediana)	4,7	6,4	5,8	6,6	5,4	5,1	5,1
Meses de gestação na primeira							
consulta (mediana)	3,4	2,9	3,0	2,9	3,7	3,2	3,4
Principal responsável pela							
assistência pré-natal (%)							
Médico	59,4	81,4	79,6	42,8	47,4	38,4	31,7
Outro profissional saúde	5,7	4,2	3,0	55,5	12,2	43,1	35,6
Parteira tradicional	0.4	0,1	0,2	0,0	26,0	0,9	1,5
Outro	0,1	0,0	0,1	0,2	0,8	0,1	0,3
Não recebeu cuidado	33,9	13,2	16,8	1,5	13,2	16,4	30,7
Ignorado	0,5	1,1	0,4	0,0	0,5	1,1	0,3
Local de nascimento (%)	20						
Unidade de saúde	53,2	91.5	76,8	95,3	40.4	63.6	49.6
Em casa	46.0	7.0	22.6	3,6	59.0	34,8	48,3
Outro	0.4	0,2	0.4	1.0	0.0	0,4	2,0
Ignorado	0.4	1,2	0,2	0,1	0,5	1,2	0,1
Principal responsável pela	807.0			76574			
assistência ao parto (%)							
Médico	52,9	77.6	73.8	91,7	36.8	36.7	32.2
Outro profissional saúde	3,8	10,0	10,8	3,6	3,7	27,9	24.2
Parteira tradicional	7,4	9,4	8.5	3,1	50,0	24,6	23,6
Parente ou outro	34,3	1,2	5.4	1,3	7,3	7,3	18,6
Ninguém	1,3	0.7	1,2	0,3	1,4	2,1	1,4
Ignorado	0.4	1,1	0.3	0,0	0.7	1,4	0.1
Parto cesáreo (%)	13,7	36,4	16,9	25,9	10,8	15,4	8,7
Baixo peso ao nascer ^b (%)	4.3	8,1	4.5	12,4	9,3	8,6	5,8

Fonte: MEASURE DHS (10).

a Nascidos vivos nos últimos 5 anos: Bolívia = 6 893; Brasil = 4 782; Colômbia = 5 050; Guatemala = 4 545; Nicarágua = 7 992; Peru = 15 639; República Dominicana = 4 379.

b Referido pela mulher; peso ao nascer < 2 500 g.

Uma parcela importante de mulheres não recebeu atenção pré-natal, principalmente na Bolívia e Peru (>30%). A menor taxa de ausência de assistência pré-natal foi registrada na República Dominicana (1,5%). Na Bolívia, Guatemala e Peru foram observadas altas taxas—41,7, 57,3 e 42,4%, respectivamente—de assistência ao parto por pessoas sem treinamento formal (parteiras tradicionais, parentes e outros). Na República Dominicana, Brasil e Colômbia, foram observadas altas taxas de assistência ao parto prestada por médicos. República Dominicana e Brasil apresentaram as maiores taxas de parto em estabelecimentos de saúde, enquanto que uma elevada porcentagem de partos domiciliares foi observada na Guatemala, Peru e Bolívia. A maior taxa de parto cesáreo foi observada no Brasil (36,4%), enquanto que as menores taxas foram observadas na Guatemala e Peru (10,8 e 8,7%). Bolívia e Colômbia apresentaram as menores taxas de baixo peso ao nascer (4,3 e 4,5%), enquanto que a República Dominicana apresentou a maior taxa (12,4%).

Brasil e Guatemala apresentaram as menores taxas de complicações referidas pelas mulheres, respectivamente 16,7 e 17,9%. Por outro lado, Bolívia e Peru apresentaram as taxas mais elevadas, respectivamente 51,7 e 51,8%. Para os outros países, as taxas de complicações referidas pelas mulheres foram as seguintes: Colômbia, 42,1%; Nicarágua, 42,5%; e República Dominicana, 43,0%.

A tabela 4 apresenta a distribuição das complicações citadas pelas mulheres para os partos ocorridos até 5 anos antes do inquérito. A porcentagem de trabalho de parto prolongado foi muito elevada na Bolívia (41,0%) e no Peru (34,6%). À exceção de Brasil e Guatemala, foram observadas taxas elevadas de sangramento excessivo

nos demais países. A porcentagem de convulsões referidas foi relativamente alta, principalmente nos estudos realizados na Bolívia (8,7%) e Peru (7,4%). De modo geral, dentre os países avaliados, Brasil e Guatemala apresentaram os valores globalmente mais baixos para todas as complicações referidas pelas mulheres entrevistadas.

TABELA 4. Porcentagem de complicações em gestações que resultaram em nascidos vivosª nos 5 anos que precederam o inquérito, América Latina e Caribe, década de 1990

Complicações ^b	Bolívia, 1998	Brasil, 1996	Colômbia, 1995	República Dominicana, 1996	Guatemala, 1998/1999	Nicarágua, 1997/1998	Peru, 1996
Trabalho de parto prolongado	41,0	10,3	26,6	25,9	11,3	27,5	34,6
Sangramento excessivo	22,3	5,4	25,7	25,1	7,4	28,3	34,6
Infecção vaginal	15,3	3,7	4,9	6,1	3,9	7,7	12,2
Convulsões	8,7	2,7	2,1	5,2	1,7	3,3	7,4
Nenhuma	48,3	83,3	57,9	57,0	82,1	57,5	48,2

Fonte: MEASURE DHS (10).

DISCUSSÃO

A análise dos dados de sete inquéritos demográficos de saúde realizados na América Latina e Caribe revelou uma taxa elevada de morbidade materna referida que, na maioria dos países estudados, foi superior a 40%. Em contraposição a esse achado, acredita-se que em torno de 15% das gestantes possam desenvolver complicações obstétricas de alguma gravidade, necessitando atendimento hospitalar (3,5). Dentre os inquéritos analisados, apenas dois relataram uma taxa próxima ao esperado (Brasil 16,7% e Guatemala 17,9%). As porcentagens demasiadamente elevadas de complicações referidas pelas mulheres nos demais estudos demográficos realizados na América Latina e Caribe sugerem que pode ter havido uma supervalorização de problemas menores. Embora os inquéritos demográficos de saúde sejam desenvolvidos dentro de uma sistemática bem estabelecida (10), a estratégia de validação dos questionários utilizados não é ainda uniforme. Por outro lado, na literatura podem ser identificados estudos de validação de questionários de morbidade materna grave com resultados conflitantes, sendo ainda incerta a evidência sobre quão acurada é a história de gestação e parto contada pelas mulheres (19,20).

Os inquéritos demográficos de saúde têm no viés de recordação uma característica implícita, uma vez que buscam identificar eventos ocorridos num período relativamente longo, em torno de 5 anos. Além desse viés, outros fatores podem influenciar a sua acurácia, como os aspectos sociais e culturais que adicionam complexidade ao processo saúde-doença e sua percepção. No caso de distocias associadas ao trabalho de parto prolongado, limiares dolorosos diferenciados individualizam a experiência temporal, alongando ou diminuindo a sua percepção. Os questionários também transferem, pelo menos em parte, a responsabilidade diagnóstica para o respondente, fato que pode elevar a freqüência de diagnósticos impróprios. No caso das convulsões, desmaios, calafrios e outros tremores podem ser confundidos, o que ajudaria a explicar uma porcentagem de convulsões referidas tão alta quanto 8,7% (11). De maneira análoga, os sinais e sintomas compatíveis com infecções do trato reprodutivo (febre, dor e corrimento fétido, entre outros) e mesmo de hemorragia (como sangramento abundante, fraqueza, desmaios) podem ser confundidos com outros quadros que ocorrem comumente no puerpério.

a Nascidos vivos nos últimos 5 anos: Bolívia = 6 893; Brasil = 4 782; Colômbia = 5 050; Guaternala = 4 545; Nicarágua = 7 992; Peru = 15 639; República Dominicana = 4 379.

b Algumas mulheres referiram a ocorrência de mais de uma complicação

Em demografia, a teoria da transição demográfica descreve a redução das taxas de natalidade e de mortalidade como parte do desenvolvimento socioeconômico de um país (21). Os achados do presente estudo ilustram o intrincado relacionamento existente entre as condições sociodemográficas e as condições para assistência à mulher durante a gestação e o parto. Assim, foi possível o reconhecimento de dois padrões sociodemográficos distintos e opostos de populações femininas: o primeiro é caracterizado por uma transição demográfica mais adiantada, com mulheres de maior idade, menor fertilidade, maior educação, maior atividade econômica e maior urbanização. O outro padrão caracteriza-se pelo inverso: maior fertilidade, menor educação, menor atividade econômica e menor urbanização. Quando as condições de assistência obstétrica são analisadas sob a perspectiva sociodemográfica, observa-se que, nos países onde a transição demográfica é mais evidente (por exemplo, Brasil), a assistência obstétrica caracteriza-se por ser institucionalizada, com atenção pré-natal de início mais precoce e assistência pré-natal e ao parto, essencialmente providas por profissionais de saúde.

Por outro lado, nos países em que os sinais de transição demográfica são menos evidentes (por exemplo, Guatemala), a assistência obstétrica é menos profissionalizada e menos institucionalizada. Há ainda expressiva porcentagem de mulheres que recebe assistência pré-natal e ao parto de parteiras tradicionais ou outras pessoas não qualificadas, além de um início mais tardio do pré-natal. Esses achados, que sugerem o compartilhamento de determinantes entre a transição demográfica e a assistência obstétrica mais qualificada, reforçam a necessidade de ações que ultrapassam em muito o campo estrito da saúde para a efetiva melhora das condições de saúde materna.

Concluindo, observamos padrões de assistência obstétrica que refletem o grau de desenvolvimento socioeconômico e de transição demográfica. Ademais, os achados do presente estudo sugerem que os inquéritos demográficos de saúde avaliados podem estar superestimando a ocorrência de complicações da gestação, e é possível que tais inquéritos não representem a real ocorrência de graves complicações maternas associadas à gestação e ao parto. Entre outros, existe uma subrepresentação das complicações ocorridas mais precocemente na gestação e daquelas relacionadas a abortamento e que resultaram em óbito fetal. Para um aproveitamento mais adequado das informações colhidas, sugere-se que os questionários de morbidade materna usados nos próximos inquéritos demográficos sejam previamente validados e, se necessário, que sejam desenvolvidos fatores de correção para ajuste das estimativas obtidas.

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3.2. Artigo 2

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ARTIGO ORIGINAL

Self-reported maternal morbidity and associated factors among Brazilian women

Morbidade materna auto-referida e fatores associados entre mulheres brasileiras

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SUMMARY

PURPOSE: Demographic health surveys may constitute a valuable source of information on maternal morbidity, particularly in locations where an integrated system of epidemiological surveillance with wide geographic coverage has not yet been developed.

METHODS: This study analyzed the database obtained from a national Demographic Health Survey carried out in Brasil in 1996. Data regarding how the survey was conducted, characteristics of the women interviewed who had given birth to live infants in the five preceding years, characteristics of the obstetrical care received and complications reported were evaluated.

RESULTS: Responses from a weighted total of 3,635 women were analyzed. Statistically significant differences (p<0.001) were found between geographic domains for most characteristics studied. Deliveries were predominantly hospitalbased throughout the whole country. Prevalence of self-reported maternal morbidity ranged from 15.5-22.9% in the various geographic domains analyzed. This geographic factor was found to be associated to differences in the occurrence of complications, generally and specifically, for cases of prolonged labour.

CONCLUSION: Differences in morbidity may reflect the intricate relationship between determinants of human development and maternal health conditions.

Key words: Maternal morbidity. Near miss. Demographic health survey. Brasil.

RESUMO

OBJETIVOS: Os estudos demográficos de saúde podem constituir fonte valiosa de informação sobre a morbidade materna, especialmente nos locais onde ainda não foi desenvolvido um sistema de vigilância epidemiológica integrado e de ampla cobertura geográfica.

MÉTODOS: Este estudo consiste na análise secundária do banco de dados da última Pesquisa Nacional sobre Demografia e Saúde, realizada no Brasil, em 1996. Foram analisados os dados referentes à operacionalização da pesquisa, as características das mulheres entrevistadas que tiveram gestações resultantes em nascidos vivos nos cinco anos precedentes ao inquérito, as características da assistência obstétrica e das complicações referidas por estas mulheres. RESULTADOS: As respostas de um total ponderado de 3.635 mulheres foram analisadas. Foram observadas diferenças significativas (p<0,001) entre os domínios geográficos para a major parte das características estudadas. A assistência ao parto foi predominantemente hospitalar em todo o país. A prevalência de morbidade materna referida oscilou entre 15,5% e 22,9% nos diferentes domínios geográficos analisados. Este fator geográfico esteve associado a diferenças de risco para a ocorrência de complicações em geral e, mais especificamente, para a ocorrência de trabalho de parto prolongado.

CONCLUSÃO: Estas diferenças em morbidade possivelmente refletem o intrincado relacionamento existente entre as determinantes do desenvolvimento humano e as condições de saúde materna.

Unitermos: Morbidade materna. Near miss. Inquérito demográfico de Saúde. Brasil.

INTRODUCTION

Annually, an estimated 529,000 women lose their lives due to causes related to pregnancy and childbirth, worldwide and approximately 10 million women suffer from complications during pregnancy¹. Although there is some controversy related to Brazilian statistics on maternal mortality, around 73 deaths for every 100,000 live births are believed to occur²; however, even fewer data are available on the situation of maternal morbidity.

One of the Millennium Development Goals adopted by the United Nations Member States was reduction of the worldwide maternal death ratio by three-quarters by the year 2015³, however, current trends indicate that this reduction is not likely to be achieved^{1,3}. In Brasil also, official statistics on maternal mortality have tended to remain stagnant for some years². The Brazilian government and the international community therefore need to maximize efforts to improve maternal health indexes and thereby avoid a greater number of fatalities in the country⁴.

Data collected on severe maternal morbidity has been considered potentially useful for the improvement of obstetric care, principally by enabling planners and health service administrators to set priorities^{5, 6}. However, in Brasil, the magnitude and the characteristics of severe maternal morbidity have only recently begun to receive more specific attention, albeit the potential of this subject as basis for the development of public policies remains to be evaluated. Therefore, demographic health surveys may be a valuable source of information on maternal morbidity, particularly in locations where integrated epidemiological surveillance with wide geographical coverage is yet to be established⁷.

Data from the most recent national demographic health survey (DHS), carried out in Brasil in 1996, raised the issue of maternal morbidity and investigated complications during deliveries that had occurred in the preceding five years as reported by the women interviewed ⁸. However, little seems to have been done with the data, because the concept of severe maternal morbidity as an alternative or complement to the study of maternal mortality was not well-established at that time. The present study was developed to evaluate the information from the DHS-96 on occurrence of severe maternal morbidity caused by complications during delivery or in the puerperium, and factors that may have been associated with these complications.

METHODS

This study analyzed a database from the most recent national demographic health survey, which is a sub-sample of a national survey carried out in a randomized sample of household in Brasil, in 1995. The "MEASURE DHS" project combines various databases resulting from demographic and health surveys carried out throughout the world⁸. Specific authorization to use the DHS-96 data was obtained from Macro International. The original survey was conducted using procedures in accordance with the ethical standards of the Helsinki Declaration and had been previously approved by the corresponding committee.

In the DHS-96, sampling strategy involved geographical strata consolidated in two stages, and data weighting (the inverse of the unit's probability of selection) to guarantee that the sample was representative of the country as a whole. The census sector constituted the primary sample unit (PSU) and the geographical domains corresponded to the seven regions of the survey: São Paulo, Rio de Janeiro, the East-Central (states of Minas Gerais and Espirito Santo), the South, Midwest, North and Northeast of Brasil⁹.

In accordance with the objectives of this study, the unit of analysis was pregnancy resulting in a live birth. Therefore, data processing with respect to live births in the five years preceding the survey consisted of selecting equivalent sets of variables corresponding to each infant born alive during the period (limited to 6 live births per woman interviewed), based on the database of women (mothers). Following this selection and considering the unit of analysis of interest, a new database was constructed with information on all live born infants and respective pregnancies.

Data on study methods, characteristics of the women interviewed whose pregnancies resulted in live births in the five preceding years, characteristics of the obstetric care and complications reported, were analyzed. Data obtained were presented in tables according to the set of characteristics and geographic regions of Brasil. For statistical analysis of data, the chi-squared test was used for comparisons between proportions, and 95% confidence intervals were constructed for comparison between the means, taking the peculiarities of the complex sampling

design of DHS into consideration (geographical stratum, primary sample unit and sampling weight). For the analysis of some variables for which much data was missing, geographical strata with fewer than two primary sample units were regrouped.

Finally, associations between some characteristics of the women and obstetric care they received and reported morbidities were analyzed, using multiple logistic regression analysis, taking the sampling plan into consideration and regrouping strata with only one PSU (due to missing data in the case of some variables or to the selection of cases of liveborn infants). Five multiple logistic regression models were used, in each case the dependent variable being the complications or the morbidities investigated: prolonged labour, excessive bleeding, high fever, convulsion or any combination of these complications. For all models, the predictive variables available in the database and used in this study were: geographical region of residence, age of the woman at time of childbirth, place of residence (urban/rural), number of living children, religion, ethnic group, health professional responsible for prenatal care, place of delivery, health professional responsible for delivery and the type of delivery. The software used for processing and analyzing data was the SPSS software program, version 11.5, and the Strata software program, version 7.0.

RESULTS

In the DHS carried out in Brasil in 1996, a total of 16,451 households were selected for visits, and 12,612 women were interviewed. Of these, 3,761 women had had at least one pregnancy resulting in a liveborn infant in the five preceding years, adding to 5,045 live born infants (2,690 women had only one; 882 had two; 166 had three; 22 had four; and one woman had five). The mechanism of data weighting adopted by the DHS resulted in a weighted total of 3,635 women with at least one pregnancy resulting in a livebirth and 4,782 liveborn infants. Considering the geographical domains adopted the response rate of the women interviewed in relation to the eligible women ranged from 76.4-93.6%, which was lower in the state of Rio de Janeiro and higher in the North (Table 1).

Table 1 also shows the general characteristics of women interviewed who had a liveborn infant in the five preceding years, according to the geographical domain studied. Statistically significant differences (p<0.001) were found between geographical domains for most characteristics studied, notably the lower education level of women interviewed in the Northeast compared to a predomination of women with some high school or university education in the South and in the states of Rio de Janeiro and São Paulo. In general, women interviewed came from urban areas. This proportion was particularly high in the North and in the states of Rio de Janeiro and São Paulo. The mean number of living children per woman was 2.4 (95%CI 2.4-2.5), and was lower in the states of São Paulo and Rio de Janeiro and in the Midwest, and higher in the Northeast (2.8; 95%CI 2.7-2.9). Body mass index, based on information reported by the women, was higher in the state of São Paulo and lower in the North and Northeast of the country. With relation to ethnic group, more women declared themselves to be Caucasian in the South and Southeast.

Table I - Percentage of women with at least one liveborn child in the five years preceding the survey# according to sociodemographic characteristics, mean BMI and number of liveborn children at the time of the interview, by region of the country

Characteristics of the women				Regio	on			
ē	São Paulo	Rio de Janeiro	Central-east	South	North-east	North	Central-west	Total
Women Interviewed	1,355	800	1,368	1,571	4,774	1,340	1,407	12,612
Response rate (%)	78.8	76.4	86.4	86.9	89.4	93.6	85.3	86.5
Liveborn infants born in the preceding 5 years (weighted number)	904	359	572	703	1,647	256	341	4,782
Age at interview (years)*								
15-19	9.0	10.3	6.9	8.0	11.1	14.9	8.3	9.6
20-29	53.3	40.7	48.9	46.2	52.5	56.0	62.0	51.1
30-39	34.2	41.2	37.8	37.0	30.5	23.5	26.4	33.3
40-49	3.6	7.7	6.4	8.8	5.9	5.6	3.3	5.9
Education level*								
None	1.9	2.1	3.9	1.7	12.6	5.7	5.0	5.9
Primary	28.1	23.7	48.0	34.7	44.9	32.0	33.0	37.0
High school	61.7	66.0	43.1	57.4	40.7	58.4	57.3	52.1
University	8.2	8.2	5.0	6.2	1.8	3.9	4.7	5.0
Still in education*	3.8	7.2	3.7	6.5	5.4	16.4	8.4	6.0
Marital status*			10,000			132.5	0.400)	11.3.4.
Single	7.4	6.2	7.9	5.6	6.4	13.7	8.6	7.1
Married	65.0	53.6	70.6	72.3	52.2	47.9	66.4	61.2
Stable union	18.9	33.0	13.2	14.0	30.6	27.2	15.5	22.4
Widowed	0.0	1.0	0.9	1.2	0.6	0.4	0.3	0.6
Separated / divorced	8.7	6.2	7.4	6.9	10.3	10.8	9.3	8.7
Ethnic group(a)*								
White	53.8	39.2	40.0	61.0	23.9	15.4	41.2	39.9
Non-white	46.2	60.8	60.0	39.0	76.1	84.6	58.8	60.1
Religion*								
None	6.8	11.3	3.2	4.4	6.8	3.8	5.3	6.1
Catholic	73.8	64.4	76.9	80.2	83.7	82.8	70.6	77.8
Spiritualist	3.6	3.6	1.3	1.8	0.4	0.0	3.4	1.8
Evangelical	14.2	14.4	16.0	10.0	7.5	12.5	19.9	12.0
Other	1.6	6.2	2.6	3.6	1.5	0.9	0.8	2.3
Has not worked in the previous 12 months (b) +	44.7	44.6	33.1	38.9	36.0	31.5	38.0	38.7
Residence*								
Urban	90.2	92.8	82.3	74.3	62.7	92.6	78.5	77.5
Mean BMI (kg/m²)(c)	25.0	23.9	24.7	24.8	23.6	23.2	23.8	24.2
95% CI	24.4-25.6	23.3-24.5	23.9-25.5	24.3-25.2	23.3-23.9	22.7-23.7	23.3-24.4	[24.0-24.4
Mean number of liveborn children	2.1	2.2	2.6	2.3	2.8	2.6	2.1	2.4
95% CI	1.9-2.2	1.9-2.5	2.4-2.8	2.1-2.4	2.7-2.9	2.3-2.9	2.0-2.2	[2.4-2.5]
(Weighted total)	(724)	(293)	(433)	(588)	(1,137)	(186)	(274)	(3,635)
(Total number of women)	(366)	(194)	(379)	(430)	(1,566)	(399)	(427)	(3,761)

[#]Strata with fewer than two PSU were re-grouped /*p<0.001: +p<0.02 (chi-squared test based on complex sampling design) / Data missing for: (a) 5 women; (b) 632 women; (c) 308 women.

Table 2 shows the characteristics of the obstetric care received during each pregnancy and prevalence of self-reported maternal morbidity. The mean number of prenatal visits by the women interviewed was lowest in the North and Northeast. In these regions, participation of physicians in prenatal care and at delivery was also lowest, being predominantly carried out by nursing professionals. Care during delivery was predominantly hospital-based throughout the country; however, lower rates of hospital-based care were found in the North and Northeast where caesarean section was also less frequent. Delivery by traditional midwives was practically an exception in most of the geographical domains studied; but it was more common in the North and Northeast. Regarding prevalence of self-reported maternal morbidity, no statistically significant differences were found between the geographical domains. From 15.5 to 22.9% of women reported at least one complication in their pregnancies. The most commonly reported was prolonged labour (7.4-14.9%), while convulsion was the least reported (1.7-4.5%).

Table 2 - Mean number of prenatal visits and percentage of liveborn infants # in the five years preceding the survey according to the characteristics of obstetrical care and complications related to pregnancy, by geographical region of Brasil

		Region									
Characteristic	São Paulo	Rio de Janeiro	Central-east	South	North-east	North	Central-west	Total			
Mean number of	7.6	7.8	6.6	7.6	4.4	4.8	6.8	6.2			
prenatal visits [95%CI]	[7.2-8.0]	[7.2-8.4]	[6.0-7.1]	[7.2-8.0]	[4.1-4.6]	[4.3-5.3]	[6.3-7.3]	[6.0-6.3]			
Professional responsible for prena	tal care										
Physician*	92.8	94.5	88.4	91.6	65.8	68.2	89.8	81.4			
Nurse or auxiliary nurse*	0.4	0.4	2.1	2.0	7.9	12.8	2.0	4.2			
Midwife*	0.0	0.0	0.0	0.0	0.2	0.4	0.0	1.0			
Noprenatal care*	5.5	3.8	8.6	5.0	25.2	17.1	7.0	13.2			
Did not answer	1.3	1.3	0.8	1.4	0.9	1.5	1.2	1.1			
Place of delivery											
Hospital \$*	98.2	96.2	95.1	97.4	83.4	81.9	97.1	91.5			
Home*	0.4	1.7	3.7	1.2	15.2	15.3	1.7	7.0			
Other•	0.0	0.8	0.1	0.0	0.4	0.5	0.0	0.2			
Does not know/did not respond	1.3	1.3	1.1	1.4	1.0	2.3	1.2	1.3			
Principal person responsible for de	elivery										
Physician*	93.4	95.0	89.4	87.6	57.4	55.1	92.0	77.6			
Nurse/auxiliary nurse*	3.1	1.3	5.4	5.6	18.9	19.9	4.4	10.0			
Midwife*	1.8	0.4	2.4	5.1	19.7	20.3	1.3	9.4			
Relatives / others	0.7	1.7	0.6	0.4	2.0	2.3	0.3	1.2			
No-one•	0.0	0.8	1.5	0.0	1,1	1.0	0.4	0.7			
Did not answer	1.1	0.8	0.7	1.4	0.9	1.4	1.6	1.1			
Cesarean section*	52.1	43.3	41.0	44.6	20.4	25.5	49.1	36.4			
Low birthweight @	8.3	9.7	9.4	7.6	7.4	7.4	9.1	8.1			
Complications related to pregnancy											
Prolonged labour @	7.4	10.1	11.5	9.0	11.0	14.9	11.7	10.3			
Excessive bleeding @	3.5	7.1	6.4	5.8	5.2	6.5	6.5	5.4			
High fever @	3.5	2.9	4.0	4.3	3.1	4.6	4.8	3.7			
Convulsions @	3.1	2.1	4.2	1.7	2.2	2,1	4.5	2.7			
No complications @	84.5	81.9	82.2	81.8	82.4	77.1	78.1	82.1			
(Weighted total)	(904)	(359)	(572)	(703)	(1.647)	(256)	(341)	(4,782)			
(Total number of liveborn infants)	(457)	(238)	(498)	(513)	(2.248)	(551)	(540)	(5.045)			

[#]Some strata had fewer than two PSU and were regrouped /*p<0.001 (chi-squared test based on complex sampling design) / • Chi-squared test invalid /@ P-value not significant /\$ Includes public and private hospitals, maternity homes and healthcare centres.

Table 3 shows results of the multiple logistic regression analyses. Associations were found among various factors with respect to maternal morbidities. Notably, in comparison with the state of São Paulo, some geographical regions were associated to a greater risk of occurrence of prolonged labour (East-Central, Northeast, North and Midwest regions) and complications in general (North and East-Central regions). Obstetric care provided by non-medical personnel was found to be associated with pregnancies in which fewer complications were reported, while hospital delivery tended to be associated with excessive bleeding. A larger number of liveborn infants was associated with a greater risk of complications, in general excessive bleeding and high fever. Caesarean delivery was associated with a greater risk of high fever. None of the factors tested was associated with occurrence of convulsions (a proxy to eclampsia).

		ed with various complic logistic regression anal		
Complication/	Estimated	Standard error of	Estimated	95%CI for
Associated variables	Coefficient	coefficient	odds ratio	Odds Ratio
Prolonged labour[n=4,971]				
Region of residence (vs. São Paulo):				
- Rio de Janeiro	0.33	0.30	1.40	0.77-2.53
- Central-east	0.49	0.24	1.63	1.02-2.61
- South	0.22	0.25	1.24	0.76-2.04
- Northeast	0.55	0.21	1.74	1.14-2.65
- North	0.92	0.25	2.50	1.52-4.12
- Central-west	0.50	0.26	1.66	1.01-2.73
Responsible for delivery (vs. physician):				
- Nurse or auxiliary nurse	-0.42	0.18	0.66	0.46-0.93
- Midwife	-0.36	0.18	0.70	0.50-0.99
- Relatives / others	-1.22	0.69	0.30	0.08-1.15
- No-one	-0.93	0.79	0.39	0.08-1.85
Constant	-2.48	0.20		
Excessive bleeding[n=4,972]				
Number of living children (>2)	0.42	0.15	1.52	1.13-2.06
Place of delivery (hospital)	0.83	0.29	2.28	1.28-4.06
Colour/race (coloured vs. white)	0.04	0.16	1.04	0.76-1.42
Colour/race (other vs. white)	0.54	0.27	1.72	1.02-2.91
Constant	-3.84	0.33	580E00	A CONTRACTOR
High fever[n=4,970]				
Age of mother at delivery of liveborn infant (years)	-0.04	0.02	0.96	0.93-0.99
Number of living children (>2)	0.43	0.19	1.54	1.07-2.21
Caesarean section	0.53	0.20	1.71	1.14-2.55
Constant	-2.69	0.39	1.71	1.14-2.55
	-2.07	0.37		
Convulsion [n=4.968]				
With no associated variables	_	-	-	_
General complications [n=4,966]				
Region of residence (vs. São Paulo):				
- Rio de Janeiro	0.22	0.23	1.25	0.79-1.98
- Central-east	0.18	0.19	1.20	0.83-1.74
- South	0.23	0.20	1.26	0.85-1.87
- Northeast	0.34	0.18	1.41	0.99-2.01
- North	0.69	0.21	2.00	1.33-3.00
- Central-west	0.45	0.21	1.56	1.04-2.34
Number of living children (>2)	0.28	0.09	1.33	1.10-1.60
Person responsible for delivery (vs. physician):				
- Nurse or auxiliary nurse	-0.41	0.15	0.66	0.49-0.90
- Midwife	-0.57	0.15	0.57	0.42-0.75
- Relatives/others	-1.60	0.59	0.20	0.06-0.65
- No-one	-1.31	0.69	0.27	0.07-1.04
Constant	-1.86	0.17		

DISCUSSION

There is little information available on the prevalence of severe maternal morbidity in Brasil and data on determinants and associated factors are even sparser. Information available in Brasil originates from hospital-based cross-sectional studies and from an indirect analysis based on data from the Brazilian System of Hospital Information¹⁰. These studies were more directed towards clinical aspects and biomedical risk factors, while socioeconomic and behavioural aspects associated with severe maternal morbidity have rarely been investigated. To a certain extent, these facts have restricted discussions on the subject to the biomedical field, without permitting adequate consideration of other aspects involved in the evaluation of maternal morbidity and adequate ways to combat the problem.

Data used in the present study were obtained from the most recent population-based survey carried out in Brasil a decade ago. Considering the structure of the Brazilian healthcare system, this would seem to be a useful alternative for an initial evaluation of the problems related to severe maternal morbidity. Other investigators have already found that one of the principal problems associated with use of data obtained from health surveys is the often unsatisfactory correlation between reported symptoms or diagnoses and medical diagnoses^{7, 11}. Nevertheless, it should be considered that in most cases the initial reason for seeking health services is the subjective perception by the patient him/herself of signs and symptoms understood as abnormal or suggestive of possible health problems. Therefore, use of data reported by the patients may be useful in organizing health services based on the potential demand in relation to obstetric complications⁷.

Considering the information reported by the women, prevalence of maternal morbidity seems to vary from 15.5% to 22.9% in the different geographical domains analyzed and this geographic factor was associated with differences in the risk for occurrence of complications in general and, more specifically, of prolonged labour.

Brasil is a country where great social contrasts prevail and where there are great differences in terms of human development between the macro-regions of the country. In general, lower indexes of human development are found in the North and Northeast, with higher indexes in the states of São Paulo and Rio de Janeiro and the South¹². The association found between the geographical factor and occurrence of complications in general, and with prolonged labour in particular, may be related with differences in human development that exist between the different geographical domains, reflecting differences in obstetric care, as well as other sociocultural and economic factors that interfere in the health-disease process. In this study, poorer indicators of obstetric care were found in the regions with lower human development indexes.

In Brasil, physicians are the principal professionals responsible for identifying and managing complications related to pregnancy, childbirth and the puerperium. This may be the reason why the obstetric care provided by these professionals is associated, in this study, with the care provided to women who reported obstetrical complications. On the other hand, in regions where obstetric care is usually provided by other professionals, it may be that in most pregnancies and deliveries with no complications, physicians were not requested to attend.

This study is the first to evaluate data on severe maternal morbidity during and following delivery in Brasil. Some regional differences were found in the prevalence

rates of reported maternal morbidities and these differences may reflect the intricate relationship between determinants of human development and maternal health conditions. Further in-depth studies on this subject, including a new population-based survey, preferably carried out using a validated questionnaire specifically developed for this purpose, are required before this issue can be fully understood. Results of this study will permit an evaluative comparison of the issue over time, and will also allow for a better evaluation of regional differences in the prevalence of reported maternal morbidity and its determinants, when further studies have been performed. Although the operational and financial complexity would be a limiting factor, a prospective cohort study should also be carried out to obtain more data on the determinants of maternal morbidity. This information would be useful for the development of strategies to deal with the problem and is a challenge for the future.

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Conflict of interest: none

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3.3. Artigo 3

Original Article

Population surveys using validated questionnaires provided useful information on the prevalence of maternal morbidities

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Abstract

Objectives

To evaluate the ability of population surveys to estimate the occurrence of maternal morbidities.

Study Design and Setting

A literature search was conducted using MEDLINE, EMBASE, POPLINE references from relevant papers and proceedings of scientific meetings. No restrictions were made regarding language, date, design, journal, or country. Potentially relevant papers were independently evaluated by two reviewers. Eligible studies were critically evaluated, particularly with respect to complications: eclampsia and other hypertensive complications, hemorrhages, dystocias, and infections. The questions with the highest combined values for sensitivity and specificity were identified in each study.

Results

Seven hospital-based studies involving 2,907 women were included. The gold standard was the clinical records, and the validation strategy consisted of applying questionnaires and comparing them with the gold standard. Questions regarding eclampsia and other hypertensive complications performed satisfactorily in four studies; questions on dystocia and infection in two studies each, and questions regarding hemorrhagic complications in only one study. In general, when the actual prevalence of the condition is low (\leq 5%), surveys tend to overestimate prevalence.

Conclusions

Prior validation of questionnaires on maternal morbidity is fundamental to assure adequate information. Population surveys using validated questionnaires may provide useful information on the prevalence of maternal morbidities.

Keywords: Maternal morbidity; Near miss; Maternal complications; Demographic health survey; Systematic review; Epidemiology.

What is new?

- This is the first attempt to summarize findings from several validation studies on obstetric complications in developing countries.
- Eclampsia and other hypertensive complications were recorded satisfactorily in four of seven studies; dystocia and infection in two studies each, hemorrhagic complications in only one study.
- When the actual prevalence of the condition is low (\leq 5%), surveys often overestimate prevalence.

1. Background

Complications that require medical attention and are a potential threat to the mother's life are estimated to occur in around 15% of all pregnancies at any given time [1]. Among these cases, approximately 500,000 maternal deaths occur annually worldwide [2]. Although the rate of pregnancy-related complications requiring medical attention is considered to be the same all over the world, both in developed and in developing countries, mortality in the developing world is disproportionally greater [2]. Approximately 98% of all maternal deaths in the world occur in developing countries, and a similar proportion is considered avoidable. In this context, the most effective actions for the reduction of maternal mortality have been shown to be those implemented immediately following onset of the complication, and differences in these health care provisions help explain the inequality in maternal mortality between developed and developing countries. Consequently, the focus of efforts to reduce maternal mortality has been directed toward improving the obstetric care of complications occurring during pregnancy [3].

Therefore, to offer adequate obstetric care, it is important to understand how to provide emergency obstetric care and to be aware of the possible causes of delays in implementing therapeutic interventions. Auditing and the surveillance of severe maternal morbidity are useful tools for acquiring this knowledge [4], but in many developing settings this is not feasible. Under such circumstances, population surveys could be used for obtaining essential information on maternal morbidity [5]. The first step would be to identify those women who had a severe complication during their last pregnancy from within the set of women interviewed, for example, in a demographic study. This information in itself would be very useful in that the occurrence of severe

maternal morbidity could then be quantified to some extent, and the various associated factors, including the geographic distribution of these events, could be evaluated. Furthermore, those women who suffered severe complications would be able to describe the barriers they had to overcome to receive adequate obstetric care, and report the difficulties they had to face during provision of this care [4] and [6].

However, controversy remains with respect to whether questionnaires applied to laywomen are indeed effective in obtaining accurate information on obstetric complications that occurred some time ago, this period of time often being variable. The analysis of several demographic and health surveys shows a huge variability in answer to questions on maternal complications [7-9]. Therefore, the aim of this study is to evaluate whether questionnaires on severe maternal morbidity are capable of accurately identifying women who had severe complications related to pregnancy.

2. Methods

This is a systematic review of the capacity of questionnaires applied to laywomen to accurately identify those women who suffered severe complications related to pregnancy, delivery, or the puerperium at some time in the past. To achieve this objective, a comprehensive search was carried out in the scientific literature for validation surveys of questionnaires on maternal morbidity. An initial search was conducted in databases covering a wide range of scientific journals (MEDLINE and EMBASE). These databases were investigated using the following search strategy: ("maternal morbidity questionnaires" OR "obstetric complications questionnaires" OR "maternal complications questionnaires" OR "obstetric morbidity questionnaires" OR "self-reported maternal complications" OR "self-reported maternal morbidity" OR "selfreported obstetric complications" OR "maternal near miss" OR "severe maternal morbidity" OR "severe maternal complications" OR "severe obstetric complications"). The POPLINE database was searched through the following strategy: (="obstetrics" /="pregnancy" /="mothers" /="morbidity" /="complications" /="validity") & (="questionnaires"). The electronic search was extended to all other articles related to the papers potentially relevant (using the tool "See all related articles..." available on the PubMed Web site). All the articles potentially relevant were accessed, and a full-text copy of each was obtained. In addition, the bibliographic reference lists of all these papers were checked for other possible relevant papers. Experts in the field were also contacted and meeting proceedings related to the demographic and health area were screened. No restrictions were made with respect to language, date, type of study, journal, or country of origin. However, studies focusing on the occurrence of other diseases that involved the distant recall of peripartum obstetrical events were excluded.

The citations initially identified were first evaluated on the basis of their titles and abstracts. Those considered to be clearly irrelevant or unrelated to the subject of interest were excluded. If the information supplied in the title or abstract was considered insufficient for any decision to be taken or if the citation was considered potentially relevant, the entire paper was accessed. The full-text articles thus selected were then evaluated independently by two reviewers, and a study was included in the present review on the agreement of both reviewers. Eligible studies were submitted to a critical appraisal of their methods, with emphasis on the detection of verification bias (systematic error related to inadequacies in the principle that each questionnaire applied should have its answers compared with the gold standard), and review bias (systematic error related to inadequacies in the independence between applying the questionnaire and verifying the responses against the gold standard), comprehensive description in the Methods section, and calculation of sample size, as well as whether the presentation of the results included sensitivity, specificity, and measures of variability (preferably confidence intervals [CI]).

Considering the principal causes of maternal death in developing countries, the following complications or maternal morbidities were considered of interest: eclampsia and other hypertensive complications, hemorrhagic complications (preferentially in the postpartum), dystocias, and infections. In each study, the values representing sensitivity and specificity were evaluated for each question or set of questions, and values were compiled for the best combinations of sensitivity and specificity for each complication, according to what had been presented in the correspondent article. In studies in which analysis was carried out in subgroups, whenever possible, data referring to all the cases of morbidity originating in the general population or in populations of lower risk were

compiled. The best combinations of sensitivity and specificity were identified, based on a profile of high specificity with at least moderate sensitivity [10].

The prevalence of self-reported morbidity (PSRM) and accuracy (Ac) were calculated for questions or sets of questions with sensitivity of at least 50% and specificity ≥95%, according to Ronsmans' criteria [10]. The prevalence of self-reported morbidity in population surveys may be calculated when the actual prevalence of morbidity (APM) is known or estimated, as well as the sensitivity (Sens) and specificity (Sp) of the questions applied to the population studied [10]. The prevalence of self-reported morbidity may be calculated using the following formula:

$$PSRM=(APM)\times(Sens+Sp-1)+(1-Sp).$$

Accuracy, defined as the probability of an individual to be correctly classified by a test (in this case, the questionnaire on maternal morbidity), either positively or negatively, may be determined using the following formula [11]:

$$Ac=(APM)\times(Sens)+(1-APM)\times(Sp).$$

Simulations were then carried out using arbitrary values for the APM, and the PSRM and accuracy were calculated based on the values of sensitivity and specificity obtained for each question. The following software programs were used in the data analysis: MedCalc for Windows, version 9.2.0.1 (MedCalc Software, Mariakerke, Belgium) and Microsoft Excel 2002 (Microsoft, USA).

3. Results

The two stages of electronic search (the initial search and the search of related articles) resulted in identification of 5,374 citations, whose titles and/or abstracts were evaluated. A total of 5,356 citations were excluded as being clearly irrelevant, unrelated to the subject in question, or not dealing with a study involving the validation of a questionnaire on severe maternal morbidity. Eighteen studies were evaluated in their entirety. Review of the lists of references from these studies resulted in the identification of one more study of interest, which was included in the review [5,10,12-16]. Of the 12 studies evaluated in their entirety and excluded, 11 did not involve validation of questionnaires on severe maternal morbidity [17-27]. The remaining study that was

evaluated in its entirety and excluded was a secondary study resulting from a study that had already been included [8]. A flowchart of the inclusion of studies is shown in Fig. 1.

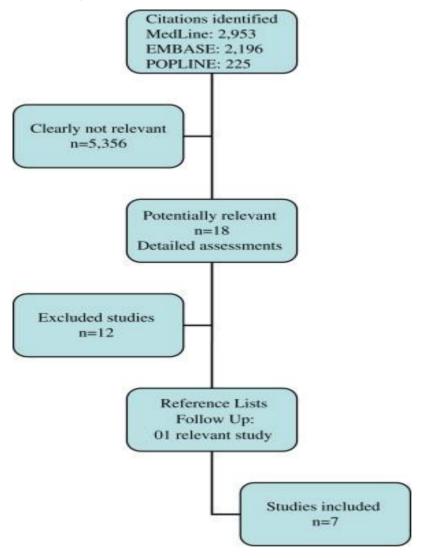


Fig. 1. Flowchart of the inclusion of studies in the review.

The principal characteristics of the studies included in the present review are shown in Table 1. All the studies included adopted a cross-sectional design (survey) for the validation of the questionnaires used. A total of 2,907 women participated in these studies, and sample sizes ranged from 207 to 1,027 participants (median = 340 participants). Prior calculation of sample size had been carried out in three studies; however, target recruitment was achieved in only one [15]. The time of recall consisted of a few days in three of the studies [14-16] and varied between three and 96 months in

the others. All studies were hospital-based and the gold standard used in all of them was the hospital records and the patients' clinical records. The definitions of the conditions studied were considered clear in six of the studies, but one study [16] failed to provide definitions, the only information provided being that the data had been extracted from the records in response to items contained in the Lewis-Murray scale [28]. The probability of the existence of a verification bias was considered low in all the studies. The probability of a review bias was considered low in four studies and uncertain in three. In all the studies, the validation strategy consisted in applying questionnaires on the occurrence of complications related to pregnancy and comparing them with the gold standard adopted for the study.

Table 1. General characteristics of the studies involving validation of questionnaires on severe maternal morbidity

Study	Methods	Evaluation of methodology
Stewart (USA/ Philippines, 1995)	Design: Cross-sectional Setting: Referral hospital in the Philippines Complications studied: Dystocia, hemorrhage, sepsis, and eclampsia. Participants: 230 women (116 cases and 114 controls) Validation strategy: The clinical records of all women with eclampsia, sepsis, and postpartum hemorrhage were reviewed. The cases of dystocia and the controls were selected randomly. From the list of women whose medical records were reviewed, the team of investigators tried to locate the women and carry out the interviews.	Verification bias: Low probability (all questionnaires answered were compared to the gold standard) Review bias: Low probability (independent teams reviewed the clinical records and applied the questionnaires; interviewers were blinded with respect to the medical diagnosis of the patient) Gold standard: Information collected retrospectively from medical records in June 1993 Definitions of study and control conditions: Clear Prior calculation of sample size: Presented (100 cases and 100 controls for each condition studied) Time of recall: From six months to four years Validation parameters: Sensitivity and specificity Measurement of variability: 95% CI
Ronsmans (UK/ Indonesia, 1997)	Design: Cross-sectional Setting: One referral hospital and two district hospitals in Indonesia	Verification bias: Low probability (all questionnaires were compared to the gold standard)

Study	Methods	Evaluation of methodology
	Complications studied: Dystocia, excessive bleeding, eclampsia, preeclampsia, and infection	Review bias: Low probability (all the interviewers were blinded to the patients' diagnoses)
	Validation strategy: The women who had the conditions of interest were recruited prospectively. A control group was composed of women with no complications. Women with a given complication of interest were also compared with women with other complications of interest.	Gold standard: Standard clinical record chart developed for the study and filled out by a research assistant Definitions of study and control conditions: Clear Prior calculation of sample size: Not presented Time of recall: Three months (data presented refer to a home interview) Validation parameters: Sensitivity, specificity, Kappa's statistics Measurement of variability: Not shown.
Seoane (USA/ Bolivia, 1998)	Design: Cross-sectional Setting: Two referral hospitals in Bolivia Complications studied: Dystocias, excessive bleeding (puerperal), convulsions/eclampsia, and infection Participants: 1,027 women, 257 of whom were classified as cases for at least one condition Validation strategy: Women were included based on information from hospital records; women who fulfilled the criteria for a certain condition (cases) were compared to those who did not fulfill that condition (controls). Women with insufficient information or those who partially fulfilled the criteria for the condition under analysis were excluded from the analysis of the validation of that specific condition.	Verification bias: Low probability (all questionnaires responded were compared with the gold standard) Review bias: Uncertain (the independence between applying the questionnaire and verifying the responses cannot be guaranteed, blinding was not used) Gold standard: Hospital record form specially developed for the study (prospective data collection) Definitions of study and control conditions: Clear Prior calculation of sample size: Not presented Time of recall: A few days (questionnaire applied at hospital discharge) Validation parameters: Sensitivity and specificity, PPV, PCA Measurement of variability: 95% CI.
Ellison (South Africa, 2000)	Design: Cross-sectional Setting: A hospital in Soweto, South Africa Complications studied: Chronic	Verification bias: Low probability (only women whose hospital records were available were included in the study) Review bias: Uncertain (independence between the interview and conferring data was not

Study	Methods	Evaluation of methodology
	hypertension, pregnancy-induced hypertension, preeclampsia, gestational diabetes, sexually transmitted diseases Participants: 517 Validation strategy: Interviews carried out among women participating in a cohort study with respect to their obstetrical history (including morbidity) were compared with hospital records.	described) Gold standard: Hospital records Definitions of study and control conditions: Clear Prior calculation of sample size: Not described Time of recall: A few days; the interview may even have been conducted prior to delivery Validation parameters: Sensitivity, specificity, reliability coefficient Measurement of variability: Not presented.
Filippi (UK/Benin, 2000)	Design: Cross-sectional Setting: Two referral hospitals and one district hospital in Benin Complications studied: Eclampsia, hemorrhage, dystocia, and infections Participants: 381women, consisting of 255 cases and 126 controls Validation strategy: A stratified sample of women with and without complications was identified retrospectively, and subjects were later interviewed in their homes	Verification bias: low probability (all questionnaires answered were compared to the gold standard) Review bias: low probability (independent teams to review the files and apply the questionnaires) Gold standard: Information recorded on medical records Definitions of study and control conditions: Clear, following algorithm Prior calculation of sample size: Described (690 women, 525 of whom had complications, while 16 were healthy) Time of recall: 3–52 months (mean 23 months) Validation parameters: Sensitivity and specificity Measurement of variability: Not shown.
Sloan (USA/ Ghana, 2001)	Design: Cross-sectional Setting: A referral hospital in Ghana Complications studied: Eclampsia, hemorrhage, dystocia (dysfunctional labor), and infections Participants: 340 women Validation strategy: Over a period of two months, all women admitted to hospital	Verification bias: Low probability (all the questionnaires were compared to the gold standard) Review bias: Low probability (independent teams carried out the review of patient records and application of questionnaires) Gold standard: Information registered in medical records Definitions of study and control conditions:

Study	Methods	Evaluation of methodology
	with obstetrical or puerperal complaints, from the seventh month of pregnancy to 42 days following delivery, were interviewed with respect to self-reported complaints related to complications of pregnancy, and compared with the results of clinical and laboratory exams carried out at the hospital	Clear Prior calculation of sample size: Described (333 women at least 50 of whom were cases with complications) Time of recall: A few days (interviews held at release from hospital) Validation parameters: Sensitivity, specificity, PPV, NPV, test of efficacy (maximum percentage of complicated and noncomplicated cases that could be correctly identified by the symptoms) Measurement of variability: 95% CI
Sou (Taiwan, 2006)	Design: Cross-sectional Setting: Referral hospital in Taiwan Complications studied: Prepartum hemorrhage and preeclampsia, as well as other, less severe complications (e.g., edema, proteinuria, gestational diabetes, etc.) Participants: 208 women Validation strategy: The participants were the mothers of children being followed-up in another study on prematurity. They were contacted by telephone and those who agreed to participate were interviewed, also by telephone. Answers were then compared with information on the respective medical records.	Verification bias: Low probability (all the completed forms were compared to the gold standard) Review bias: Uncertain because independence between telephone interviews and data collection was not described. In addition, no blinding procedure was described. Gold standard: Information obtained by reviewing medical records Definitions of study and control conditions: Not presented; reported only that the data were taken from the medical records and corresponded to items on the Lewis-Murray scale Prior calculation of sample size: Not described Time of recall: Not described, but the interviews occurred between 31 and 96 months after delivery Validation parameters: Sensitivity, specificity, likelihood ratio Measurement of variability: Not presented.

Abbreviations: PPV, positive predictive value; NPV, negative predictive value; PCA, percentage of concordance of answers with the gold standard; 95% CI, 95% Confidence Interval.

Verification bias: Systematic error related to inadequacies in the principle that each questionnaire applied should have its answers compared with the gold standard.

Review bias: Systematic error related to inadequacies in the independence between application of the questionnaire and verification of the answers with the gold standard.

The best combinations of sensitivity and specificity for each question or set of questions, according to the type of complication reported by the woman, are shown in Table 2.

Four studies dealing with the occurrence of eclampsia and other hypertensive complications achieved the target of at least 50% sensitivity and 95% specificity [5,10,12,16]. Two studies [5] and [13] that included questions on dystocia and infection reached these targets, whereas questions regarding hemorrhagic complications that met this profile were observed in only one study [5].

Table 2. Best result for sensitivity and specificity for a question or set of questions according to the type of complication reported by the woman, in studies of validation of questionnaires of severe maternal morbidity

Study	Eclampsia and other hypertensive complications		Hemorrhagic complications		Dystocia		Infection	
	Sens	Sp	Sens	Sp	Sens	Sp	Sens	Sp
Stewart	44	96	43	92	69	97	56	99
(USA/Philippines, 1995)	(21-69)	(92-98)	(30-58)	(86-95)	(54-81)	(93-99)	(23-84)	(83-92)
Ronsmans (UK/ Indonesia, 1997)	100.00	95.3	44.4	98.8	35.2	87.2	NA	93.2
Seoane	50	98.6	68.8	88.9	21.2	90.4	NA	99.3
(USA/Bolivia, 1998)	(28.2-	(97.5-	(41.3-	(82.7 –	(11.3-	(85.4-		(98.5-100)
	71.8)	99.7)	89.0)	95.1)	31.1)	95.4)		
Ellison (South Africa, 2000)	40.0	66.3	NA	NA	NA	NA	NA	NA
Filippi UK/ Benin, 2000)	72.7	100.0	58.9	96.8	69.4	100.0	70.0	100.0
Sloan	NA	99.0	70	91	74	83	25	99
USA/Ghana, 2001)		(99-100)	(35-93)	(87-94)	(60-85)	(78-87)	(1-81)	(97-100)
Sou Taiwan, 2006)	66.7	100.0	78.9	84.1	NA	NA	NA	NA

Abbreviaitons: Sens, sensitivity; Sp, specificity; NA, not available. Note: Shadowed areas mean that both Ronsmans' criteria were met.

Table 3 lists the estimated values of the prevalence of self-reported morbidity and the accuracy of the selected questions, attributing different arbitrary values for the actual prevalence of morbidity. The prevalence of morbidity was shown to be overestimated in 22.2% of the simulations (12:54), and the possibility of the prevalence of self-reported morbidity being overestimated was three times greater when actual prevalence was ≤5% (odds ratio [OR] = 4.0; 95% CI = 1.06–15.08). The levels of accuracy observed were high, but showed a tendency to decrease as the actual prevalence increased.

Table 3. Prevalence levels of reported morbidity and accuracy of selected questions, a attributing different arbitrary values to each "actual" prevalence of morbidity^b

Self-reported maternal morbidity	"Actual prevalence" (values in %)						
	1.0	5.0	10.0	15.0	20.0	25.0	
Eclampsia							
Ronsmans							
Self-reported prevalence	5.7	9.5	14.2	19.0	23.8	28.5	
Accuracy	95.3	95.5	95.8	96.0	96.2	96.5	
Seoane							
Self-Reported Prevalence	1.9	3.8	6.3	8.7	11.1	13.6	
Accuracy	98.1	96.2	93.7	91.3	88.9	86.5	
Filippi							
Self-Reported Prevalence	0.7	3.6	7.3	10.9	14.5	18.2	
Accuracy	99.7	98.6	97.3	95.9	94.5	93.2	
Sou							
Self-reported prevalence	0.7	3.3	6.7	10.0	13.3	16.7	
Accuracy	99.7	98.3	96.7	95.0	93.3	91.7	
Hemorrhage							
Filippi	ı	ı	ı	ı	ı	ı	
Self-reported prevalence	3.8	6.0	8.8	11.6	14.3	17.1	

Self-reported maternal morbidity	elf-reported maternal morbidity "Actual prevalence" (values in %					
	1.0	5.0	10.0	15.0	20.0	25.0
Accuracy	96.4	94.9	93.0	91.1	89.2	87.3
Dystocia						
Stewart						
Self-reported prevalence	3.7	6.3	9.6	12.9	16.2	19.5
Accuracy	96.7	95.6	94.2	92.8	91.4	90.0
Filippi						
Self-reported prevalence	0.7	3.5	6.9	10.4	13.9	17.4
Accuracy	99.7	98.5	96.9	95.4	93.9	92.4
Infection						
Stewart						
Self-reported prevalence	1.6	3.8	6.5	9.3	12.0	14.8
Accuracy	98.6	96.9	94.7	92.6	90.4	88.3
Filippi						
Self-reported prevalence	0.7	3.5	7.0	10.5	14.0	17.5
Accuracy	99.7	98.5	97.0	95.5	94.0	92.5

Abbreviations: PSRM, prevalence of self-reported morbidity; APM, "actual" prevalence of morbidity; Ac, accuracy; Sp, Specificity; Sens, Sensitivity.

PSRM = APM X (Sens + Sp - 1) + (1 - 1Sp)

 $Ac = APM \times (Sens) + (1 - APM)$

4. Discussion

The present review found that an intermediate proportion of questionnaires on maternal morbidity perform acceptably according to Ronsmans' criteria [10] when the subject of

^a Questions with sensitivity ≥50% and specificity ≥95%.

b Applying the same questions in the populations studied:

investigation is the occurrence of eclampsia and other hypertensive complications. When the criteria are the identification of infectious complications and dystocias, a lower proportion of questionnaires are found to give an acceptable performance, and when the criteria are hemorrhagic complications, only one questionnaire presents an acceptable performance. Population-based surveys on severe maternal morbidity should be validated locally to study the sensitivity and specificity of each question and combination of questions, with a view to improving their performance. The results of the present review suggest that it is possible to investigate the occurrence of complications of pregnancy using population surveys; nevertheless, there are some factors that have to be considered to obtain more consistent data.

All the studies included in the present review contain a possible selection bias in that women participating in hospital-based studies may differ from the rest of the population. In places where health care services are sparse, the profile of women attending health services may be different from those who do not attend, either due to questions of geographical access or because the determinants for seeking health services suffer interference from diverse sociocultural aspects [15]. These aspects may interfere in the perception of the health-disease process, and hence, interfere in the value applied to the clinical diagnosis.

Therefore, the principal validation parameters used in the studies included in this review were sensitivity and specificity. With respect to the selection bias that was unavoidable given the design adopted by the studies, caution should be used in interpreting findings, because the values obtained in the populations of women studied may be different from those that would be obtained in general populations [12]. Thus, it would be reasonable the supposition that the selection bias would be minimized in surveys conducted in populations with a high rate (i.e., >90%) of deliveries occurred in hospitals.

Another aspect that should be considered is that both accuracy and prevalence of self-reported morbidity interact with the actual prevalence of morbidity investigated in the population. According to this, when the actual prevalence rates are lower (probably the case of severe maternal morbidity), there is a tendency to overestimate rates. In situations of high specificity and low actual prevalence, accuracy levels are

fundamentally determined by the specificity, and are therefore very high. The use of accuracy as an indicator of validity should be considered within this context because low actual prevalence rates may create a distorted impression of validity [11].

Therefore, considering the selection bias and the interaction of the actual prevalence of morbidity with the values of specificity and sensitivity, estimates of the prevalence of self-reported morbidity should be analyzed with caution. Whenever possible, a prior validation of the questionnaire to be used in the survey should be recommended to achieve prevalence rates closer to reality, preferably in a similar population [13].

Evidently, the contribution of population surveys is more relevant in populations in which reliable statistics on maternal morbidity are unavailable. However, despite the drawbacks considered above, population surveys may be the only source of information available in many places [5]. In such places, women who survive severe complications of pregnancy may be able to contribute toward improving obstetric care with their information and experience. To be able to adequately attribute meaning for data obtained through population surveys in their actual context, it is fundamental that questionnaires on severe maternal morbidity be previously validated and that alternatives be sought to reduce the selection bias. One of these alternatives may be concurrent or post-survey validation, using a representative subsample whose responses would be compared with the gold standard.

In conclusion, as well as recommending caution in the interpretation of findings of prevalence in population surveys, this review must also emphasize the need for local validation of the questionnaires used in these surveys. This procedure may be able to provide data on the prevalence of self-reported maternal morbidity that would lead to a more accurate picture of the real situation. Stratification of the results for different regions or states may also lead to more concrete guidance for the development of policies and implementation of recommendations on clinical and/or obstetrical procedures requiring greater attention within the realm of health care provided during pregnancy, delivery, and in the puerperium for women in that particular population. Moreover, in the planning of future surveys, the type of questions to be included and the types of population previously studied should be taken into consideration in an effort to

compose a set of questions more adequate for identifying actual complications and maternal morbidities.

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RESEARCH

Severe maternal morbidity / near miss as a proxy for maternal mortality: the 2005 WHO global survey on maternal and perinatal health

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Running title: maternal near miss as a proxy for maternal mortality

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Abstract

Objective: To develop an indicator of severe maternal morbidity/near miss as a proxy for maternal mortality and to assess its association with maternal factors and perinatal outcomes.

Method: Multicenter cross-sectional study using a stratified multistage cluster random sampling design. Maternal and perinatal information were collected from hospital records of all women admitted for delivery from 120 randomly selected hospitals located in eight randomly selected Latin American countries. The main outcomes were Intra-hospital occurrence of severe maternal morbidity, and its association with maternal characteristics and perinatal outcomes.

Results: among 97,095 deliveries evaluated, 2,964 (34 per 1000) women admitted to Intensive Care Unit and/or undergoing a hysterectomy and/or receiving a blood transfusion and/or presenting a cardiac or renal complication and/or having eclampsia had a higher risk of dying. Older women, those without partner, primipara or para ≥3 and with a Caesarean Section in the previous pregnancy were independently associated with the occurrence of severe maternal morbidity. It was also positively associated with an increase in the occurrence of low and very low birth weight, stillbirths, early neonatal deaths, admissions to neonatal intensive care unit and prolonged maternal postpartum stay. These women had also an increased risk of Caesarean Section (adjusted risk ratio: 1.57, 95%CI 1.49 to 1.65).

Conclusions: using a combination of some severe maternal morbidities it was possible to identify two thirds of maternal deaths. Around 34 women experienced a severe maternal morbidity per thousand deliveries. They should probably be a better target for interventions aimed to reduce maternal mortality and could be called "maternal near miss".

Keywords: Global Survey, severe maternal morbidity, maternal near miss

Introduction

Approximately 15 000 women die every year in Latin America and Caribbean of causes related to pregnancy. The maternal mortality ratio, around 130 maternal deaths per 100 000 live births, is intermediary between those observed in developed and in less developed countries. 1

When maternal deaths are less frequent they become a poorer source of information to improve maternal health. These less frequent deaths tend to provide less generalizable information. Thus, it has been suggested that severe maternal morbidity could be used as a better indicator in these situations.^{2,3} In addition, severe maternal morbidity remains a public health problem in Latin America.

Women who survive pregnancy, childbirth and postpartum severe complications could be a surrogate to understand the pattern of conditions, delays and avoidable factors that contribute to maternal death.² This is the concept of maternal near miss.⁴ There was some controversy regarding its definition⁵, but recently the World Health Organization defined maternal near miss as a woman who nearly died but survived a complication during pregnancy, childbirth or within 42 days of termination of pregnancy.⁶

Considering the intermediate level of maternal mortality, the assessment of maternal near miss may be especially useful in Latin America. This paper describes the occurrence of severe maternal morbidity / maternal near miss in large hospitals from Latin America and Caribbean. We also assessed the association between this condition and maternal risk factors and perinatal outcomes.

Methods

The 2005 WHO Global Survey on Maternal and Perinatal Health was designed to explore the relationship between rates of Caesarean delivery and maternal and perinatal outcomes in selected medical institutions. It is a multi-country and multicentre study that gathered information also on severe maternal complications in Latin America. Details of its methods have been published elsewhere. ^{7,8} Briefly, the WHO Global Survey was implemented through a worldwide network of health institutions. These institutions were selected using a stratified multistage cluster sampling design. In 2005, anonymous maternal and perinatal information were collected from hospital records of all women admitted for delivery from 120 randomly selected hospitals located in eight randomly selected Latin American and Caribbean countries. Data were collected during a two to three months period in each institution and entered in an online data system delivered by MedSciNet AB, Sweden.

Definitions and outcomes

In 2005, the recently defined WHO criteria for maternal near miss were not available. Despite of it, we used indicators of severe maternal morbidity, such as Intensive Care Unit admission, blood transfusion, eclampsia, hysterectomy, respiratory, cardiac and renal complications. These indicators and other diagnostic entities were evaluated as predictors of maternal deaths during pregnancy, childbirth and the first postpartum week. It was assumed that the best combination of severe maternal morbidity indicators and clinical conditions diagnosis should identify the set of women that have been very close to maternal death but survived it. In this way, the ability of such events and clinical diagnosis to predict the occurrence of maternal deaths was evaluated. Women who

survived to these selected conditions during pregnancy or childbirth were considered as maternal near misses.

The association between maternal characteristics and the occurrence of severe maternal morbidity were assessed. These characteristics were age, marital status, schooling years, parity, number of antenatal visits, obesity, Caesarean Section in the previous pregnancy, and the type of health facility (public, social security or private). The outcomes evaluated were postpartum stay, low and very low birth weight, admission to Neonatal Intensive Care Unit, stillbirth, early neonatal death and mode of delivery.

Analysis

Initially, the ability of management indicators and clinical diagnosis to predict maternal deaths was evaluated. Sensitivity, specificity, likelihood ratios, and case fatality ratio were used to identify good predictors of maternal death. Likelihood ratios and their 95%CI were obtained and a strong association was considered whenever likelihood ratio was greater than 10.9 The case fatality ratio was also calculated (number of maternal morbidities for each maternal death during hospital admission until the seventh postpartum day). Once identified the indicators highly associated with maternal deaths, they were combined and this set was evaluated using the same strategy. As abovementioned, the operational definition of maternal near miss used was based on this set of indicators.

The occurrence of near miss per country was explored. Summary estimates were determined proportionally to the population size of each country. The association between maternal and institutional characteristics and the severe maternal morbidity

status was assessed with crude and adjusted odds ratios, using simple and multiple logistic regression models with all maternal characteristics studied except body mass index due to missing data.

Finally, the crude associations between maternal near miss and perinatal outcomes were evaluated using a cohort approach with risk ratios and their 95%CI. A logistic regression model for each outcome was then developed, including all possible predictors. Body mass index was excluded considering the high number of missing data. Sixty one women with no information on life status at discharge were excluded. Mode of delivery was tested in the model only as outcome. Statistical analyses were carried out using the SAS computer software program, version 9.1.3 (SAS Institute Inc., Cary, North Carolina, USA, 2003). The WHO Global Survey research project was approved by the national ethical committee of each country and the WHO Scientific and Ethical Review Group and the Ethics Review Committees. Some of the large hospitals in Mexico and Argentina and all hospitals in Brazil independently approved the protocol.

Results

One hundred and twenty institutions from eight Latin American countries contributed to the total of 97,095 deliveries that have been included in this study, of whom 96,026 were live births. There were twenty five maternal deaths during hospital admission until the seventh postpartum day. Table 1 shows the evaluation of several indicators of maternal morbidity tested for prediction of maternal deaths. Hysterectomy, Intensive Care Unit admission, blood transfusion, cardiac or renal complication and eclampsia presented the highest likelihood ratios. When a woman was admitted to the ICU or had undergone a hysterectomy or received a blood transfusion or presented a cardiac or renal

complication or had eclampsia, she had a higher risk of dying. In our sample this high-risk group comprised 2,964 women, with a LR of 21.1 (95% CI 15.7-28.4). This set of criteria would capture 16 of 25 maternal deaths, with a case: fatality ratio of 185:1. Women who survived these conditions during pregnancy or childbirth were classified as maternal near misses according to our operational definition.

Table 2 shows estimates of such defined near misses and its components in selected Latin American countries. The occurrence of near misses was more frequent in Cuba and Brazil and less frequent in Paraguay. The use of intensive care unit by women during pregnancy was more common in Brazil and rare in Nicaragua and Paraguay. Blood transfusion was higher used in Cuba and Mexico. For the whole sample including the eight countries, the proportional mean near miss ratio was around 34 per 1000 deliveries (Figure 1).

Table 3 summarizes some characteristics of severe maternal morbidity (SMM) women and non SMM women. Women aged > 35 years, women without partner, primipara or para \geq 3 were independently associated with the occurrence of near miss. Taking public health facilities as reference, social security institutions were independently associated with higher levels of near miss while private institutions had fewer. There were few near misses among women with less than 12 schooling years.

Women with caesarean section in the last pregnancy had an increased risk for severe maternal morbidity, regardless of whether their current delivery was by Caesarean section or not. The association between caesarean section in the last pregnancy and severe maternal morbidity remained statistically significant when adjusting the model for current mode of delivery (data not shown). Table 4 shows the crude and adjusted associations between near miss and selected maternal and perinatal outcomes. In both

analyses, the occurrence of near miss was positively associated with an increase in the occurrence of low and very low birth weight, admission to neonatal intensive care unit, stillbirths, early neonatal deaths and prolonged maternal postpartum stay. A near miss woman had also an increased risk of caesarean section (adjusted risk ratio: 1.57, 95%CI 1.49-1.65).

Discussion

A set of conditions has been identified as being associated with maternal deaths. A woman admitted to the Intensive Care Unit or undergoing hysterectomy or receiving blood transfusion or presenting cardiac or renal complication or having eclampsia had an increased risk of dying during pregnancy, childbirth or early postpartum days. In this study, survivors of the above-mentioned conditions were entitled near miss cases. Women aged > 35 years, primipara or para 3 or over; without partner or with a Caesarean Section in previous pregnancy had a higher risk of becoming a near miss case.

It is not surprising that age, marital status and parity, well-known predictors of maternal deaths, were also found to be associated with the occurrence of maternal near miss. This finding encourages the use of maternal near misses as a proxy or a surrogate of deaths in the evaluation of maternal health interventions. It could be included in audits in health facilities where the occurrence of maternal deaths is rare.

Low maternal education was found as protective to the occurrence of maternal near miss. Furthermore, a previous C-section was independently associated with increased risk for maternal near misses. Caesarean section was reported to increase maternal morbidity in Latin America.^{7,10} Women of lower education are known in Latin

America to have less Caesarean section. The worldwide trend of increasing Caesarean section rates may be associated with iatrogenic maternal morbidity and possibly maternal deaths.^{7,10}

The association between maternal near miss and a poor perinatal outcome was expected and it is very high.¹¹ Babies delivered from near miss women are smaller, require more frequently intensive care and have a higher risk of dying in the first week of life. In addition, near miss women have more stillbirths.

Limitations of the study

There are some limitations that should be addressed. The current operational definition of near miss included both management indicators (admission to intensive care unit, blood transfusion, and hysterectomy) and clinical diagnoses. The application of management criteria is influenced by the availability and use of these resources. In addition, these findings are mostly based in data recorded in medical charts, what could have prevented the full standardization of medical diagnoses. Other limitation is the small number of maternal deaths in which our operational near miss definition was based on. All these maternal deaths occurred during hospital admission and some transferred or discharged women may have died and were not included.

Implications of results

On the other hand, this study is based on a large dataset, probably the world largest dataset to date on severe maternal complications, such as peripartum hysterectomy, blood transfusions and ICU use during pregnancy and childbirth. Because most

deliveries in the region occur in the facilities, the survey results are likely to represent the state of care during childbirth in Latin America and Caribbean. In addition, the strength of the association between indicators of severe maternal morbidity and maternal deaths makes even more relevant the concept of near miss for the improvement of maternal health. In the future, these findings can also be compared with those from Africa and Asia. This will enable the acquisition of a global view of severe maternal morbidity and near miss. Furthermore, future epidemiologic studies or similar surveys on maternal and perinatal health can be performed using the indicators currently reported or even using the more strict and precise criteria recently proposed by WHO.⁶

Based on these findings, it is possible to conclude that the concept of maternal near miss do can be seen as a proxy to maternal deaths. The appropriate management of complications of pregnancy and the timely provision of emergency obstetric care is crucial to improve maternal health and perinatal outcomes.

WHAT IS ALREADY KNOWN ON THIS TOPIC

- Latin America and Caribbean have intermediate levels of maternal mortality
- When maternal deaths are less frequent they become a poorer source of information to improve maternal health

WHAT THIS STUDY ADDS

- The concept of maternal near miss can be a proxy to maternal deaths in large datasets.
- Maternal near miss is associated with worse perinatal outcome
- Caesarean Section in the previous pregnancy is associated with an increased risk of complications during pregnancy and childbirth.

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Table 1. Performance of several indicators of maternal morbidity for prediction of maternal deaths before hospital discharge and

the respective case fatality ratio

tne respective of	Jugo Iutun	Prevalence	Number				
Indicator §	n	of SMM per 1000 deliveries	of maternal deaths	Case fatality ratio	Sensitivity (95%CI)	Specificity (95%CI)	LR* (95%CI)
Hysterectomy	151	1.56	7	22:1	28.0 (27.7-28.3)	99.9 (99.8-99.9)	249.7 (105.8-589.2)
ICU	1102	11.35	12	92:1	48.0 (47.7-48.3)	98.9 (98.8-98.9)	80.4 (36.8-175.9)
Transfusion	1340	13.80	9	149:1	36.0 (35.7-36.3)	98.6 (98.6-98.7)	40.2 (17.8-90.8)
Cardiac/renal complications	483	4.97	3	161:1	12.5 (12.3-12.7)	99.5 (99.5=99.5)	27.3 (8.2-90.8)
Eclampsia	253	2.61	1	253:1	4.0 (3.9-4.1)	99.7 (99.7-99.8)	15.9 (2.2-117.5)
Respiratory complication	593	6.11	1	593:1	4.2 (4.0-4.3)	99.4 (99.3-99.4)	6.8 (0.9-50.1)
Diabetes	742	7.64	1	742:1	4.0 (3.9-4.1)	99.2 (99.2-99.3)	5.4 (0.7-39.9)
Vaginal bleeding	2134	21.98	2	1067:1	8.0 (7.8-8.2)	97.8 (97.7-97.9)	3.9 (0.9-16.4)
Uterotonics	21431	220.72	12	1786:1	48.0 (47.7-48.3)	77.9 (77.6-78.1)	3.3 (1.5-7.1)
Hypertension	9415	96.97	4	2353.7:1	16.0 (15.8-16.2)	90.3 (90.1-90.5)	1.8 (0.6-5.2)
Referral	33504	345.06	11	3046:1	44.0 (43.7-44.3)	65.5 (65.2-65.8)	1.5 (0.7-3.3)
Pielonefritis or any UTI	14443	148.75	2	7221:1	8.0 (7.8-8.2)	85.0 (84.8-85.2)	0.5 (0.1-2.1)

[§] For the indicators severe anemia, malaria and sickle cell disease there were no deaths identified * LR: likelihood ratio (strong association with LR>10)
ICU: intensive care unit SMM: severe maternal morbidity UTI: urinary tract infection

Table 2. Occurrence of maternal near misses* per 1000 deliveries in selected health facilities by country and each indicator of severe morbidity

Country	Population Size (million inhabitants)	NMR X1000	ICU X1000	Hysterectomy X1000	Blood transfusion X1000	Cardiac/renal complication X1000	Eclampsia X1000
Argentina	36.2	21.96	11.8	1.9	9.2	4.2	0.9
Brazil	169.8	40.67	21.4	1.1	9.6	7.5	4.7
Cuba	11.2	44.22	16.0	2.3	23.0	6.8	1.3
Ecuador	12.1	25.78	9.5	1.2	11.5	1.9	3.0
Mexico	97.5	32.60	7.7	1.9	16.6	6.6	3.2
Nicaragua	5.3	22.71	3.0	0.5	15.6	3.0	1.8
Peru	26.7	23.07	8.7	1.1	13.0	3.7	2.1
Paraguay	5.5	14.75	4.3	2.6	6.3	1.2	2.3
Total*	364.4	34.31	14.7	1.5	12.2	6.2	3.5

^{*}Women surviving to ICU or Hysterectomy or Blood transfusion or Cardiac or renal complications or eclampsia during pregnancy, childbirth and the first seven postpartum days

^{*}the total estimates are proportional to the population size

NMR: Near Miss Ratio (number of near miss cases per 1000 deliveries)

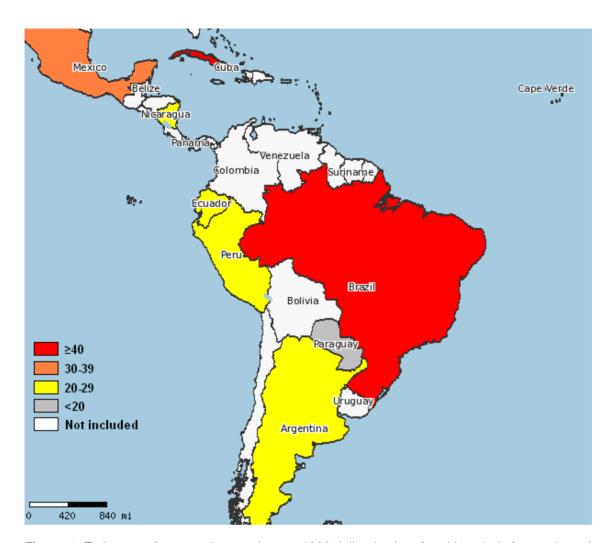


Figure 1: Estimates of maternal near miss per 1000 deliveries in referral hospitals from selected Latin American and Caribbean countries.

Table 3. Women's characteristics associated with near miss# (crude and adjusted estimates)*

	- Committee as		With fical in	<u>_</u>	usica estimates,
<u> </u>	SMM		Non SMM	Crude	Adjusted
Characteristic	%	N	N	OR (95% CI)	OR (95%CI)
Λαο					
Age 10-19 yr	2.99	530	17178	1.03 (0.93-1.14)	0.99 (0.88-1.10)
20-34 yr	2.99	2003	66860	1.03 (0.93-1.14)	0.99 (0.66-1.10)
	-		9997		
>35 yr	4.00	417		1.39 (1.25-1.55)	1.40 (1.20-1.64)
Missing		2	48		
Marital Status					
No partner	3.36	697	20072	1.15 (1.05-1.25)	1.21 (1.10-1.64)
With partner	2.94	2233	73662	1	1
Missing	2.01	22	349	•	•
Wilsonig			0-13		
Schooling years					
< 7 yr	2.76	662	23345	0.72 (0.63-0.82)	0.70 (0.62-0.80)
7-12 yr	3.07	1769	55877	0.80 (0.72-0.90)	0.82 (0.73-0.92)
>12 yr	3.79	395	10024	` 1 ′	` 1
Missing		126	4837		
9					
Parity					
Primipara	3.18	1062	32344	1.17 (1.08-1.27)	1.37 (1.24-1.51)
2-3 deliveries	2.73	1225	43606	1	1
>3 deliveries	3.54	663	18077	1.31 (1.19-1.44)	1.28 (1.15-1.42)
Missing		2	56	,	
<u> </u>					
Number of antenatal v					
0-3	3.15	506	15546	1.03 (0.93-1.14)	1.05 (0.94-1.16)
>3	3.06	2356	74612	1	1
Missing		90	3925		
01 11 (0111 0017)	~ \				
Obesity (BMI>30 Kg/m	,	1050	0.4540	1 00 (0 00 1 17)	*
Yes	2.98	1059	34510	1.08 (0.99-1.17)	
Not	2.77	1199	42052	1	
Missing		694	17521		
C-Section in the previ	oue preamanc	v			
Yes	4.09	y 538	12628	1.46 (1.33-1.61)	1.63 (1.47-1.81)
Not	2.84	2362	80881	1.40 (1.33-1.01)	1.03 (1.47-1.01)
Missing	2.04	52	574	ı	ı
Missing		52	574		
Type of health facility					
Public	3.65	2147	68712	1	1
Social security	3.65	720	19022	1.21 (1.11-1.32)	1.24 (1.13-1.36)
Private	1.32	85	6349	0.43 (0.34-0.53)	0.29 (0.21-0.42)
			33.13	3. 10 (0.01 0.00)	3.20 (5.21 41.2)
Total@		2952	94083		
#144					

^{*}Women surviving to ICU or hysterectomy or blood transfusion or cardiac or renal complications or eclampsia during pregnancy, childbirth and the first seven postpartum days &Simple and multiple logistic regression model (including all variables excepting BMI) *BMI was not used in multiple analyses due to the high number of missing data

^{@61} women with no information on maternal death were excluded

Table 4. Crude and adjusted risk ratios of maternal and perinatal outcomes among near miss women[&]

women [°]					
	S	MM	Non SMM	Crude RR	Adjusted RR
Outcomes	%	n	N	(95%CI)	(95% CI)
Postpartum stay ≥7					
Yes	15.82	318	1692	6.12 (5.46-6.86)	4.76(4.20-5.40)
Not	2.71	2567	92212	1	1
Missing		67	179		
Low birth weight (<	:2500a)				
Yes	8.13	694	7843	2.83 (2.64-3.03)	2.38 (2.19-2.58)
Not	2.54	2247	86066	1	1
Missing		11	174	•	•
Very low birth weig					
Yes	14.21	209	1262	5.29 (4.59-6.09)	4.36 (3.72-5.12)
Not	2.86	2732	92647	1	1
Missing		11	174		
Admission to neon	atal ICII				
Yes	7.70	797	9552	2.73 (2.57-2.91)	2.11 (1.95-2.28)
Not	2.39	2044	83553	1	1
Missing	2.00	111	978		·
Stillbirth					
Yes	11.32	107	832	4.07 (3.34-4.96)	3.95 (3.17-4.94)
Not	2.96	2843	93183	1	1
Missing		2	62		
Early neonatal deat	th				
Yes	15.49	92	502	6.03 (4.84-7.50)	4.77 (3.74-6.07)
Not	2.87	2739	92616	1	1
Missing	2.07	121	965	ı	ı
iviiooiiiy		141	900		
Mode of delivery £					
Vaginal	1.90	1191	61497	1	1
Cesarean	5.12	1756	32515	1.72 (1.67-1.78)	1.57 (1.49-1.65)
Missing	•	5	71	_ ()	- (
		0050	0.4000		
Total*		2952	94083		

^{*}Women surviving to ICU or hysterectomy or blood transfusion or cardiac or renal complications or eclampsia during pregnancy, childbirth and the first seven postpartum days

[&]amp; Logistic regression model for cohort studies with adjustment for all predictors (age, marital status, schooling years, parity, number of antenatal visits, Caesarean section in previous pregnancy and type of facility), but not for BMI [£] Mode of delivery was tested in the model only as outcome

^{* 61} women with no information on maternal death were excluded

3.5. Artigo 5

Near missed voices: narratives of women who almost died during pregnancy and childbirth - an emerging "maternal near miss syndrome"

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ABSTRACT

Background: An improvement in maternal health conditions will only effectively be achieved when, in addition to reducing the number of deaths, the burden of severe complications of pregnancy is reduced. The main objective of this study is to contribute towards furthering knowledge on aspects related to the burden of severe maternal morbidity. Methods: This is a qualitative study based on narratives of women who survived severe complications of pregnancy and who were admitted in the intensive care unit of a public university hospital in the city of Campinas, Brazil. The study was carried out in sample of 30 women recruited between April 2007 and January 2008. Prior to hospital discharge, eligible women who agreed to participate were submitted to a semi-directed interview. The interviews were recorded and the transcripts were submitted to a thematic analysis. Results: Two major themes were identified, one more closely related to the experience of a critical illness and the other to the experience of care. A complex set of reactions was found in the women who survived, indicating the occurrence of acute stress related disorders. Conclusions: Based on narratives of women who almost died during pregnancy and childbirth, we described an acute stress disorder that may be associated with the occurrence of severe maternal complications the maternal near miss syndrome. The major intrinsic value of describing such syndrome is to raise awareness of health care providers to the non physical aspects of complications related to pregnancy and childbirth. An integrated healthcare may useful to attenuate the burden that maternal complications impose to millions of women every year around the world.

Key words: severe maternal morbidity, maternal near miss, maternal health, narrative, qualitative research

One of the development goals established in the Millennium Declaration is a 75 percent reduction in maternal mortality worldwide until 2015, reflecting the significance of this event to the health of populations (1). In addition to reducing the number of deaths, a real improvement in maternal health conditions can only be achieved when the burden of the severe complications of pregnancy is reduced. Whereas the absolute number of maternal deaths occurring annually is around 500,000, a further 9 million women annually are estimated to suffer severe complications of pregnancy. Of these, a relevant percentage will bear long term physical and psychological sequelae, contributing to the magnitude of the burden of these complications (2,3).

A strategy that may be able to contribute towards the improvement of maternal health is the appropriate evaluation and management of women who have survived severe complications. Cases of maternal near-miss and maternal deaths share many characteristics, but the former are much more frequent. This can enable even small facilities to study near miss cases, develop strategies for dealing with it and function as a model to improve the patient safety. However, one of the most important characteristic of the evaluation of cases of near-miss is the fact that the woman herself is able to give direct testimony with respect to what, how, when and why the facts occurred in a certain way (4-6).

Nevertheless, there are still few studies about the experiences of survivors of severe maternal morbidity (7,8). Acute stress disorders and posttraumatic stress disorders (PTSD) may play a role in the development of long term sequelae and contribute to the overall burden of severe maternal morbidity (9). Along with the paucity of data, the main motivation to perform this study has been arisen from our clinical practice and following some quantitative approaches to severe maternal morbidities (10). We believe that evaluating, beyond the numbers, the experience of survivors of severe maternal morbidity can be useful to understand some of the non physical aspects that may compose the long term burden of pregnancy complications. This study investigates the emotional experience of women who survived severe complications related to pregnancy.

Methods

This is a qualitative, exploratory study based on narratives of women who survived severe complications related to pregnancy. In this study we adopted a definition of severe maternal morbidity based on admission to an intensive care unit during pregnancy or the puerperium, since this made the identification of cases easier and because these women had traversed the full spectrum of healthcare, ranging from primary units to the intensive care unit (ICU) of a tertiary referral hospital (11).

Setting

Campinas is a Brazilian city located in the state of São Paulo. In 2006, its population was estimated at 1,039,297 inhabitants (12). Its metropolitan area is composed of 19 municipalities with approximately 3.5 million inhabitants. The human development index of the city of Campinas is 0.852, life expectancy at birth is 72.2 years and the literacy rate is 95 percent (13). The maternal mortality ratio was around 40/100,000 liveborn infants in 2005. In this area, nearly all women receive skilled care during childbirth in healthcare facilities and the percentage of non assisted pregnant women during childbirth is considered irrelevant.

Brazil has a public healthcare system that includes universal access to all citizens. Nonetheless, a supplementary healthcare system based on health insurances or on individual, private resources is frequently used, mainly by the population of higher socioeconomic levels. The Center for Women's Integrated Healthcare (CAISM) is a public university hospital and a referral center for women's healthcare. Its intensive care unit was inaugurated in 2002, and receives women from the entire region of Campinas and, occasionally, from other regions. Between 2002 and 2007, a total of 750 women were hospitalized in this unit during pregnancy or puerperium, and maternal mortality occurred in 3.2 percent of these admissions. One of the operating principles of this ICU is the humanization of care, including long family visiting hours and the presence of a companion of the woman's choice. The main cause of hospitalization in this unit consists of complications resulting from hypertension (57.3%), followed by complications resulting from haemorrhage (13.7%), infection (4.8%) or abortion (3.2%) and clinical/surgical complications (21.0%) (14).

Sample

The sample was recruited in accordance with the technique of purposeful sampling from a group of women who were discharged from the ICU between April 2007 and January 2008 (15,16). Based on a previous study (9), it was established that a total of 30 women should be interviewed. The intention was that the sample would be representative of the pattern of causes of hospitalization of severe maternal morbidity in the institution (14) and, therefore, 30 would be the number necessary to have at least two cases of each main cause.

Women eligible for the study (surviving a severe maternal morbidity condition requiring admission to ICU but already discharged from ICU) were identified during their hospitalization in the ICU and were invited to participate in the study close to their hospital discharge. During the study period 125 women were admitted to the ICU and therefore one fourth were interviewed. On average, they stayed six days in the hospital and were interviewed in the fifth day. One women refused to participate and there were no exclusions after enrolment. Three fourths of the cases had caesarean section and four hysterectomies were performed. All the participants were assured that their participation in the study was voluntary and confidential.

Data Collection

Data were collected during semi-directed interviews (16-18) carried out still during hospitalization but close to hospital discharge. The 30 women who participated in the study were interviewed in a private room after providing their informed consent. A pre-interview was carried out to obtain sociodemographic data (age, parity, marital status, place of residence, education level, whether head of the household, socioeconomic level). The interviews were conducted by a trained female interviewer, based roughly in an interview guide. The guide included topics such as the initial expectations related to the pregnancy, the perception of the complication, the transferral process and care, and experiences, views and opinions related to the severe state of health. These interviews were recorded digitally and lasted around 45 minutes each.

The criteria of the Brazilian Association of Market Research Institutes were used to define economic status by applying a standardized questionnaire that had been validated for this purpose in Brazil. These criteria take into consideration the education level of the head of the household and ownership of items of comfort and household. The economic level was classified as A, B, C, D or E, "A" being the economic level with the greatest purchasing power and "E" with the lowest (19). This is the instrument most frequently used in Brazil for this type of evaluation.

Data Analysis

All interviews were transcribed verbatim in the language used in the interview, Brazilian Portuguese. The transcripts were checked against the recordings before data analysis. Data collection and analysis happened concurrently and themes from early interviews were used to guide subsequent ones. Data were analyzed for thematic content by one rater (JPS) and cross checked by a second one (MJDO). There was an initial thematic frame based on the topics of the interview guide, but emerging themes were included and the coding structure and the guide were revised as necessary (15,17). Data were managed using the *Ethnograph*® software (20, 21).

This study was developed following approval by the Institutional Review Board. An informed consent was obtained before inclusion of each woman in the study. To preserve the confidentiality of the women interviewed, fictitious names were given to people and institutions during transcription. The sponsors of the study had no role in the study design, data collection, analysis, interpretation, or report_writing.

Results

Thirty women discharged from the intensive care unit between April 2007 and January 2008 were interviewed. The general characteristics of these women are described in Table 1. Two major themes emerged during data analysis; one more closely related to the experience of the critical illness and other more closely related to the experience of care itself. The apparent interrelationship between the physical experience of critical state of health, the sense of the imminence of death, the fear, and other specific experiences are presented below.

Physical Experience of Critical State of Health

The physical perception of critical state of health was a significant experience for all the women interviewed. In general, the physical experience of severe morbidity was characterized by unpleasant sensations previously unknown to the majority of women, which generated distress:

I was worried because I knew that I was severely ill. I couldn't walk properly, then I couldn't speak properly; suddenly I couldn't breathe properly, couldn't eat...(Vera).

And all that afternoon, I was taking (magnesium) sulphate and feeling bad just the same. Feeling my heart beating and the burning sensation... I thought the feeling of death must be just like this, really (Luciana).

For many of the women, the physical experience and the way in which they perceived that they were ill defined their state of mind during the course of their disease.

When I looked at myself, I saw that I was all swollen. The doctors discovered that I had to undergo heart drainage. Then I got pneumonia. Something was always happening; I thought I was never going to get [better]. Then, the baby was born and the swelling started to go away; I was sure I was going home (Vanessa, a woman who experienced eclampsia, cardiac tamponade secondary to pericardial effusion and fetal death).

Another significant aspect of the physical experience is the perspective that the abnormalities perceived may be long-lasting and the possible social implications of this fact.

I think it was when I realized that I was not managing to walk in the ICU and, when I managed to walk, I noticed that I had put on 20 kilos. This was the biggest issue for me; it frightened me. My body was very deformed; then I thought I would never get back to being normal again. My belly swelled up a lot. Then my biggest worry was about my husband and how he would react to this... (Marta, who was in a coma for several days due to eclampsia).

The treatment and recovery process was difficult for almost all the women. The physical discomfort associated with the severe disease and the treatment of this condition was emphasized by some of the women:

I was confined to bed. Everything in bed...bath, everything had to be done in bed...I knew that I had to get used to it. And I got used to it. My sister came, my husband came, my brother came by every day, whenever he could. They got me out of bed, walked around with me, everything.... I was there for such a long time; there were times when I despaired. It was something I had to get used to (Lucia).

In the fragment of speech above, it is evident that, in addition to the harshness of the process, there was a route of acceptance that many of the women went through during severe morbidity. This is a recurrent theme, often associated with religiosity and a figure of divinity. The physical experience resulting from severe morbidity is intense and leads to a sensation that death is imminent. This is one of the most significant aspects of the entire experience of severe morbidity and the subject is described in detail as follows.

Perception of the imminence of death and the transitoriness of life

In general, the occurrence of a severe complication during pregnancy was an unexpected event, and the sensation of the transitoriness of human life was felt by many women.

I didn't expect that it would be this snowball, that the ground would open up under me, that I would be in a hole...because it's a tunnel; anyone who goes through this knows that life is short. (Ana, a 35-year old woman hospitalized for a complication related to hypertension).

Together with this feeling that life is short, the majority of women interviewed had the impression that death was close or imminent. This feeling was frequently reinforced by the occurrence of disagreeable organic experiences such as pain and dyspnoea. The perception of the inevitability of death led to concerns with respect to their loved ones, particularly their children

I thought I was going to die, really...because I wasn't well, couldn't walk, breathe, nothing... (Célia).

I was already in the ICU...When I figured it out, I was already there. That was a huge shock to me. I thought I wouldn't survive to raise my child. The pain was enormous, too much suffering.... (Maria).

For many women, this moment was accompanied by great emotional distress and the need for support from the people closest to them was very important:

I fell into despair, because I really thought I was going to die. I asked staff to call someone from my family...I was desperate, I can't explain it. I thought about my other child...I was terrified....I wanted someone with me, my husband, someone... (Marília).

I lay quiet, just expecting to die, not even having my child, not going home. And I kept asking them to call someone from my family... (Viviane).

The perception that death was close was a striking experience for the majority of the women and this is a central aspect throughout the entire experience of severe maternal morbidity.

Fear

If the physical experience appears to move in the direction of a sensation of impending death, fear appears to be its driving force. In the presence of severe complications, all the women were frightened. Sometimes this fear was mild; at other times it was terrifying and paralyzing. During the interview, the experience of fear was relived with great intensity and the women were moved emotionally. This feeling of fear was often poorly defined and frequently permeated the entire experience. The relationship between fear, the physical experience and the sensation of imminent death was clear in many of the statements.

Fear...I was afraid....Fear...Terrified of dying....It is a very strange feeling, you can't know what it is like (Aparecida).

Fear...I was afraid. I had difficulty breathing and I thought I wouldn't be able to bear it (Vanessa).

Frustration

The occurrence of an unexpected complication that interfered with the natural progression of pregnancy was met with frustration by some of the women. It was as if they were experiencing the loss of an idealized pregnancy and had to face a real and difficult one. Likewise, some women felt as if they were incompetent or incapable of performing the physiological process of reproduction.

My husband spent the entire night with me in the ICU...He held my hand, but I had no more strength, I didn't want to go on living, and he was there fighting alongside me, asking me to stay... He has another daughter of 16...and I told him, I swore to him that I wouldn't die because I had to stay for the two of them; I wanted the three of them, but God took it away...I just don't know why. I've tried and tried to find out why everyone in my family had more than two children and I have none. I have to discover the reason for this, because I am never going to have any; I can't understand it; I want to understand, but I can't ... (Viviane).

I had a normal delivery and I didn't even manage to see the baby [stillborn]. I didn't want to see it. That's something that I don't want to [talk about]...It hurts me very much when I talk about these things. I don't want to talk about this part of it, how much I wanted this baby, ... (Carolina).

Alienation

A large proportion of the women interviewed appear to have become alienated when faced with the processes involved in their disease and its treatment. Various factors may influence this attitude, ranging from the woman's state of health to questions of gender that persist even today, the woman's faith in a superior Being who has control over the process, and the way in which the healthcare service itself operates.

I didn't even know that I was going to be transferred. They called my husband to the hospital; they didn't tell [me] anything. When my husband got there, I didn't even know really how things worked, I didn't have time to think properly about how it was going to be or anything like that. They had already put me in an ambulance with the doctor and a nurse and I was already on my way here...(Michele)

From the interviews that were carried out, it is clear that the family members, particularly the husband, retained a prominent role in the woman's actions with respect to her health. Sometimes, these people took on a role that might have been expected from the woman herself.

He [the husband] told me to stay home and get myself ready. So, I stayed, took a bath, got ready, everything...Because he didn't want to come in our car. He went to the municipal health service, got an ambulance, told them that I was very swollen. There was just time for him to go and get the ambulance and then we came here (Adriana).

I never liked hospitals, never liked doctors. I always avoided hospitals; so she [an aunt] just didn't say anything to me; she put me in the car and took me to hospital and I couldn't do anything about it (Aline).

In this context, when faced with critical situations, many of the women delegated the solution to their problems to God. This attitude apparently caused no conflict between the aspects that would be considered human and those that would be considered divine in the recovery process. It would appear that nourishing faith was the only thing that many of the women could do under these circumstances and that, in some way, doing so brought them comfort.

I started to feel strange, because I thought I was going to...[die]. All this went through my head. So I put my life in God's hands for Him to decide what to do (Marilia).

First, you cling to God, because it is He who saves you...Of course, He gave knowledge to the doctors to take care of us, but if you also put your faith in God, everything becomes easier....(Carina).

Dealing with memory gaps and the need for information

A considerable proportion of the women interviewed experienced alterations in consciousness, went into stages of coma or remained under sedation for periods of time because of mechanical ventilation. So, many "woke up" in the ICU, after many significant facts had already occurred in their lives. Many did not see their babies being born, dying or being buried, and these facts impacted negatively on their experience of childbirth and delivery. This awakening to the discovery that capital events in the woman's life had already occurred may, in itself, be something very dramatic.

My delivery was by caesarean section and I don't remember the baby being born...I don't remember...the baby being born...[Aline, very distressed].

I don't remember anything at all, from the moment I lost consciousness in my bedroom [at home]. I woke up here, asking where I was. My father was beside me...Then I touched my

belly and asked; "Where is my baby?" He said: "No, you have already had the baby". But I said: "But where is she, I want to see her" ... "You are here in Campinas and she is back in our town" (Mirtes).

For some of these women, the feeling that there is a part missing in the "film" of their lives is something that upsets them greatly and makes it more difficult to accept the losses that they have experienced.

When my baby was born, I didn't see him...I wanted to know what they had done with him...I still want to understand. I can't get this out of my head (Carolina, whose baby was stillborn).

About two months after being discharged from hospital, this same woman sought one of the professionals who had cared for her and reported difficulty in accepting what had happened. She had already been given the facts on several different occasions, but perhaps because she had been unable to experience them completely, she had difficulty in accepting them emotionally. She also said that for this reason, she was unable to get rid of the baby's things. She was unable even to remove the things from the bedroom that would have been the baby's. She complained that these attitudes were harming her marriage and the manner in which she related to people. Ever since she had been discharged from hospital, she had been undergoing psychological treatment.

Another aspect related to understanding what is happening is the need the women have for information.

The most significant aspect...I think it was being back home, with nothing to do, without even knowing really what actually happened...Ah, I think that was the worst time of all (Priscila).

They [the nurses] talked to me and explained what was really happening...my fear about coming here was that they would have to open me up again or operate on me again. I think I was ill because of that and they explained everything to me. I felt very safe. (Helena).

Although requests for information are frequently ignored by healthcare professionals or repressed by the women themselves, the majority stated that information with respect to what was happening was reassuring.

I feel safer, much safer when there is someone to tell me everything...(Marta).

Displacement of the centre of emotions from the woman to the child and her other children, and grief.

One of the fundamental aspects of the experience of severe maternal morbidity is the displacement of the centre of emotions from the woman to the child. Even when there is a real risk of death for the woman, many of them maintain the focus of their attention not on their own health but on the wellbeing of the child. Or this centre of attention may be divided among her other children.

I was going to the ICU, but it was to save the baby, because what I wanted more than anything was this, for them to save the baby. Really, I didn't even care about my own life; what I wanted was her. (Lourdes).

Fear. I was afraid that something would happen to the baby. It already happened to my mother; to me too...I had already had a miscarriage. I was frightened. [response to interviewer's question: "And what about you?"]. No, not me, I only thought about the baby (Benedicta).

I was afraid of dying because of my children...I have a little one four years old and now I have the baby; that's why I was afraid of dying. (Diana)

Something that occurs frequently when severe maternal morbidity is present is an early rupture of the bond between the mother and child. Even if attempts are made to encourage mutual visits, the intensive care environment where both mother and child may be receiving care represents a considerable impediment to the full experience of motherhood. In this emotional atmosphere, the moment when the pregnancy is lost is often the most significant moment of the entire experience. Many of the women found it difficult to accept such a huge loss.

I think the most difficult thing has been the distance between my baby and myself...(Carina).

Knowing that I had survived this....that I was leaving the ICU while my baby was going into it; this was terrible. (Alexandra).

It was the loss, the tremendous loss of her [the baby] (Marina).

The night before, my baby... she was moving a lot, really a lot. The next day, the ultrasound exam showed that the baby was dead...And then I had the impression that she hadn't died... that she was still alive, that she was moving inside me...But I wanted somehow to see if I could manage to hear her little heart beating again, but I couldn't... So I couldn't accept the reasons for it...It was as if she had begged me for help and I hadn't helped her that night, to do what had to be done... (Simone)

A tactic used by some of the women to deal with a significant loss was by considering a next pregnancy.

[About the most significant moment]: It was when the baby was born...I thought it might be alive...Even though I knew it wasn't...this was really sad...if I could, I would get pregnant again today, just to feel that little thing moving inside me again... (Antonia)

Then, when fetal death occurred, the possibility of a definitive loss of fertility was an emotion that was frequently present. This made the moment even more dramatic for some women.

The infection was spreading and there was nothing I could do about it. I thought I wouldn't manage to control it and I started to think that I would lose my uterus. This devastated me (Silvia).

Severe maternal morbidity as an opportunity for inner growth

One aspect identified in the analysis of the women interviewed is that the majority managed to find something positive in the experience. Many of the women began to see life in a different way. Many women may have interpreted severe morbidity in this way:

I think that in one way it was good...I think I was needing to be shaken up...Because sometimes we give importance to people who aren't worth it...to things that don't deserve it...I think I really had to go through this...(Ana)

In this respect, some of the women mentioned:

• the need to give more value to the simple things in life:

[with respect to the past]: Ah, I think I did everything I could. Maybe I should have given more importance to simpler things like taking a bath or eating...[she cries] (Vera)

• The importance of giving value to people who are truly fond of them, and to family.

I was afraid I was going to die. I was very frightened. So, now I am going to look at life differently...I'm going to spend more time with my family [cries], it's difficult [cries]; only God knows the sacrifice I have been through... (Carina)

• God and giving less value to material things.

When we go through a situation like this, we begin to appreciate life more; we begin to give more value to things related to God...We stop being so obsessed with material things, because health is something very important...It changed the reference I have of things. (Célia)

Abandoning risky behaviour.

I am going to give up smoking and control my blood pressure too. (Marta)

Other reactions of women with severe maternal morbidity

The experience of severe maternal morbidity is an individual experience that provokes a series of reactions in women. Some of these reactions have already been described above, these being the most significant and most easily generalized; however, there are other, less frequent reactions that are nonetheless relevant for a significant proportion of the women. One of these less common reactions is regression, which may be more or less evident.

So, for me it was very important; they [the healthcare professionals] were like my father and mother; they took care of me, really took care of me, my health and the health of my daughter. This was a very significant moment; I'll never forget it. (Julia)

Latent feelings of blame may appear during a severe complication. Occasionally, this sense of blame may be understood as a form of punishment.

You know, I don't even want to remember it; I cried and cried. I was so upset; I was ashamed, feeling guilty. (Benedicta)

I sinned...This pregnancy is something that I did that was really wrong, and now I have to deal with the consequences. (Roberta)

On the other hand, some women have the idea that the complications may be a result of their own behaviour and, when they are unable to identify this kind of behaviour in their past history, may feel that the complication is unfair. I am suffering for an error that I did not commit...I am sure I did nothing! (Carolina)

Some women reported having difficulty in relating to other people during the complication, reflecting a form of isolation. Occasionally, this difficulty was responsible for not allowing them to share their suffering even with those closest to them.

I keep quiet; I don't say anything...I don't touch on the subject...to this day...because I got out of the [neonatal] ICU and my baby is still in there (Roberta).

Nevertheless, some women perceived that, as well as themselves, their family also had difficulty in speaking about their moments of greatest significance.

The only person who spoke to me about it was my husband. Down there, he said: "I thought I was going to lose you..." And I said: "No, I'm not going [to die]. Not yet..." Then he went on to say: "You can't leave your daughter..." I said: "I'm not leaving either of you". That's all...He never touched on the subject again...To this day he never talked about it again...(Ivete).

Delays

Some women report having noticed the occurrence of a delay in receiving the correct diagnosis or in the implementation of therapeutic actions. According to the perception of all the women interviewed, these delays occurred either before arriving at the referral hospital, because they themselves delayed seeking help or because opportunities had been missed in the healthcare institutions of origin.

I stayed at home without doing anything from half past three until ten. [Interviewer: Tell me about that day. You were at home; you had a headache and...]. I had a convulsion. (Roberta).

On the third day [postpartum], my belly began to swell. I went to the emergency service near my home, and there the doctor told me that I had gases and that I should take Luftal® and go back home. Then he gave me an injection in the vein and I managed to get to sleep. The next day, the pain continued and I went back to the "A" Hospital, where the baby was born. Dr. R said: "It is gases indeed; you can go back home and continue taking Luftal®". On the third day I returned to the "A" hospital; I couldn't bear the pain and my belly was getting bigger and bigger. There, Dr. F. examined me and said: "No, you are being admitted to hospital now". So, they put me in the hospital and I remember that they took blood for testing and then they operated on me immediately. I was very frightened... I understand that if they had suspected that something was wrong on the very first day, this whole complication could have been minimized. I think that three days was too long, the delay made the situation rather worse. (Lucia)

In general, the means of transportation used to reach the healthcare service at the onset of the complication varied; some women using their own means of transportation or that of others, while others used ambulances from the public healthcare sector. None of the women emphasized this issue as constituting a problem or as a cause of additional delay. On the other hand, all the women transferred from healthcare units to the institute were brought by public service ambulances.

Relationship with the healthcare personnel

Some of the women complained about the way in which they were treated by certain healthcare professionals, principally those in the healthcare units of origin and in emergency departments. These complaints, which referred to doctors and other healthcare professionals, included reports of attitudes understood as being excessively short, and a lack of attention, as well as a distant and non-humanized attitude.

Sometimes there are few of them for many of us, but it is better to spend a longer time with the patient and provide a better quality of care than to do everything quickly and sometimes complicate the person's situation. (Ana).

The only thing that I would like to see improved would be the way in which that doctor talks to people. (Michele).

There are people who don't care in the slightest about what you are going through; they just stay there like this [the woman being interviewed lowers her head and pretends to write], they don't listen to you, they don't examine you to find out what is really wrong with you....That's why errors happen in our lives. (Luciana)

In general, the referral hospital and its healthcare workers were seldom criticized and, in fact, were more frequently praised by the women.

Transferral to hospital and to the ICU

These were two significant moments for the majority of the women. The transferral to the hospital, mainly for the women who lived in neighbouring towns, made them feel that their condition was really severe.

I thought: Ah, I am going there and there will be no one that I know. I'm going to be alone in those dark rooms that were only a figment of my imagination since I had never been here. This place is far away from my home; what am I going to do? [I was] Very frightened, because we hear a lot of stories about here, you know... about the people who come here and don't survive. So I was very frightened. (Helena)

With respect to the ICU, this feeling was even stronger.

From that moment onwards, I was frightened, terrified...I thought I was going to die, that I was already dying... (Carolina).

I was desperate, because what we hear about ICU is nothing like what I experienced while I was there... (Vanessa).

I was afraid, principally when I had to go into the ICU in my hometown. Then I learned that I would be transferred to this hospital and I calmed down, because I knew that this was a referral hospital and I would be taken care of. (Célia)

Nevertheless, almost all the women stated that they felt cared for in the ICU, a feeling that comforted them.

They made me comfortable, took care of me...They always asked if I was well, how I was feeling. And there were always people smiling when I looked at them. It's always good to know that there are people looking after you and smiling too, because if you never get a smile, you will end up not smiling too; so for me it was great there. (Carina)

Discussion

The principal findings of the study suggest that the majority of women who survive severe complications of pregnancy present a significant set of emotional reactions to severe maternal morbidity. Beginning with a severe complication of pregnancy, intense, disagreeable physical experiences occur that produce a sensation of impending death. Their fear is very intense and is associated with the imminence of death and the possibility of harm to the baby. Motivated by these factors, the women become involved in a complex process of reviewing their life history and their expectations for the future. Women who have lost their babies or have a very sick baby are particularly at risk of experiencing adverse psychological consequences. The complex emotional

responses to the severe complications related to pregnancy could be summarized as follows:

- **Triggering components:** a potentially fatal complication during pregnancy, delivery or in the postpartum period; the unpleasant physical experience associated with the critical state of health:
- Main components: feeling of impending death and fear;
- Additional components: women's emotional displacement to the baby and the
 woman's other children; frustration at losing an idealized gestation; gaps in memory;
 alienation and apathy; in mourning due to losing the baby; reviewing personal history
 and perspectives for the future; isolation; regression; blame; intrusive memories;
 rumination on the events.

Although additional research is warranted, these reactions taken in conjunction could suggest a syndrome associated with severe maternal complications. In this regard, acute stress disorders and PTSD are being progressively recognized in recent years. This and other studies describing traumatic experiences during pregnancy, the puerperium, and childbirth may contribute to the knowledge and understanding of causes, reactions, and effects of such terrifying experiences in the context of maternal and perinatal health. These studies may also help to initiate a process of awareness rising among healthcare providers about the non physical components of severe maternal morbidity.

Life-threatening events have been clearly associated with the experiences that cause PTSD. However, the responses hereby reported may fall into the realm of acute stress disorder, which are often preliminary to PTSD if they are not resolved (22,23). We hypothesize that the suggested maternal near miss syndrome would be a particular expression of acute stress disorder related to severe acute maternal complications.

Some of these reactions may be understood within an essentialist viewpoint. Within a gender perspective, procreation is a female attribute (24). The "failure" of a normal

pregnancy may damage the woman's self-perception and may hamper fulfilment of some of her social roles. This may contribute towards alienation, isolation and feelings of frustration and loss, as are evident in the narratives analyzed.

This study also explored the occurrence of delays in the provision of healthcare. The Brazilian healthcare system is stratified according to the complexity of care, and the migration of users across its different levels should occur in such a way as to ensure that the health problem is compatible with the capacity to provide care. However, a large percentage of the delays observed in the present study were a result of the woman's own delay in seeking help, not so much because of the time the women took to realize that they were sick, but more as a result of their delay in deciding to seek help. One point that remains to be clarified is to what extent these delays were a result of the women's underestimation of the potential severity of their condition, of their anticipation of difficulties in obtaining care or their difficulty in undertaking natural roles. Many women criticized doctors and other health care professionals for not looking at them or listening to them appropriately suggesting the occurrence of substandard care.

This study has limitations that need to be considered. A major weakness of this study is the fact that the interviews were conducted only in the hospital. This may contribute to a possible courtesy bias, which could explain the absence of criticism of the referral facility itself. Another aspect is that a realistic and more firm perception of "inner growth" would more likely be achieved when the woman returns home, in the absence of institutional support. This study was also not primarily designed to explore the impact of stillbirths and early neonatal deaths in the experience of severe maternal morbidity. Nevertheless, considering our findings on women's emotional displacement to the baby and the mourning due to losing the baby this issue should be a topic for further research.

In addition, laywomen are not always equipped to analyze delays of care. It would be necessary to perform very detailed interviews about what happened from the time they left home to the time of the interview in an appropriately large sample. Moreover, women who were unconscious for part of the time cannot really comment on details about the occurrence of delays.

Now that clinical care is increasingly evidence-based, qualitative research can be used to contextualize the findings of quantitative research in order to implement these findings in the most appropriate way and within a wider perspective. The construction of qualitative theories may contribute towards raising the awareness of the healthcare professionals to important factors in certain situations (26). This may be the case with severe maternal morbidity. The complexity of emotional experiences observed in this study and the manner that some health care providers were perceived suggest the need for a more integrated management of the woman, not only restricted to the biomedical events that trigger the process of morbidity.

In this context and considering the present findings, the proposal of a series of measures to manage the woman who develops severe maternal morbidity could be relevant to reduce the burden of the complications. As well as accurately identifying the cause of morbidity and implementing an evidence-based therapeutic strategy as early as possible in the process, we believe that other elements are required to improve the management of this ordeal. We propose that there should always be a named professional responsible for the care of the woman and that this fact should be made clear to the woman and to her family. The woman and her family should always be aware of what is going on. If a severe complication of pregnancy should occur, full social support should be implemented and a companion of the woman's choice should

be allowed to remain with her. Psychological support and spiritual comfort should be available, offered preferably but not exclusively by specialized professionals. Nonetheless, additional studies are required to increase knowledge on the overall burden of severe maternal morbidity, its relationship with the performance of the role of motherhood and the occurrence of post-traumatic stress and other long term effects. In addition, the effectiveness of a strategy of integrated assistance in cases of severe maternal morbidity, such as the one proposed here, should be evaluated within the context of reducing the burden imposed by this condition.

Conclusion

Based on narratives of women who almost died during pregnancy and childbirth, we described an acute stress disorder that may be associated with the occurrence of severe maternal complications, what we are calling maternal near miss syndrome. The major intrinsic value of describing such as a syndrome is to raise awareness of health care providers to the non physical aspects of complications related to pregnancy and childbirth. We believe that an integrated healthcare, encompassing the physical, psychological, social and spiritual women's dimensions would be useful to attenuate the burden that maternal complications impose to millions of women every year around the world.

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Table 1. The main characteristics of the women interviewed

Characteristic	n	%	
Mean age (years)	26.1 (15-4)	2)	
Parity (at interview)			
1	17	56.7	
2	10	33.3	
>2	3	10.0	
Women that had loss their babies	6	20.0	
Marital status			
With partner	20	66.7	
Without partner	10	33.3	
Living in Campinas	9	30.0	
Education (mean number of years)	8.4 (4-13)		
Head of household	7	23.3	
Economic status*			
A	0	-	
В	3	10.0	
C	18	60.0	
D	8	26.7	
E	1	3.3	
Main cause of complication			
Hypertension	18	60.0	
Infection	3	10.0	
Haemorrhage	2	6.7	
Clinical/Surgical	7	23.3	
Total women interviewed	30		

^{*} The criteria of the Brazilian Association of Market Research Institutes were used to identify the economic status ("A" being the economic level with the greatest purchasing power and "E" with the lowest) (19)

3.6. Artigo 6

Women recalled more accurately process indicators than obstetric complications in a severe maternal morbidity survey

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Abstract

Objective: To validate a questionnaire on severe maternal morbidity and to evaluate the maternal recall of complications related to pregnancy and childbirth.

Methods: 386 survivors of severe and acute maternal complications and 123 women that delivered without major complications between 2002 and 2007 were interviewed by telephone about the occurrence of obstetric complications and events related to their treatment. Their answers were compared with their medical records. Likelihood ratios were used as main estimators of accuracy.

Results: Women did not recall accurately the occurrence of obstetric complications, especially haemorrhage and infection. The likelihood ratios were <5 for hemorrhage and infection, while for eclampsia they almost reached 10. The information recalled by laywomen regarding hysterectomy, intensive care unit admission and blood transfusion were found to be highly correlated with finding evidence of the event in the medical records (likelihood ratios ranging from 12.7-240). The higher length of time between delivery and interview was associated with poor recall.

Conclusion: Process indicators are better recalled by women than the obstetric complication per se and should be considered when developing a questionnaire on severe maternal morbidities.

Key words: Severe maternal morbidity; Near miss; Obstetric complication; Maternal health; Survey

1. Introduction

Each year, more than 500,000 avoidable maternal deaths occur worldwide. Most of these deaths take place in the developing world. [1] Alongside family planning and preventing unsafe abortions activities, the most effective actions for the reduction of maternal mortality are those implemented immediately following the onset of an unexpected complication during pregnancy or childbirth. Delays in implementing required interventions have been associated with the inequality in maternal mortality between developed and developing countries [2].

These delays in health care provision can be identified by auditing the cases of survivors of severe and acute complications [3]. However, in several countries the surveillance of severe maternal morbidity (near miss) remains unstructured. In these places, the use of population health surveys could be an alternative to obtain information on the barriers that women had to overcome to receive adequate obstetric care [4].

For many years, demographic and health surveys have been used to study maternal and perinatal heath in developing countries [5]. A systematic review has observed that population surveys using validated questionnaires provided useful information on the prevalence of maternal morbidities. The problem is that few nationwide population surveys have used formally validated questionnaires. Prior validation of questionnaires on maternal morbidity would be advised to improve the quality of the information, once large variations were observed among different obstetric complications [6].

We believe that estimating the prevalence of severe maternal morbidity and evaluating various associated factors can be useful to improve health systems and their preparedness. Thus, we developed a questionnaire on severe maternal morbidity, as a

tool to identify the survivors of severe and acute complications related to pregnancy. Some main questions of this questionnaire had been included in the recently concluded Brazilian Demographic Health Survey [7] which is expected to provide valuable information on the occurrence of maternal complications and the need for especial procedures for the care of women during pregnancy and childbirth as a proxy for identifying acute episodes of severe maternal morbidity or maternal near miss. Therefore, the aim of this study is to validate this questionnaire and to evaluate the maternal recall of complications and procedures for the care related to pregnancy and childbirth.

2. Methods

This is a validation study evaluating the capacity of a questionnaire applied during a survey to laywomen to identify those who survived severe complications related to pregnancy and childbirth in the last five years. This study was carried out at the maternity hospital of the University of Campinas (UNICAMP), a teaching hospital that provides tertiary care to women from a region of approximately three million inhabitants in the state of São Paulo, southeast of Brazil.

Women who had and women who had not severe complications participated of this study. Women who presented severe complications were identified among those who were admitted to the obstetrical intensive care unit of the institution between October 2002 and September 2007. Women who did not present severe complications were identified among those who stayed in the rooming inn ward after delivery in the same period. Considering the feasibility of this study, requiring to interview women at different time periods after the childbirth, only those women who could be contacted

through telephone were included. During the period from July 2007 through October 2007, the women were contacted by telephone for verbal consent and interview. The study was approved by the Institutional Review Board prior to initiation.

2.1 Measurements

A pre-coded, structured questionnaire about severe maternal morbidity was developed based on previous validated questionnaires [4,8-13]. We aimed to identify the most severe cases and questions related to obstetric complications that are major contributors to maternal deaths in Brazil were included (pre-eclampsia/eclampsia, haemorrhage and infection) [14]. In addition, questions on selected process indicators were included as proxies of severe maternal morbidity. Process indicators, such as admission to intensive care unit, blood transfusion, hysterectomy, transfer to a referral hospital, laparotomy and others, have been used to identify severely ill women during pregnancy and childbirth [15]. This questionnaire was developed in Brazilian Portuguese, and it was pre-tested before in an independent sample of women through telephone interviews. Minor refinements were performed after pre-testing. Basically, the content of the questions included in this questionnaire is presented in the tables and it contains all questions in fact used in the 2006 Brazilian DHS [7].

After ethical approval, the hospital information system provided detailed contact information of all women admitted to the obstetric intensive care unit during the five years period (2002 to 2007) and of those low risk women that stayed at the rooming inn postpartum ward during the same period. One hundred and eighty women from this low risk postpartum ward have been randomly selected with the purpose to assure that information would also be available for negative cases of the gold standard (without a

severe maternal morbidity condition) in order to make possible the evaluation of the performance of each criteria. Then, a mixed list including only name and contact information on both categories of women was prepared to maintain the interviewers unaware of the actual condition of each woman in this regard.

Three trained interviewers contacted the women through telephone, under the supervision of a research assistant skilled in teleresearch in the field of reproductive health. The interviewers were not acknowledged whether the woman that was being contacted was from the group of women with severe complications or not. Those women who were unable to be traced at all via telephone after 5 unsuccessful attempts were excluded. Otherwise, the attempts continued until a definite success was obtained with a complete interview or a posterior unsuccessful contact. The maximum number of attempts per case to reach an interview was 16. The interviews were recorded and the answers were entered concurrently into an integrated database in SPSS by the interviewer who was in front of a computer with a headset while doing the interview and with access to the database. The research assistant supervisor checked five percent of the data collected against the voice recording, providing feedbacks to each interviewer regarding errors, way of going in depth in a specific question, and checking that appropriate corrections were performed in the database. This checking of data quality was performed concurrently as the interviews were being performed.

In addition, other four distinct data collectors independently abstracted the corresponding information from medical records using separate standardized forms. They were also unaware of the condition of severe maternal morbidity or not for each woman they were going to collect such information. Five percent of the medical records were also abstracted twice as a quality control procedure performed by another

supervisor, with the necessary corrections being performed when necessary. This information was then introduced in another database in SPSS. After testing for consistence and cleaned, both databases were matched by the hospital register number and then merged for the planned analysis.

2.2 Analysis

The capacity of the questionnaire to identify those women who survived severe complications was assessed using the information on medical records as the "gold standard". Sensitivity and specificity were calculated for each question and combinations of questions for the main diagnosis and procedures related to the topic under study. Sensitivities and specificities were calculated comparing each case with a positive answer in the questionnaire with all other women who gave a negative answer for the same question. Sensitivity was calculated as the number of true positives divided by the number of true positives plus false negatives. Specificity was calculated as the number of true negatives divided by the number of true negatives plus false positives. In addition, we calculated likelihood ratios and their 95%CI for the performance of each question and they were our main estimators of accuracy. Likelihood ratios were calculated as sensitivity/(1-specificity). If specificity were perfect, 0.99 was used instead. A likelihood ratio >10 was considered highly correlated with confirming the event recalled by the woman in the medical records [13,16]. The 95% confidence intervals (Fleiss' quadratic for sensitivity and specificity and classic Wald for likelihood ratio) and p-values for characteristics comparison were also calculated. All statistical analyses were performed using the SPSS v.11.5 and Epi.Info v.6.04d softwares.

3. Results

Between October 2002 and September 2007, 673 women were admitted to the obstetric intensive care unit, with 655 survivors. In the same period, 12,198 women were admitted to the low-risk rooming inn ward and 180 have been randomly selected for telephone interview. From a total of 574 women that were reached through telephone, 386 women with severe complications (58.9% success rate in interviewing) and 123 women without severe complications (68.3% success rate) were interviewed. Five women declined participation in the study. The age, parity, marital status and the interval between the delivery and the interview date are shown in Table 1. The frequency of obstetrical complications and indicators of management as recorded in the medical records are presented in Table 2 for women who really experienced a severe maternal morbidity during pregnancy or childbirth.

Table 3 shows the performance of maternal recall of obstetrical complications assessed by questions and combinations of questions against medical records. Overall, women did not recall accurately the occurrence of obstetric complications, especially hemorrhage and infection. The likelihood ratios for the questions and their combinations were <5 for hemorrhage and infection, while those related to eclampsia were nearer 10. One combination of questions related to eclampsia ("Did you have any seizure or convulsion during pregnancy, childbirth and postpartum days?" + "Have you ever had any seizure or convulsion before the pregnancy?") had a likelihood ratio of 9.8.

Table 4 presents the performance of maternal recall of events and interventions during a severe complication related to pregnancy. The information recalled by laywomen regarding hysterectomy, intensive care unit admission and blood transfusion

were found to be highly correlated with finding evidence of the same correspondent event in the medical records (likelihood ratios ranging from 12.7-240). On the other hand, laparotomy, inter-hospital transference, mechanical ventilation and postpartum stay above one week performed worse than the three previous ones, all of them with LR well below 5.

For the three management procedures with the best performance as indicators of severe maternal morbidity (hysterectomy, admission to ICU and blood transfusion) an additional analysis was performed to try to identify factors possibly associated with this finding. The only that showed to be significant was the time elapsed between the occurrence of the severe maternal morbidity episode and the interview. The higher length of time was associated with poor recall (data not shown in table).

4. Discussion

This study addressed the question of how accurately women recall events occurred during their pregnancy and childbirth, especially those related to severe complications that could be life threatening. We found that process indicators were better recalled by laywomen than obstetric complications. Hysterectomy, Intensive Care Unit admission and blood transfusion were accurately recalled. Eclampsia could be regarded as in an upper intermediate accuracy level, while hemorrhage and infection were poorly recalled. We also found that inaccuracy was associated with higher intervals between the delivery and the interview.

Obstetric complications are commonly assumed as among the most remarkable events that a woman can experience during pregnancy and childbirth. However, previous studies have shown that women recall obstetric complications in a varied way. Most of

these studies found that eclampsia could be satisfactorily recalled, while there was more uncertainty regarding hemorrhage, dystocia and infection [4,6]. In our study, eclampsia was the only obstetric complication that nearly achieved a reliable accuracy. And despite the frequent severity, hemorrhage and infection were not accurately recalled.

We observed also that length of time from pregnancy until interview is one of the factors that may affect the way that women recount their stories of pregnancy and childbirth. Severely ill women during pregnancy and childbirth may experience altered mental states that transiently impair their memories about the events associated with the complication. In this context, amnesia and memory gaps are described as frequent components of severe maternal morbidity [17,18]. All these factors can contribute to a low performance of questions referring to obstetric complications in population surveys.

On the other hand, process indicators have been used as proxies of severe maternal morbidities during the last 15 years [15]. However, to the extent of our knowledge, they had never been tested in population surveys. We found that some of them, especially intensive care unit admission, hysterectomy and blood transfusion were recalled with high accuracy. These three indicators are consistently associated with severe maternal morbidity in several studies. Our findings encourage the use of these process indicators in population studies as an adjunct to improve our understanding of maternal health. Besides some concerns that may have regarding using process indicators worldwide for this purpose, considering the inequalities in accessibility of these procedures for all women during childbirth could introduce a bias, they were consistently found to be correctly recorded by women experiencing a severe maternal morbidity episode, as found in the database for Latin America from the WHO Global Survey on maternal and perinatal health [19]

Nevertheless, there are some points that should be addressed. Once medical records were our golden standard, our validation study relies on the recall of hospitalized women. This is an unavoidable selection bias when medical records are used as golden standard. It is necessary to consider that in places where healthcare services are irregular or insufficient, women who attend health services may be different from those who do not attend, either because of geographical access difficulties or other aspects. In Brazil, and particularly in the region where the study was conducted, the rate of hospitalization for delivery is very high (>98%) and it may have minimized this bias. Other selection bias that we have to consider is that we only included in the study women that could be reached by telephone. Women who do not have telephone or who have changed their phone number can be different from those who could have been reached by phone. We needed to base our study in telephone interviews considering the feasibility and the practical aspects of this approach. However, in this region the telephone coverage is high, mainly when we consider the sum of fixed lines and mobile ones. However, we were unable to estimate the actual impact of this selection bias in our study.

In addition, severe maternal morbidity is a condition with low prevalence in general obstetric populations, and there is an interaction between the accuracy, the prevalence of self-reported morbidity and the actual prevalence of morbidity. The occurrence of high specificities associated with low actual prevalence results in accuracy being essentially determined by the specificity. The use of accuracy as the main indicator of validity can eventually overestimate the validity [20]. In our study, most of the questions and combinations tested revealed higher specificities and we artificially increased the prevalence of complications by including only 123 women without severe complications. Caution should be exercised when applying these findings to general

populations, although our main estimator of accuracy, the likelihood ratio, is less dependent of the base rate of the target event [13]. This should be a matter of concern when using the data from the validation of these questions for the results of the recent Brazilian DHS which used some of the questions already validated.

We conclude that it is possible to assess severe maternal morbidity through population surveys. We observed that process indicators are more accurately recalled than obstetric complication per se and that length of time from pregnancy until interview can affect the maternal recall. In this context, we would re-emphasize the need of local validation and recommend the addition of locally relevant process indicators in the questionnaires. Finally, population surveys may be useful as an exploratory tool where more precise and elaborated approaches are not feasible. Furthermore, additional research is needed on the determinants of poor accuracy and the use of process indicators in population surveys.

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Table 1. Distribution of women according to some characteristics by the occurrence of severe maternal morbidity (SMM)

Characteristic	SMM	No SMM	p &	
A an at hinth (many)			0.030	
Age at birth (years)	10.4	12.0	0.030	
Up to 19	10.4	13.0		
20 - 24	22.5	34.1		
25 - 29	26.7	22.8		
30 - 34	21.8	20.3		
≥ 35	18.7	9.8		
Parity #			0.119	
0	42.1	33.9		
1	26.6	36.5		
≥ 2	31.4	29.6		
Marital status [@]			0.519 \$	
With partner	68.0	71.7	0.01)	
Without partner	32.0	28.3		
Length of time between	0.025			
Up to 1	42.7	32.5		
2	22.3	17.1		
3	17.1	25.2		
≥ 4	17.9	25.2		
Total	386	123		

^{*}SMM cases: with at least one related diagnosis and/or procedure Pearson Chi-square test; Schi-square test with Yates correction Missing information for: 11 women; 104 women

Table 2. Distribution of women who had an episode of severe maternal morbidity according to main diagnosis or procedures performed

Diagnosis	%
Eclampsia	7.3
Hemorrhage before, during or after delivery	16.3
Sepsis	6.7
Jaundice	1.8
Procedures	
Admission to ICU	99.5
Use of mechanical ventilation	17.1
Transfer to other hospital	28.8
Laparotomy	6.7
Hysterectomy	7.5
Post partum stay above 7 days	29.5
Blood transfusion	25.4
Total women	386 (100%)

Table 3. Performance of questioning women in a survey for the diagnosis of eclampsia, hemorrhage and infection during pregnancy or childbirth as indicators of SMM (n=509)

Diagnosis	Sensitivity	Specificity	Likelihood ratio	
	[95% CI]	[95% CI]	[95% CI]	
Eclampsia				
Woman had convulsions, seizures or "crisis" during pregnancy, delivery or postpartum	96.4	87.5	7.7	
	[79.8–99.8]	[84.2 – 90.3]	[6.4-9.9]	
The previous plus: woman had not had convulsions before	89.3	90.9	9.8	
	[70.6–97.2]	[87,8 – 93,2]	[7.16-13.30]	
The previous plus: woman had an increase in blood pressure during pregnancy	60,7	93,3	9.1	
	[40,7–77,9]	[90,6 – 95,3]	[5.83-14.29]	
The previous plus: woman had swelling in her legs, face or hands during pregnancy, delivery or postpartum	53,6	93,8	8.6	
	[34,2–72,0]	[91,1 – 95,7]	[5.27-14.0]	
The second previous plus: woman had "turbid vision" during pregnancy, delivery or postpartum	39,3	95,0	7.9	
	[22,1–59,3]	[92,6 – 96,7]	[4.31-14.40]	
All five criteria	35,7	95,4	7.8	
	[19,3–55,9]	[93,0 – 97,0]	[4.10-14.85]	
Hemorrhage				
Women had bleeding during pregnancy or an increased bleeding during delivery or postpartum	81.0	69.7	2.7	
	[68.7–89.4]	[65.2 – 73.9]	[2.22-3.22]	
The previous plus: bleeding wet the clothes, the bed or the floor	55.6	81.6	3.0	
	[42.6–67.9]	[77.6 – 85.0]	[2.25-4.06]	
Infection				
Woman had high fever during pregnancy or after delivery	69.2	77.2	3.0	
	[48.1–84.9]	[73.2 – 80.8]	[2.24-4.12]	
Woman had high fever during pregnancy or after delivery with chills	57.7	83.6	3.5	
	[37.2–76.0]	[80.0 – 86.8]	[2.40-5.19]	
Woman had high fever during pregnancy or after delivery but she had not other disease during pregnancy	53.8 [33.7–72.9]	83.2 [79.5 – 86.4]	3.2 [2.14-4.83]	
Woman had high fever during pregnancy or after delivery and had also stinky vaginal discharge	38.5	85.1	2.6	
	[20.9–59.3]	[81.5 – 88.1]	[1.52-4.39]	
Woman had high fever during pregnancy or after delivery with chills but she had not other disease during pregnancy	42.3 [24.0–62.8]	88.4 [85.1 – 91.1]	3.6 [2.19-6.09]	
Woman had high fever during pregnancy or after delivery with chills and had also stinky vaginal discharge	30.8 [15.1–51.9]	89.9 [86.7 – 92.3]	3.0 [1.61-5.72]	
All the four criteria	23.1	92.8	3.2	
	[9.8–44.1]	[90.0 – 94.8]	[1.47-6.88]	

Table 4. Performance of questioning women in a survey for several procedures during pregnancy or childbirth as indicators of severe maternal morbidity (n=509)

Procedure	Sensitivity [95% CI]	Specificity [95% CI]	Likelihood ratio [95% CI]	
Lystaractomy	100.0	99.6	240.0*	
Hysterectomy	[85.4 - 100.0]	[98.3 - 99.9]	[60.20-956.88]	
Admission to Intensive Care Unit	97.1	96.0	24.3*	
Admission to intensive Care Unit	[94.8 - 98.5]	[90.4 - 98.5]	[10.29-57.33]	
Blood transfusion	89.8	92.9	12.6*	
Blood transfusion	[81.6 - 94.7]	[89.9 - 95.1]	[8.90-18.19]	
Langratamy	69.2	88.2	5.9	
Laparotomy	[48.1 - 84.9]	[84.9 - 90.9]	[4.12-8.36]	
Inter hearital transfer	86.5	74.6	3.4	
Inter-hospital transfer	[78.4 - 92.0]	[70.0 - 78.8]	[2.84-4.10]	
Mechanical ventilation	84.8	70.9	2.9	
Mechanical ventilation	[73.4 - 92.1]	[66.4 - 75.0]	[2.44-3.48]	
Doctmontum stay > and woods	87.7	65.3	2.5	
Postpartum stay > one week	[79.9 - 92.9]	[60.4 - 70.0]	[2.17-2.94]	

3.7. Artigo 7

The challenge of studying maternal near miss in the community: findings of the 2006 Brazilian Demographic Health Survey

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Abstract

Objectives: To obtain an estimate of maternal near miss in Brazil and also explore its associated factors.

Methods: Analyses of the database of the 2006 Brazilian Demographic and Health Survey with emphasis in the data of reported maternal complications. This survey applied a validated questionnaire to evaluate the occurrence of maternal complications and key interventions associated with severe maternal morbidity. According to a pragmatic definition, any woman reporting the occurrence of eclampsia, hysterectomy, blood transfusion or admission to the Intensive Care Unit was considered as a near miss case. Associations between the socio-demographic characteristics and the maternal near miss were evaluated.

Results: A total of 5,025 women with at least one live birth in the last five years were interviewed. Around 22% of them reported the occurrence of complications during the pregnancy. The prevalence of maternal near miss in Brazil, using a pragmatic definition based on the occurrence of eclampsia, hysterectomy, admission to the ICU and blood transfusion was 21,1 per 1,000 live births. An increased risk of maternal near miss was found only among the women with low education.

Conclusions: Nearly 70,000 maternal near miss cases are estimated to occur in Brazil per year. A pragmatic definition of maternal near miss was useful to obtain more reliable information at the community level, at least in the settings where the core interventions are fairly available. Questions about clinical signs and symptoms provided less reliable information and alternatives to study the maternal near miss in the less developed settings should be investigated.

Key words: Severe maternal morbidity; Maternal near miss; Obstetric complication; Maternal health; Demographic Health Survey

1. Introduction

A total of 10 million women worldwide are estimated to present severe complications of pregnancy every year and half million women die, mostly in developing countries [1,2]. In Brazil, the maternal mortality ratio is estimated to be about 75 maternal deaths per 100,000 live births, but larger uncertainty exists on the occurrence of severe maternal complications [3]. Information on women that nearly died bur survived of complications which occurred during the pregnancy and puerperium (maternal near miss) is considered to be useful to identify health systems failures [2,4-6]. In the settings where an integrated epidemiological surveillance with wide geographical coverage is yet to be established, community-based surveys have been suggested as a possible source of information on maternal morbidity and mortality [7-10].

In fact, for several years demographic and health surveys have been used to gather information on maternal and perinatal heath in several developing countries [11]. However, in the context of large, nationwide population surveys, only few of these studies have used formally validated questionnaires [12]. In Latin America, the occurrence of complications related to pregnancy reported in demographic and health surveys (DHS) was found to be overestimated, ranging from 16.7% in Brazil (1996) to 51.8% in Peru (1996) [13,14]. These estimates are essentially based on the maternal recall of complications and several factors may interfere with this recall among lay women. These factors would include variations in the perception of severity, misunderstandings about the complications themselves, and the time between the complication and the interview itself [8,10,15,16]. The severe maternal morbidity has

also been associated with a set of mental and emotional responses (e.g. fear, altered mental status, amnesia) that could also impair the maternal recall of the complication [16]. Despite of these difficulties, population surveys using validated questionnaires were able to provide useful information on the prevalence of maternal morbidities [12]. Thus, formal validation of questionnaires on maternal morbidity would be recommended to improve the quality of the information.

Based on this systematic review of validated questionnaires about complications during pregnancy, a new questionnaire was developed. It also included questions about interventions highly associated with the severe maternal morbidity (i.e. intensive care unit admission, blood transfusion and hysterectomy) [4,17]. In general, the questionnaire validation study observed that women recalled more accurately the interventions than the obstetric complications, while the occurrence of eclampsia was marginally well recalled and hemorrhage and infection were not accurately recalled [15]. The validated questionnaire was included in the 2006 Brazilian Demographic and Health Survey and the aim of this study is to obtain an estimate of maternal near miss in Brazil and also explore its associated factors.

2. Methods

This study analyses the database of the Brazilian DHS carried out in 2006-2007 with emphasis in the data of reported maternal complications [18]. This survey applied a validated questionnaire to evaluate the occurrence of maternal complications and key interventions associated with severe maternal morbidity. The questionnaire was developed considering a previous systematic review [12] and it was concurrently

validated [15]. The survey was conducted following the approval of the corresponding institutional review board.

The Brazilian 2006 DHS used a probabilistic, complex sampling design: stratified with cluster in two stages (census area and household) and weighting data. The 10 geographical strata were defined according to the five Brazilian macro-regions (North, Northeast, Southeast, South, and Central-West) and household situation (urban and rural). The primary sampling unit (PSU) was the census area, and this cluster was selected by simple random sampling (SRS), within each stratum. The weighting variable was calculated involving the inverse of the unit's probability of selection and adjustments for non-response and post-stratification [18].

The characteristics of the women interviewed whose pregnancies resulted in live births in the five years preceding the survey, the complications reported by these women and data on the interventions that these women reported were analysed according to the region of the country. The maternal near miss was evaluated using the pragmatic definition developed in a large facility-based study held in Latin America [17]. This definition is compatible with the findings of the validation study, where the information recalled by the women on the occurrence of hysterectomy, blood transfusion, ICU admission and eclampsia was highly correlated with confirming the recalled event in the medical records [15]. According to this pragmatic definition, any woman reporting the occurrence of eclampsia, hysterectomy, blood transfusion or admission to the Intensive Care Unit was considered as a severe maternal morbidity / near miss case.

Associations between the socio-demographic characteristics of the women and the occurrence of severe maternal morbidity were evaluated. For the statistical analysis of data, the odds ratio (OR) and respective 95% confidence intervals were calculated and multiple logistic regression analysis was performed. The peculiarities of the complex sampling design of the DHS were taken into consideration during the statistical analysis (geographical stratum, primary sampling unit and sampling weight). Finally, a model was developed using data from the 2006 Brazilian DHS, Ministry of Health / Interagency Network for Health Information (DATASUS/RIPSA) and the Brazilian Institute of Geography and Statistics (IBGE) to obtain estimates for the maternal near miss cases in Brazil [3,18-20]. The softwares used for processing and analysing data was the SPSS software program, version 11.5, the Stata software program, version 7.0 and Epi Info, version 6.04d.

3. Results

The 2006 Brazilian Demographic and Health Survey interviewed 15,575 women in 13,056 interviewed households with at least one eligible woman in the five Brazilian geographic regions. About one third of these women (5,025) reported at least one live birth in the last five years. A total of 6,833 pregnancies were reported, corresponding to 19,987,263 pregnancies in the expanded sample. The women reporting at least one live birth and in the last five years were interviewed using the questionnaire on the complications during pregnancy, childbirth and postpartum and constitute the study population of this report, as well as the pregnancies during these five years (Table 1).

As a general description of the surveyed population, around 40% of the women live in the State capitals or big cities, with higher proportion in the Southeast and lower proportion in the North. A total of 53% of the women were between 20 and 29 years old and in the South and the Southeast region, fewer adolescents and more women with 40 or more years were interviewed. As regards to the education, 2.7% of the women had no formal education, 52% had completed the fundamental education, 37.6% had completed the high school and 7.6% completed the superior education. A total of 12.8% of the women were still studying. In the South and Southeast region, fewer women had no formal education but, in the North and the Northeast, only 3.5% and 4.8% of the women completed the superior education. Fifteen percent of the women had no partner and no inter-regional differences were observed regarding to this. The self reported ethnicity or skin colour was white for 35.3% of the women, 10.6% self reported as black, 48.4% as Pardo and 5.7% as yellow or red. Pardo is a Brazilian Portuguese term used to refer to mullato or brown skinned persons. In the South region, 67% of the women were white and a similar proportion was *Pardo* in the North and Northeast. Concerning the religion, 61.3% were Catholic, 26.0% were Evangelic, 3.4% had other religion and 9.3% had no religion. The proportion of Catholics was slightly higher in the Northeast region while lower in the Southeast region. About 40% of the women were not working in the last 12 months and this proportion was lower in the South and Southeast region (Data not showed in table).

Table 2 shows the prevalence of self reported morbidities. Around 22% of the women reported the occurrence of any complications during the pregnancy, and no regional differences were observed. Eclampsia or the first occurrence of seizures during

pregnancy and puerperium was around 0.6%, except in the North where it was reported by almost 1% of the women. Hemorrhage was reported by 18.4% of the women and infection by 1.0%. The reported prevalence of infection was higher (2.2%) in the North region. Report of procedures being used for these complications was also low, ranging from 0.2% for postpartum hysterectomy, 0.5% for admission to an ICU, 0.8% for blood transfusion, to 4% for hospital postpartum stay above seven days. The rates of admission to ICU were higher for Northeast and Central West regions. These complications together with some procedures were reported by 22.9% of women.

According to the pragmatic definition, Table 3 presents information on occurrence of maternal near miss. It also relates the current findings with those of the questionnaire validation study, presenting corrected prevalence rates. Overall, the prevalence of maternal near miss in Brazil, using a pragmatic definition based on the occurrence of eclampsia, hysterectomy, admission to the ICU and blood transfusion is 21 per 1,000 live births. Minimal variation was found applying correction factors derived from the validation study.

Table 4 explores the associations between the women's socio-demographic characteristics and the maternal near miss. A significant increased risk of maternal near miss was found only among the women with low education. No associations were found between maternal near miss and the marital status, ethnicity, religion, working status, place of residence, region and number of previous live births.

Table 5 summarizes population and health information of Brazil and presents the estimates for maternal near miss at the national level. According to these estimates, the

maternal near miss ratio for the country is around 21 cases per 1,000 live births, reaching around 69,800 cases of maternal near miss per year in the whole country.

4. Discussion

Nearly 70,000 maternal near miss cases are estimated to occur in Brazil per year. These estimates are derived from the 2006 Brazilian DHS and open data from Ministry of Health / Interagency Network for Health Information (DATASUS/RIPSA) and the Brazilian Institute of Geography and Statistics (IBGE) [18-20]. The DHS was performed including a validated questionnaire and applying a pragmatic definition based on the occurrence of eclampsia, hysterectomy, admission to the ICU and blood transfusion [15]. As regards to maternal near miss associated factors, an increased risk was found only among the women with low formal education.

In 1996, a previous demographic and health survey was carried out in Brazil and gathered information on maternal complications during pregnancy and puerperium. According to that survey, the prevalence of women reporting at least one complication was about 18% (ranging from 15.5% to 22.9%, depending on the geographic region) [14]. However, a comparison with the present survey is difficult. While an apparent increase of the prevalence of complications could be noted (the present survey found about 22% of women reporting at least one complication during the pregnancy), this conclusion is barely supported. The questionnaires are different, the 1996 one was not validated, and the 2006/07 questionnaire has shown poor accuracy in the questions regarding haemorrhagic and infectious complications. From the socio-demographic standpoint, many of the 1996 and the 2006/07 findings are similar, showing persistent

disparities between the Brazilian geographic region in terms of human development, with inequalities that benefits mainly the Southeast and South regions.

This study has limitations that should be mentioned. First, the validation study of the questionnaire was implemented concurrently to the demographic and health survey. This was a really needed approach, essentially due to time constraints. Second, the validation was performed through telephonic interviews with women discharged from a single tertiary hospital located in one of the most developed regions of Brazil (city of Campinas, State of São Paulo, human development index = 0.852). Third, the questions based on interventions had a much better accuracy in comparison to the questions about the signals and symptoms related to the complications [15]. And finally, it is widely known that estimates based on indicators of management are heavily affected by the availability of the resource / intervention [4,15]. Thus, the overall estimates for maternal near miss may have been affected by the existing regional differences in Brazil. However, a surprising finding was the higher rates of admission to an ICU in the Northeast and Central West regions, definitely not the most developed ones in the country.

Despite the above mentioned drawbacks, this study has strengths that should be highlighted. The pragmatic definition of maternal near miss adopted in this study is supported by a large facility-based study held in Latin America. Hysterectomy, blood transfusion, ICU admission and eclampsia were found to be highly associated with maternal deaths [17]. The validation study has also shown a very good correlation between the medical records and the maternal recall of these factors. This study also adds to the methodological aspects of studying maternal near miss at the

population/community level in middle income countries. The main lessons learned from this challenging process of developing a tool to gather information about severe maternal complications and maternal near miss at the community level could be summarized as follows. The pragmatic definition of maternal near miss was useful to obtain more reliable information at the community level, at least in the settings where the core interventions are fairly available. Questions about clinical signs and symptoms provided less reliable information and alternatives to study the maternal near miss in the less developed settings should be investigated. A possible alternative could be met assessing the information provided by community health workers and traditional birth assistants in the settings where their workforce is largely applied.

Further research will certainly refine the model and provide more precise estimates of maternal near miss in Brazil. Whatever the final estimate, it is needed to move forward from the descriptive understanding of the problem to the conceptualization of an integrated package of care to reduce mortality and minimize the burden of maternal complications. To achieve such a goal, one probable measure to best influence the results would be a timely identification of these severe maternal morbidities. This could be reached only if a real system of surveillance could be prospectively proposed, mainly for health facilities, followed by appropriate guidelines and flowcharts to be used by health professionals for treating or referring the cases identified.

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Table 1. Number of households, women, response rate among women, number of live births (LB) and pregnancies in the last five years, by region. DHS, Brazil, 2006

Characteristics	Region					
	N	NE	SE	S	CW	Total
Households With at least one eligible woman	2,148	2,520	2,820	2,868	2,700	13,056
Women Eligible Interviewed	2,971 2,608	3,461 3,166	3,773 3,344	3,615 3,296	3,591 3,161	17,411 15,575
Response rate among women (%)	87.8	91.5	88.6	91.2	88.0	89.5
LB last five years (weighted number)	1,102	974	977	964	1,039	5,056
Women with at least one LB last five years	1,008	951	992	1,022	1,052	5,025
Pregnancies in the last five years	1,485	1,346	1,294	1,298	1,410	6,833
Pregnancies in the last five years (expanded sample)	2,091,529	5,874,461	7,898,838	2,549,198	1,573,237	19,987,263

N: North NE: Northeast SE: Southeast S: South CW: Center West LB: Live births

Table 2. Proportion of pregnancies* in the last five years before the survey, according to complications and procedures, by region. DHS, Brazil, 2006

	Region					
Complications and procedures	N	NE	SE	S	CW	Total
Eclampsia Had seizures during PDP but had not had before (a)	0.9	0.5	0.6	0.5	0.5	0.6
Hemorrhage Heavy bleeding wetting clothes, etc. during pregnancy or in the 3 first days postpartum (b)	17.8	19.4	18.0	18.7	17.2	18.4
Infection Had high fever after delivery/ abortion with chills and a smelling vaginal discharge (c)	2.2	0.7	0.8	1.4	0.6	1.0
Procedures Hysterectomy (d) Admission to ICU (e) Blood transfusion (f) Inter-hospital transfer (g) Mechanical ventilation (h) Postpartum stay >1 week (h)	0.1 0.4 1.2 1.3 1.9 4.6	0.2 0.8 0.7 2.7 2.0 4.5	0.3 0.4 0.7 2.5 1.8 3.9	0.1 0.2 1.0 1.4 1.3 3.7	0.2 0.8 1.0 2.9 0.9 3.0	0.2 0.5 0.8 2.3 1.7 4.0
Any	22.0	24.3	22.3	23.1	21.9	22.9
Pregnancies in the last five years	1,485	1,346	1,294	1,298	1,410	6,833

N: North NE: Northeast SE: Southeast S: South CW: Center West

PDP: pregnancy, delivery and postpartum ICU: Intensive care unit

Missing values for: (a) 105 pregnancies; (b) 74; (c) 114; (d) 417; (e) 83; (f) 94; (g) 78; (h) 85

^{*} Weighted data

Table 3. Rates of self reported indicators of maternal near miss among women during pregnancies* in the last five years before the survey. DHS, Brazil, 2006

Indicator of Maternal Near Miss	Validated Sensitivity #	Validated Specificity #	LR#	Crude maternal near miss rate (per 1,000 pregnancies	Adjusted maternal near miss rate (per 1,000 pregnancies)
Eclampsia (a)	89.3	90.9	9.8	6.0	6.3
Hysterectomy (b)	100.0	99.6	240.0	2.2	2.2
Admission to ICU (c)	97.1	96.0	24.3	5.2	5.2
Blood transfusion (d)	89.8	92.9	12.7	8.1	8.9
Any of four above (e)	97.7	94.3	17.2	20.0	21.1

^{*} Weighted data # Validated sensitivity, specificity and LR from Souza et al., 2009 [15]

Missing values for: (a) 105 pregnancies; (b) 417; (c) 83; (d) 94; (e) 443 pregnancies

Table 4. Crude and adjusted estimated risk of maternal near miss among women with at least one live birth in the last five years before the survey, according to socio-demographic characteristics. DHS, Brazil, 2006

Characteristics of	Total •	With	Without	OR (95%CI)	OR _{adj} (95% CI) [@]
women		SMM	SMM (a)		
Age at interview (years)					
15-29	63.1	61	2984	1.00 (ref.)	1.00 (ref.)
30-39	30.1	45	1,527	1.44 [0.96-2.17]	1.78 [0.86-3.70]
40-49	6.8	13	308	2.06 [1.07-3.92]	2.56 [0.73-8.97]
Schooling years (b)					
Without/Fundamental	54.5	87	2,814	1.94 [1.26-2.98]	2.01 [1.06-3.81]
High School	45.5	32	2,003	1.00 (ref.)	1.00 (ref.)
Currently studying (c)					
No	87.1	105	4,225	1.05 [0.58-1.93]	1.08 [0.44-2.64]
Yes	12.9	14	593	1.00 (ref.)	1.00 (ref.)
Marital status (d)					
Without partner	15.2	22	819	1.11 [0.67-1.81]	1.06 [0.47-2.39]
With partner	84.8	97	3,996	1.00 (ref.)	1.00 (ref.)
Ethnic /skin color (e)					
White	35.1	34	1,715	1.00 (ref.)	1.00 (ref.)
Non white	64.9	83	3,049	1.37 [0.90-2.10]	1.07 [0.54-2.12]
Religion (f)					
No one	9.4	11	411	1.00 (ref.)	1.00 (ref.)
Some	90.6	108	4,402	0.92 [0.47-1.82]	1.02 [0.39-2.63]
Working in the last 12 m	nonths (g)				
Yes	60.3	77	2,799	1.00 (ref.)	1.00 (ref.)
No	39.7	42	2,017	0.76 [0.51-1.12]	0.83 [0.38-1.85]
Residence (h)					
Capital or big cities	39.6	40	1,507	1.11 [0.74-1.65]	1.14 [0.57-2.25]
Other	60.4	79	3,297	1.00 (ref.)	1.00 (ref.)
Region					
N, NE, CW	45.4	77	2,880	1.23 [0.83-1.84]	1.24 [0.68-2.27]
SE, S	54.6	42	1,939	1.00 (ref.)	1.00 (ref.)
Number of live births					
≥ 2	53.7	80	2,906	1.35 [0.90-2.03]	0.62 [0.32-1.20]
<2	46.3	39	1,913	1.00 (ref.)	1.00 (ref.)
Total women (a)	4,938	119	4,819		

Missing values for: (a) 87 women; Missing values for other: (b) 2 women; (c) 1; (d) 4; (e) 57; (f) 6; (g) 3; (h) 15.

Table 5. Population estimates of near miss for Brazil

Population size *	183,987,291
Crude number of live births (per 1,000 inhabitants) #	18.0
Maternal mortality ratio (per 100,000 live births) [@]	74.7
Maternal near miss ratio (per 1,000 live births)	21.1
Number of maternal near miss (per year)	69,800
* [20] *[19] [@] [3]	

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Research on Severe Maternal Morbidities and Near-Misses in

Brazil: What We Have Learned

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Abstract

The occurrence of complications during pregnancy depends less on the degree of human development than differences in the way complications in pregnancy are detected and managed. It is the quick diagnosis and correct management that really contribute to the enormous differences in maternal mortality ratios between countries and regions. Understanding of the determinants of maternal mortality may be improved by studying cases of severe maternal morbidity. In this paper, various approaches to the concept of severe maternal morbidity and near-misses are discussed, and the relationship between these and maternal deaths. Although no consensus has been reached on a strict definition of near-miss or severe maternal morbidity, we show that the definitions used may be

tailored to support diverse objectives, including monitoring progress, epidemiological surveillance and auditing of health care. We conclude that the versatility of the concept, the greater frequency of cases available for study and the possibility of interviewing the survivors of severe complications all support the value of studying severe maternal morbidity to help guide local efforts to reduce maternal mortality. Although this may almost be a reality in developed countries, it continues to represent an important and difficult challenge to overcome in places where its benefits would be most evident.

Résumé

L'apparition de complications pendant la grossesse dépend moins du degré de développement humain que des différences dans la détection et la gestion de ces cas. Ce sont le diagnostic rapide et la gestion adaptée qui contribuent réellement aux énormes différences entre le taux de maternité maternelle de pays et régions. L'étude des cas de grave morbidité maternelle peut aider à comprendre les facteurs de la mortalité maternelle. Cet article étudie plusieurs définitions du concept de grave morbidité maternelle et d'« échappée belle », et la relation entre ces cas et les décès maternels. Même s'il n'y a pas de consensus sur une définition stricte des « échappées belles » ou de la morbidité maternelle grave, nous montrons que les définitions utilisées peuvent être conçues de manière à soutenir différents objectifs, notamment le suivi des progrès, la surveillance épidémiologique et le contrôle des soins de santé. Nous en concluons que la versatilité du concept, la fréquence accrue de cas disponibles pour l'étude et la possibilité d'interroger les patientes ayant survécu sont autant d'arguments en faveur de l'étude de la morbidité maternelle grave pour guider les activités locales de réduction de la mortalité maternelle. Si c'est presque une réalité dans les pays développés, cela demeure un défi difficile à relever là où ses avantages seraient les plus évidents.

Resumen

La presencia de complicaciones durante el embarazo depende menos del grado de desarrollo humano que de las diferencias en la forma en que se detectan y manejan. Un diagnóstico rápido y manejo correcto contribuyen a las enormes diferencias en razones de mortalidad materna entre países y regiones. El estudio de casos de morbilidad

materna grave ayuda a entender mejor los determinantes de la mortalidad materna. Este artículo trata de diversos enfoques respecto al concepto de la morbilidad materna severa y casos que casi conducen a la muerte, así como la relación entre estos y muertes maternas. Aunque no se ha establecido una definición estricta de dichos casos o de la morbilidad materna severa, se muestra que las definiciones utilizadas pueden adaptarse para apoyar diversos objetivos: el monitoreo de los avances, la vigilancia epidemiológica y la auditoría de los servicios de salud. Concluimos que la versatilidad del concepto, el aumento en casos disponibles para el estudio y la posibilidad de entrevistar a las sobrevivientes, apoyan el valor de estudiar la morbilidad grave para guiar los esfuerzos locales por disminuir la mortalidad materna. Aunque esto es casi una realidad en los países desarrollados, continúa siendo un gran reto difícil de vencer en lugares donde sus beneficios serían más evidentes.

Keywords: near-miss; severe maternal mortality and morbidity; health surveillance systems; Brazil

Although reducing the number of maternal deaths is one of the Millennium Development Goals, these deaths constitute merely the tip of the iceberg of severe morbidity related to pregnancy, childbirth and the puerperium. The extent of all this morbidity is still unknown, but must be confronted before any real improvement in maternal health can in fact take place. The incidence of acute complications during pregnancy may possibly be similar in both developed and developing countries; nevertheless, the differences in how these complications are detected and managed may be responsible for the enormous gap in maternal mortality ratios and in the incidence of long-term sequelae.¹

Since the 1990s, a special group of women who have survived acute and severe complications of pregnancy and who escaped death by luck or by receiving timely, appropriate care, have attracted the attention of investigators and policy-makers. Their experience is known as a "near-miss". These women share important characteristics with those who die during pregnancy, childbirth or the puerperium, and constitute a proxy model for maternal death. Moreover, studying what happened to them is made

easier by their greater numbers and the possibility of being able to listen to them directly.³⁻⁵

Although the concept of near-miss is already well-established, a consensual definition has yet to be adopted, including how the women comprising this group may be recognised. Considering the potential of near-misses to contribute to the development of strategies for reducing maternal mortality, we decided to study different aspects of them using different approaches.

This paper summarises a series of studies on maternal morbidity carried out by our research group at the Department of Obstetrics and Gynecology, School of Medical Sciences, Universidade Estadual de Campinas (UNICAMP) in Campinas, Brazil, and discusses their findings and significance. Over the last 20 years, our group has been working in the field of maternal mortality and more recently maternal near-misses almost entirely with local resources. There is an unfortunate negative belief as regards most research that, after a study has been performed, practically nothing will actually change in the setting where it was carried out. This is exactly what we do not want to happen with our data. We took up the challenge of writing a more conceptual paper outlining our experience, in order to share with other research groups from the developing world what can be done locally with limited resources. The paper covers the definition of a near-miss, the scoring system we developed for severe maternal morbidity, population-based studies and surveys that we undertook, information systems we set up in health and monitoring, and what we have learned from listening to women's experiences. The papers reporting this research have been or are in process of being published elsewhere and are referenced in this paper.

Definitions

Following a long history of concern about and research on the subject of maternal mortality in Brazil, we recently began to intensify our interest in near-misses by carrying out a systematic literature review of the published data on the incidence of near-misses and the different operational definitions of them adopted in the studies. We found that the majority (57%) of studies on the subject had adopted definitions related to the

complexity of management of the cases (i.e. admission to intensive care units, need for hysterectomy or transfusions of blood derivatives), while 24% defined them according to the presence of certain clinical conditions (i.e. severe pre-eclampsia or uterine rupture), 15% according to the presence of organ failure (i.e. respiratory or renal failure, coma or shock) and 3% were based on a mixture of criteria (i.e. severe maternal morbidity score). In the studies reviewed, the near-miss ratio reported varied from 0.3/1,000 to 101.7/1,000 deliveries and the case-fatality ratio varied from 2:1 to 223:1. The review also found a tendency towards a greater in-hospital incidence of cases of near-miss in the studies in developing countries than in developed countries.⁹

Evaluating the definitions and the scoring system for severe maternal morbidity

Our institution is a tertiary referral centre in the city of Campinas, São Paulo state, one of the most developed regions of Brazil. Approximately 3,000 deliveries are carried out annually there. Although a good part of the cases attended here are considered high risk, the occurrence of maternal death in this centre is infrequent. If we were to use only cases of maternal death for auditing the quality of obstetric care, it would probably be a fairly ineffective approach because of the low rate of maternal death. Likewise, services that deal with few obstetric cases or less complex cases find it difficult to use only cases of maternal death to evaluate the quality of obstetric care offered and the difficulties faced by women in obtaining maternity care. A long period of time would be required to accumulate a reasonable number of cases and by then it would be too late for a good number of women. Hence, we felt it was valuable to study cases of severe maternal morbidity and near-misses, to see what they would teach us about dealing with obstetric complications.

To evaluate the applicability of the different concepts of severe maternal morbidity and obstetric near-miss in hospitals, we surveyed cases of severe maternal morbidity in our hospital over a one-year period. For this, different sets of criteria were used, as shown in Box 1. These are not, of course, the only criteria used for identifying cases of severe maternal morbidity, but perhaps they are the most comprehensive ones. They allowed us to make additional assessments of other criteria for a near-miss in this

population (including admission to an intensive care unit, organ dysfunction and the scoring of severe maternal morbidity).

Box 1. Criteria used to identify and classify cases of near-miss

Waterstone's criteria11

- · Severe pre-eclampsia
- Eclampsia
- · HELLP syndrome (haemolysis, elevated liver enzymes, low platelets)
- · Severe haemorrhage
- · Severe sepsis
- · Uterine rupture

Mantel's criteria¹²

- · Admission to an intensive care unit for whatever
- · Hypovolaemia requiring five or more units of packed red blood cells
- · Pulmonary oedema
- · Emergency hysterectomy for any reason
- · Admission to an intensive care unit for sepsis
- · Intubation and ventilation for more than 60 minutes except for general anaesthesia
- Diabetic ketoacidosis
- · Coma for more than 12 hours
- · Cardio-respiratory arrest
- · Peripheral O, saturation <90% for more than 60 minutes
- Ratio Pa O₂/FiO₂ <300mmHg
- · Oliguria, defined as diurese <400ml/24h, refractory to careful hydration or to furosemide or dopamine
- · Acute urea deterioration to 15mmol/l or creatinine >400mmol/l
- · Jaundice with pre-eclampsia
- · Thyrotoxic crisis
- · Acute thrombocytopenia requiring transfusion of
- Sub-arachnoid or intra-parenchymatous haemorrhage
- · Anaesthetic accident: (1) severe hypotension associated with epidural or rachidian anaesthesia, hypotension defined as systolic pressure <90 mmHg for more than 60 minutes; (2) failure in tracheal intubation requiring anaesthetic reversion

centre or in the intensive care unit were evaluated for the presence of criteria indicative of severe maternal morbidity. During this period, two maternal deaths occurred and 124 cases of severe maternal morbidity were identified. Mantel's criteria¹² vielded 112 cases of near-miss while Waterstone's criteria¹¹ yielded 90 cases, with an overlapping of both definitions in 78 cases. A total of 112 women were admitted to the intensive care unit, 35 for intensive support and 77 for monitoring and surveillance. A total of 45 women developed organ dysfunction. The principal causes of severe maternal morbidity found are shown in Table 1. They consisted predominantly of hypertensive syndromes, which are also the most common conditions found in cases of maternal deaths in this region. In this group of women, the use of diagnostic or therapeutic interventions not habitually carried out in low-risk obstetric care was evaluated (referred to here as "special procedures"). A total of 126 of these interventions were carried out, the most frequent being central venous access, echocardiography and mechanical ventilation. The mean period of hospitalisation was 10.3 (± 13.24) days. With respect to surveillance of severe maternal morbidity, we found that a two-tiered strategy of surveillance (screening and confirmation) would be more consistent and possibly more effective. 10

During the study period, all the women hospitalised in the obstetric wards, obstetric

Table 1. Primary determinant factors of nearmiss cases, Campinas, Brazil, 2003–2004

Primary determinants of near-misses		
Hypertension	57.3	
Haemorrhage	13.7	
Sepsis	4.8	
Abortion	3.2	
Non-obstetric	21.0	

As a result of these findings, we tested the application of the severe maternal morbidity scoring system in this same group of women. The severe maternal morbidity scoring system is based on the existence of a continuum of morbidity, with normal pregnancy at one end, passing through the occurrence of a complication and different degrees of severity with maternal death at the other end.¹³ Initially, we sought to identify the greatest possible number of cases of severe maternal morbidity by using a wide range of

criteria. Next, a specific scoring system was applied in each case, depending on the presence or absence of factors of severity (organ failure, admission to intensive care, transfusion of more than three blood derivatives, prolonged intubation and major surgical interventions other than caesarean section). This system permits identification of the most severe cases, and once the score is applied to the survivors of severe maternal morbidity, it is possible to identify cases of near-miss.

According to the scoring system as applied to our sample, 20 cases were classified as near-miss and 104 cases as other severe maternal morbidity. Considering duration of hospitalisation and the use of special procedures, we observed that the group of nearmiss women required more complex care over a longer period of time compared to women in the group of other severe morbidities (p<0.05). The mean number of special procedures carried out in the group of women with near-misses was 3.75 (±2.34) per case, whereas in the group of other severe morbidities, the number was 0.38 (±0.83). The mean duration of hospitalisation in near-miss cases was 24.2 days (±28.1), whereas in the group of other severe morbidities, this period was 7.6 days (±4.3). Among the cases of near-miss, there was a predominance of cases of haemorrhage, while in cases of other severe morbidities, hypertensive complications predominated. This institutional data does not necessarily reflect the national figures on maternal morbidity and mortality. We could hypothesise that hypertensive complications are more prevalent and heterogeneous in terms of severity and that they are more effectively managed in a tertiary facility. The implications for practice of haemorrhage being the main determinant cause of a near-miss, taking into account that it is generally identified as having the most complex complications, are that it demands the prompt availability of surgical, anaesthetic and haemotherapeutic procedures. This study provided additional validation of the severe maternal morbidity scoring system, and we concluded that the same scoring system could be used to objectively describe and identify the most extreme cases of severe maternal morbidity (near-misses). 14,15

The use of different sets of criteria for identifying cases of severe maternal morbidity and/or near-misses worldwide is a problem that still needs to be resolved, especially for purposes of comparing data. It was not our intention to set unique criteria, but rather to

show our experience in testing different criteria in the field. A common definition and standard procedures for the identification of severe maternal morbidity and near-miss cases should probably be addressed in the near future. The World Health Organization and other international health agencies could play a major role in this challenge.

Population-based study of severe maternal morbidity

After investigating the concept of severe maternal morbidity and near-miss in a hospital environment, we carried out a population-based study of the occurrence of severe maternal morbidity and maternal and perinatal mortality in the city of Campinas. Hospital coverage for obstetric cases in the region is almost 100%, with only 0.4% of home deliveries being reported in 1996. The few cases of deliveries taking place outside the hospital are due to the current trend of home delivery among women with a high socio-economic status and to deliveries occurring on the way to hospital. In both cases, maternal and perinatal complication rates are not very likely to be significant.*

The cases of interest were identified by prospective surveillance carried out in all the maternity hospitals (public and private) in the city over a three-month period. The objective was to identify all the cases of maternal and perinatal death and severe maternal morbidity. The cases of maternal morbidity were identified in accordance with a set of criteria similar to that used in the hospital-based study. All the cases identified were submitted to clinical audit by the municipal and regional Maternal Mortality Committees.¹⁷

A total of 158 adverse perinatal events were identified. In this period, 4,491 liveborn infants were delivered and there were 32 fetal deaths, or 34.9 fetal deaths per 1,000 deliveries. Four maternal deaths (maternal mortality ratio 89 per 100,000 live births) and 95 cases of severe maternal morbidity (21.2 per 1,000 live births) occurred. The case-fatality ratio was 24:1. Hypertensive complications were responsible for 57.8% of cases of severe maternal morbidity, followed in frequency by cases of post-partum haemorrhage. The audit process revealed that provision of appropriate care was delayed in 54 cases (34%). Of these 54 cases, in 32 (59%), the delay occurred in initiating adequate treatment despite the fact that the woman had already reached a health care

service; in 23 cases (43%), the delay occurred in seeking care; and in only 7 cases (13%) was the delay caused by difficulty in obtaining access to health services. ¹⁷ The majority of delays, then, were due to a physician's decisions as regards both time and appropriateness of care. During the audit process specifically for the cases of severe maternal morbidity, it was found that the delays were mainly due to lack of timely use of magnesium sulphate for pre-eclampsia, management of pre-eclampsia and hypertension, adherence to antenatal care guidelines, management of obstetric haemorrhage or use of prophylaxis for post-partum haemorrhage. We recommended that these topics become a priority part of the content of refresher courses for professionals and also that the institutions involved should check whether any constraints existed that were causing delays in or failure to implement best practice. 17

It is important to note that in this proxy population-based prospective study, the causes of severe maternal morbidity were very similar to those obtained in the previously described institutional study. 10 This is relevant as it indicates that it is possible to identify interventions that could be carried out during antenatal care 19,20 or deliverv²⁰ to try to reduce the risk of maternal death from specific, identified problems.

The main conclusions of this study were that, despite the large number of cases, investigation of the cases of severe maternal morbidity was feasible. Moreover, the process of auditing these cases led to increased experience in a wide spectrum of causes of maternal morbidity, which also motivated the members of the Maternal Mortality Committees to tackle determinants of maternal death. Hypertensive complications and post-partum haemorrhage were highlighted as priority topics for training. Concrete recommendations for changing the practice of physicians in order to address these issues were to use audit and feedback on proper evidence based interventions, the opinions of local leaders on when and how to implement such evidence based interventions and the use of reminders of best practices.²¹

Information systems in health and monitoring of severe maternal morbidity

In several countries, much of the information on health is routinely collected by governmental and/or non-governmental organisations. The use of information on health stored in public information systems may be useful for the continuous and prospective monitoring of severe maternal morbidity. If these systems operated automatically and concurrently with the care provided (using, for example, the hospital cost management systems) a mechanism of local or in-hospital alert could be established so that a differentiated support system would trigger therapeutic or preventive interventions, in each case automatically indicated by the system.²²

In the case of maternal morbidity, the development of such a system and mechanisms of alert constitute an innovation designed to stop the progression of a woman through the continuum of severe morbidity and to prevent a maternal death. However, very few countries systematically use this approach. 23,24 In Brazil, one of the principal public sources of information on health is the Ministry of Health. In this context, we carried out a study²⁵ with the aim of identifying the medical records of those women with conditions suggestive of severe maternal morbidity, using the Brazilian Hospital Information System (HIS). The criteria shown in Box 1 have been adapted to permit recognition of the records stored in the Hospital Information System. In addition to identifying the records, we also attempted to describe the diagnoses and the procedures used, with the aim of identifying factors associated with maternal death. The records of women hospitalised during pregnancy, delivery or in the puerperium in the 27 Brazilian state capitals in 2002 were analysed. The records of the women who had at least one of the criteria that we had adopted as defining severe maternal morbidity were selected. The records of 32,379 women with at least one factor suggestive of severe maternal morbidity were identified, as well as 154 maternal deaths (case-fatality ratio 210:1). The consolidated ratio of severe maternal morbidity observed was 44.3/1,000 liveborn infants. Despite several limitations, principally the need for a structured information system, the perspective of routinely using the information collected was found to be promising²⁵ for setting up an automatic mechanism of alert. However, implementation of this mechanism first requires the development of agile local information systems to make it viable.

Estimating maternal morbidity by population surveys

Population surveys and demographic and health surveys may constitute good sources of information on maternal morbidity, particularly in places where integrated systems of epidemiological information have not yet been implemented. ^{18,26} We analysed the information obtained from demographic and health surveys carried out in Latin America and the Caribbean on maternal morbidity. The databases of seven population surveys carried out in the 1990s in Bolivia, Brazil, Colombia, Dominican Republic, Guatemala, Nicaragua and Peru contained indirect information on maternal morbidity identified through complications reported as associated with childbirth. The rate of complications reported by the women surveyed was very high, 20–40% of all deliveries in the majority of the countries. We concluded that the majority of these demographic and health surveys involving questions on maternal morbidity resulted in over-estimation of the occurrence of morbidity, possibly because they were not adequately validated.²⁷

Using this same approach, we recently evaluated the situation in Brazil by geographical region from data in a 1996 demographic and health survey. This showed a varied panorama of reported complications, ranging from around 15% in the state of São Paulo to as high as 23% in the northern part of the country. These variations were in line with the degree of economic and human development of the different regions of the country, with complications being significantly greater in the east central, northeast, north and west central parts of the country, the least developed areas of Brazil. This finding has stimulated our decision to continue investigating the regional distribution of occurrences of severe maternal morbidity, probably through a process of geographical referencing, taking into consideration the geographic location of the occurrences and the local demographic characteristics, as well as the characteristics of the quantity and quality of maternal health services available. This currently represents a challenge to both scientists and health planners, if measures specifically aimed at combating local and regional difficulties are to be recommended and implemented with the clear objective of avoiding delays and improving maternal health.

To further evaluate the question of the validity of questionnaires on morbidity, we carried out a systematic review on the subject. This was our first attempt to summarise

the findings of various studies on the validation of questionnaires on severe maternal morbidity in developing countries. We found that information on the occurrence of eclampsia and other hypertensive complications in the same seven surveys from Latin American and the Caribbean mentioned earlier was considered satisfactorily accurate in four out of seven studies, dystocia and infection in only two, and the questions dealing with haemorrhagic complications were considered satisfactory in only one. Another finding of this review was that, when the true prevalence of the condition investigated is low (<5%), studies frequently over-estimate prevalence.²⁹

We therefore suggest that questionnaires on severe maternal morbidity included in demographic and health surveys should be previously validated and, if necessary, correction factors developed to adjust for the estimates obtained.²⁹ In view of these findings, we developed a questionnaire for the evaluation of the occurrence of severe maternal morbidity in Portuguese. This questionnaire is currently being validated and the correction factors obtained may be used to interpret future population surveys that adopt this instrument.

Listening to women's experience

One of the principal advantages of case studies of near-misses is the possibility of hearing the experience of the women directly. Women who have survived potentially fatal complications in pregnancy or the puerperium are believed to be able to adequately report the obstacles and delays they had to face to assure their survival. Onsidering these points, we designed a qualitative research study to acquire knowledge on the experience of women who have survived acute and severe complications during pregnancy and the puerperium. Our preliminary findings show that there were difficulties and obstacles that the women had to overcome to receive adequate care when the complication developed, including problems related to the quality of primary level care, lack of local resources, poverty and correspondent social disadvantages, and delays in the referral process. This study is still in process, but its findings will provide important insights into the causes of maternal morbidity in our region. Transferring knowledge coming from research into practice is a difficult task, especially in developing country settings. However, the lessons already learnt from women indicate

the need for improvement of local primary level care in identifying and referring complications during pregnancy so that they can be adequately and comprehensively managed in time.

Discussion

No consensus has yet been reached on how best to recognise cases of severe maternal morbidity and obstetric near-miss. Although lack of standardisation in the definition and evaluation methods represents an aspect that still requires improvement, since this deficiency hampers comparison between services and over time, the diversity of applications of the concept represents its versatility. As described in the previous sections, the definition of morbidity or near-miss may be tailored to each purpose or to each population of interest, and this facilitates its use at the different levels for action and planning.

For a long time, reducing the number of complications occurring during pregnancy was the principal objective of many programmes aimed at reducing maternal mortality.³¹ Nevertheless, the majority of acute, severe obstetric complications are considered difficult to predict and seldom possible to prevent, which may explain, in part, the failure of a good number of these programmes.³² On the other hand, appropriate treatment for the majority of these complications is known and timely treatment may avoid the occurrence of a great number of maternal deaths. In this context, the study of severe maternal morbidity and cases of near-miss may contribute towards improving strategies for combating acute complications of pregnancy, thus contributing towards reducing the number of deaths. However, probably the main reason why more progress in reducing maternal mortality has not been made is not the lack of knowledge of what the complications are or what to do about them, but rather the organisation, delivery and utilisation of services. This appears to include significant regional differences, as found in Brazil. For this reason, research on these factors should be repeated, whenever possible, in different contexts to determine the local characteristics upon which the adoption of appropriate interventions depends. In fact, up to the present moment, no large population-based studies that deal directly with severe maternal morbidity (nearmiss) have been carried out. In our view, this justifies performing a large, prospective, international, multicentre study, preferably in developing countries in which maternal mortality is high, to learn more about the condition and the factors associated with it.

A system of epidemiological surveillance based on the early identification of cases of severe maternal morbidity would permit a more adequate level of monitoring and care, stopping the progression of women through the continuum of morbidity and preventing the occurrence of avoidable deaths.⁴ On the other hand, carrying out audits of the care provided in cases of severe maternal morbidity may permit a local diagnosis of the causes of delay either in seeking, gaining access to or receiving adequate care. This type of audit is being used more and more frequently as a complement to the reviews of maternal death and may help support the planning of actions adapted for each situation identified.³³

Conclusions

The study of severe maternal morbidity may contribute significantly to the formulation of strategies to reduce maternal mortality. The versatility of the concept, together with the greater frequency of cases and the possibility of directly interviewing the survivors of severe complications, allows local actions to be implemented within a global perspective to improve maternal health. Recommendations for changing practice would be the implementation of multi-faceted strategies based on audit and feedback.

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^{*} There might be some concern about the use of multiple hospital-based studies as a proxy for a population-based study because, according to Fortney and Smith, ¹⁸ they include only women who sought treatment. However, in the specific situation of Campinas, the "untreated" segment of the target population was considered to be irrelevant.

4. Discussão Geral

Nos locais onde os sistemas de vigilância epidemiológica não estão ainda aptos a incorporar o conceito do *near mis*s materno, os inquéritos populacionais poderiam ser uma fonte de informação. E, de maneira geral, as pesquisas de demografia e saúde têm sido utilizadas já há diversos anos para a obtenção de informação em diversos países em desenvolvimento. Entretanto, através de uma revisão sistemática, observamos que no contexto de grandes pesquisas de âmbito nacional, apenas poucos inquéritos têm usado questionários formalmente validados. Possivelmente por este motivo, na América Latina, a ocorrência de complicações da gestação, parto e puerpério observada em inquéritos populacionais tem sido superestimada, variando de quase 17% (Brasil) a 52% (Peru) nos estudos da década de 1990.

Estas estimativas são essencialmente baseadas na percepção das mulheres sobre a ocorrência de complicações e na sua recordação. Entretanto, tanto a percepção das complicações quanto a recordação materna são afetados por diversos fatores. O estudo qualitativo realizado, assim como a própria validação do questionário desenvolvido, evidenciam diferenças na percepção das complicações, mal entendimentos sobre o que são as complicações e o prejuízo provocado pelo

tempo na capacidade de recordar o evento. Mais especificamente, pudemos evidenciar que a morbidade materna grave está associada com um conjunto de reações mentais e emocionais, como o medo, os estados mentais alterados e a amnésia, que podem interferir com a capacidade da mulher recordar adequadamente os eventos associados à morbidade materna grave.

Apesar destas dificuldades, a revisão sistemática da literatura evidenciou que os inquéritos populacionais validados haviam sido capazes de produzir informações úteis para a estimativa de prevalência de complicações relacionadas à gestação. Assim, a validação formal dos questionários utilizados em inquéritos populacionais passou a ser recomendada para a obtenção de informações de melhor qualidade.

Com base na revisão sistemática de questionários validados, um novo questionário foi desenvolvido. Foram também incluídas questões sobre o uso de intervenções relacionadas ao manejo das complicações graves. Estas intervenções, isto é, histerectomia, transfusão sanguínea e admissão em unidade de terapia intensiva, mais a ocorrência de eclâmpsia, formaram a base para uma definição pragmática de *near miss* materno, por estarem altamente associadas à ocorrência de morte materna. De maneira geral, o estudo de validação observou que as mulheres recordaram de maneira mais acurada as intervenções e a ocorrência de eclampsia, enquanto outras complicações como a hemorragia e a infecção não foram bem recordadas. Da mesma forma, o uso da definição pragmática de *near miss* através do novo questionário pode ser validado, tendo

este questionário sido incluído na Pesquisa Nacional de Demografia e Saúde de 2006/2007.

A partir deste ponto, com a conclusão da PNDS, pode ser realizada uma estimativa da prevalência de *near miss* materno no Brasil (21 casos/1.000 nascidos vivos). Tomando por referência os indicadores de mortalidade materna no Brasil, a razão de caso:fatalidade seria de 26:1, enquanto o número total de casos de *near miss* maternos no Brasil estaria ao redor de 70.000 casos por ano. Em relação aos fatores associados ao *near miss* materno, foi observado um risco aumentado associado apenas à baixa escolaridade.

Em comparação com a PNDS 1996, teria ocorrido um aumento do número de complicações referidas pelas mulheres durante a gravidez e puerpério. Entretanto, esta comparação é difícil, uma vez que os questionários são diferentes, o inquérito de 1996 usou um questionário não validado, e o questionário de 2006/07 mostrou uma acurácia muito pobre das questões relacionadas à infecção e hemorragia. Do ponto de vista sócio-demografico, os achados de agora e de dez anos atrás são similares, sendo persistentes muitas das disparidades existentes entre as diferentes regiões geográficas do Brasil.

Esta tese tem limitações e estas devem ser mencionadas. A primeira delas é que por uma absoluta necessidade de tempo (a PNDS tinha um calendário próprio, que não pertencia aos pesquisadores destes projetos), o estudo de validação foi conduzido de maneira concomitante com a PNDS. Um procedimento não ideal, porém adotado em outros estudos semelhantes. Em segundo lugar, o estudo de

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validação foi realizado através de entrevistas telefônicas, com mulheres que haviam sido tratadas em um único hospital terciário de uma das regiões mais desenvolvidas do Brasil (Centro de Atenção Integral à Saúde da Mulher – CAISM/UNICAMP - cidade de Campinas, SP, índice de desenvolvimento humano = 0,852). Terceiro, as questões baseadas em intervenções tiveram um desempenho muito melhor em comparação com as questões sobre sinais e sintomas relacionados com as complicações. E finalmente, é amplamente conhecido o fato de que as estimativas baseadas em indicadores de manejo podem ser profundamente afetadas pela disponibilidade dos recursos de saúde ou intervenções. Assim, é possível que as estimativas de prevalência do *near miss* materno tenham sido afetadas pelas diferenças regionais existentes no Brasil.

Em que pesem as limitações acima mencionadas, esta tese pode ter contribuído para o desenvolvimento metodológico deste novo indicador de saúde. A definição pragmática de *near miss* utilizada no inquérito populacional foi desenvolvida através de um dos maiores estudos realizados em saúde materna e perinatal envolvendo instituições de saúde da America Latina. Os componentes da definição pragmática mostraram-se altamente associados com a mortalidade, além de, ao serem referidos pelas mulheres, apresentarem uma alta correlação com os dados de prontuário médico. Por fim, a experiência acumulada com os projetos desta tese, e de outros que compõem a abordagem ampla de pesquisa sobre o *near miss* materno, pode contribuir para o desenvolvimento de uma definição internacional de *near miss* materno pela Organização Mundial da Saúde (OMS, 2008).

As principais lições aprendidas neste processo desafiador de desenvolver um instrumento para estudar o *near miss* materno na comunidade podem ser sumarizadas da seguinte forma. A definição pragmática de *near miss* materno foi útil para a obtenção de informações mais confiáveis a partir da comunidade, pelo menos nas regiões onde as intervenções que integram a definição estão mais disponíveis. Questões sobre sinais e sintomas relacionados com complicações forneceram informações menos confiáveis e alternativas para estudar o *near miss* materno nos locais com menos recursos devem ser investigadas. Uma possível alternativa poderia ser encontrada através da avaliação das informações fornecidas pelos trabalhadores de saúde da comunidade ou parteiras tradicionais onde a sua força de trabalho é relevante e a informação hospitalar é inexistente ou pouco significativa.

No conjunto, esta tese demonstra que o *near miss* materno é um conceito versátil, que pode ser utilizada para diversos fins, incluindo monitoramento, vigilância epidemiológica, controle de qualidade e para orientação do cuidado de mulheres com complicações graves. A versatilidade do conceito, a maior freqüência dos casos e a possibilidade de entrevistar as mulheres *a posteriori* suportam o valor de se estudar o *near miss* materno para guiar os esforços locais para reduzir tanto a mortalidade materna quanto a carga das complicações graves.

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5. Conclusões

- 1. A compilação, consolidação e análise das informações obtidas por inquéritos populacionais sobre as complicações da gestação na América Latina e Caribe revelaram que a ocorrência relatada de complicações graves da gestação nos inquéritos avaliados está muito acima da taxa de 15% citada na literatura, podendo ter sido superestimada. A validação prévia dos questionários utilizados para coleta de dados nesse tipo de estudo é extremamente importante para gerar dados mais adequados.
- 2. A avaliação da informação coletada através da Pesquisa Nacional de Demografia e Saúde de 1996 sobre a ocorrência de complicações da gestação, parto e puerpério no Brasil revelou que a prevalência das complicações referidas pelas mulheres variou de 15.5-22.9% na várias regiões demográficas analisadas.
- 3. A avaliação da habilidade de inquéritos populacionais em estimar a ocorrência de complicações da gestação, parto e puerpério, através de uma revisão sistemática da literatura, revelou que poucos inquéritos populacionais de âmbito nacional usaram questionários validados, e aqueles que o fizerem obtiveram informações mais úteis e confiáveis.

- 4. Os elementos essenciais para a avaliação populacional do *near miss* materno referem-se à ocorrência de eclâmpsia, histerectomia, transfusão de sangue e admissão a UTI. Estes elementos apresentam-se altamente associados à mortalidade materna e compõem uma definição pragmática de *near miss* materno.
- 5. Baseados nas narrativas de mulheres que quase morreram durante a gravidez, parto e puerpério, nós descrevemos um distúrbio de reação aguda ao estresse associado à morbidade materna grave a síndrome do *near miss* materno. Estados alterados de consciência e amnésia são fatores que podem prejudicar a futura recordação das complicações ocorridas.
- 6. O estudo de validação demonstrou que as mulheres recordaram de maneira mais acurada as intervenções a que foram submetidas e a ocorrência de eclâmpsia, enquanto outras complicações como a hemorragia e a infecção não foram bem recordadas. O emprego da definição pragmática de *near miss* mostrou-se possível em termos populacionais.
- 7. De acordo com esta definição pragmática, baseada na ocorrência de eclâmpsia, histerectomia, internação à UTI e transfusão de sangue, estima-se a ocorrência de 69.800 casos de *near miss* materno por ano no Brasil, com prevalência aproximada ao redor de 21 casos/1.000 nascidos vivos. Mulheres de baixa escolaridade apresentam risco aumentado de desenvolver a condição.

8. No conjunto, esta tese demonstra a versatilidade do conceito de *near miss*, cuja definição pode ser estrita ou pragmática, e utilizada para diversos fins, incluindo monitoramento, vigilância epidemiológica, controle de qualidade e para orientação do cuidado. A versatilidade do conceito, a maior freqüência dos casos e a possibilidade de entrevistar as mulheres suportam o valor de se estudar o *near miss* materno para guiar os esforços locais na redução da mortalidade materna e da carga das complicações graves.

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7. Anexos

Anexo 1. Carta de aprovação no CEP

FACULDADE DE CIÊNCIAS MÉDICAS COMITÊ DE ÉTICA EM PESQUISA

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

CEP, 30/11/06. (Grupo III)

PARECER PROJETO: N° 573/2006 (Este n° deve ser citado nas correspondências referente a este projeto) **CAAE:** 0452.0.146.000-06

I-IDENTIFICAÇÃO:

PROJETO: "VOZES DA MORBIDADE MATERNA GRAVE - NARRATIVAS DE MULHERES QUE QUASE MORRERAM DURANTE A GRAVIDEZ, PARTO OU PUERPÉRIO".

PESQUISADOR RESPONSÁVEL: José Guilherme Cecatti INSTITUIÇÃO: CAISM/UNICAMP

APRESENTAÇÃO AO CEP: 06/10/2006

APRESENTAR RELATÓRIO EM: 24/10/07 (O formulário encontra-se no site acima)

II - OBJETIVOS

Descrever as vivências de mulheres que sofreram complicações agudas e graves durante o ciclo grávido-puerperal.

III - SUMÁRIO

Trata-se de um estudo qualitativo de natureza exploratória cujo instrumento de coleta de dados será a entrevista semi-dirigida. As participantes serão 30 mulheres que tenham migrado de nível de complexidade no sistema de saúde durante uma complicação potencialmente fatal, culminando na admissão em uma unidade de terapia intensiva especializada de um hospital terciário, sem a facilitação de acesso proporcionada pelo acompanhamento pré-natal no referido hospital, sendo pelo menos cinco com complicações hipertensivas, cinco com complicações hemorrágicas e cinco com complicações clínicas. As entrevistas serão gravadas, transcritas e analisadas buscando-se a identificação de padrões e temas em comum, com auxílio do software "The Ethnograph".

IV - COMENTÁRIOS DOS RELATORES

Projeto adequado. O Termo de Consentimento Livre e Esclarecido foi reformulado, estando de acordo. <u>Solicitamos que o titulo do projeto seja totalmente suprimido para não causar receio ao sujeito de pesquisa desnecessariamente.</u>

V - PARECER DO CEP

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

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atendendo todos os dispositivos das Resoluções 196/96 e complementares, resolve aprovar sem restrições o Protocolo de Pesquisa, bem como ter aprovado o 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 integra, 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.

VII - DATA DA REUNIÃO

Homologado na X Reunião Ordinária do CEP/FCM, em 24 de outubro de 2006.

Profa. Dra. Carmey Sílvia Bertuzzo
PRESIDENTE DO COMITÊ DE ÉTICA EM PESQUISA
FCM / UNICAMP

Anexo 2. Carta de aprovação no CEP



FACULDADE DE CIÊNCIAS MÉDICAS COMITÊ DE ÉTICA EM PESQUISA

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CEP, 21/12/06. (Grupo III)

PARECER PROJETO: N° 574/2006 (Este n° deve ser citado nas correspondências referente a este projeto)

CAAE: 0453.0.146.000-06

I-IDENTIFICAÇÃO:

PROJETO: "ESTUDO PARA VALIDAÇÃO DO QUESTIONÁRIO DE MORBIDADE MATERNA GRAVE".

PESQUISADOR RESPONSÁVEL: José Guilherme Cecatti INSTITUIÇÃO: CEMICAMP e CAISM / UNICAMP

APRESENTAÇÃO AO CEP: 06/10/2006

APRESENTAR RELATÓRIO EM: 21/12/07 (O formulário encontra-se no site acima)

II - OBJETIVOS

Objetivo Geral: validar um questionário sobre morbidade materna grave. Objetivos Específicos: Quantificar a sensibilidade e a especificidade na detecção de complicações obstétricas através de questões selecionadas ou de combinações de questões realizadas em entrevistas com mulheres em comparação com os diagnósticos registrados em prontuários médicos; Avaliar possíveis fatores interferentes na qualidade do relato de mulheres sobre complicações obstétricas graves, em especial o tempo decorrido entre a complicação e a entrevista e a escolaridade.

III - SUMÁRIO

A população serão mulheres egressas da Unidade de Terapia Intensiva de Adultos (UTI-A) da CAISM durante o ciclo gravídico puerperal como a população base para o estudo (grupo A). No grupo B serão mulheres egressas da enfermaria de alojamento conjunto da CAISM. O tamanho da amostra será de 350 mulheres, sem que 100 serão do grupo B. Critérios de inclusão no grupo A: aceitação voluntária em participar do estudo, após receber informações sobre o mesmo e gravação via telefônica de seu consentimento; ser egressa da UTI-A da CAISM após ter apresentado uma complicação da gravidez, parto ou puerpério. Critérios de inclusão no grupo B: aceitação voluntária da mulher em participar no estudo, após receber informações sobre o mesmo e gravação via telefônica de seu consentimento; ser egressa da enfermaria de Alojamento Conjunto do CAISM; não ter sido internada na UTI-A do CAISM.

Serão aplicados questionário estruturados e pré-codificados via telefônica às mulheres selecionadas, seguida de posterior comparação com os dados abstraídos dos prontuários médicos destas mulheres para compor o padrão-ouro. O contato telefônico será realizado por um grupo de entrevistadoras especialmente treinadas em telepesquisa e para o projeto em questão, nas dependências do CEMICAMP. Após a realização das entrevistas, os respectivos prontuários serão revisados para verificação das informações obtidas através das entrevistas, conforme o instrumento de coleta de dados. Os dados serão armazenados e analisados utilizando o software

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Epi Info. Será calculada a sensibilidade e a especificidade de cada questão ou da combinação de questões para a detecção de complicações obstétricas, tendo como padrão ouro às informações registradas nos respectivos prontuários. Serão calculados os respectivos intervalos de confiança. Serão realizadas comparações entre o período de recordação e o desempenho de cada questão chave, bem como entre a escolaridade da mulher e o desempenho de cada questão chave.

IV - COMENTÁRIOS DOS RELATORES

O estudo não oferece riscos para os sujeitos e poderá auxiliar na organização da assistência. O Termo de Consentimento Livre Esclarecido é lido pelo entrevistador, via telefônica, onde será feita uma explicação sobre o estudo e o motivo do contato. A seguir, será obtido o consentimento verbal da mulher, que será gravado, bem como toda a entrevista. Haverá uma chave de identificação que será mantida em sigilo pelos pesquisadores envolvidos. O orçamento está descrito e terá recursos provenientes da FAPESP.

V - PARECER DO CEP

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 com recomendação o Protocolo de Pesquisa, 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

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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.

VII - DATA DA REUNIÃO

Homologado na X Reunião Ordinária do CEP/FCM, em 24 de outubro de 2006.

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

Anexo 3. Questionário de morbidade materna grave da PNDS 2006

HISTÓRIA DAS GRAVIDEZES A PARTIR DE 2001

255 ATENÇÃO ENTREVISTADORA: NÃO ESQUEÇA DE INCLUIR AS PERDAS A PARTIR DE JANEIRO DE 2001

CASO NÃO TENHA TIDO NENHUMA GRAVIDEZ A PARTIR DE JANEIRO DE 2001 → <u>PULE PARA P280</u> NO CASO DE GRAVIDEZ DE GÊMEOS, TRIGEMEOS, ETC, TRATA-SE DE <u>UMA</u> GRAVIDEZ, ASSIM, ANOTE APENAS UMA VEZ.

ANOTE NA 256 AS DATAS DE NASCIMENTO OU DE TÉRMINO DA GRAVIDEZ E NA 257 O RESULTADO DA GRAVIDEZ

	ATENCAO DADA ODDEM DE	GRAVIDEZES (DA MAIS RECENTE PARA A MAIS ANTIGA)					
	ATENÇAO PARA ORDEM DE GRAVIDEZES – SEMPRE COMECE PELA ULTIMA	ÚLTIMA	PENÚLTIMA	ANTEPENÚL- TIMA	4 ^A . ANTERIOR	5 ^A . ANTERIOR	
	GRAVIDEZ)	(1)	(2)	(3)	(4)	(5)	
256	Data de nascimento ou do término da gravidez	MÊS	MÊS	MÊS	MÊS	MÊS	
	Não sabe mês, anote "98"	ANO	ANO	ANO	ANO	ANO	
	Não sabe ano, anote "9998"						
257	RESULTADO DA GRAVIDEZ	Único NV1 (PULE P/259)	Único NV1 (PULE P/259)	Único NV1 (PULE P/259)	Único NV1 (PULE P/259)	Único NV1 (PULE P/259)	
	(NV=NASCIDO VIVO)	Único Perda2	Único Perda2	Único Perda2	Único Perda2	Único Perda2	
		Múlitplo NV3 (PULE P/259)	Múlitplo NV3 (PULE P/259)	Múlitplo NV3 (PULE P/259)	Múlitplo NV3 (PULE P/259)	Múlitplo NV3 (PULE P/259)	
		Múltilplo Perda4	Múltilplo Perda4	Múltilplo Perda4	Múltilplo Perda4	Múltilplo Perda4	
258	Esta GRAVIDEZ que você perdeu foi um aborto	AE 1	AE 1	AE1	AE1	AE1	
	espontâneo, um aborto provocado, uma gravidez nas trompas ou um nascido morto?	AP 2	AP2	AP2	AP2	AP2	
	CODIGOS	GT3	GT3	GT3	GT3	GT3	
	AE = ABORTO ESPONTANEO AP = ABORTO PROVOCADO GT = GRAVIDEZ NAS TROMPAS NM=NASCIDO MORTO	NM 4	NM 4	NM4	NM4	NM4	
259	Quantos meses durou esta GRAVIDEZ?						
		Não sabe 98	Não sabe 98	Não sabe 98	Não sabe 98	Não sabe 98	
260	Nesta gravidez ou parto, você teve algum tipo de complicação?	Sim1 Não2 (PULE p/ 268)	Sim1 Não2 (PULE p/ 268)	Sim1 Não2 (PULE p/ 268)	Sim1 Não2 (PULE p/ 268)	Sim1 Não2 (PULE p/ 268)	
	(NS = NÃO SABE)	NS8 (PULE p/ 268)	NS8 (PULE p/ 268)	NS8 (PULE p/ 268)	NS8 (PULE p/ 268)	NS8 (PULE p/ 268)	
261	Você teve algum desmaio	Sim1	Sim1	Sim1	Sim1	Sim1	
_0.	durante esta complicação?	Não2	Não2	Não2	Não2	Não2	
		Não sabe98	Não sabe98	Não sabe98	Não sabe98	Não sabe98	
262		Sim1	Sim1	Sim1	Sim1	Sim1	
262	Você foi internada por uma complicação nesta gravidez?	Não2 (PULE P/266)	Não2 (PULE P/267)	Não2 (PULE P/267)	Não2 (PULE P/267)	Não2 (PULE P/267)	
		Não sabe98 (PULE P/266)	Não sabe98 (PULE P/267)	Não sabe98 (PULE P/267)	Não sabe98 (PULE P/267)	Não sabe98 (PULE P/267)	

		ÚLTIMA	PENÚLTIMA	ANTEPENÚL- TIMA	4 ^A . ANTERIOR	5 ^A . ANTERIOR
		(1)	(2)	(3)	(4)	(5)
263	Você teve que ser transferida	Sim1	Sim1	Sim1	Sim1	Sim1
	para outro hospital com mais	Não2	Não2	Não2	Não2	Não2
	recursos por causa de alguma destas complicações?	Não sabe98	Não sabe98	Não sabe98	Não sabe98	Não sabe98
264	Você foi internada na UTI, nesta ocasião?	Sim1	Sim1	Sim1	Sim1	Sim1
		Não2	Não2	Não2	Não2	Não2
		Não sabe98	Não sabe98	Não sabe98	Não sabe98	Não sabe98
265	Você precisou de aparelhos para respirar, nesta ocasião ?	Sim1	Sim1	Sim1	Sim1	Sim1
		Não2	Não2	Não2	Não2	Não2
		Não sabe98	Não sabe98	Não sabe98	Não sabe98	Não sabe98
266	Seu útero foi retirado por causa	Sim1		1100 000011100		1100 000011100
200	Seu útero foi retirado por causa desta complicação?	Não2				
		Não sabe98				
267	Após o parto / perda você permaneceu mais de uma	Sim1	Sim1	Sim1	Sim1	Sim1
	semana internada?	Não2	Não2	Não2	Não2	Não2
		Não Sabe98	Não Sabe98	Não Sabe98	Não Sabe98	Não Sabe98
268	Você teve aumento da pressão durante a gravidez?	Sim1	Sim1	Sim1	Sim1	Sim1
	3.0	Não2 (PULE p/271)	Não2 (PULE p/271)	Não2 (PULE p/271)	Não2 (PULE p/271)	Não2 (PULE p/271)
		NS98 (PULE p/271)	NS98 (PULE p/271)	NS98 (PULE p/271)	NS98 (PULE p/271)	NS98 (PULE p/271)
269	Você teve convulsões durante a gravidez, parto ou após o parto?	Sim1	Sim1	Sim1	Sim1	Sim1
		Não2 (PULE p/271)	Não2 (PULE p/271)	Não2 (PULE p/271)	Não2 (PULE p/271)	Não2 (PULE p/271)
		NS98 (PULE p/271)	NS98 (PULE p/271)	NS98 (PULE p/271)	NS98 (PULE p/271)	NS98 (PULE p/271)
270	Você já havia apresentado	Sim1	Sim1	Sim1	Sim1	Sim1
	convulsões antes?	Não2	Não2	Não2	Não2	Não2
		Não sabe98	Não sabe98	Não sabe98	Não sabe98	Não sabe98
271	Você apresentou sangramento que molhou as suas roupas, a	Sim1	Sim1	Sim1	Sim1	Sim1
	cama ou o chão, <u>durante</u> a	Não2	Não2	Não2	Não2	Não2
	gravidez?	Não sabe98	Não sabe98	Não sabe98	Não sabe8	Não sabe98
272	Você apresentou sangramento intenso que molhou as suas roupas, a cama ou o chão nos 3 primeiros dias após o parto /	Sim1	Sim1	Sim1	Sim1	Sim1
		Não2 (PULE p/274)	Não2 (PULE p/274)	Não2 (PULE p/274)	Não2 (PULE p/274)	Não2 (PULE p/274)
	perda?	NS98 (PULE p/274)	NS98 (PULE p/274)	NS98 (PULE p/274)	NS98 (PULE p/274)	NS98 (PULE p/274)
273	Você recebeu transfusão de sangue por causa desse	Sim1 Não2	Sim1 Não2	Sim1 Não2	Sim1 Não2	Sim1 Não2
	sangramento?	Não sabe98	Não sabe98	Não sabe98	Não sabe98	Não sabe98

274	Você teve febre alta após o parto	SIM1	SIM1	SIM1	SIM1	SIM1
	ou aborto?	Não2	Não2	Não2	Não2	Não
		(PULE p/277)	(PULE p/277)	(PULE p/277)	(PULE p/277)	(PULE p/277)
		NS98 (PULE p/277)	NS98 (PULE p/277)	NS98 (PULE p/277)	NS98 (PULE p/277)	NS (PULE p/277)
275	Esta sua febre veio com calafrios?	SIM1	SIM1	SIM1	SIM1	SIM1
		NÃO2	NÃO2	NÃO2	NÃO2	NÃO2
		Não sabe98	Não sabe98	Não sabe98	Não sabe98	Não sabe98
276	Essa febre veio acompanhada de um corrimento muito mal cheiroso?	SIM1	SIM1	SIM1	SIM1	SIM1
		NÃO2	NÃO2	NÃO2	NÃO2	NÃO2
		Não sabe8	Não sabe8	Não sabe8	Não sabe8	Não sabe8
277	CONFIRA 254	SE O TOTAL FOR MAIS DE 1 PROSSIGA COM A COLUNA 2	SE O TOTAL FOR MAIS DE 2 PROSSIGA COM A COLUNA 3	SE O TOTAL FOR MAIS DE 3 PROSSIGA COM A COLUNA 4 (48	SE O TOTAL FOR MAIS DE 4 PROSSIGA COM A COLUNA 5 (5ª.	PROSSIGA 27
	Número de gravidezes desde janeiro de 2001=	(PENÚLTIMA GRAVIDEZ).	(ANTEPENÚLTIM A GRAVIDEZ).	ANTERIOR).	ANTERIOR).	
		SE O TOTAL = 1 PROSSIGA 278	SE O TOTAL = 2 PROSSIGA 278	SE O TOTAL = 3 PROSSIGA 278	SE O TOTAL = 4 PROSSIGA 278	
278	CONFIRA 257 ANOTE O NÚMERO DE GRAVIDEZES QUE RESULTARAM EM PERDA A PARTIR DE JANEIRO DE 2001 !!! SE NENHUMA ANOTE "00"					
279	CONFIRA 226 ANOTE O TOTAL DE PERDAS !!!					

Anexo 4 - Aceite de publicação no Bull World Health Org



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BLT/2008/057828

Severe maternal morbidity / near miss as a proxy for maternal mortality: the 2005 WHO global survey on maternal and perinatal health

Joao P Souza, Jose Guilherme Cecatti, Anibal Faundes, Sirlei S Morais, Jose Villar, Guillermo Carroli, Metin Gulmezoglu, Daniel Wojdyla, Nelly Zavaleta, Allan Donner, Alejandro Velasco, Vicente Bataglia, Eliette Valladares, Marius Kublickas, Arnaldo Acosta, and World Health Organization 2005 Global Survey on Ma Perinatal Health Research Group

Decision: Provisional Acceptance/Request Revision; **Decision Date:** 27 Oct 2008

Date Received: 15 Aug 2008 **Article Type:** Research

Corresponding Author: Jose Guilherme Cecatti

Article Category: Epidemiology; Maternal health; Reproductive health; Women's health;

Mortality

Supplemental Files: 0

Reviewer 1 Comments for the Author Reviewer 2 Comments for the Author

Anexo 5. Aceite de publicação no Birth

RE: Submission to Birth

Diony Young [diony@frontiernet.net]

Enviada em: qui 20/11/2008 14:26

Para: cecatti@unicamp.br

Dear Dr. Cecatti,

Thank you very much for sending the revision of your article, "Near missed voices: narratives of women who almost died during pregnancy and childbirth - an emerging "maternal near miss syndrome'," for publication in Birth.

I am satisfied that you have largely addressed the reviewers' concerns, and I am pleased to advise you and your co-authors that we accept the article for publication in Birth after some minor revision.

I have edited some of the quotations to omit repetitive material. Those changes are on the attached revision as track changes. Please tell me if these changes are ok.

When you have revised your paper as suggested above, please send a hard copy and matching disk or CD in Microsoft Word, IBM compatible. I will be in touch if I have further questions at a later date.

I am attaching a Blackwell copyright form for you to complete and return to me via regular mail.

Thank you very much for your work in preparing this interesting paper for publication in Birth.

Please advise your receipt of this e-mail.

Yours sincerely,

Diony Young, Editor

Diony Young Editor, Birth 31 Stuyvesant Mnr. Geneseo, New York 14454 USA

Anexo 6. Confirmação de submissão de publicação ao J Clin Epidemiol

Desconectar Pasta Atual: Entrada Escrever Endereços Pastas Opções Procurar Ajuda Filtros Squirrel Mail Lista de sentemor | Preving | Linguishian | Encommission of movement ago | Respender | Respender a todos Mensagons | Apagar Assunto: A manuscript number has been assigned to your submission De: ltugwell@uottawa.ca Data: Ter, Novembro 25, 2008 8:23 pm Para: cecatti@unicamp.br Prioridade: Normal Filtros de Automatically | From | To | Subject Mensagem: Opções: Ver eabeçalho completo | Ver Versão para impressão | Baixar como um arquivo Ms. Ref. No.: JCE-08-568 Title: Women recalled more accurately process indicators than obstetric complications in a severe maternal morbidity survey Journal of Clinical Epidemiology Dear Dr. Cecatti, Your submission entitled "Women recalled more accurately process indicators than obstetric complications in a severe maternal morbidity survey" has been assigned following manuscript number: JCE-08-568. You may check on the progress of your paper by logging on to the Elsevier Editor System as an author. The URL is http://eos.elsevger.com/jce/. Your username is: cecatti Your password is: cecatti53428 Thank you for submitting your work to this journal. Kind regards, Laura Fitzpatrick Editorial Assistant Journal of Clinical Epidemiology Ontario Editorial Office TEL: FAX:

E-mail: ltugwell@acctawa.ca