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What is the quality of the maternal near-miss case reviews in the WHO European Region? cross-sectional study in Armenia, Georgia, Latvia, Republic of Moldova and Uzbekistan

Running title: Quality of the near-miss case reviews

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ABSTRACT

Objectives The maternal near-miss case review (NMCR) cycle is a type of clinical audit aiming at improving quality of maternal health care by discussing near-miss cases. In several countries this approach has been introduced and supported by WHO and partners since 2004, but information on the quality of its implementation is missing. This study aimed at evaluating the quality of the NMCR implementation in selected countries within the WHO European Region.

Design Cross sectional study

Settings Twenty-three maternities in Armenia, Georgia, Latvia, Moldova, Uzbekistan

Assessment tools A predefined checklist including 50 items, according to the WHO methodology. Quality in the NMCR implementation was defined by summary scores ranging from 0 (totally inappropriate) to 3 (appropriate).

Results Quality of the NMCR implementation was heterogeneous among different countries, and within the same country. Overall, the first part of the audit cycle (from case identification to case analysis) was fairly well performed (average score 2.00, 95%CI 1.94 to 2.06), with the exception of the "inclusion of users views" (average score 0.66, 95%CI 0.11 to 1.22), while the second part (developing recommendations, implementing them, ensuring quality) was poorly performed (average score 0.66, 95%CI 0.11 to 1.22). Each country had at least one champion facility, where quality of the NMCR cycle was acceptable. Quality of the implementation was not associated with its duration. Gaps in implementation were of technical, organisational, and attitudinal nature.

Conclusions Ensuring quality in NMCR implementation may be difficult but achievable. The high heterogeneity in results within the same country suggests that quality of the NMCR implementation depends, to a large extent, from hospital factors, including staff's commitment, managerial support, local coordination. Efforts should be put in preventing and mitigating common barriers that hamper successful NMCR implementation.

Article summary: strengths and limitations of this study

- Maternal near-miss case reviews (NMCR) are a type of clinical audit aiming at improving quality of maternal health care; evidence has showed that their use can be effective in reducing preventable mortality and morbidity, however their implementation can be challenging due to a number of reasons (technical, cultural organisational).
- This is the first study reporting on the quality of the NMCR in Central Asia and Eastern Europe.
- The assessment was based on a predefined checklist, providing the opportunity to evaluate the implementation of the NMCR approach in a standardised manner.
- Future assessments could monitor progress in specific areas, and extend the evaluation to other facilities/countries.
- More implementation studies should explore interventions aiming at improving quality of the NMCR implementation in different settings.

Keywords

Maternal health; near miss case review; standard based assessment; quality of care; middle income countries

Disclosure of interests

None competing interest

List of abbreviations

MoH= Ministry of Health
NMCR= Near miss cases review
UNFPA= United Nation Population Fund
WHO = World Health Organization

INTRODUCTION

Ensuring adequate quality of health care is a primary objective of the World Health Organization (WHO) Global Strategy for Women's, Children's and Adolescent's Health 2016-2030 (1) and of Health 2020, the European strategic framework setting the policy directions for the 53 Member States in the WHO European Region (2). Quality in health care is recognized as essential for the health and well-being of the population, and as a basic aspect of human rights (3-5).

Among the different strategies aiming at improving quality of care at maternity services, the facility-based maternal near miss cases review (NMCR) cycle was proposed by WHO in 2004 as a type of clinical audit (6-8). In respect to mortality audit, the near-miss case review has the advantage to imply less legal issues, and is therefore perceived as more acceptable by staff. Near-miss cases are defined as a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within six weeks after pregnancy (9). In the facility-based NMCR all hospital staff involved in the management of the chosen near-miss case - including midwives, nurses and ancillary staff - get together to discuss and evaluate the care provided against national evidence-based guidelines, local protocols and standards of care. The aim of the case review is to critically discuss local management, procedures and attitudes, and to identify areas that can be further improved (9). Actions to improve quality of maternal health care are proposed and agreed by hospital staff, and subsequently monitored to check their implementation, as for a continuous quality improvement process (9). One of the key characteristic of this

methods is the bottom-up approach, aiming at facilitating local ownership of the process, commitment in implementing the proposed recommendations, and team-building. Currently, the review of severe maternal morbidity cases ("near-miss" events) is recommended by WHO as a key action to eliminate avoidable maternal and perinatal mortality and morbidity and improve the quality of care (10).

While in some countries within the WHO European Region (such as UK, Norway, the Netherlands) the practice of reviewing maternal near miss cases was introduced by the government or by professional associations, with major investments, in several other countries (most often middle-income countries) its implementation was assisted by the WHO and/or United Nation Population Fund (UNFPA). In the later scenario, coverage and quality of the NMCR implementation were usually discussed during workshops (11-13); however, so far they were never evaluated according to a systematic methodology.

In 2015, WHO developed a checklist for assessing the quality of the implementation of the NMCR cycle through a systematic methodology (9). This study aimed at evaluating the quality of the NMCR implementation in five countries of eastern Europe and central Asia, using the WHO checklist, to identify common strengths and weaknesses among different settings.

MATERIAL AND METHODS

Population and setting

The assessment was conducted in Armenia, Georgia, Latvia, Republic of Moldova, and Uzbekistan between June 2015 and October 2016. Countries were chosen based on the following criteria : i) activities planned by the Ministry of Health (MoH) included a quality assessment of the NMCR; ii) there was a request for technical assistance from WHO or UNFPA.

In all of the countries the NMCR approach was introduced following the WHO methodology (9). The year of NMCR introduction differed among countries: for example, in Georgia piloting of NMCR started only six months before this assessment, while in the Republic of Moldova it started 10 years before the assessment (Table 1).

The number of facilities visited in each country depended on the total number of hospitals implementing the NMCR cycle: in Armenia, Georgia and Latvia all facilities implementing the NMCR were visited; in Moldova and Uzbekistan, where a large number of maternities are implementing the NMCR, a sample was selected in agreement with the MoH and the national NMCR coordinator/s, following a geographical criteria (i.e. so that different regions were represented) and including different type of hospitals. Overall, 23 maternities were visited in the five selected countries (Table 1).

Data collection

Each facility was visited for at least the duration of a whole day by two independent external experts with long term experience in NMCR implementation. The international

team was joined by the national assessors, experienced in NMCR implementation at local level. The team was under the leadership of one international assessor (AB), who participated to all hospital visits, with the objective of ensuring standards procedures in all assessments.

The assessment was carried out using a checklist developed by WHO to evaluate the quality of the NMCR cycle at hospital level (Table S1). The checklist was developed by WHO in 2014, field tested and optimised for use in early 2015 (9). The methodology for the quality assessment is fully described in a WHO manual (9). Briefly, the checklist includes 50 items, grouped in 11 domains. The sources of information for the assessment includes: direct observation and evaluation of one or more NMCR sessions; discussion with participants, coordinators and managers; documents from the NMCR sessions (templates and notes from the sessions); local documents (regional/local policies and guidance documents; protocols and standards for care; documents related to quality assurance, monitoring and supervision; reports on NMCR activities); national documents (national policies and guidance documents, guidelines, reports on NMCR implementation). According to the WHO methodology, using the WHO manual (9) as source of standards, each of the 50 items was scored from 0 (totally inappropriate) to 3 (appropriate) (Table S1). For each of the 11 domains the arithmetic mean among all the items in that domain was calculated.

In each facility, immediately after the assessment, feedback were discussed with the local staff and plans for improvement of the NMCR implementation were developed, using a

simple matrix (Table S1).

After completing the visits to all maternities in the country, a national restitution workshop was organised involving representatives from the hospitals, health authorities, professional organisations and partners. During the workshop, achievements and constrains were presented and underlying reasons were discussed. Recommendations for improvement were developed and synthesised in a standard pre-defined simple matrix (Table S1).

Ethical considerations

Activities were initiated upon request of the MoH and carried out in close collaboration with the country health authorities. Information to hospital staff was provided by MoH representatives and local authorities. All people involved in the NMCR sessions were informed about the purpose of the visit and oral consent from the hospital staff and local coordinators and facilitators participating to the observed sessions was obtained. The review of near-miss cases was carried forward anonymously, i.e. information that may have disclosed the identity of the patient, or providers of care, were not reported (9). This study did not aim at directly comparing countries or single facilities with different background, context, and timelines of implementation, therefore results of the assessment are reported in an anonymous way, according to WHO methodology (9). Detailed finding of the assessment together with feedback on how to improve quality of the NMCR implementation were provided to each facility and to each country individually.

RESULTS

The assessment pointed out that quality of the implementation of the NMCR cycle was heterogeneous among different countries, as well as among different facilities within the same country. Table 2 reports the results of the summary scores, for each of the 11 domains of the WHO assessment checklist.

Overall, the first part of the audit cycle (step 1-6 in Table 2, i.e. from case identification to case analysis) was on average fairly well performed in all countries (average score 2.00, 95%CI 1.94 to 2.06), with the exception of the domain "inclusion of users' views" which was poorly implemented in most facilities (average score 1.06, 95%CI 0.07 to 2.05). The second part of the audit cycle (step 7-10), which involves developing appropriate recommendations, implementation of the recommendations, follow up, documentation and dissemination of results within the facility and the country, was on average poorly performed in all countries (average score 1.20, 95%CI 0.93 to 1.46). In particular, The domain 11 "ensuring quality in the NMCR cycle", which implies a process of periodical quality assessment, development of recommendation for quality improvement, and related actions, was substandard (average score 0.66, 95%CI 0.11 to 1.22), with the exception of country E, where regular monitoring and supervision was carried out by a team that included national and international members.

In each country it was possible to identify at least one "champion" facility, where quality of the NMCR cycle had only minor deficiencies (A-H3, B-H4, C-H1, D-H3, EH1 and H2). On the other hand, in a few facilities (A-H2, B-H1 and H3, CH6) most of the areas assessed

were judged as “totally inappropriate”.

In some facilities examples of good practices were also observed for single domains problematic at a country-level. For examples, despite inclusion of users views was substandard in most facilities in countries B and D (average scores 1.11, 95%CI 0 to 2.22 and 0.61, 95%CI 0 to 1.48 respectively) single facilities reached good scores (B-H4 had a score of 3 and D-H3 had a score of 2), being able to regularly interview women and incorporating their views in the development of recommendations to improve hospital care (Table 2).

On average, quality of the implementation of NMCR was on a higher level in Country E, where evaluation scores pointed out that there were only few weakness in implementation compared to other countries (average score 2.12, 95%CI 1.84 to 2.39).

Table 3 summarises main common strengths and weaknesses in the quality of the NMCR implementation, as divided in three categories: (i) those mostly related to technical aspects, (ii) those predominantly of organisational nature, and (iii) those related to the attitude toward the NMCR. The main technical strength was that, beside the existence of appropriate technical skills in the methodology, most facilities developed several recommendations that were achievable, realistic, time-bound- and with a potential impact on the quality of care. Although recommendations were not always well documented (thus resulting in low scores under domain 10, gaps in reporting not always indicated gaps in implementation, and in many cases several recommendations were actually implemented. This was a common observation in country B, where recommendations were poorly

recorded, but several actions to improve quality of care -such as setting up emergency kits and related protocols, and introducing the Modified Obstetric Early Warning Score (MEOWS) chart (14)- were actually implemented. Among strength in organisational aspects, the most important was that NMCR were regularly held, and staffing at all levels, including midwives, participated. Main strengths in attitude included the endorsement and application of the basic principles of the NMCR (confidentiality, openness, respecting diverting opinions, avoiding blame).

Main gaps in technical aspects were: inappropriate case reconstruction; case analysis not getting to the "real point" and not using a "why but why" approach (i.e. discussion of underlying causes); recommendations not being fully SMART (Specific, Measurable, Achievable, Realistic, Time-bound (15). Main gaps of organisational nature were: lack of continuity in the role of facilitator/coordinator; lack of proper dissemination of the results (i.e. circulation of information within the facility level and at national level on how many and what type of recommendations were developed); lack of follow up on previous recommendations. Major gaps in adopting the background philosophy and principles of the NMCR were observed in some facilities such as: lack of respect for other people's opinion; persistence of blaming and judging others rather than using the NMCR cycle to discuss and improve ways of working; insufficient involvement of mid-level staff. Lack of inclusion of the users' view, which was a frequent observation, was reported to be due to the lack of trained interviewers, and this was interpreted as not merely an organisational gap, but also as a gaps in attitude, i.e. lack of understanding the importance of taking into account the women's point of view (attitude of the providers). Finally, common to most facilities, there

was insufficient monitoring and evaluation, and lack of a quality assurance mechanism. In most cases this gap was due to deficiencies in establishing and efficiently running a NMCR coordination system at national level.

Recommendations developed by local stakeholders during the national restitution workshops were setting-specific. Nevertheless, there were several similarities. The most frequent/relevant recommendations developed for implementation at different levels - hospital level, national level, WHO and development partners - are reported in Table 4.

Examples of the observed impact of the NMCR on quality of care at facility level are reported in Table S2. Despite progress was often poorly reported both in the hospital and in national reports, several achievements could be observed. These included improved use of national clinical guidelines, development and use of local protocols and standards of care, better availability and organisation of emergency services, improved autonomy of midwives, and positive dynamics such as improved team working.

DISCUSSION

This study aimed at evaluating the quality of the NMCR in selected countries within the WHO European Region using a standardised checklist and methodology. Overall the assessment pointed out that the practise of reviewing near-miss cases at hospital level is currently ongoing in all countries included in this study; however, both coverage and quality of the implementation of the NMCR cycle is heterogeneous. Overall, while first part of the audit cycle (from case identification to case analysis) was fairly well performed, with

the exception of the "inclusion of users views", the second part of the audit cycle (developing recommendations, implementing them, ensuring quality) was in general poorly performed. Gaps in implementation were both of technical, organisational, and attitudinal nature.

These findings are not entirely surprising. Previous, although less systematic, evaluations in the same geographical area pointed a series of challenges (7,8,11,12) in effectively implementing the review of near-miss cases at facility level. Beside technical and organisational challenges, the successful implementation of clinical audits such as the NMCR often calls for a major change in staff's attitude (7,8,11,12). In the country assessed, especially in the Ex-Soviet countries, the successful implementation of the NMCR aims at moving away from a "traditional" system of carrying forward clinical audits, where blame and punishment were the routine, subjective judgment were the rule and audit involved only doctors, while midwives, other mid-level staff and service users had no voice (7,8,11,12). The "traditional" audit system mainly resulted in punishing single individuals, rather than at looking to the health system failures and finding solutions at organisational level (7,8,11,12). Changing practices involved building knowledge and skills together with a drastic shift in attitude. Given these substantial constrains, the successful implementation of the NMCR at least in one country (Country E) and in several champion maternities in other countries, must be seen as a positive achievement, proving that NMCR can be successfully implemented in different settings.

This paper reports the quality of the NMCR implementation in middle income countries (Armenia, Moldova, Uzbekistan are lower middle income countries, Georgia is an upper

middle income countries), where the NMCR was carried forward with relatively limited resources. Findings of this assessment cannot be generalised to other high-income countries of the WHO European region, such as UK, Norway, the Netherlands, where the practice of reviewing maternal near miss cases has been institutionalised, with major investments (16-18). However, it must be acknowledged that the review of near miss cases at facility level is still not a routine practice in many European countries. We were unable to identify any study reporting on a standard-based assessment of the quality of the NMCR, from any country of the WHO European region.

Interestingly, findings of this study suggest that quality of the implementation of the NMCR cycle is not strictly associated to the duration of the implementation: two countries where implementation started respectively short term before this assessment (country C) and long term before this assessment (country E) were the most successful in achieving high quality in the NMCR cycle. However, it is also true that adequate time is needed for implementation, and completing a pilot phase in a country cannot take less than 18-24 months from the first technical workshop. In this regards, it must be acknowledge that country B started piloting just six months before the quality assessment; observed results in this country can be interpreted as satisfying given the short time frame.

The high heterogeneity in results within the same country (such as in the case of country A, B, and D) suggests that quality of the NMCR implementation depends, to a large extent, from hospital factors, including staff's commitment, managerial support, local coordination. These results are in line with a systematic review on facilitators and barriers to effective implementation of NMCR cycle, pointing out that hospital factors (good leadership),

together with a system of coordination (which often includes external support), are key enablers for effective NMCR implementation (19).

This assessment pointed out that, despite WHO recommends conducting an interview with the women/her family for each near miss case, inclusion of women's view was still substandard in many of the assessed facilities. However, some facilities (B-H4, D-H3) reached good scores even when this domain was problematic at a country level (Table 2), thus proving that the inclusion of users views was feasible. In the WHO framework, experience of care is one of the two key components of quality of maternal and newborn health care, along with provision of care (1,2). The views of women and their families can provide relevant information on aspects related to case management, including important details on what happened, such as organizational issues and communication issues which are usually not reported in the medical notes. Additionally, user views can provide important inputs for the development of recommendations, both related to improving case management and to improve women's rights, such as the right to (unbiased) information, and the right to a non-discriminatory care (1,2). In a study in Moldova it was observed that the implementation of NMCR improved attitude towards patients (20), while in Kazakhstan it successfully improved patients satisfaction (21,22).

This study points out that quality in the reporting on the NMCR activities was overall low. The WHO manual now provides a series of templates to facilitate and uniform reporting (9). Sustained monitoring and evaluation based on appropriate reporting, as well as periodical quality assessments should be part of a strategy to achieve quality in the NMCR implementation.

This paper has the merit of reporting the actual state of implementation of NMCR, in a real setting and not in a study setting where the NMCR were implemented in a limited number of facilities, with dedicated human and financial resources, and for a limited period of time. Another strength of the study is that the evaluation was carried out in a systematic way using a predefined standardised tool and methodology, aiming at evaluating all key aspects that contribute to overall NMCR quality (table S1) (9). To our knowledge, no other previous similar systematic evaluations have been performed.

We acknowledge that the scoring system utilised by the checklist may be open to some subjectivity. However, this scoring system is similar to other scoring systems extensively used by WHO in the last 15 years for systematic, standard based, quality assessments, and it proved to be able to capture key elements of quality of the implementation in both implementation and research settings (23-27). No other validated tools or scoring systems exist to assess quality of the NMCR. The checklist and its score system were field tested before use, until when they were considered satisfactory covering all key aspects of quality of NMCR (9). The score is attributed by a team of experts, thus reducing subjectivity of the single individual in the evaluation (9).

As a second limitation we acknowledge that in two out of the total five countries (Moldova and Uzbekistan), although the sample of hospitals covered a significant proportion of deliveries, it remains a convenience sample based on MoH indications, and one cannot exclude a selection bias towards the better performing institutions. However, we emphasize that the main purpose of the assessment was to create an opportunity at

national level do discuss quality of the NMCR, and develop recommendations for improvement. Subsequent assessments could monitor progress in specific areas, and extend the evaluation to other facilities. The assessment could also be carried forward in other countries. Based on the results of this study, in the future more efforts should be put in evaluating the quality of the implementation of NMCR on a regular basis. More implementation studies should explore interventions aiming at improving quality of the NMCR implementation in different settings.

The objective of this study was not evaluating the impact of the implementation of the NMCR, but rather the quality of the process. Nevertheless, several achievements could be observed (Table S2), despite this type of information was not consistently available. These results are in line with other studies (28-42) and a systematic review (39) reporting that NMCR is an effective strategy in improving quality of care when measured against predefined standards and it may even significantly reduce maternal mortality in high burden countries (43).

Conclusions

Ensuring high quality in the implementation of the NMCR may be difficult in countries of eastern Europe and central Asia but achievable. In the future more efforts should be put in evaluating the quality of the implementation of NMCR on a regular basis, capitalising from these lessons, and preventing and mitigating common barriers that hamper successful implementation. The availability of a new manual on how to implement and to monitor the NMCR at facility level, of a standard methodology for assessing quality of the NMCR, as

well as templates for reporting (9) may facilitate this process. More implementation studies should explore interventions aiming at improving quality of the NMCR in different settings.

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Author contributions

AB and ML conceived the study, analysed the data and wrote the first draft of the paper

AB, SH, HK, SB, SI, MJ, ID, GM, GL collected data and contribute to the final draft of the paper

GL and GM contributed by procuring funds

All author contributed to the final version of the paper.

Data Sharing statement

Additional details on the country assessments can be obtain from the first author

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Table 1. Characteristics of the countries and of the maternities assessed

	Armenia	Georgia	Latvia	Moldova	Uzbekistan
World Bank Classification [1]	Lower middle income	Upper Middle Income	High income	Lower middle income	Lower middle income
Population (thousands), total*	2969	4358	2060	3514	28541
GNI per capita, PPP US$*	6990	3280	21020	3690	1720
Maternal mortality ratio, adjusted*	30	67	34	41	28
Neonatal mortality rate [2]	10	15	5	9	14
Institutional deliveries as % of total deliveries [2]	99.4	98.3	NA	99.4	97.3
National introductory workshop on NMCR [3]	2007		2012	2005	2005
First national technical workshop on NMCR [3]	2009	2015	2013	2005	2007
Number of hospital implementing NMCR [3]	3	6	2	13	62
Number of hospital assessed	3	6	2	6	6
Type of hospitals	1 regional 2 district	2 regional 4 district	1 regional, 1 district	2 regional, 4 district	3 regional 3 district
Number of births/year in the hospital assessed **	6125	8570	8152	13311	23309

[1] Source: The World Bank, Country and Lending Groups. (2014) Historical classification. Available: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519 (Accessed 9 March 2017).

[2] Source: UNICEF Country statistics http://www.unicef.org/statistics/index_countrystats.html (accessed Dec 7, 2016)

[3] Source: WHO mission reports

Table 2. Summary scores

	A			B						C		D						E					
	H1	H2	H3	H1	H2	H3	H4	H5	H6	H1	H2	H1	H2	H3	H4	H5	H6	H1	H2	H3	H4	H5	H6
1. Internal organisation	1	1	2.5	1	2.1	0.8	2.8	2.3	1.9	3	2	1.7	1.9	1.9	1.6	2.5	0.5	2.9	2.6	2.7	2.3	2.7	2.3
2. Case identification	2.3	1	1.5	2	3	2	3	3	3	3	2.3	2.2	2.5	2.8	3	2	2.1	3	3	3	3	0.7	3
3. Respect of ground rules	1.5	1.5	2.5	1	2	1	3	3	2	3	3	2	1.5	1	1.5	2	1	3	3	3	3	3	3
4. Case presentation	1.6	1.4	2	0.3	2	0.7	2.3	2	0.7	2.5	3	1.8	0.8	2.5	1.7	2.3	1.2	2.3	1.7	1.3	1	2	2
5. Inclusion of users views	0	0	0	0.3	1.7	0	3	1.2	0.5	2.5	1.3	0.3	0	2	0	1.4	0	1.8	2.6	2	1.4	1.2	1.2
6. Case analysis	1.5	1	2.5	0.1	1.4	0.3	2	1.6	1.2	2.1	2.6	2.2	0.9	2	1.4	1.3	0.7	2.5	2.8	1.7	1	2.4	1.3
7. Development of recommendations	0.3	1	2	0.1	1.1	0	2	1.8	1.7	1.8	2.6	1.8	0.1	2.3	1	1.9	0.4	3	2.6	1.7	1	2.3	1.3
8. Implementation of recommendations	0	0.5	2	0	0	0	1	1.7	2	2	1.3	0.8	0	3	0.8	2	0.5	3	2.5	1.5	2.5	3	3
9. Follow up	0	0	1.5	0	0	0	0	0	3	2	2.5	0	0	3	0	1.6	1.3	2.8	1.5	1.5	1.5	2	1.5
10. Documentation and results diffusion	0.3	0.3	2	0.5	1	0.5	2.5	1	2	1.7	1	0.8	0.6	1.5	1.1	0.6	0.3	1.8	2	2.5	2	2.7	1
11. Ensuring quality in the NMCR	0	0	0	NA	NA	NA	NA	NA	NA	1	1	0	0	0	0	1	0.3	1.5	1.7	1.2	1.2	1.2	1.2

NA= in country B piloting started only six months before the quality assessment; for this reason the domain 11 was considered not applicable

Colour legend

RED= scores between 0.0 to 0.9

YELLOW= scores between 1.0 at 1.9

GREEN= scores between 2.0 at 3.0

Table 3. Recommendations made by local stakeholders on how to improve NMCR quality

Hospital level	1) Ensure managerial support for the organisation of the NMCR and for the implementation of the resulting recommendations 2) Aim at regular sessions 3) Ensure active participation of all staff involved in case management, including mid-level staffing 4) Ensure that ground rules are respected 5) Ensure that the review follows the steps suggested in the WHO manual [7] 6) Ensure that user's views are collected and taken into consideration 7) Ensure that recommendations developed are SMART* 8) Ensure that every session starts by following up on the previous recommendations 9) Document the implementation of the recommendations (provide date and description) 10) Document, analyse and disseminate results of the NMCR at hospital level, including type of recommendations developed and percentage of those implemented
National level	1) Set up/strengthen the national coordinating team 2) Develop a plan for regular quality assessment and reinforcement 3) Strengthen technical skills among staffing on the principles, methods and practices of the NMCR cycle 4) Practical training on how to conduct interviews in order to collect women's views 5) Support networking activities among facilities (eg exchange visits) 6) Document, analyse and disseminate results of the NMCR at national level
WHO and other development partners	1) Ensure regular and timely technical support for capacity development, including developing skills for women interviews 2) Provide support for developing legal framework and national guidance manual for NMCR 3) Support regular monitoring of the implementation in a coordinated manner 4) Support results dissemination and discussion 5) Support timely quality assessments and subsequent actions for quality improvement 6) Support networking activities among facilities /countries with the objective of improve quality of NMCR cycle 7) Ensure continuous support for updating key national guidelines, local protocols, standards for clinical practice

Abbreviations: NM= near-miss; NMCR= near-miss case review; SMART= Specific, Measurable, Achievable, Realistic, Time-bound (15)

Table 4. Strength and weakness observed in the quality of the NMCR implementation

	STRENGTH	WEAKNESS
TECHNICAL	In all countries: ▪ Technical skills on performing NMCR were on average fair ▪ Local protocols were on average present and used ▪ Recommendations were usually developed, with several SMART characteristics (Achievable, Realistic, Time-bound) Especially in Country E: ▪ Most maternity teams were able to analyze efficiently a NM case, and to develop relevant recommendations to improve quality and organization of care, and follow-up their implementation.	▪ Case definition not complying with national definition ▪ Lack of existence and use of local protocols for case analysis ▪ Some lack of knowledge and skills in NMCR methodology Case summary, case reconstruction door-to-door, case analysis (including getting to the real point, and what we did good, shortcomings and underlying reasons using the 'why-but-why') not performed well performed in all facilities ▪ Recommendations not fully SMART* (often not Specific nor Measurable)
ORGANISATION	In all countries: ▪Staffing at all levels (including midwives and nurses) was involved and in some cases encouraged by facilitator to actively participate in the review process. ▪Session participants were mostly those involved in care provision of the case reviewed, and, generally, felt free to ask questions and express their opinions. ▪ NMCR mostly happened on a regular basis Especially in Country E: ▪An excellent national plan for implementation was developed ▪ Appropriate normative regulations were developed through regular NMCR sessions ▪ By 2015, 90% of maternity facilities were trained and implementing NMCR Regional NMCR coordinators were	▪ Lack of local written procedure for NMCR ▪Irregular meetings in some facilities ▪ Lack of involvement of staffing who managed the case ▪ Lack of a regional/national coordination and/or continuity in facilitator/coordinator role, and/or support from them lack of trained interviewers ▪ Absence of local leaders ▪ Lack of support from hospital manager in organisation of the NMCR and in the implementation of the recommendation ▪ Lack of follow up on previous recommendations ▪Lack of production, dissemination and discussion of results of the NMCR cycle ▪ Lack of periodical evaluations of the quality of the NMCR ▪When evaluations of the quality was performed, no mechanism ensured that

	established ▪There was sustained support from MoH; WHO and partners (also Latvia)	resulting recommendations were taken up
ATTITUDE	In all countries ▪ Basic BTN principles were respected in most facilities, including confidentiality ▪Multidisciplinary approach to case reviews was evident in most facilities ▪Managers offered substantial support to organization of NMCR sessions and implementation of recommendations. ▪Staff found this method useful to improve quality and organization of care ▪Midwives role as participants, but also as coordinators and facilitators Interviews became a routine in most facilities (in particular in Latvia) Especially in Country E:: ▪ Facilitators succeeded to create and maintain an open and non-threatening environment during sessions; staff felt free to put forward (or ask) questions and express their opinions (also Country C) ▪The point of view of women was always collected and presented; some interviews were of excellent quality (also Country C) ▪Professionals were praised in case of good care	▪ In some cases lack of respect of other people's opinion, persistence of blaming, persistence of a wrong attitude that suggested "judging others", rather than moving towards thinking "the review is about us" ▪Lack of active participation in the discussion ▪Insufficient involvement of mid-level staffing ▪ Lack of the interviews with woman in some facilities ▪ Even where the interview was collected, women's view not taken into account when recommendation are implemented ▪Staff not always praised when quality and appropriate care given ▪Staff considers developing recommendations a mere formality, they were not eager to implement them, and take on the role and the responsibility to change practice. ▪Persistence of a system that advocates punishment in some facilities

Abbreviations: NM= near-miss; NMCR= near-miss case review; SMART= Specific, Measurable, Achievable, Realistic, Time-bound (15)

Table S1. Checklist to assess the quality of the NMCR cycle at hospital level and matrix to develop local recommendations

Checklist to assess the quality of the NMCR cycle at hospital level and matrix to develop local recommendations

Facility name _____ _____ Date _____

INSTRUCTIONS

Sources of information:

- Direct observation and evaluation of a NMCR session
- Discussion with participants
- Discussion with coordinators and managers
  - Documents from the NMCR sessions: Records/notes of the sessions: templates, cases summaries, summary of the interviews with women and other care-takers (family, documents in support of the recommendations and their implementation, other related documentation (photo etc.)
- Other related documents:

  National documents
  - National policies, and guidance documents
  - National clinical guidelines
  - National documents related to quality assurance, monitoring and supervision
  - National summary reports on NMCR implementation

  Local documents
  - Regional/local policies, and guidance documents
  - Local clinical protocols and standards for care provision
  - Local documents related to quality assurance, monitoring and supervision
  - Local summary reports

Reference: the reference for all key items is the WHO manual "How to implement the maternal Near-Miss Case Review (NMCR) cycle at hospital level"

Methods of scoring:

1) Score each single item as follows: Score 0= totally inappropriate; Score 1= major problems; Score 2= some deficiencies; Score 3= appropriate.

2) In the blue row calculate the mean of the scores for each key item in the group. This is the score for that group of items.

	SCORE	Comments
INTERNAL ORGANISATION/PREPARATION		
1. A local written procedure to implement the NMCR cycle exists		
2. Support from management is adequate		
3. Regular meetings are held		
4. Each meeting has adequate duration		
5. All key staff involved in the NM case is invited to the session		
6. Very limited (and justified) participation of people who were not involved in the management of the NM case reviewed		
7. All material need is prepared before the session		
CASE IDENTIFICATION AND SELECTION		
8. The agreed NM definition is used (same definition in all the country)		

9. The NM cases are correctly identified		
10. A NM case is appropriately selected for review among those identified		
GROUND RULES		
11. Ground rules for the NMCR are respected, especially confidentiality, respect of other people's opinion and refrain from blaming single individuals		
NMCR SESSION: CASE PRESENTATION		
12. The case is appropriately summarised and presented by one participant (paper copies; flip charts; slides)		
13. A "door to door" reconstruction, with all relevant details, is provided by all staff involved in care provision		
14. The clinical records of the patient, whose case is reviewed, are available during the meeting, if additional information is needed		
NMCR SESSION: INCLUSION OF USERS VIEWS		
15. The opinions of the woman (*i.e. informative contents on real facts, and her perceptions and views*), and if appropriate of relatives and/or friends, is collected (interview), for each NM case reviewed		
16. The interview(s) is/are appropriately summarised and presented		
17. The key findings from the interview (i.*e. same definition as above*) are appropriately taken into consideration in the case analysis		
18. The key findings (i.*e. same definition as above*) from the interview are appropriately taken into consideration for the prioritisation and development of solution		
NMCR SESSION: CASE ANALYSIS		
19. The case-analysis is performed following a structured analytical approach		
20. The case management is analysed from admission to discharge: a "door to door" approach is used		
21. The case is reviewed comparing actual management versus evidence (clinical guidelines, protocols and standards)		
22. The positive aspects of care provision ("what we did good") are identified and documented		
23. The staff is praised for the positive aspects of care provision		
24. The critical aspects of care ("what did not go well") are appropriately identified, focusing on the most important issues ("getting to the real point")		
25. The real underlying reasons for substandard care ("why but why?") are identified, discussed and documented		
26. The facilitator ensures that ground rules are respected, all steps of the session are completed, notes are taken		
27. Staff of all types and roles (including midwives and nurses) actively and openly participate in the case analysis		
28. The results of the case-analysis are documented (using the templates)		
NMCR SESSION: DEVELOPMENT OF RECOMMENDATIONS		
29. A list of SPECIFIC recommendations linked to the NM case is always developed, including responsible people and timelines		
30. The recommendations target the main problem (s) and the main underlying factors		

31. Most of the recommendations refer to actions to be carried forward at the hospital performing the review		
32. The recommendations use as reference clinical guidelines, protocols and standards		
33. The recommendations are SMART (specific, measurable, achievable, realistic, time-bound)		
34. The recommendations give due consideration to women's rights in hospital: effective communication, emotional support, respect and dignity		
35. The recommendations include an adequate division of tasks among hospital staff		
36. Recommendations that need action at regional/national level are effectively identified		
37. The facilitator ensures that ground rules are respected, all steps of the session are completed, notes are taken		
38. Staff of all types and roles (including midwives and nurses) participate actively and openly		
39. The recommendations are documented (using the templates)		
IMPLEMENTATION OF RECCOMENDATIONS		
40. The agreed recommendations are implemented (at least 75%)		
41. Managers/local health authorities actively support implementation of recommendations		
42. The implementation of recommendations is documented (using the template)		
NMCR SESSION: FOLLOW UP		
43. The NMCR session starts with a follow up of the previous session, checking that recommendations have been implemented		
44. In case the agreed actions were not taken, reasons are discussed, and a new recommendation is developed, including responsible people and timelines		
DOCUMENTATIONS ON THE NMCR CYCLE AND EFFECTIVE DIFFUSION OF RESULTS - AT FACILITY LEVEL		
45. A folder is kept for each NM case containing all key documentation, including the follow up phase (see manual); cases are recorded in a register/log book		
46. At hospital level, an appropriate summary of relevant information regarding the NMCR cycle is regularly disseminated and discussed, without compromising confidentiality, among staff, managers, and health authorities (see manual)		
47. Effective communication of key information is provided by hospital coordinators to national coordinator(s)		
ENSURING QUALITY IN THE NMCR CYCLE		
48. Collaboration of the local team with the national/regional coordinator has been effective		
49. Periodical evaluations of the quality of the NMCR has been planned		
50. Previous recommendations from quality assessment has been taken into consideration and translated into actions		

SUMMARY TABLE

MAIN STRENGTHS: **1.** **2.** **3.** **4.**
MAIN WEAKNESSES: **1.** **2.** **3.** **4.**
COMMENTS: **1.** **2.** **3.** **4.**

MATRIX. Recommendations for improving the quality of the NMCR cycle at hospital level (expand as needed)

Priority areas that need to be improved	Action agreed	Responsible person	Timeline

Table S2. Reported impact of the NMCR on quality of care at facility level

- Use of national clinical guidelines
- Development and use of protocols at facility level (for doctors and for midwives) for obstetric complications (eg post-partum haemorrhages, eclampsia, sepsis)
- Development and implementation of standards of care
- Development of capacities among staff of all levels (doctors, midwives, nurses) to critically analyse cases identifying real underling reasons for near-miss (eg lack of organisation or lack of communication), comparing management to guidelines, protocols and standards of care, and to successfully carry forward a self-assessment
- Improved autonomy of mid level staff, in particular midwives providing first emergency care without doctors
- Availability of emergency team 24/24h in case of emergencies ~~case~~
- In the admission and on labour ward, a system in place which allows to call all relevant staff in case of an emergency (emergency button)
- Availability of emergency lab 24/24h
- Availability of staff 24/24h in the event of a need for blood transfusion, especially in rural areas
- Set up of separate room for managing emergency cases
- Availability of emergency kit for managing emergency cases
- Improved availability of essential drugs, such as misoprostol, i/v antihypertensive
- Enhanced collaboration between clinical staff and management of the facility, for improving practical aspects of organisation of care (eg supplies, maintenance, staff shifts)
- Development of clear job description to specific roles and responsibilities, facilitating effective team work
- Improved monitoring after caesarean section and/or obstetric complications (eg training and use of checklists)
- Improved team work
- Reported improvement in quality of care delivered *

*not further specified in available local/national reports.

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What is the quality of the maternal near-miss case reviews in the WHO European Region? Cross-sectional study in Armenia, Georgia, Latvia, Republic of Moldova and Uzbekistan

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Running title: Quality of the near-miss case reviews

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ABSTRACT

Objectives The maternal near-miss case review (NMCR) cycle is a type of clinical audit aiming at improving quality of maternal health care by discussing near-miss cases. In several countries this approach has been introduced and supported by WHO and partners since 2004, but information on the quality of its implementation is missing. This study aimed at evaluating the quality of the NMCR implementation in selected countries within the WHO European Region.

Design Cross sectional study

Settings Twenty-three maternity units in Armenia, Georgia, Latvia, Moldova, Uzbekistan

Assessment tools A predefined checklist including 50 items, according to the WHO methodology. Quality in the NMCR implementation was defined by summary scores ranging from 0 (totally inappropriate) to 3 (appropriate).

Results Quality of the NMCR implementation was heterogeneous among different countries, and within the same country. Overall, the first part of the audit cycle (from case identification to case analysis) was fairly well performed (average score 2.00, 95%CI 1.94 to 2.06), with the exception of the "inclusion of users views" (average score 0.66, 95%CI 0.11 to 1.22), while the second part (developing recommendations, implementing them, ensuring quality) was poorly performed (average score 0.66, 95%CI 0.11 to 1.22). Each country had at least one champion facility, where quality of the NMCR cycle was acceptable. Quality of the implementation was not associated with its duration. Gaps in implementation were of technical, organisational, and attitudinal nature.

Conclusions Ensuring quality in the NMCR may be difficult but achievable. The high heterogeneity in results within the same country suggests that quality of the NMCR implementation depends, to a large extent, from hospital factors, including staff's commitment, managerial support, local coordination. Efforts should be put in preventing and mitigating common barriers that hamper successful NMCR implementation.

Article summary: strengths and limitations of this study

- This is the first study reporting on the quality of the hospital based near-miss case review (NMCR) in Central Asia and Eastern Europe.
- The assessment included five countries within the WHO European Region and was based on a predefined checklist, providing the opportunity to evaluate the implementation of the NMCR approach in a standardised manner.
- In three countries facilities included in the evaluation accounted for all facilities implementing the NMCR within in the country. In the remaining two countries, where the NMCR were implemented in more hospitals, facilities were chosen in dialogue with local authorities (non-probability sampling), and not at random; however, criteria used to select facilities included also geographical distribution (i.e. so that different regions were represented) and hospital type (i.e. different types of hospitals were selected).

Keywords

Maternal health; near miss case review; standard based assessment; quality of care; middle-income countries

Disclosure of interests

None competing interest

List of abbreviations

MoH= Ministry of Health
NMCR= Near miss cases review
UNFPA= United Nation Population Fund
WHO = World Health Organization

INTRODUCTION

Ensuring adequate quality of health care is a primary objective of the World Health Organization (WHO) Global Strategy for Women's, Children's and Adolescent's Health 2016-2030 (1) and of Health 2020, the European strategic framework setting the policy directions for the 53 Member States in the WHO European Region (2). Quality in health care is recognized as essential for the health and well-being of the population, and as a basic aspect of human rights (3-5).

Among the different strategies aiming at improving quality of care at maternity services, the facility-based maternal near miss cases review (NMCR) cycle was proposed by WHO in 2004 as a type of clinical audit (6-8). In respect to mortality audit, the near-miss case review has the advantage to imply less legal issues, and is therefore perceived as more acceptable by staff. Near-miss cases are defined as a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within six weeks after pregnancy (9). In he facility-based NMCR all hospital staff involved in the management of the chosen near-miss case - including obstetricians, midwives, nurses and ancillary staff - get together to discuss and evaluate the care provided against national evidence-based guidelines, local protocols and standards of care. The aim of the case review is to critically discuss local management, procedures and attitudes, and to identify areas that can be further improved (9). Actions to improve quality of maternal health care are proposed and agreed by hospital staff, and subsequently monitored to check their implementation, as for a continuous quality improvement process (9). One of the key characteristics of this

method is the bottom-up approach, aiming at facilitating local ownership of the process, commitment in implementing the proposed recommendations, and team-building. Currently, the review of severe maternal morbidity cases ("near-miss" events) is recommended by WHO as a key action to eliminate avoidable maternal and perinatal mortality and morbidity and improve the quality of care (10).

While in some countries within the WHO European Region (such as UK, Norway, the Netherlands) the practice of reviewing maternal near miss cases was introduced by the government or by professional associations, in several other countries (most often middle-income countries) its implementation was assisted by the WHO and/or United Nation Population Fund (UNFPA). In the later scenario, coverage and quality of the NMCR implementation were usually discussed during workshops (11-13), but so far they have not been evaluated using a systematic methodology.

In 2015, WHO developed a checklist for assessing the quality of the implementation of the NMCR cycle at hospital level through a systematic methodology (9). This study aimed at evaluating the quality of the NMCR implementation in five countries of Eastern Europe and central Asia, using the WHO checklist, to identify common strengths and weaknesses among different settings.

MATERIAL AND METHODS

Population and setting

The assessment was conducted in Armenia, Georgia, Latvia, Republic of Moldova, and Uzbekistan between June 2015 and October 2016. Countries were chosen based on the following criteria: i) activities planned by the Ministry of Health (MoH) included a quality assessment of the NMCR; ii) there was a request for technical assistance from WHO or UNFPA.

In all of the countries the NMCR approach was introduced following the WHO methodology (9). The year of NMCR introduction differed among countries (Table 1).

The number of facilities visited in each country depended on the total number of hospitals implementing the NMCR cycle: in Armenia, Georgia and Latvia all facilities implementing the NMCR were visited; in Moldova and Uzbekistan, where a large number of maternity units are implementing the NMCR, a sample was selected in agreement with the MoH and the national NMCR coordinator/s, following a geographical criteria (i.e. so that different regions were represented) and including different type of hospitals. Overall, 23 maternity units were visited in the five selected countries (Table 1).

Data collection

Each facility was visited for at least the duration of a whole day by two independent external experts with long term experience in NMCR implementation. The international team was joined by the national assessors, experienced in NMCR implementation at local level. The team was under the leadership of one international assessor (AB), who

participated to all hospital visits, with the objective of ensuring standards procedures in all assessments.

The assessment was carried out using a checklist developed by WHO to evaluate the quality of the NMCR cycle at hospital level (Table S1). The checklist was developed by WHO in 2014, field-tested and optimised for use in early 2015 (9). The methodology for the quality assessment is fully described in a WHO manual (9). Briefly, the checklist includes 50 items, grouped in 11 domains. The sources of information for the assessment includes: direct observation and evaluation of one or more NMCR sessions; discussion with participants, coordinators and managers; documents from the NMCR sessions (templates and notes from the sessions); local documents (regional/local policies and guidance documents; protocols and standards for care; documents related to quality assurance, monitoring and supervision; reports on NMCR activities); national documents (national policies and guidance documents, guidelines, reports on NMCR implementation). According to the WHO methodology, using the WHO manual (9) as source of standards, each of the 50 items was scored from 0 (totally inappropriate) to 3 (appropriate) (Table S1). For each of the 11 domains the arithmetic mean among all the items in that domain was calculated.

In each facility, immediately after the assessment, feedbacks were discussed with the local staff and plans for improvement of the NMCR implementation were developed, using a simple matrix (Table S1).

After completing the visits to all maternity units in the country, a national restitution

workshop was organised involving representatives from the hospitals, health authorities, professional organisations and partners. During the workshop, achievements and constraints were presented and underlying reasons were discussed. Recommendations for improvement were developed and synthesised in a standard pre-defined simple matrix (Table S1).

Ethical considerations

Activities of this observational study were initiated upon request of the MoHs and carried out in close collaboration with the health authorities; ethical approval was not required. Information to hospital staff was provided by MoH representatives and local authorities. All people involved in the NMCR sessions were informed about the purpose of the visit and oral consent from the hospital staff and local coordinators and facilitators participating to the observed sessions was obtained. The review of near-miss cases was carried forward anonymously, i.e. information that may have disclosed the identity of the patient, or providers of care was not reported (9). This study did not aim at directly comparing countries or single facilities with different background, context, and timelines of implementation, therefore results of the assessment are reported in an anonymous way, according to WHO methodology (9). Detailed finding of the assessment together with feedback on how to improve quality of the NMCR implementation were provided to each facility and to each country individually.

RESULTS

The assessment pointed out that quality of the implementation of the NMCR cycle was heterogeneous among different countries, as well as among different hospitals within the same country. Table 2 reports the results of the summary scores, for each of the 11 domains of the WHO assessment checklist.

Overall, the first part of the audit cycle (step 1-6 in Table 2, i.e. from case identification to case analysis) was on average fairly well performed in all countries (average score 2.00, 95%CI 1.94 to 2.06), with the exception of the domain "inclusion of users' views" which was poorly implemented in most facilities (average score 1.06, 95%CI 0.07 to 2.05). The second part of the audit cycle (step 7-10), which involves developing appropriate recommendations, implementation of the recommendations, follow up, documentation and dissemination of results within the facility and the country, was on average poorly performed in all countries (average score 1.20, 95%CI 0.93 to 1.46). In particular, the domain 11 "ensuring quality in the NMCR cycle", which implies a process of periodical quality assessment, development of recommendation for quality improvement, and related actions, was overall substandard (average score 0.66, 95%CI 0.11 to 1.22), with the exception of country E, where regular monitoring and supervision was carried out by a team that included national and international members.

In each country it was possible to identify at least one "champion" facility, where quality of the NMCR cycle had only minor deficiencies (A-H3, B-H4, C-H1, D-H3, EH1 and H2). On the other hand, in a few facilities (A-H2, B-H1 and H3, CH6) most of the areas assessed were judged as "totally inappropriate".

In some facilities examples of good practices were also observed for domains that were on average implemented on a substandard level at a country-level. For examples, despite inclusion of users views was substandard in most facilities in countries B and D (average scores 1.11, 95%CI 0 to 2.22 and 0.61, 95%CI 0 to 1.48 respectively) single facilities reached good scores (B-H4 had a score of 3 and D-H3 had a score of 2), being able to regularly interview women and incorporating their views in the development of recommendations to improve hospital care (Table 2).

On average, quality of the implementation of NMCR was on a higher level in Country E, where evaluation scores pointed out that there were only few weaknesses in implementation compared to other countries (average score 2.12, 95%CI 1.84 to 2.39).

Table 3 summarises main common strengths and weaknesses in the quality of the NMCR implementation, as divided in three categories: (i) those mostly related to technical aspects, (ii) those predominantly of organisational nature, and (iii) those related to the attitude toward the NMCR. The main technical strength was that, beside the existence of appropriate technical skills in the methodology, most facilities developed several recommendations that were achievable, realistic, time-bound- and with a potential impact on the quality of care. Although recommendations were not always well documented (thus resulting in low scores under domain 10,) gaps in reporting results did not always indicated actual gaps in implementation, and in many cases several recommendations were actually implemented. This was a common observation in country B, where recommendations were poorly recorded, but several actions to improve quality of care -such as setting up

emergency kits and related protocols, and introducing the Modified Obstetric Early Warning Score (MEOWS) chart (14)- were actually implemented. Among strength in organisational aspects, the most important was that NMCR were regularly held, and staffing at all levels, including midwives, participated. Main strengths in attitude included the endorsement and application of the basic principles of the NMCR (confidentiality, openness, respecting diverting opinions, avoiding blame).

Main gaps in technical aspects were: inappropriate case reconstruction; case analysis not getting to the "real point" and not using a "why but why" approach (i.e. discussion of underlying causes); recommendations not being fully SMART (Specific, Measurable, Achievable, Realistic, Time-bound (15). Main gaps of organisational nature were: lack of continuity in the role of facilitator/coordinator; lack of proper dissemination of the results (i.e. circulation of information within the facility level and at national level on how many and what type of recommendations were developed); lack of follow up on previous recommendations. Major gaps in adopting the background philosophy and principles of the NMCR were observed in some facilities such as: lack of respect for other people's opinion; persistence of blaming and judging others rather than using the NMCR cycle to discuss and improve ways of working; insufficient involvement of mid-level staff. Lack of inclusion of the users' view, which was a frequent observation, was reported to be due to the lack of trained interviewers, and this was interpreted as not merely an organisational gap, but also as a problem in attitude of the of the health providers, i.e. lack of understanding the importance of taking into account the women's point of view. Finally, common to most facilities, there was insufficient monitoring and evaluation, and lack of a quality assurance

mechanism. In most cases this was due to deficiencies in establishing and efficiently running a NMCR coordination system at national level.

Recommendations developed by local stakeholders during the national restitution workshops were setting-specific. Nevertheless, there were several similarities. The most frequent/relevant recommendations developed for implementation at different levels - hospital level, national level, WHO and development partners - are reported in Table 4.

Examples of the observed impact of the NMCR on quality of care at facility level are reported in Table S2. Despite progress was often poorly reported both in the hospital and in national reports, several achievements could be observed. These included improved use of national clinical guidelines, development and use of local protocols and standards of care, better availability and organisation of emergency services, improved autonomy of midwives, and positive dynamics such as improved team working.

DISCUSSION

This study aimed at evaluating the quality of the NMCR at hospital level in selected countries within the WHO European Region using a standardised checklist and methodology. Overall the assessment pointed out that the practise of reviewing near-miss cases at hospital level is currently ongoing in all countries included in this study; however, both coverage and quality of the implementation of the NMCR cycle is heterogeneous. Overall, while first part of the audit cycle (from case identification to case analysis) was fairly well performed, with the exception of the “inclusion of users’ views”, the second part

of the audit cycle (developing recommendations, implementing them, ensuring quality) was in general poorly performed. Gaps in implementation were both of technical, organisational, and attitudinal nature.

These findings are not entirely surprising. Previous, although less systematic, evaluations in the same geographical area pointed a series of challenges (7,8,11,12) in effectively implementing the review of near-miss cases at facility level. Beside technical and organisational challenges, the successful implementation of clinical audits such as the NMCR often calls for a major change in staff's attitude (7,8,11,12). In the country assessed, especially in the Ex-Soviet countries, the successful implementation of the NMCR aims at moving away from a "traditional" system of carrying forward clinical audits, where blame and punishment were the routine, subjective judgment were the rule and audit involved only doctors, while midwives, other mid-level staff and service users had no voice (7,8,11,12). The "traditional" audit system mainly resulted in punishing single individuals, rather than at looking to the health system failures and finding solutions at organisational level (7,8,11,12). Changing practices involved building knowledge and skills together with a drastic shift in attitude. Given these substantial constraints, the successful implementation of the NMCR at least in one country (Country E) and in several champion maternity units in other countries, must be seen as a positive achievement, proving that NMCR can be successfully implemented in different settings.

This paper reports the quality of the NMCR implementation in middle-income countries (Armenia, Moldova, Uzbekistan are lower middle income countries, Georgia is an upper middle income countries), where the NMCR was carried forward with relatively limited

resources. Findings of this assessment cannot be generalised to other high-income countries of the WHO European region, such as UK, Norway, the Netherlands, where the practice of reviewing maternal near miss cases has been institutionalised, with major efforts on creating also coordinating mechanisms (16-18). However, it must be acknowledged that the review of near miss cases at facility level is still not a routine practice in many European countries. We were unable to identify any study reporting on a standard-based assessment of the quality of the NMCR from any country of the WHO European region.

Interestingly, findings of this study suggest that quality of the implementation of the NMCR cycle is not strictly associated to the duration of the implementation. However, it is also true that adequate time is needed for implementation, and completing a pilot phase in a country cannot take less than 18-24 months from the first technical workshop. In this regard, it must be acknowledged that country B started piloting just six months before the quality assessment; therefore, observed results in this country can be interpreted as satisfactory given the short time frame.

The high heterogeneity in results within the same country (such as in the case of country A, B, and D) suggests that quality of the NMCR implementation depends, to a large extent, from hospital factors, including staff's commitment, managerial support, and local coordination. These results are in line with a systematic review on facilitators and barriers to effective implementation of NMCR cycle, pointing out that hospital factors (good leadership), together with a system of coordination (which often includes external support), are key enablers for effective NMCR implementation (19).

This assessment pointed out that, despite WHO recommends conducting an interview with the women/her family for each near miss case, inclusion of women's view was still substandard in many of the assessed facilities. However, some facilities (B-H4, D-H3) reached good scores even when this domain was problematic at a country level (Table 2). In the WHO framework, "experience of care" is one of the two key components of quality of maternal and newborn health care, along with "provision of care" (1,2). The views of women and their families can provide relevant information on aspects related to case management, including important details on what happened, such as organizational issues communication issues, and respectful care. In a study in Moldova it was observed that the implementation of NMCR improved attitude towards patients (20), while in Kazakhstan it successfully improved patients' satisfaction (21,22).

This study points out that quality in the reporting on the NMCR activities was overall low. The WHO manual now provides a series of templates to facilitate a uniform reporting (9). Sustained monitoring and evaluation based on appropriate reporting, as well as periodical quality assessments should be part of a strategy to achieve quality in the NMCR implementation.

This paper has the merit of reporting the actual state of implementation of NMCR in a real setting and not in a study setting (where usually a limited number of facilities is involved for a limited period of time, with dedicated human and financial resources). Another strength of the study is that the evaluation was carried out in a systematic way using a predefined standardised tool and methodology, aiming at evaluating all key aspects that contribute to

overall NMCR quality (table S1) (9). To our knowledge, no other previous similar systematic evaluations have been performed.

We acknowledge that the scoring system utilised by the checklist may be open to some subjectivity. However, this scoring system is similar to others extensively used by WHO in the last 15 years for systematic, standard based, quality assessments, and it proved to be able to capture key elements of quality of the implementation in both pragmatic and research settings (23-27). No other validated tool or scoring system exist to assess quality of the NMCR. The checklist and its score system were field tested before use, until when they were considered satisfactory covering all key aspects of quality of NMCR (9). The score is attributed by a team of experts, thus reducing subjectivity of the single individual in the evaluation (9).

As a second limitation we acknowledge that in two out of the total five countries (Moldova and Uzbekistan), the sample was selected based on MoH indications (non-probability sampling), and one cannot exclude a selection bias towards the better performing institutions. However, we emphasize that the main purpose of the assessment was to create an opportunity at national level do discuss quality of the NMCR, and to develop recommendations for improvement. Subsequent assessments could extend the evaluation to other facilities and monitor progress in specific areas.

Based on the results of this study, in the future more efforts should be put in evaluating the quality of the implementation of NMCR on a regular basis. More implementation studies

should explore interventions aiming at improving quality of the NMCR implementation in different settings.

The objective of this study was not evaluating the impact of the implementation of the NMCR, but rather the quality of the process. Nevertheless, several achievements could be observed (Table S2), despite this type of information was not consistently available. These results are in line with other studies (28-41) and a systematic review reporting that NMCR is an effective strategy in improving quality of care when measured against predefined standards and it may even significantly reduce maternal mortality in high burden countries (42).

Conclusions

Ensuring high quality in the implementation of the NMCR may be difficult in countries of Eastern Europe and central Asia, but achievable. In the future more efforts should be put in evaluating the quality of the implementation of NMCR on a regular basis, capitalising from these lessons, and preventing and mitigating common barriers that hamper successful implementation. The availability of a new manual on how to implement and to monitor the NMCR at facility level, and of a standard methodology for assessing quality of the NMCR, as well as templates for reporting (9) may facilitate this process.

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Author contributions

AB and ML conceived the study, analysed the data and wrote the first draft of the paper

AB, SH, HK, SB, SI, MJ, ID, GM, GL collected data and contribute to the final draft of the paper

GL and GM contributed by procuring funds

All author contributed to the final version of the paper.

Data Sharing statement

Additional details on the country assessments can be obtain from the first author

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Table 1. Characteristics of the countries and of the maternity units assessed

	Armenia	Georgia	Latvia	Moldova	Uzbekistan
World Bank Classification [1]	Lower middle income	Upper Middle Income	High income	Lower middle income	Lower middle income
Population (thousands), total*	2969	4358	2060	3514	28541
GNI per capita, PPP US$*	6990	3280	21020	3690	1720
Maternal mortality ratio, adjusted*	30	67	34	41	28
Neonatal mortality rate [2]	10	15	5	9	14
Institutional deliveries as % of total deliveries [2]	99.4	98.3	NA	99.4	97.3
National introductory workshop on NMCR [3]	2007		2012	2005	2005
First national technical workshop on NMCR [3]	2009	2015	2013	2005	2007
Number of hospital implementing NMCR [3]	3	6	2	13	62
Number of hospital assessed	3	6	2	6	6
Type of hospitals	1 regional 2 district	2 regional 4 district	1 regional, 1 district	2 regional, 4 district	3 regional 3 district
Number of births/year in the hospital assessed **	6125	8570	8152	13311	23309

[1] Source: The World Bank, Country and Lending Groups. (2014) Historical classification. Available: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519 (Accessed 9 March 2017).

[2] Source: UNICEF Country statistics http://www.unicef.org/statistics/index_countrystats.html (accessed Dec 7, 2016)

[3] Source: WHO mission reports

Table 2. Summary scores

	A			B						C		D						E					
	H1	H2	H3	H1	H2	H3	H4	H5	H6	H1	H2	H1	H2	H3	H4	H5	H6	H1	H2	H3	H4	H5	H6
1. Internal organisation	1	1	2.5	1	2.1	0.8	2.8	2.3	1.9	3	2	1.7	1.9	1.9	1.6	2.5	0.5	2.9	2.6	2.7	2.3	2.7	2.3
2. Case identification	2.3	1	1.5	2	3	2	3	3	3	3	2.3	2.2	2.5	2.8	3	2	2.1	3	3	3	3	0.7	3
3. Respect of ground rules	1.5	1.5	2.5	1	2	1	3	3	2	3	3	2	1.5	1	1.5	2	1	3	3	3	3	3	3
4. Case presentation	1.6	1.4	2	0.3	2	0.7	2.3	2	0.7	2.5	3	1.8	0.8	2.5	1.7	2.3	1.2	2.3	1.7	1.3	1	2	2
5. Inclusion of users views	0	0	0	0.3	1.7	0	3	1.2	0.5	2.5	1.3	0.3	0	2	0	1.4	0	1.8	2.6	2	1.4	1.2	1.2
6. Case analysis	1.5	1	2.5	0.1	1.4	0.3	2	1.6	1.2	2.1	2.6	2.2	0.9	2	1.4	1.3	0.7	2.5	2.8	1.7	1	2.4	1.3
7. Development of recommendations	0.3	1	2	0.1	1.1	0	2	1.8	1.7	1.8	2.6	1.8	0.1	2.3	1	1.9	0.4	3	2.6	1.7	1	2.3	1.3
8. Implementation of recommendations	0	0.5	2	0	0	0	1	1.7	2	2	1.3	0.8	0	3	0.8	2	0.5	3	2.5	1.5	2.5	3	3
9. Follow up	0	0	1.5	0	0	0	0	0	3	2	2.5	0	0	3	0	1.6	1.3	2.8	1.5	1.5	1.5	2	1.5
10. Documentation and results diffusion	0.3	0.3	2	0.5	1	0.5	2.5	1	2	1.7	1	0.8	0.6	1.5	1.1	0.6	0.3	1.8	2	2.5	2	2.7	1
11. Ensuring quality in the NMCR	0	0	0	NA	NA	NA	NA	NA	NA	1	1	0	0	0	0	1	0.3	1.5	1.7	1.2	1.2	1.2	1.2

NA= in country B piloting started only six months before the quality assessment; for this reason the domain 11 was considered not applicable

Colour legend

RED= scores between 0.0 to 0.9

YELLOW= scores between 1.0 at 1.9

GREEN= scores between 2.0 at 3.0

Table 3. Strengths and weaknesses observed in the quality of the NMCR implementation

	STRENGTHS	WEAKNESSES
TECHNICAL	In all countries: ▪ Technical skills on performing NMCR were on average fair ▪ Local protocols were on average present and used ▪ Recommendations were usually developed, with several SMART characteristics (Achievable, Realistic, Time-bound) Especially in Country E: ▪ Most maternity teams were able to analyze efficiently a NM case, and to develop relevant recommendations to improve quality and organization of care, and follow-up their implementation.	▪ Case definition not complying with national definition ▪ Lack of existence and use of local protocols for case analysis ▪ Some lack of knowledge and skills in NMCR methodology ▪ Case summary, case reconstruction door-to-door, case analysis (including getting to the real point, and what we did good, and identifications of the underlying reasons using the 'why-but-why') not performed well performed in all facilities ▪ Recommendations not fully SMART* (often not Specific nor Measurable)
ORGANISATION	In all countries: ▪Staffing at all levels (including midwives and nurses) was involved and in some cases encouraged by facilitator to actively participate in the review process. ▪Session participants were mostly those involved in care provision of the case reviewed, and, generally, felt free to ask questions and express their opinions. ▪ NMCR mostly happened on a regular basis Especially in Country E: ▪An excellent national plan for implementation was developed ▪ Appropriate normative regulations were developed through regular NMCR sessions	▪ Lack of local written procedure for NMCR ▪Irregular meetings in some facilities ▪ Lack of involvement of staffing who managed the case ▪ Lack of a regional/national coordination and/or continuity in facilitator/coordinator role, and/or support from them lack of trained interviewers ▪ Absence of local leaders ▪ Lack of support from hospital manager in organisation of the NMCR and in the implementation of the recommendation ▪ Lack of follow up on previous recommendations ▪Lack of production, dissemination and discussion of results of the NMCR cycle ▪ Lack of periodical evaluations of the quality of the NMCR ▪When evaluations of the quality was

	▪ By 2015, 90% of maternity facilities were trained and implementing NMCR Regional NMCR coordinators were established ▪There was sustained support from MoH; WHO and partners (also Latvia)	performed, no mechanism ensured that resulting recommendations were taken up
ATTITUDE	In all countries ▪ Basic BTN principles were respected in most facilities, including confidentiality ▪Multidisciplinary approach to case reviews was evident in most facilities ▪Managers offered substantial support to organization of NMCR sessions and implementation of recommendations. ▪Staff found this method useful to improve quality and organization of care ▪Midwives role as participants, but also as coordinators and facilitators Interviews became a routine in most facilities (in particular in Latvia) Especially in Country E:: ▪ Facilitators succeeded to create and maintain an open and non-threatening environment during sessions; staff felt free to put forward (or ask) questions and express their opinions (also Country C) ▪The point of view of women was always collected and presented; some interviews were of excellent quality (also Country C) ▪Professionals were praised in case of good care	▪ In some cases lack of respect of other people's opinion, persistence of blaming, persistence of a wrong attitude that suggested "judging others", rather than moving towards thinking "the review is about us" ▪Lack of active participation in the discussion ▪Insufficient involvement of mid-level staffing ▪ Lack of the interviews with woman in some facilities ▪ Even where the interview was collected, women's view not taken into account when recommendation are implemented ▪Staff not always praised when quality and appropriate care given ▪Staff considers developing recommendations a mere formality, they were not eager to implement them, and take on the role and the responsibility to change practice. ▪Persistence of a system that advocates punishment in some facilities

Abbreviations: NM= near-miss; NMCR= near-miss case review; SMART= Specific, Measurable, Achievable, Realistic, Time-bound (15)

Table 4. Recommendations made by local stakeholders on how to improve NMCR quality

Hospital level	1) Ensure managerial support for the organisation of the NMCR and for the implementation of the resulting recommendations 2) Aim at regular sessions 3) Ensure active participation of all staff involved in case management, including mid-level staffing 4) Ensure that ground rules are respected 5) Ensure that the review follows the steps suggested in the WHO manual [7] 6) Ensure that user's views are collected and taken into consideration 7) Ensure that recommendations developed are SMART* 8) Ensure that every session starts by following up on the previous recommendations 9) Document the implementation of the recommendations (provide date and description) 10) Document, analyse and disseminate results of the NMCR at hospital level, including type of recommendations developed and percentage of those implemented
National level	1) Set up/strengthen the national coordinating team 2) Develop a plan for regular quality assessment and reinforcement 3) Strengthen technical skills among staffing on the principles, methods and practices of the NMCR cycle 4) Practical training on how to conduct interviews in order to collect women's views 5) Support networking activities among facilities (eg exchange visits) 6) Document, analyse and disseminate results of the NMCR at national level
WHO and other development partners	1) Ensure regular and timely technical support for capacity development, including developing skills for women interviews 2) Provide support for developing legal framework and national guidance manual for NMCR 3) Support regular monitoring of the implementation in a coordinated manner 4) Support results dissemination and discussion 5) Support timely quality assessments and subsequent actions for quality improvement 6) Support networking activities among facilities /countries with the objective of improve quality of NMCR cycle 7) Ensure continuous support for updating key national guidelines, local protocols, standards for clinical practice

Abbreviations: NM= near-miss; NMCR= near-miss case review; SMART= Specific, Measurable, Achievable, Realistic, Time-bound (15)

Table S1. Checklist to assess the quality of the NMCR cycle at hospital level and matrix to develop local recommendations

Checklist to assess the quality of the NMCR cycle at hospital level and matrix to develop local recommendations

Facility name _____ _____ Date _____

INSTRUCTIONS

Sources of information:

- Direct observation and evaluation of a NMCR session
- Discussion with participants
- Discussion with coordinators and managers
  - Documents from the NMCR sessions: Records/notes of the sessions: templates, cases summaries, summary of the interviews with women and other care-takers (family, documents in support of the recommendations and their implementation, other related documentation (photo etc.)
- Other related documents:

  National documents
  - National policies, and guidance documents
  - National clinical guidelines
  - National documents related to quality assurance, monitoring and supervision
  - National summary reports on NMCR implementation

  Local documents
  - Regional/local policies, and guidance documents
  - Local clinical protocols and standards for care provision
  - Local documents related to quality assurance, monitoring and supervision
  - Local summary reports

Reference: the reference for all key items is the WHO manual "How to implement the maternal Near-Miss Case Review (NMCR) cycle at hospital level"

Methods of scoring:

1) Score each single item as follows: Score 0= totally inappropriate; Score 1= major problems; Score 2= some deficiencies; Score 3= appropriate.
2) In the blue row calculate the mean of the scores for each key item in the group. This is the score for that group of items.

	SCORE	Comments
INTERNAL ORGANISATION/PREPARATION		
1. A local written procedure to implement the NMCR cycle exists		
2. Support from management is adequate		
3. Regular meetings are held		
4. Each meeting has adequate duration		
5. All key staff involved in the NM case is invited to the session		
6. Very limited (and justified) participation of people who were not involved in the management of the NM case reviewed		
7. All material need is prepared before the session		
CASE IDENTIFICATION AND SELECTION		
8. The agreed NM definition is used (same definition in all the country)		

9. The NM cases are correctly identified		
10. A NM case is appropriately selected for review among those identified		
GROUND RULES		
11. Ground rules for the NMCR are respected, especially confidentiality, respect of other people's opinion and refrain from blaming single individuals		
NMCR SESSION: CASE PRESENTATION		
12. The case is appropriately summarised and presented by one participant (paper copies; flip charts; slides)		
13. A "door to door" reconstruction, with all relevant details, is provided by all staff involved in care provision		
14. The clinical records of the patient, whose case is reviewed, are available during the meeting, if additional information is needed		
NMCR SESSION: INCLUSION OF USERS VIEWS		
15. The opinions of the woman (*i.e. informative contents on real facts, and her perceptions and views*), and if appropriate of relatives and/or friends, is collected (interview), for each NM case reviewed		
16. The interview(s) is/are appropriately summarised and presented		
17. The key findings from the interview (i.*e. same definition as above*) are appropriately taken into consideration in the case analysis		
18. The key findings (i.*e. same definition as above*) from the interview are appropriately taken into consideration for the prioritisation and development of solution		
NMCR SESSION: CASE ANALYSIS		
19. The case-analysis is performed following a structured analytical approach		
20. The case management is analysed from admission to discharge: a "door to door" approach is used		
21. The case is reviewed comparing actual management versus evidence (clinical guidelines, protocols and standards)		
22. The positive aspects of care provision ("what we did good") are identified and documented		
23. The staff is praised for the positive aspects of care provision		
24. The critical aspects of care ("what did not go well") are appropriately identified, focusing on the most important issues ("getting to the real point")		
25. The real underlying reasons for substandard care ("why but why?") are identified, discussed and documented		
26. The facilitator ensures that ground rules are respected, all steps of the session are completed, notes are taken		
27. Staff of all types and roles (including midwives and nurses) actively and openly participate in the case analysis		
28. The results of the case-analysis are documented (using the templates)		
NMCR SESSION: DEVELOPMENT OF RECOMMENDATIONS		
29. A list of SPECIFIC recommendations linked to the NM case is always developed, including responsible people and timelines		
30. The recommendations target the main problem (s) and the main underlying factors		

31. Most of the recommendations refer to actions to be carried forward at the hospital performing the review		
32. The recommendations use as reference clinical guidelines, protocols and standards		
33. The recommendations are SMART (specific, measurable, achievable, realistic, time-bound)		
34. The recommendations give due consideration to women's rights in hospital: effective communication, emotional support, respect and dignity		
35. The recommendations include an adequate division of tasks among hospital staff		
36. Recommendations that need action at regional/national level are effectively identified		
37. The facilitator ensures that ground rules are respected, all steps of the session are completed, notes are taken		
38. Staff of all types and roles (including midwives and nurses) participate actively and openly		
39. The recommendations are documented (using the templates)		
IMPLEMENTATION OF RECCOMENDATIONS		
40. The agreed recommendations are implemented (at least 75%)		
41. Managers/local health authorities actively support implementation of recommendations		
42. The implementation of recommendations is documented (using the template)		
NMCR SESSION: FOLLOW UP		
43. The NMCR session starts with a follow up of the previous session, checking that recommendations have been implemented		
44. In case the agreed actions were not taken, reasons are discussed, and a new recommendation is developed, including responsible people and timelines		
DOCUMENTATIONS ON THE NMCR CYCLE AND EFFECTIVE DIFFUSION OF RESULTS - AT FACILITY LEVEL		
45. A folder is kept for each NM case containing all key documentation, including the follow up phase (see manual); cases are recorded in a register/log book		
46. At hospital level, an appropriate summary of relevant information regarding the NMCR cycle is regularly disseminated and discussed, without compromising confidentiality, among staff, managers, and health authorities (see manual)		
47. Effective communication of key information is provided by hospital coordinators to national coordinator(s)		
ENSURING QUALITY IN THE NMCR CYCLE		
48. Collaboration of the local team with the national/regional coordinator has been effective		
49. Periodical evaluations of the quality of the NMCR has been planned		
50. Previous recommendations from quality assessment has been taken into consideration and translated into actions		

SUMMARY TABLE

MAIN STRENGTHS: **1.** **2.** **3.** **4.**
MAIN WEAKNESSES: **1.** **2.** **3.** **4.**
COMMENTS: **1.** **2.** **3.** **4.**

MATRIX. Recommendations for improving the quality of the NMCR cycle at hospital level (expand as needed)			
Priority areas that need to be improved	**Action agreed**	**Responsible person**	**Timeline**

Table S2. Reported impact of the NMCR on quality of care at facility level

- Use of national clinical guidelines
- Development and use of protocols at facility level (for doctors and for midwives) for obstetric complications (eg post-partum haemorrhages, eclampsia, sepsis)
- Development and implementation of standards of care
- Development of capacities among staff of all levels (doctors, midwives, nurses) to critically analyse cases identifying real underling reasons for near-miss (eg lack of organisation or lack of communication), comparing management to guidelines, protocols and standards of care, and to successfully carry forward a self-assessment
- Improved autonomy of mid level staff, in particular midwives providing first emergency care without doctors
- Availability of emergency team 24/24h in case of emergencies ~~case~~
- In the admission and on labour ward, a system in place which allows to call all relevant staff in case of an emergency (emergency button)
- Availability of emergency lab 24/24h
- Availability of staff 24/24h in the event of a need for blood transfusion, especially in rural areas
- Set up of separate room for managing emergency cases
- Availability of emergency kit for managing emergency cases
- Improved availability of essential drugs, such as misoprostol, i/v antihypertensive
- Enhanced collaboration between clinical staff and management of the facility, for improving practical aspects of organisation of care (eg supplies, maintenance, staff shifts)
- Development of clear job description to specific roles and responsibilities, facilitating effective team work
- Improved monitoring after caesarean section and/or obstetric complications (eg training and use of checklists)
- Improved team work
- Reported improvement in quality of care delivered *

*not further specified in available local/national reports.

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What is the quality of the maternal near-miss case reviews in the WHO European Region? Cross-sectional study in Armenia, Georgia, Latvia, Republic of Moldova and Uzbekistan

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What is the quality of the maternal near-miss case reviews in the WHO European Region? Cross-sectional study in Armenia, Georgia, Latvia, Republic of Moldova and Uzbekistan

Running title: Quality of the near-miss case reviews

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ABSTRACT

Objectives The maternal near-miss case review (NMCR) cycle is a type of clinical audit aiming at improving quality of maternal health care by discussing near-miss cases. In several countries this approach has been introduced and supported by WHO and partners since 2004, but information on the quality of its implementation is missing. This study aimed at evaluating the quality of the NMCR implementation in selected countries within the WHO European Region.

Design Cross sectional study

Settings Twenty-three maternity units in Armenia, Georgia, Latvia, Moldova, Uzbekistan

Assessment tools A predefined checklist including 50 items, according to the WHO methodology. Quality in the NMCR implementation was defined by summary scores ranging from 0 (totally inappropriate) to 3 (appropriate).

Results Quality of the NMCR implementation was heterogeneous among different countries, and within the same country. Overall, the first part of the audit cycle (from case identification to case analysis) was fairly well performed (mean score 2.00, 95%CI 1.94 to 2.06), with the exception of the "inclusion of users views" (mean score 0.66, 95%CI 0.11 to 1.22), while the second part (developing recommendations, implementing them, ensuring quality) was poorly performed (mean score 0.66, 95%CI 0.11 to 1.22). Each country had at least one champion facility, where quality of the NMCR cycle was acceptable. Quality of the implementation was not associated with its duration. Gaps in implementation were of technical, organisational, and attitudinal nature.

Conclusions Ensuring quality in the NMCR may be difficult but achievable. The high heterogeneity in results within the same country suggests that quality of the NMCR implementation depends, to a large extent, from hospital factors, including staff's commitment, managerial support, local coordination. Efforts should be put in preventing and mitigating common barriers that hamper successful NMCR implementation.

Article summary: strengths and limitations of this study

- This is the first study reporting on the quality of the hospital based near-miss case review (NMCR) in Central Asia and Eastern Europe.
- The assessment included five countries within the WHO European Region and was based on a predefined checklist, providing the opportunity to evaluate the implementation of the NMCR approach in a standardised manner.
- In three countries facilities included in the evaluation accounted for all facilities implementing the NMCR within in the country. In the remaining two countries, where the NMCR were implemented in more hospitals, facilities were chosen in dialogue with local authorities (non-probability sampling), and not at random; however, criteria used to select facilities included also geographical distribution (i.e. so that different regions were represented) and hospital type (i.e. different types of hospitals were selected).

Keywords

Maternal health; near miss case review; standard based assessment; quality of care; middle-income countries

Disclosure of interests

None competing interest

List of abbreviations

IQL= interquartile
MoH= Ministry of Health
NMCR= Near miss cases review
UNFPA= United Nation Population Fund
WHO = World Health Organization
95%CI= 95% Confidence intervals

INTRODUCTION

Ensuring adequate quality of health care is a primary objective of the World Health Organization (WHO) Global Strategy for Women's, Children's and Adolescent's Health 2016-2030 (1) and of Health 2020, the European strategic framework setting the policy directions for the 53 Member States in the WHO European Region (2). Quality in health care is recognized as essential for the health and well-being of the population, and as a basic aspect of human rights (3-5).

Among the different strategies aiming at improving quality of care at maternity services, the facility-based maternal near miss cases review (NMCR) cycle was proposed by WHO in 2004 as a type of clinical audit (6-8). In respect to mortality audit, the near-miss case review has the advantage to imply less legal issues, and is therefore perceived as more acceptable by staff. Near-miss cases are defined as a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within six weeks after pregnancy (9). In he facility-based NMCR all hospital staff involved in the management of the chosen near-miss case - including obstetricians, midwives, nurses and ancillary staff - get together to discuss and evaluate the care provided against national evidence-based guidelines, local protocols and standards of care. The aim of the case review is to critically discuss local management, procedures and attitudes, and to identify areas that can be further improved (9). Actions to improve quality of maternal health care are proposed and agreed by hospital staff, and subsequently monitored to check their implementation, as for a continuous quality improvement process (9). One of the key characteristics of this

method is the bottom-up approach, aiming at facilitating local ownership of the process, commitment in implementing the proposed recommendations, and team-building. Currently, the review of severe maternal morbidity cases ("near-miss" events) is recommended by WHO as a key action to eliminate avoidable maternal and perinatal mortality and morbidity and improve the quality of care (10).

While in some countries within the WHO European Region (such as UK, Norway, the Netherlands) the practice of reviewing maternal near miss cases was introduced by the government or by professional associations, in several other countries (most often middle-income countries) its implementation was assisted by the WHO and/or United Nation Population Fund (UNFPA). In the later scenario, coverage and quality of the NMCR implementation were usually discussed during workshops (11-13), but so far they have not been evaluated using a systematic methodology.

In 2015, WHO developed a checklist for assessing the quality of the implementation of the NMCR cycle at hospital level through a systematic methodology (9). This study aimed at evaluating the quality of the NMCR implementation in five countries of Eastern Europe and central Asia, using the WHO checklist, to identify common strengths and weaknesses among different settings.

MATERIAL AND METHODS

Population and setting

The assessment was conducted in Armenia, Georgia, Latvia, Republic of Moldova, and Uzbekistan between June 2015 and October 2016. Countries were chosen based on the following criteria: i) activities planned by the Ministry of Health (MoH) included a quality assessment of the NMCR; ii) there was a request for technical assistance from WHO or UNFPA.

In all of the countries the NMCR approach was introduced following the WHO methodology (9). The year of NMCR introduction differed among countries (Table 1).

The number of facilities visited in each country depended on the total number of hospitals implementing the NMCR cycle: in Armenia, Georgia and Latvia all facilities implementing the NMCR were visited; in Moldova and Uzbekistan, where a large number of maternity units are implementing the NMCR, a sample was selected in agreement with the MoH and the national NMCR coordinator/s, following a geographical criteria (i.e. so that different regions were represented) and including different type of hospitals. Overall, 23 maternity units were visited in the five selected countries (Table 1).

Data collection

Each facility was visited for at least the duration of a whole day by two independent external experts with long term experience in NMCR implementation. The international team was joined by the national assessors, experienced in NMCR implementation at local level. The team was under the leadership of one international assessor (AB), who

participated to all hospital visits, with the objective of ensuring standards procedures in all assessments.

The assessment was carried out using a checklist developed by WHO to evaluate the quality of the NMCR cycle at hospital level (Table S1). The checklist was developed by WHO in 2014, field-tested and optimised for use in early 2015 (9). The methodology for the quality assessment is fully described in a WHO manual (9). Briefly, the checklist includes 50 items, grouped in 11 domains. The sources of information for the assessment includes: direct observation and evaluation of one or more NMCR sessions; discussion with participants, coordinators and managers; documents from the NMCR sessions (templates and notes from the sessions); local documents (regional/local policies and guidance documents; protocols and standards for care; documents related to quality assurance, monitoring and supervision; reports on NMCR activities); national documents (national policies and guidance documents, guidelines, reports on NMCR implementation). According to the WHO methodology, using the WHO manual (9) as source of standards, each of the 50 items was scored from 0 (totally inappropriate) to 3 (appropriate) (Table S1). For each of the 11 domains the arithmetic mean and 95% confidence intervals (95%CI) among all the items in that domain were calculated. The median and the range between the first and third quartile (IQL range) were also calculated.

In each facility, immediately after the assessment, feedbacks were discussed with the local staff and plans for improvement of the NMCR implementation were developed, using a simple matrix (Table S1).

After completing the visits to all maternity units in the country, a national restitution workshop was organised involving representatives from the hospitals, health authorities, professional organisations and partners. During the workshop, achievements and constraints were presented and underlying reasons were discussed. Recommendations for improvement were developed and synthesised in a standard pre-defined simple matrix (Table S1).

Ethical considerations

Activities of this observational study were initiated upon request of the MoHs and carried out in close collaboration with the health authorities; ethical approval was not required. Information to hospital staff was provided by MoH representatives and local authorities. All people involved in the NMCR sessions were informed about the purpose of the visit and oral consent from the hospital staff and local coordinators and facilitators participating to the observed sessions was obtained. The review of near-miss cases was carried forward anonymously, i.e. information that may have disclosed the identity of the patient, or providers of care was not reported (9). This study did not aim at directly comparing countries or single facilities with different background, context, and timelines of implementation, therefore results of the assessment are reported in an anonymous way, according to WHO methodology (9). Detailed finding of the assessment together with feedback on how to improve quality of the NMCR implementation were provided to each facility and to each country individually.

RESULTS

The assessment pointed out that quality of the implementation of the NMCR cycle was heterogeneous among different countries, as well as among different hospitals within the same country. Table 2 reports the results of the summary scores, for each of the 11 domains of the WHO assessment checklist.

Overall, the first part of the audit cycle (step 1-6 in Table 2, i.e. from case identification to case analysis) was on average fairly well performed in all countries (mean score 2.00, 95%CI 1.94 to 2.06), with the exception of the domain "inclusion of users' views" which was poorly implemented in most facilities (mean score 1.06, 95%CI 0.12 to 2.00). The second part of the audit cycle (step 7-10), which involves developing appropriate recommendations, implementation of the recommendations, follow up, documentation and dissemination of results within the facility and the country, was on average poorly performed in all countries (mean score 1.20, 95%CI 0.93 to 1.46). In particular, the domain 11 "ensuring quality in the NMCR cycle", which implies a process of periodical quality assessment, development of recommendation for quality improvement, and related actions, was overall substandard (mean score 0.66, 95%CI 0.05 to 1.28), with the exception of country E, where regular monitoring and supervision was carried out by a team that included national and international members.

In each country it was possible to identify at least one "champion" facility, where quality of the NMCR cycle had only minor deficiencies (A-H3, B-H4, C-H1, D-H3, EH1 and H2). On the other hand, in a few facilities (A-H2, B-H1 and H3, CH6) most of the areas assessed

were judged as “totally inappropriate”.

In some facilities examples of good practices were also observed for domains that were on average implemented on a substandard level at a country-level. For examples, despite inclusion of users views being substandard in most facilities in countries B and D (mean scores 1.11, 95%CI 0 to 2.22 and 0.61, 95%CI 0 to 1.48 respectively) single facilities reached good scores (B-H4 had a score of 3 and D-H3 had a score of 2), being able to regularly interview women and incorporating their views in the development of recommendations to improve hospital care (Table 2).

On average, quality of the implementation of NMCR was on a higher level in Country E, where evaluation scores pointed out that there were only few weaknesses in implementation compared to other countries (mean score 2.12, 95%CI 1.84 to 2.39).

Table 3 summarises main common strengths and weaknesses in the quality of the NMCR implementation, as divided in three categories: (i) those mostly related to technical aspects, (ii) those predominantly of organisational nature, and (iii) those related to the attitude toward the NMCR. The main technical strength was that, beside the existence of appropriate technical skills in the methodology, most facilities developed several recommendations that were achievable, realistic, time-bound- and with a potential impact on the quality of care. Although recommendations were not always well documented (thus resulting in low scores under domain 10,) gaps in reporting results did not always indicated actual gaps in implementation, and in many cases several recommendations were actually implemented. This was a common observation in country B, where recommendations

were poorly recorded, but several actions to improve quality of care -such as setting up emergency kits and related protocols, and introducing the Modified Obstetric Early Warning Score (MEOWS) chart (14)- were actually implemented. Among strength in organisational aspects, the most important was that NMCR were regularly held, and staffing at all levels, including midwives, participated. Main strengths in attitude included the endorsement and application of the basic principles of the NMCR (confidentiality, openness, respecting diverting opinions, avoiding blame).

Main gaps in technical aspects were: inappropriate case reconstruction; case analysis not getting to the "real point" and not using a "why but why" approach (i.e. discussion of underlying causes); recommendations not being fully SMART (Specific, Measurable, Achievable, Realistic, Time-bound (15). Main gaps of organisational nature were: lack of continuity in the role of facilitator/coordinator; lack of proper dissemination of the results (i.e. circulation of information within the facility level and at national level on how many and what type of recommendations were developed); lack of follow up on previous recommendations. Major gaps in adopting the background philosophy and principles of the NMCR were observed in some facilities such as: lack of respect for other people's opinion; persistence of blaming and judging others rather than using the NMCR cycle to discuss and improve ways of working; insufficient involvement of mid-level staff. Lack of inclusion of the users' view, which was a frequent observation, was reported to be due to the lack of trained interviewers, and this was interpreted as not merely an organisational gap, but also as a problem in attitude of the of the health providers, i.e. lack of understanding the importance of taking into account the women's point of view. Finally, common to most

facilities, there was insufficient monitoring and evaluation, and lack of a quality assurance mechanism. In most cases this was due to deficiencies in establishing and efficiently running a NMCR coordination system at national level.

Recommendations developed by local stakeholders during the national restitution workshops were setting-specific. Nevertheless, there were several similarities. The most frequent/relevant recommendations developed for implementation at different levels - hospital level, national level, WHO and development partners - are reported in Table 4.

Examples of the observed impact of the NMCR on quality of care at facility level are reported in Table S2. Despite progress was often poorly reported both in the hospital and in national reports, several achievements could be observed. These included improved use of national clinical guidelines, development and use of local protocols and standards of care, better availability and organisation of emergency services, improved autonomy of midwives, and positive dynamics such as improved team working.

DISCUSSION

This study aimed at evaluating the quality of the NMCR at hospital level in selected countries within the WHO European Region using a standardised checklist and methodology. Overall the assessment pointed out that the practise of reviewing near-miss cases at hospital level is currently ongoing in all countries included in this study; however, both coverage and quality of the implementation of the NMCR cycle is heterogeneous. Overall, while first part of the audit cycle (from case identification to case analysis) was

fairly well performed, with the exception of the "inclusion of users' views", the second part of the audit cycle (developing recommendations, implementing them, ensuring quality) was in general poorly performed. Gaps in implementation were both of technical, organisational, and attitudinal nature.

These findings are not entirely surprising. Previous, although less systematic, evaluations in the same geographical area pointed a series of challenges (7,8,11,12) in effectively implementing the review of near-miss cases at facility level. Beside technical and organisational challenges, the successful implementation of clinical audits such as the NMCR often calls for a major change in staff's attitude (7,8,11,12). In the country assessed, especially in the Ex-Soviet countries, the successful implementation of the NMCR aims at moving away from a "traditional" system of carrying forward clinical audits, where blame and punishment were the routine, subjective judgment were the rule and audit involved only doctors, while midwives, other mid-level staff and service users had no voice (7,8,11,12). The "traditional" audit system mainly resulted in punishing single individuals, rather than at looking to the health system failures and finding solutions at organisational level (7,8,11,12). Changing practices involved building knowledge and skills together with a drastic shift in attitude. Given these substantial constraints, the successful implementation of the NMCR at least in one country (Country E) and in several champion maternity units in other countries, must be seen as a positive achievement, proving that NMCR can be successfully implemented in different settings.

This paper reports the quality of the NMCR implementation in middle-income countries (Armenia, Moldova, Uzbekistan are lower middle income countries, Georgia is an upper

middle income countries), where the NMCR was carried forward with relatively limited resources. Findings of this assessment cannot be generalised to other high-income countries of the WHO European region, such as UK, Norway, the Netherlands, where the practice of reviewing maternal near miss cases has been institutionalised, with major efforts on creating coordinating mechanisms (16-18). However, it must be acknowledged that the review of near miss cases at facility level is still not a routine practice in many European countries. We were unable to identify any study reporting on a standard-based assessment of the quality of the NMCR from any country of the WHO European region.

Interestingly, findings of this study suggest that quality of the implementation of the NMCR cycle is not strictly associated to the duration of the implementation. However, it is also true that adequate time is needed for implementation, and completing a pilot phase in a country cannot take less than 18-24 months from the first technical workshop. In this regard, it must be acknowledged that country B started piloting just six months before the quality assessment; therefore, observed results in this country can be interpreted as satisfactory given the short time frame.

The high heterogeneity in results within the same country (such as in the case of country A, B, and D) suggests that quality of the NMCR implementation depends, to a large extent, from hospital factors, including staff's commitment, managerial support, and local coordination. These results are in line with a systematic review on facilitators and barriers to effective implementation of NMCR cycle, pointing out that hospital factors (good leadership), together with a system of coordination (which often includes external support), are key enablers for effective NMCR implementation (19).

This assessment pointed out that, despite WHO recommends conducting an interview with the women/her family for each near miss case, inclusion of women's view was still substandard in many of the assessed facilities. However, some facilities (B-H4, D-H3) reached good scores even when this domain was problematic at a country level (Table 2). In the WHO framework, "experience of care" is one of the two key components of quality of maternal and newborn health care, along with "provision of care" (1,2). The views of women and their families can provide relevant information on aspects related to case management, including important details on what happened, such as organizational issues communication issues, and respectful care. In a study in Moldova it was observed that the implementation of NMCR improved attitude towards patients (20), while in Kazakhstan it successfully improved patients' satisfaction (21,22).

This study points out that quality in the reporting on the NMCR activities was overall low. The WHO manual now provides a series of templates to facilitate a uniform reporting (9). Sustained monitoring and evaluation based on appropriate reporting, as well as periodical quality assessments should be part of a strategy to achieve quality in the NMCR implementation.

This paper has the merit of reporting the actual state of implementation of NMCR in a real setting and not in a study setting (where usually a limited number of facilities is involved for a limited period of time, with dedicated human and financial resources). Another strength of the study is that the evaluation was carried out in a systematic way using a predefined standardised tool and methodology, aiming at evaluating all key aspects that contribute to

overall NMCR quality (table S1) (9). To our knowledge, no other previous similar systematic evaluations have been performed.

We acknowledge that the scoring system utilised by the checklist may be open to some subjectivity. However, this scoring system is similar to others extensively used by WHO in the last 15 years for systematic, standard based, quality assessments, and it proved to be able to capture key elements of quality of the implementation in both pragmatic and research settings (23-27). No other validated tool or scoring system exists to assess quality of the NMCR. The checklist and its score system were field tested before use, until when they were considered satisfactory covering all key aspects of quality of NMCR (9). The score is attributed by a team of experts, thus reducing subjectivity of the single individual in the evaluation (9).

As a second limitation we acknowledge that in two out of the total five countries (Moldova and Uzbekistan), the sample was selected based on MoH indications (non-probability sampling), and one cannot exclude a selection bias towards the better performing institutions. However, we emphasize that the main purpose of the assessment was to create an opportunity at national level do discuss quality of the NMCR, and to develop recommendations for improvement. Subsequent assessments could extend the evaluation to other facilities and monitor progress in specific areas.

Based on the results of this study, in the future more efforts should be put in evaluating the quality of the implementation of NMCR on a regular basis. More implementation studies

should explore interventions aiming at improving quality of the NMCR implementation in different settings.

The objective of this study was not evaluating the impact of the implementation of the NMCR, but rather the quality of the process. Nevertheless, several achievements could be observed (Table S2), despite this type of information was not consistently available. These results are in line with other studies (28-41) and a systematic review reporting that NMCR is an effective strategy in improving quality of care when measured against predefined standards and it may even significantly reduce maternal mortality in high burden countries (42).

Conclusions

Ensuring high quality in the implementation of the NMCR may be difficult in countries of Eastern Europe and central Asia, but achievable. In the future more efforts should be put in evaluating the quality of the implementation of NMCR on a regular basis, capitalising from these lessons, and preventing and mitigating common barriers that hamper successful implementation. The availability of a new manual on how to implement and to monitor the NMCR at facility level, and of a standard methodology for assessing quality of the NMCR, as well as templates for reporting (9) may facilitate this process.

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Author contributions

AB and ML conceived the study, analysed the data and wrote the first draft of the paper

AB, SH, HK, SB, SI, MJ, ID, GM, GL collected data and contribute to the final draft of the paper

GL and GM contributed by procuring funds

All author contributed to the final version of the paper.

Data Sharing statement

Additional details on the country assessments can be obtain from the first author

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Table 1. Characteristics of the countries and of the maternity units assessed

	Armenia	Georgia	Latvia	Moldova	Uzbekistan
World Bank Classification [1]	Lower middle income	Upper Middle Income	High income	Lower middle income	Lower middle income
Population (thousands), total*	2969	4358	2060	3514	28541
GNI per capita, PPP US$*	6990	3280	21020	3690	1720
Maternal mortality ratio, adjusted*	30	67	34	41	28
Neonatal mortality rate [2]	10	15	5	9	14
Institutional deliveries as % of total deliveries [2]	99.4	98.3	NA	99.4	97.3
National introductory workshop on NMCR [3]	2007		2012	2005	2005
First national technical workshop on NMCR [3]	2009	2015	2013	2005	2007
Number of hospital implementing NMCR [3]	3	6	2	13	62
Number of hospital assessed	3	6	2	6	6
Type of hospitals	1 regional 2 district	2 regional 4 district	1 regional, 1 district	2 regional, 4 district	3 regional 3 district
Number of births/year in the hospital assessed **	6125	8570	8152	13311	23309

[1] Source: The World Bank, Country and Lending Groups. (2014) Historical classification. Available: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519 (Accessed 9 March 2017).

[2] Source: UNICEF Country statistics http://www.unicef.org/statistics/index_countrystats.html (accessed Dec 7, 2016)

[3] Source: WHO mission reports

Table 2. Summary scores

	A			B						C		D						E						Mean (95%CI)	Median (IQL range)
	H1	H2	H3	H1	H2	H3	H4	H5	H6	H1	H2	H1	H2	H3	H4	H5	H6	H1	H2	H3	H4	H5	H6		
1. Internal organisation	1	1	2.5	1	2.1	0.8	2.8	2.3	1.9	3	2	1.7	1.9	1.9	1.6	2.5	0.5	2.9	2.6	2.7	2.3	2.7	2.3	2.0 (1.3-2.6)	2.1 (1.7-2.5)
2. Case identification	2.3	1	1.5	2	3	2	3	3	3	3	2.3	2.2	2.5	2.8	3	2	2.1	3	3	3	3	0.7	3	1.7 (1.0-2.4)	2.8 (2.0-3.0)
3. Respect of ground rules	1.5	1.5	2.5	1	2	1	3	3	2	3	3	2	1.5	1	1.5	2	1	3	3	3	3	3	3	2.2 (1.4-2.9)	2.2 (1.5-3.0)
4. Case presentation	1.6	1.4	2	0.3	2	0.7	2.3	2	0.7	2.5	3	1.8	0.8	2.5	1.7	2.3	1.2	2.3	1.7	1.3	1	2	2	1.7 (1.0-2.3)	1.8 (1.1-2.2)
5. Inclusion of users views	0	0	0	0.3	1.7	0	3	1.2	0.5	2.5	1.3	0.3	0	2	0	1.4	0	1.8	2.6	2	1.4	1.2	1.2	1.0 (0.1-2.0)	1.2 (0.3-1.7)
6. Case analysis	1.5	1	2.5	0.1	1.4	0.3	2	1.6	1.2	2.1	2.6	2.2	0.9	2	1.4	1.3	0.7	2.5	2.8	1.7	1	2.4	1.3	1.5 (0.8-2.3)	1.5 (1.1-2.0)
7. Development of recommendations	0.3	1	2	0.1	1.1	0	2	1.8	1.7	1.8	2.6	1.8	0.1	2.3	1	1.9	0.4	3	2.6	1.7	1	2.3	1.3	1.4 (0.6-2.3)	1.7 (1.0-1.9)
8. Implementation of recommendations	0	0.5	2	0	0	0	1	1.7	2	2	1.3	0.8	0	3	0.8	2	0.5	3	2.5	1.5	2.5	3	3	1.4 (0.3-2.4)	1.5 (0.8-2.3)
9. Follow up	0	0	1.5	0	0	0	0	0	3	2	2.5	0	0	3	0	1.6	1.3	2.8	1.5	1.5	1.5	2	1.5	1.1 (0.4-2.2)	1.5 (0.0-1.9)
10. Documentation and results diffusion	0.3	0.3	2	0.5	1	0.5	2.5	1	2	1.7	1	0.8	0.6	1.5	1.1	0.6	0.3	1.8	2	2.5	2	2.7	1	1.2 (0.5-2.0)	1.1 (0.7-1.9)
11. Ensuring quality in the NMCR	0	0	0	NA	NA	NA	NA	NA	NA	1	1	0	0	0	0	1	0.3	1.5	1.7	1.2	1.2	1.2	1.2	0.6 (0.1-1.2)	1.0 (0.1-1.2)

NA= in country B piloting started only six months before the quality assessment; for this reason the domain 11 was considered not applicable (NA)

Colour legend

RED= scores between 0.0 to 0.9

YELLOW= scores between 1.0 at 1.9

GREEN= scores between 2.0 at 3.0

Table 3. Strengths and weaknesses observed in the quality of the NMCR implementation

	STRENGTHS	WEAKNESSES
TECHNICAL	In all countries: ▪ Technical skills on performing NMCR were on average fair ▪ Local protocols were on average present and used ▪ Recommendations were usually developed, with several SMART characteristics (Achievable, Realistic, Time-bound) Especially in Country E: ▪ Most maternity teams were able to analyze efficiently a NM case, and to develop relevant recommendations to improve quality and organization of care, and follow-up their implementation.	▪ Case definition not complying with national definition ▪ Lack of existence and use of local protocols for case analysis ▪ Some lack of knowledge and skills in NMCR methodology ▪ Case summary, case reconstruction door-to-door, case analysis (including getting to the real point, and what we did good, and identifications of the underlying reasons using the 'why-but-why') not performed well performed in all facilities ▪ Recommendations not fully SMART* (often not Specific nor Measurable)
ORGANISATION	In all countries: ▪Staffing at all levels (including midwives and nurses) was involved and in some cases encouraged by facilitator to actively participate in the review process. ▪Session participants were mostly those involved in care provision of the case reviewed, and, generally, felt free to ask questions and express their opinions. ▪ NMCR mostly happened on a regular basis Especially in Country E: ▪An excellent national plan for implementation was developed ▪ Appropriate normative regulations were developed through regular NMCR sessions	▪ Lack of local written procedure for NMCR ▪Irregular meetings in some facilities ▪ Lack of involvement of staffing who managed the case ▪ Lack of a regional/national coordination and/or continuity in facilitator/coordinator role, and/or support from them lack of trained interviewers ▪ Absence of local leaders ▪ Lack of support from hospital manager in organisation of the NMCR and in the implementation of the recommendation ▪ Lack of follow up on previous recommendations ▪Lack of production, dissemination and discussion of results of the NMCR cycle ▪ Lack of periodical evaluations of the quality of the NMCR ▪When evaluations of the quality was

	▪ By 2015, 90% of maternity facilities were trained and implementing NMCR Regional NMCR coordinators were established ▪There was sustained support from MoH; WHO and partners (also Latvia)	performed, no mechanism ensured that resulting recommendations were taken up
ATTITUDE	In all countries ▪ Basic BTN principles were respected in most facilities, including confidentiality ▪Multidisciplinary approach to case reviews was evident in most facilities ▪Managers offered substantial support to organization of NMCR sessions and implementation of recommendations. ▪Staff found this method useful to improve quality and organization of care ▪Midwives role as participants, but also as coordinators and facilitators Interviews became a routine in most facilities (in particular in Latvia) Especially in Country E:: ▪ Facilitators succeeded to create and maintain an open and non-threatening environment during sessions; staff felt free to put forward (or ask) questions and express their opinions (also Country C) ▪The point of view of women was always collected and presented; some interviews were of excellent quality (also Country C) ▪Professionals were praised in case of good care	▪ In some cases lack of respect of other people's opinion, persistence of blaming, persistence of a wrong attitude that suggested "judging others", rather than moving towards thinking "the review is about us" ▪Lack of active participation in the discussion ▪Insufficient involvement of mid-level staffing ▪ Lack of the interviews with woman in some facilities ▪ Even where the interview was collected, women's view not taken into account when recommendation are implemented ▪Staff not always praised when quality and appropriate care given ▪Staff considers developing recommendations a mere formality, they were not eager to implement them, and take on the role and the responsibility to change practice. ▪Persistence of a system that advocates punishment in some facilities

Abbreviations: NM= near-miss; NMCR= near-miss case review; SMART= Specific, Measurable, Achievable, Realistic, Time-bound (15)

Table 4. Recommendations made by local stakeholders on how to improve NMCR quality

Hospital level	1) Ensure managerial support for the organisation of the NMCR and for the implementation of the resulting recommendations 2) Aim at regular sessions 3) Ensure active participation of all staff involved in case management, including mid-level staffing 4) Ensure that ground rules are respected 5) Ensure that the review follows the steps suggested in the WHO manual [7] 6) Ensure that user's views are collected and taken into consideration 7) Ensure that recommendations developed are SMART* 8) Ensure that every session starts by following up on the previous recommendations 9) Document the implementation of the recommendations (provide date and description) 10) Document, analyse and disseminate results of the NMCR at hospital level, including type of recommendations developed and percentage of those implemented
National level	1) Set up/strengthen the national coordinating team 2) Develop a plan for regular quality assessment and reinforcement 3) Strengthen technical skills among staffing on the principles, methods and practices of the NMCR cycle 4) Practical training on how to conduct interviews in order to collect women's views 5) Support networking activities among facilities (eg exchange visits) 6) Document, analyse and disseminate results of the NMCR at national level
WHO and other development partners	1) Ensure regular and timely technical support for capacity development, including developing skills for women interviews 2) Provide support for developing legal framework and national guidance manual for NMCR 3) Support regular monitoring of the implementation in a coordinated manner 4) Support results dissemination and discussion 5) Support timely quality assessments and subsequent actions for quality improvement 6) Support networking activities among facilities /countries with the objective of improve quality of NMCR cycle 7) Ensure continuous support for updating key national guidelines, local protocols, standards for clinical practice

Abbreviations: NM= near-miss; NMCR= near-miss case review; SMART= Specific, Measurable, Achievable, Realistic, Time-bound (15)

Table S1. Checklist to assess the quality of the NMCR cycle at hospital level and matrix to develop local recommendations

Checklist to assess the quality of the NMCR cycle at hospital level and matrix to develop local recommendations

Facility name _____ _____ Date _____

INSTRUCTIONS

Sources of information:

- Direct observation and evaluation of a NMCR session
- Discussion with participants
- Discussion with coordinators and managers
  - Documents from the NMCR sessions: Records/notes of the sessions: templates, cases summaries, summary of the interviews with women and other care-takers (family, documents in support of the recommendations and their implementation, other related documentation (photo etc.)
- Other related documents:

  National documents
  - National policies, and guidance documents
  - National clinical guidelines
  - National documents related to quality assurance, monitoring and supervision
  - National summary reports on NMCR implementation

  Local documents
  - Regional/local policies, and guidance documents
  - Local clinical protocols and standards for care provision
  - Local documents related to quality assurance, monitoring and supervision
  - Local summary reports

Reference: the reference for all key items is the WHO manual "How to implement the maternal Near-Miss Case Review (NMCR) cycle at hospital level"

Methods of scoring:

1) Score each single item as follows: Score 0= totally inappropriate; Score 1= major problems; Score 2= some deficiencies; Score 3= appropriate.
2) In the blue row calculate the mean of the scores for each key item in the group. This is the score for that group of items.

	SCORE	Comments
INTERNAL ORGANISATION/PREPARATION		
1. A local written procedure to implement the NMCR cycle exists		
2. Support from management is adequate		
3. Regular meetings are held		
4. Each meeting has adequate duration		
5. All key staff involved in the NM case is invited to the session		
6. Very limited (and justified) participation of people who were not involved in the management of the NM case reviewed		
7. All material need is prepared before the session		
CASE IDENTIFICATION AND SELECTION		
8. The agreed NM definition is used (same definition in all the country)		

9. The NM cases are correctly identified		
10. A NM case is appropriately selected for review among those identified		
GROUND RULES		
11. Ground rules for the NMCR are respected, especially confidentiality, respect of other people's opinion and refrain from blaming single individuals		
NMCR SESSION: CASE PRESENTATION		
12. The case is appropriately summarised and presented by one participant (paper copies; flip charts; slides)		
13. A "door to door" reconstruction, with all relevant details, is provided by all staff involved in care provision		
14. The clinical records of the patient, whose case is reviewed, are available during the meeting, if additional information is needed		
NMCR SESSION: INCLUSION OF USERS VIEWS		
15. The opinions of the woman (*i.e. informative contents on real facts, and her perceptions and views*), and if appropriate of relatives and/or friends, is collected (interview), for each NM case reviewed		
16. The interview(s) is/are appropriately summarised and presented		
17. The key findings from the interview (i.*e. same definition as above*) are appropriately taken into consideration in the case analysis		
18. The key findings (i.*e. same definition as above*) from the interview are appropriately taken into consideration for the prioritisation and development of solution		
NMCR SESSION: CASE ANALYSIS		
19. The case-analysis is performed following a structured analytical approach		
20. The case management is analysed from admission to discharge: a "door to door" approach is used		
21. The case is reviewed comparing actual management versus evidence (clinical guidelines, protocols and standards)		
22. The positive aspects of care provision ("what we did good") are identified and documented		
23. The staff is praised for the positive aspects of care provision		
24. The critical aspects of care ("what did not go well") are appropriately identified, focusing on the most important issues ("getting to the real point")		
25. The real underlying reasons for substandard care ("why but why?") are identified, discussed and documented		
26. The facilitator ensures that ground rules are respected, all steps of the session are completed, notes are taken		
27. Staff of all types and roles (including midwives and nurses) actively and openly participate in the case analysis		
28. The results of the case-analysis are documented (using the templates)		
NMCR SESSION: DEVELOPMENT OF RECOMMENDATIONS		
29. A list of SPECIFIC recommendations linked to the NM case is always developed, including responsible people and timelines		
30. The recommendations target the main problem (s) and the main underlying factors		

31. Most of the recommendations refer to actions to be carried forward at the hospital performing the review		
32. The recommendations use as reference clinical guidelines, protocols and standards		
33. The recommendations are SMART (specific, measurable, achievable, realistic, time-bound)		
34. The recommendations give due consideration to women's rights in hospital: effective communication, emotional support, respect and dignity		
35. The recommendations include an adequate division of tasks among hospital staff		
36. Recommendations that need action at regional/national level are effectively identified		
37. The facilitator ensures that ground rules are respected, all steps of the session are completed, notes are taken		
38. Staff of all types and roles (including midwives and nurses) participate actively and openly		
39. The recommendations are documented (using the templates)		
IMPLEMENTATION OF RECCOMENDATIONS		
40. The agreed recommendations are implemented (at least 75%)		
41. Managers/local health authorities actively support implementation of recommendations		
42. The implementation of recommendations is documented (using the template)		
NMCR SESSION: FOLLOW UP		
43. The NMCR session starts with a follow up of the previous session, checking that recommendations have been implemented		
44. In case the agreed actions were not taken, reasons are discussed, and a new recommendation is developed, including responsible people and timelines		
DOCUMENTATIONS ON THE NMCR CYCLE AND EFFECTIVE DIFFUSION OF RESULTS - AT FACILITY LEVEL		
45. A folder is kept for each NM case containing all key documentation, including the follow up phase (see manual); cases are recorded in a register/log book		
46. At hospital level, an appropriate summary of relevant information regarding the NMCR cycle is regularly disseminated and discussed, without compromising confidentiality, among staff, managers, and health authorities (see manual)		
47. Effective communication of key information is provided by hospital coordinators to national coordinator(s)		
ENSURING QUALITY IN THE NMCR CYCLE		
48. Collaboration of the local team with the national/regional coordinator has been effective		
49. Periodical evaluations of the quality of the NMCR has been planned		
50. Previous recommendations from quality assessment has been taken into consideration and translated into actions		

SUMMARY TABLE

MAIN STRENGTHS: **1.** **2.** **3.** **4.**
MAIN WEAKNESSES: **1.** **2.** **3.** **4.**
COMMENTS: **1.** **2.** **3.** **4.**

MATRIX. Recommendations for improving the quality of the NMCR cycle at hospital level (expand as needed)			
Priority areas that need to be improved	**Action agreed**	**Responsible person**	**Timeline**

Table S2. Reported impact of the NMCR on quality of care at facility level

- Use of national clinical guidelines
- Development and use of protocols at facility level (for doctors and for midwives) for obstetric complications (eg post-partum haemorrhages, eclampsia, sepsis)
- Development and implementation of standards of care
- Development of capacities among staff of all levels (doctors, midwives, nurses) to critically analyse cases identifying real underling reasons for near-miss (eg lack of organisation or lack of communication), comparing management to guidelines, protocols and standards of care, and to successfully carry forward a self-assessment
- Improved autonomy of mid level staff, in particular midwives providing first emergency care without doctors
- Availability of emergency team 24/24h in case of emergencies ~~case~~
- In the admission and on labour ward, a system in place which allows to call all relevant staff in case of an emergency (emergency button)
- Availability of emergency lab 24/24h
- Availability of staff 24/24h in the event of a need for blood transfusion, especially in rural areas
- Set up of separate room for managing emergency cases
- Availability of emergency kit for managing emergency cases
- Improved availability of essential drugs, such as misoprostol, i/v antihypertensive
- Enhanced collaboration between clinical staff and management of the facility, for improving practical aspects of organisation of care (eg supplies, maintenance, staff shifts)
- Development of clear job description to specific roles and responsibilities, facilitating effective team work
- Improved monitoring after caesarean section and/or obstetric complications (eg training and use of checklists)
- Improved team work
- Reported improvement in quality of care delivered *

*not further specified in available local/national reports.