

Implementation of Nationwide Evidence- and Consensus-Based Guidelines to Harmonize Neonatal Care in The Netherlands

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Background: A Dutch committee for National Guidelines in Neonatology developed nineteen evidence- and consensus-based guidelines to be used in all Dutch neonatal intensive care units (NICUs). The primary goal was to make clinical practices more uniform and consistent.

Objective: This study investigated to what extent the guidelines were implemented and which factors played a role in implementation.

Study design: A mixed method study design was used to investigate both the level and the process of implementation. A nationwide, multicenter, cross-sectional survey was performed using a validated instrument for measuring the level of implementation (Normalization Measure Development questionnaire, NoMAD). The number of implemented guidelines per NICU and the frequency and content of the amendments that NICUs made to the original consensus guidelines were analyzed. Through semi-

structured interviews, perceived barriers and facilitators for implementation were explored.

Participants: Fellows and neonatologists working at all ten Dutch level 3-4 NICUs were eligible.

Results: On an average, NICUs implemented 12.6 (of 19) guidelines (range 6-17). The Normalization Process Scale was 54 (of 65). Main influencing factors impeding implementation were guideline-related (e.g., unpractical, lengthy guidelines) and personal (e.g., an active representative responsible for local implementation).

Conclusion: The implementation of our guidelines appears to be successful. Ways for improvement can be distinguished in personal, guideline-related and external factors. Empowerment of local representatives was considered most essential.

Keywords: Guideline development, Neonatal intensive care unit, Quality improvement.

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In medical practice, evidence is often lacking, and local agreements are frequently made, potentially resulting in divergence from guidelines [1]. In newborn care (where evidence is particularly scarce), these divergences are extensive [2]. To create more consistency in newborn care, a consensus targeted approach is necessary.

In 2014, a Dutch committee called N3 recommendations (N3R), part of Neonatology Network Netherlands (N3) was founded. Through the development of national evidence- and consensus-based guidelines, aim was to improve harmonization of neonatal care. The European Foundation for the Care of Newborn Infants (EFCNI) addresses disparities in the provision and quality of European neonatal care by developing reference standards as a source for the national development of guidelines and protocols [3,4]. In

the Vermont Oxford Network (VON), an international collaboration in neonatology, neonatal intensive care units (NICUs) work together to formulate potentially better practices that are implemented locally [5].

The success of guidelines depends on content quality and on their actual implementation [6,7]. Successful implementation depends on the consideration of a variety of barriers and the use of adequate strategies to overcome them [8]. We studied the implementation level of our guidelines, and the factors influencing implementation.

METHODS

The Netherlands consists of 17.4 million inhabitants and has approximately 170,000 live births per year [9]. There are ten level 3-4 neonatal intensive care units (NICUs) with 108

neonatologists and 26 fellows. In total, there are 195 NICU beds, where approximately 5000 patients are admitted annually [10]. Every NICU has one representative on N3R.

The guidelines were developed based on a comparison of existing local protocols and comprehensive literature searches followed by Grading of Recommendations Assessment, Development and Evaluation (GRADE) processes. Where evidence was lacking or inconclusive, N3R followed Delphi structured processes to form consensus. After multiple feedback rounds available for all neonatologists and fellows, the final guidelines, based on input from all Dutch NICUs, available evidence and consensus, were approved (**Web Fig. 1**). The intention was for every NICU to upload the consensus guidelines into their local guideline system. The agreement was to allow NICUs to make logistic, but not substantive amendments.

To achieve both a breadth and depth of understanding, this study follows a mixed-method approach, combining quantitative data from a questionnaire and qualitative data from semi-structured focus group interviews [11]. All parts of the study received clearance from the Radboudumc medical ethical committee. The Standards for Quality Improvement Reporting Excellence (SQUIRE) 2.0 were used as a framework [12]. A nationwide, multicenter, cross-sectional, digital survey was conducted.

One of the theories for understanding and measuring implementation is the normalization process theory (NPT) [13,14]. Finch, et al. [15,16] developed and validated an NPT-based questionnaire, the Normalization Measure Development questionnaire (NoMAD). A validated Dutch translation, customized to our particular situation, was used [17]. The original NoMAD contains twenty questions, of which thirteen were deemed appropriate for our survey. The NoMAD distinguishes four constructs playing a central role in generating implementation. A more practical approach, considering three groups of factors (personal, guideline-related and external factors) was used [8], and therefore, five questions were added.

The survey was pilot-tested by two neonatologists (non-N3R members), and modified based on their feedback. The final version contained three parts: Part A concerned demographic information; Part B collected three general normalization ratings about current and future use; and, Part C contained 13 items from the NOMAD instrument and five additional questions. Answer options were according to a five-point Likert scale. There was option B (“I don’t know” or “not relevant”) to ensure that non-applicable questions were skipped.

Survey invitations were sent via e-mail. Informed consent was obtained at the beginning. Data were collected

over three weeks in April, 2019; reminders were sent after one and two weeks. The completed surveys were automatically collected (Castor Electronic Data Capture EDC 2019.1) and stored anonymously.

Local versions of the guidelines were retrieved and compared with the original documents. Amendments were recorded, distinguishing logistic (defined as necessary changes due to local logistic circumstances) and substantive (defined as changes in content) amendments. The COREQ (COnsolidated criteria for REporting Qualitative research) checklist was used to report items of importance [20].

The interview guide was created by three investigators (ET, MH and RdJ) and critically appraised (AO). The interview guide concerned two themes (perceived facilitators and barriers) each subdivided into three subthemes (personal, guideline-related and external factors [8]. Questions concerning the aim of N3R, the acceptance, and the development of the guidelines were added. Printed forms showing results from the survey and an overview of local amendments per NICU were used as background information.

To reach depth, group interviews were conducted or (in case of planning issues) dyadic interviews [21]. Neonatologists and fellows working at Dutch level 3-4 NICUs, except N3R members, were considered eligible. The interviews were conducted between May and June, 2019. A convenience group participated in the interviews from each NICU. The interviews were recorded (WS-806 voice recorder, Olympus), transcribed anonymously, and deleted after transcription.

Statistical analysis: While the data were considered ordinal, nonparametric analyses were performed. The individual normalization process scale (NPS) was calculated by summing 13 construct items per person [15]. Differences between fellows/neonatologists, N3R member or not, and gender were analyzed, and correlations between age and years of experience were calculated. The total factor score (TFS) was calculated by summing 17 factor questions, as was the score for each factor group. Differences between factor groups were analyzed with the Kruskal-Wallis test or a median test (depending on the difference in variance between factor groups, analyzed with Levene test for equality of variances). Option B answers were valued at zero points.

The construct scores were correlated to the three general normalization ratings to check the validity after our alterations [16,17]. Outcomes were interpreted following the categorization (0: no correlation, 0.1-0.29: poor, 0.3-0.59: fair, 0.6-0.79: moderate, 0.8-0.99: very strong, 1: perfect) [19]. IBM SPSS statistics, version 25 (IBM Corporation) was used.

For the qualitative part, a thematic template analysis based on the interview guide was used [22]. Transcripts were analyzed independently by two researchers (ET and MH). Discrepancies were discussed with a third researcher (RdJ) until consensus was reached. A qualitative analysis tool (ATLAS.ti Scientific Software Development GmbH Version 8.3.20) was used.

RESULTS

When the survey aired, all the 134 neonatologists and fellows working in the NICUs were approached; 63 (47%) completed the survey (**Table I**). Distribution of completed surveys among the NICUs is shown in **Web Fig. 2**.

Distributional characteristics of the scale scores are shown in **Fig. 1**. With respect to the NPS, majority of the participants (strongly) agreed with the statements. The total NPS scores of all participants, neonatologists, fellows, and N3R and non-N3R members followed similar response patterns. There were no significant differences in total NPS score by role (neonatologists/fellows or gender). Age and years of experience were also not related to NPS results [age: $r=0.257$ ($P=0.042$); years of experience: $r=0.231$ ($P=0.069$)].

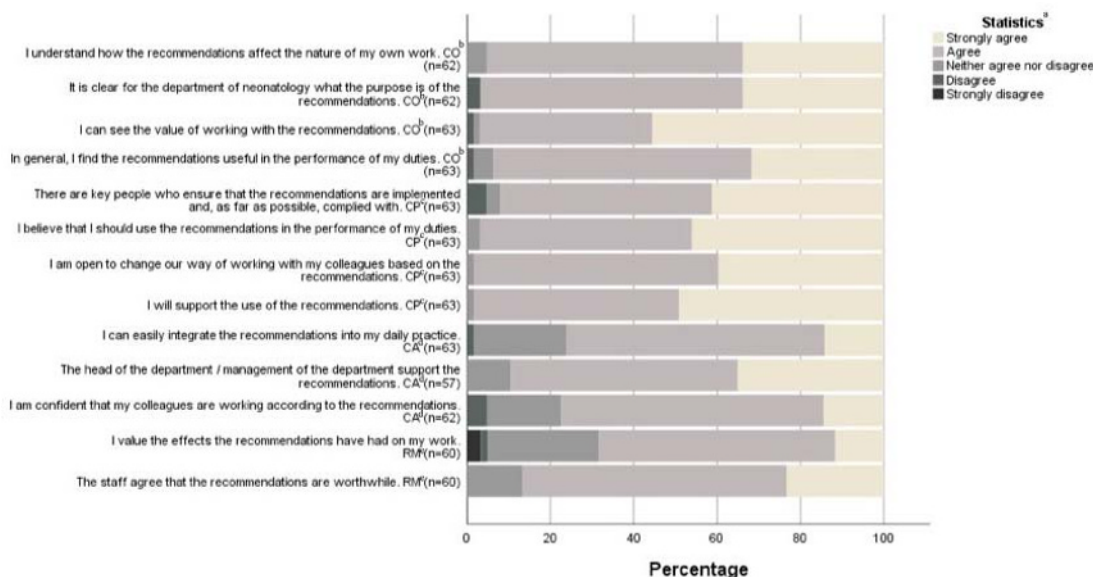
Median (IQR) scores were 4 (4-5), 4 (3-4) and 4 (4-5) for personal, guideline-related and external factors, respectively. There was a significant difference between guideline-related factors and the other groups ($P<0.001$). Factor group

Table I Demographic Background of Survey Participants and Total Research Population (N=63)

Characteristics	No. (%)
<i>Role^a</i>	
Fellow, n=26	16 (61.5)
Neonatologist, n=108	47 (43.5)
<i>Committee member^a</i>	
Yes, n=10	10 (100)
No, n=124	53 (42.7)
Male gender	21 (33.3)
<i>Age (y)</i>	
30-39	20 (31.7)
40-49	26 (41.3)
50-59	13 (20.6)
60-65	4 (6.3)
<i>NICU experience (y)</i>	
0-5	19 (30.2)
6-10	16 (25.3)
11-15	13 (20.6)
16-20	5 (7.9)
21+	10 (15.9)

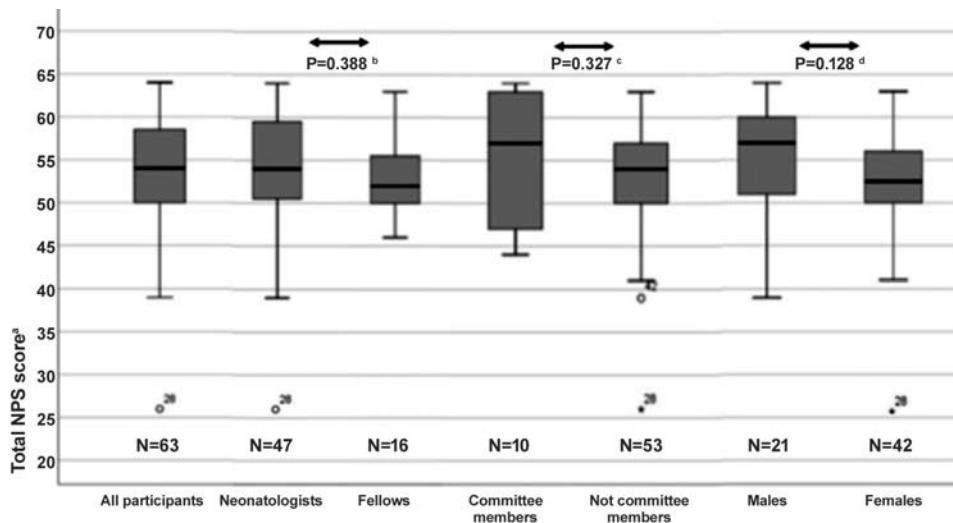
Data in no. (%). ^aPercentages are out of total with that role.

explained 13.8% of the variability in rank scores. Correlations between construct scores and the three general normalization ratings were assessed to investigate the



^aPercentages of responses reporting strongly disagree, disagree, neutral, agree, strongly agree are shown. ^bcoherence (CO); ^ccognitive participation (CP).

Fig. 1 Frequency distribution of responses to questions that are part of the normalization process scale. For interpretation: maximum score is 65 points (five points per question, thirteen questions). More agreement with the statements indicates a more positive attitude towards the guidelines.



^aTotal normalization process scale (NPS) score. All boxplots are presented as medians and IQR. ^bDifferences in total NPS score between neonatologists and fellows; ^cbetween committee/noncommittee members; and ^dbetween males and females were tested using Mann-Whitney U test.

Fig. 2 Boxplots of the total normalization process scale score per group.

validity of the survey. Similar to the out-comes in NoMAD validation studies, all correlation coefficients can be interpreted as fair to moderately strong [19].

The amendments of the 19 guidelines for all NICUs were studied ($n=190$). In total, 126 (66.3%) guidelines were uploaded into local protocol systems. On an average, NICUs implemented 12.6 guidelines (range 6-17). Every NICU made logistic and substantive amendments; in total, 379 amendments were made, of which 69 were logistic.

Interviews were conducted with at least one fellow and one neonatologist per NICU. In total, 12 fellows and 14 neonatologists were interviewed. Interviews lasted between 28-54 minutes. The majority of the participants agreed with the aims of N3R. Positive aspects mentioned were the value of collective expertise, insight into the gaps in evidence-based medicine, and the need for more consistency towards patients, parents, and colleagues. Negative aspects were scarce and almost exclusively related to guidelines where it was harder to reach consensus. Fellows were in general very satisfied with the existence of the guidelines and felt more secure when using them (**Web Box I**).

Perceived factors with corresponding barriers and facilitators and illustrative quotations are demonstrated in **Web Table I**. An active representative for local implementation was considered to be the key by the most participants. Being part of the developmental process or feedback rounds was also considered a facilitator.

For guidance-related factors, participants were unanimous on the fact that guidelines should be concise

with a clear step-by-step plan. Many were in favor of accompanying flowcharts. Few participants stated that information was not always substantiated. In contrast, others said that the underlying reason for action is clear and that information is sufficiently retraceable. For external factors, some guidelines were not applicable to a specific NICU and therefore not implemented (for example a surgical guideline). In other situations, the guideline was not compliant with the NICU (for example, the congenital diaphragmatic hernia guideline has been developed for NICUs without extra corporeal membrane oxygenation (ECMO) and therefore not implemented in NICUs with ECMO).

The availability of consulting specialists (for instance, pediatric cardiologists) was mentioned as both a facilitator and a barrier. When consulting specialists were familiar with the guidelines, participants would use the guidelines during consultation. Otherwise, participants stated that they would rather ask a consultant's opinion.

A local culture open to change was considered an important factor, whereby a clear aim supported by the whole team is considered the key.

DISCUSSION

The primary aim of the study was to evaluate the implementation of national evidence- and consensus- based NICU guidelines. Considering the NPS results, this implementation seems successful: most Dutch neonatologists and fellows have implemented (the majority of) the guidelines into their daily practice (total NPS 54/65).

WHAT IS ALREADY KNOWN?

- The success of guidelines depends on content quality and their implementation.

WHAT THIS STUDY ADDS?

- The structure of a national committee, comprised of local representatives from every practice involved, appears to be appropriate for the development of readily accepted evidence- and consensus-based guidelines.

However, there is room for improvement. Not all guidelines were implemented, and NICUs differed in the amount of local implementation and (logistic and substantial) amendments. Based on our results, focus should lie primarily on guideline-related factors and active representatives. Furthermore, many interview participants stated that just by performing this study, N3R increased awareness and therefore implementation of their guidelines. Repetitive evaluation of guideline implementation is therefore recommended. A generally applicable advice regarding guideline implementation strategy is presented in **Web Table II**.

An important factor was having an active local representative. This finding is supported by a study of Lago, et al. [23]. Creating and maintaining a strong connection between representatives was considered beneficial, supporting the N3R structure with representatives from every NICU. In consonance with our results on guideline-related factors, a study by Donnell, et al. [24] states that a guideline should have clear action steps. Some participants emphasized the importance of the scientific background of the guidelines, which has also been previously reported [24]. It is important to realize that as consistent high-level evidence is often lacking in medicine, consensus may be the only way to achieve guidelines.

In contrast to the study by Davis, et al. [25] suggesting that early-career physicians are more receptive to clinical practice guidelines, there was no indication for less implementation among more experienced doctors compared to early-career doctors [25].

Due to the mixed-method study design, broad and in-depth insight was gained at both the level and process of implementation. Neonatologists and fellows from every NICU in the Netherlands participated, which resulted in a representative sample. However, this study also had some limitations. In the absence of a gold standard, the level of implementation was measured with the second-best option: a validated tool. Even though slight alterations were made, a validation test shows correlations similar to those in the original study [16]. Furthermore, with this study design, presumed practice was investigated instead of actual practice. However, this does not make the answers less relevant. Future research could comprise repetitive audits

investigating actual practice. The distribution of fellows/neonatologist and N3R members/no N3R member in the survey is different from the distribution of practicing physicians; this may have led to response bias. In this study, no other stakeholders were investigated, such as NICU nurses.

Our process of development and implementation of national guidelines, combined with the lessons learned from this study, demonstrates a suitable approach for those in other nations or specialties with the desire to develop nationwide guidelines. Due to the coronavirus (COVID-19) pandemic, doctors have become more accustomed to meeting digitally, making our strategy applicable for larger geographical areas. Our strategy appears to be applicable for countries with identical numbers of NICUs, but this is unclear for countries with large numbers of NICUs. In future research, a follow-up study demonstrating the impact of the suggestions for improving implementation could be performed.

Strategies for improving implementation are multifactorial and can be distinguished in personal, guideline-related and external factors. Improving guideline-related factors seems a good starting point since they scored lowest and are probably easiest to change. Ways to empower representatives should be discussed among N3R members and their staffs, since they were considered essential.

Almost all participants in this study supported the aim of N3R and valued the guidelines. It turns out that even when experts' opinions seem far apart, forming a national consensus is desired by most.

Ethics clearance: Institutional Ethics Committee of the Radboudumc; No. IRB 2020-6274 dated March, 2020.

Note: Additional material related to this study is available with the online version at www.indianpediatrics.net

Contributors: EST, RCJdeJ, FC, MvdL, KAdeB-M, EEMM, HJN, SAP, MEvdP, RV: substantial contributions to the study, including: Conceptualization, methodology, investigation, data curation and formal analysis, participating in writing (drafting the initial manuscript); MH, MvS, AJMC: substantial contributions to the study, including: Supervision, conceptualization, methodology, investigation, interpretation of data, data curation, formal analysis, resources, participating in writing (review and editing of the

manuscript). All authors provided final approval to the version to be published and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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