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Feasibility of combining the BabyCheck and Pulse Oximetry to Assess Illness Severity in Infants Younger Than Six Months in Out-of-Hours Primary Care

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Feasibility of combining the BabyCheck and Pulse Oximetry to Assess Illness Severity in Infants Younger Than Six Months in Out-of-Hours Primary Care

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Abstract

Purpose:

To determine the feasibility of implementing the BabyCheck (a clinical checklist grading the severity of illness) in combination with pulse oximetry in infants younger than six months presenting at an out-of-hours emergency general practitioner post, with the goal of supporting referral decisions to the hospital.

Methods:

We conducted a prospective feasibility study at a Dutch out-of-hours general practitioner service between March 2024 and February 2026. Infants younger than six months presenting with acute illness were eligible. The combined assessment consisted of the BabyCheck questionnaire and pulse oximetry, guided by a predefined flowchart. The primary outcome was feasibility. Feasibility was predefined as completion of both assessments in at least 80% of included infants. Secondary outcomes included referral outcomes and general practitioners' perceptions of usefulness.

Results:

A total of 133 infants were included, of whom 109 (82%) underwent complete assessment, meeting the predefined feasibility threshold. 21 infants were referred to the emergency department, 20 referrals were considered appropriate. Of 88 infants initially managed in primary care, one was subsequently classified as a delayed referral. General practitioners considered the combined assessment useful in 67 of 106 evaluated cases (63%).

Conclusion:

The combined use of the BabyCheck and pulse oximetry in young infants in out-of-hours primary care is feasible and may support clinical decision-making and referral decisions.

What is known

- The BabyCheck provides a structured method for assessing illness severity in infants younger than 6 months and has previously been evaluated in both primary care and hospital settings.
- Pulse oximetry provides objective physiological measurements but is not routinely used in young infants in primary care.

What is new

- The BabyCheck questionnaire combined with pulse oximetry was feasible in 82% of the included infants.
- Among infants who completed the BabyCheck and pulse oximetry assessment, 20 of 21 referred infants were considered appropriately referred, while one delayed referral occurred among 88 infants initially managed in primary care.

Key words

- BabyCheck
- Feasibility study
- Infant
- Primary care
- Pulse oximetry

List of abbreviations

ED: emergency department

GP(s): general practitioner(s)

PO: pulse oximetry

SpO_2: oxygen saturation

Introduction

Infants under one year of age have the highest consultation rate in primary care, averaging more than four visits within the first six months of life. [1-3] In the Netherlands, all acutely ill children are first assessed by a general practitioner (GP), who acts as a gatekeeper and determines whether referral to a paediatrician is necessary. Despite this high consultation rate, the prevalence of serious illness in this population remains low, at approximately 1%. [4]

This contrast underscores the critical gatekeeping role of the GP in identifying infants who require further evaluation. Assessing illness severity in young infants is particularly challenging, as many clinical signs and symptoms, such as crying, vomiting, or feeding difficulties, are non-specific and may occur in both mildly and seriously ill infants, limiting their discriminative value. [5,6] As a result, telephone triage is often insufficient to reliably assess illness severity in young infants, leading to frequent referrals for clinical assessment.[7] Early recognition of serious illness is essential, as infants can deteriorate rapidly.

The Netherlands Triage System, derived from the Manchester Triage System, is a reliable tool for determining whether patients, both children and adults, should be assessed by a GP.[8] However, once an infant presents to the GP, structured and validated tools to assess illness severity and guide referral decisions are lacking. The absence of objective decision support complicates the balance between avoiding unnecessary referrals and preventing delays in care for severely ill infants. Referral to the emergency department (ED) can be time-consuming for parents, patients and healthcare providers, and paediatric ED is relatively cost-inefficient for low-acuity conditions.[9] Furthermore, multiple studies have demonstrated that a significant proportion of paediatric ED visits are non-urgent.[10-12]

In the United Kingdom, the BabyCheck scoring system was developed and validated as a clinical checklist to quantify illness severity in infants up to six months of age. The BabyCheck consists of nineteen signs and symptoms that together generate a weighted severity score. The tool has been validated in multiple settings with a low prevalence of serious illness, [13-16] and has been found practical and manageable by both parents and GPs.[17,18] Although a randomized controlled trial found that distribution of BabyCheck booklets to an unselected group of mothers did not reduce GP consultation rates, the authors suggested that the BabyCheck may be more effective when implemented into a structured clinical assessment strategy.[19]

Low oxygen saturation (SpO_2) and abnormal heart rate may be early indicators of infectious, respiratory, or circulatory pathology in infants. [20-21] As visual assessment of skin colour is often unreliable and heart rate measurement by auscultation can be inaccurate, objective assessment using pulse oximetry (PO) can be a valuable adjunct. Although PO is widely used in older children and adults, It is not routinely used by GPs in young infants, partly because age-appropriate devices and sensors are not always available.

The aim of this study was to assess the feasibility of implementing the BabyCheck in combination with PO assessment in infants younger than six months presenting at an out-of-hours emergency GP service. Secondary objectives were to describe referral outcomes and GPs' perceptions of the usefulness of the combined assessment.

Methods

Between March 2024 and February 2026, we conducted a study at an out-of-hours emergency GP service in Leiderdorp, the Netherlands, in collaboration with the paediatric department of the Alrijne Hospital. This out-of-hours GP service serves a large regional population and functions as a primary point of care for acute paediatric presentations outside regular office hours. The study was approved by the local medical ethics committee, and written informed consent was obtained from both the parents or legal guardians prior to inclusion.

Infants younger than six months presenting to the out-of-hours emergency GP service with acute illness were eligible for inclusion. Infants presenting with trauma, requiring immediate resuscitation, or referred to hospitals other than the Alrijne Hospital were excluded. In accordance with national GP guidelines, infants younger than one month with fever (≥38.0 °C), as well as infants younger than three months with fever (≥38.0 °C) without an apparent source were excluded, as these infants should always be referred according to the national guidelines for GPs.

After arrival at the out-of-hours emergency GP service, parents or legal guardians were informed about the study, and consent was obtained prior to any study procedures. The BabyCheck consists of 19 weighted signs

and symptoms, including feeding difficulties, vomiting, altered alertness, respiratory symptoms and physical examination findings. Higher scores indicate a greater likelihood of severe illness. Parents or legal guardians subsequently completed the BabyCheck questionnaire. SpO_2 and heart rate were then measured using pulse oximetry with a Nellcor PM10N device (Medtronic). During the consultation, the GP also completed the BabyCheck scoring form. In cases of disagreement between parental and GP assessments, the GP's assessment took precedence.

Referral decisions were supported by a predefined flowchart combining the BabyCheck score thresholds and PO parameters (figure 1). The cut-off values were based on the internationally used Paediatric Early Warning Score and the National Institute for Health and Care Excellence (NICE) guidelines, as proposed by the Dutch Association of Pediatricians. These cut values are consistent with the expert opinion of pediatricians of the Alrijne Hospital.

Based on this flowchart, infants were either managed in primary care or referred to a paediatrician for further evaluation. GPs retained full autonomy and could override the flowchart when deemed clinically necessary. Referred infants were evaluated at the emergency department by a paediatrician, where further diagnostic evaluation, treatment, or follow-up was provided as deemed necessary by the paediatrician.

Referral outcomes were evaluated based on the paediatrician’s clinical judgement at the ED and review of hospital medical records. A referral was classified as appropriate if it resulted in diagnostic evaluation, treatment, or follow-up that could not have been provided in primary care. For infants who were not initially referred, hospital medical records were reviewed to identify presentations to the paediatric emergency department within 48 hours after the initial GP consultation. A referral was considered delayed if an infant subsequently required hospital-based care that could not have been provided in primary care, or if the paediatrician judged that earlier referral would have been appropriate.

To evaluate the use of the combined assessment in daily practice, GPs were asked whether the combination of the BabyCheck and PO was useful for assessing illness severity and whether it influenced their referral decision.

Statistical analyses

Data are presented as numbers and percentages. Statistical analyses were performed using IBM SPSS Statistics version 29.0.

Ethical considerations

The study was approved by the Medical Ethics Committee of the Leiden University Medical Center (LUMC) (NL84259.058.23) and was registered at ClinicalTrials.gov (NCT05954975).

Results

Feasibility

During the study period, parents of 133 infants younger than six months were approached for participation. Both the BabyCheck assessment and pulse oximetry measurements were successfully completed in 109 infants (Figure 2).

In 24 infants, the combined assessment was not completed. Reasons included incomplete BabyCheck documentation by the GP, unsuccessful measurement of SpO_2 or heart rate, GP refusal to participate, parental refusal, or identification of exclusion criteria after inclusion. Feasibility was therefore achieved in 109 of 133 infants (82%).

Sensitivity and specificity

Of the 109 infants who completed the assessment, 21 were referred to the paediatric emergency department. Of these referrals, 20 referrals were classified as appropriate and one as inappropriate. Among the 88 infants who were not referred, 87 were correctly classified, while one was retrospectively classified as a delayed referral.

Based on these outcomes, the sensitivity of the combined assessment for identifying infants requiring referral was 95% (20/21), and the specificity for correctly identifying infants who did not require referral was 99% (87/88).

Perceived usefulness of the combined assessment

GPs completed the evaluation question regarding usefulness in 106 of 109 cases (97%). The assessment was considered useful for evaluating illness severity in 67 of 106 cases (63%), while 39 of 106 cases (37%) were considered not useful. Three responses (3%) were missing.

Discussion

In this prospective feasibility study, the implementation of a combined BabyCheck and PO assessment in infants younger than six months presenting to an out-of-hours GP service achieved the predefined feasibility threshold. Although the study was not designed to evaluate effectiveness, the combined assessment demonstrated high sensitivity and specificity for identifying infants requiring referral to the ED. Furthermore, GPs considered the approach useful for assessing illness severity in the majority of cases.

In current primary care practice, the assessment of young infants largely relies on clinical judgement without structured decision support. Our findings are consistent with previous studies demonstrating that BabyCheck is feasible and acceptable for use by both parents and GPs. [15] [18] While earlier research primarily focused on the checklist alone, our findings suggest that combining a clinical checklist with objective measurements may support clinical decision-making and support referral decisions. The low number of infants requiring hospital-based care in this study aligns with the low prevalence of serious illness in primary care populations, [4] highlighting the importance of tools that help distinguish infants who require referral from the majority who can be safely managed in primary care.

Despite achieving the predefined feasibility threshold of 80%, several practical challenges were identified. Patient inclusion was slower than anticipated and depended on additional personnel, including the coordinating researcher and medical students. These findings suggest that implementation in routine clinical practice may be challenging under current workload and staffing conditions and may require integration into existing clinical workflows or additional support.

This study has several strengths and limitations. The prospective design enabled evaluation of the combined assessment during routine clinical practice. In addition, the combination of a clinical checklist with objective physiological measurements provided a structured approach to assessing illness severity in young infants. Referral outcomes were based on the paediatrician's clinical judgement, offering clinically relevant measures of appropriateness. However, the single-centre design may limit generalizability to other primary care settings.

Incomplete inclusion due to workload may have introduced selection bias. In addition, the small number of infants requiring hospital-based care limited the precision of the exploratory diagnostic estimates.

In conclusion, the combined use of the BabyCheck and PO appears feasible and may support GPs in assessing illness severity in young infants. Further research is needed to evaluate its effect on clinical decision-making and referral outcomes, as well as its implementation in routine clinical practice.

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342 **Statements and declarations:**

343 **Funding:** Medtronic provided an unrestricted grant for the project. They also provided 3 portable Nellcor
344 oximeters with sensors to enable this study. They had no role in the study design, data collection, data analysis,
345 data interpretation or writing of the report.

346 **Competing interests**: The authors declare no competing interests.

347 **Author contribution:** AH: co-conducted the study, wrote the first draft of the manuscript and submitted the
348 manuscript. MGP: reviewed and edited the manuscript and approved the final version of the manuscript DOMK:
349 co-conducted the study, reviewed and edited the manuscript and approved the final version of the manuscript.
350 ABtP: co-conducted the study, supervised the study, reviewed and edited the manuscript and approved the final
351 version of the manuscript. ICN: co-conducted the study, supervised the study, reviewed and edited the
352 manuscript and approved the final version of the manuscript

353 All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy
354 or integrity of any part of the work are appropriately investigated and resolved.

355 **Ethics approval**

356 The study was approved by the Medical Ethics Committee of the Leiden University Medical Center (LUMC)
357 (NL84259.058.23).

358 **Consent to participate**

359 Written informed consent was obtained from the parents or legal guardians.

360 **Consent to publish**

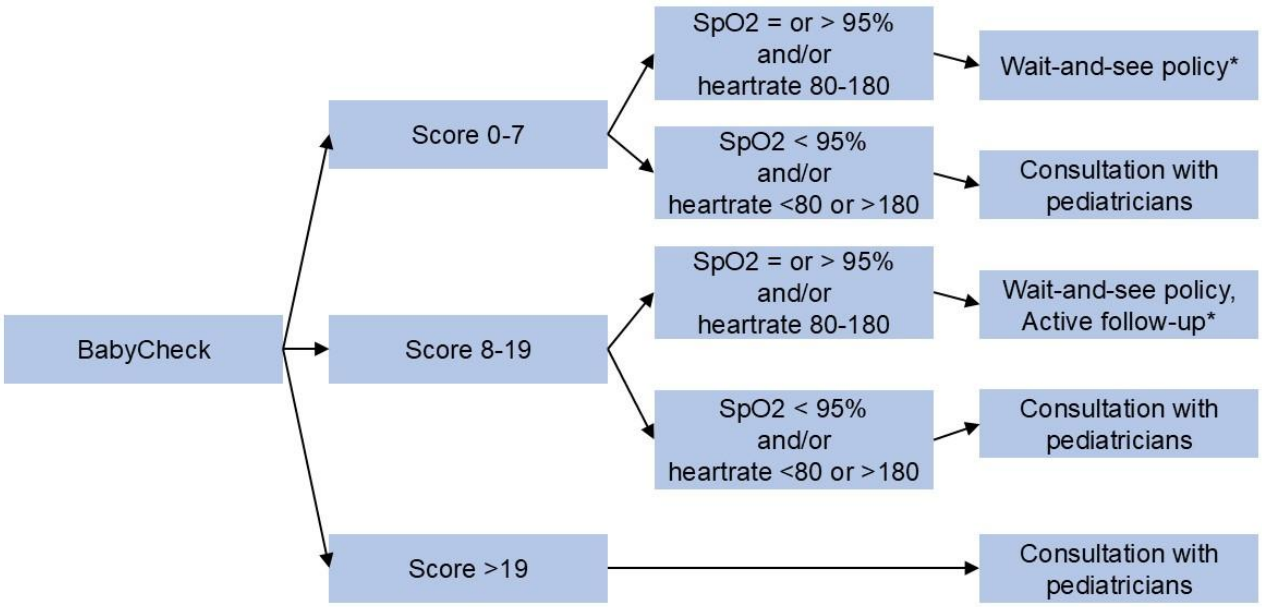
361 Not applicable.

362 **Data availability**

363 The data supporting the findings of this study are not publicly available due to privacy and ethical
364 considerations. Data may be made available from the corresponding author upon reasonable request, subject to
365 applicable ethical and institutional requirements.

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367 **Fig. 1 flowchart: BabyCheck combined with PO**



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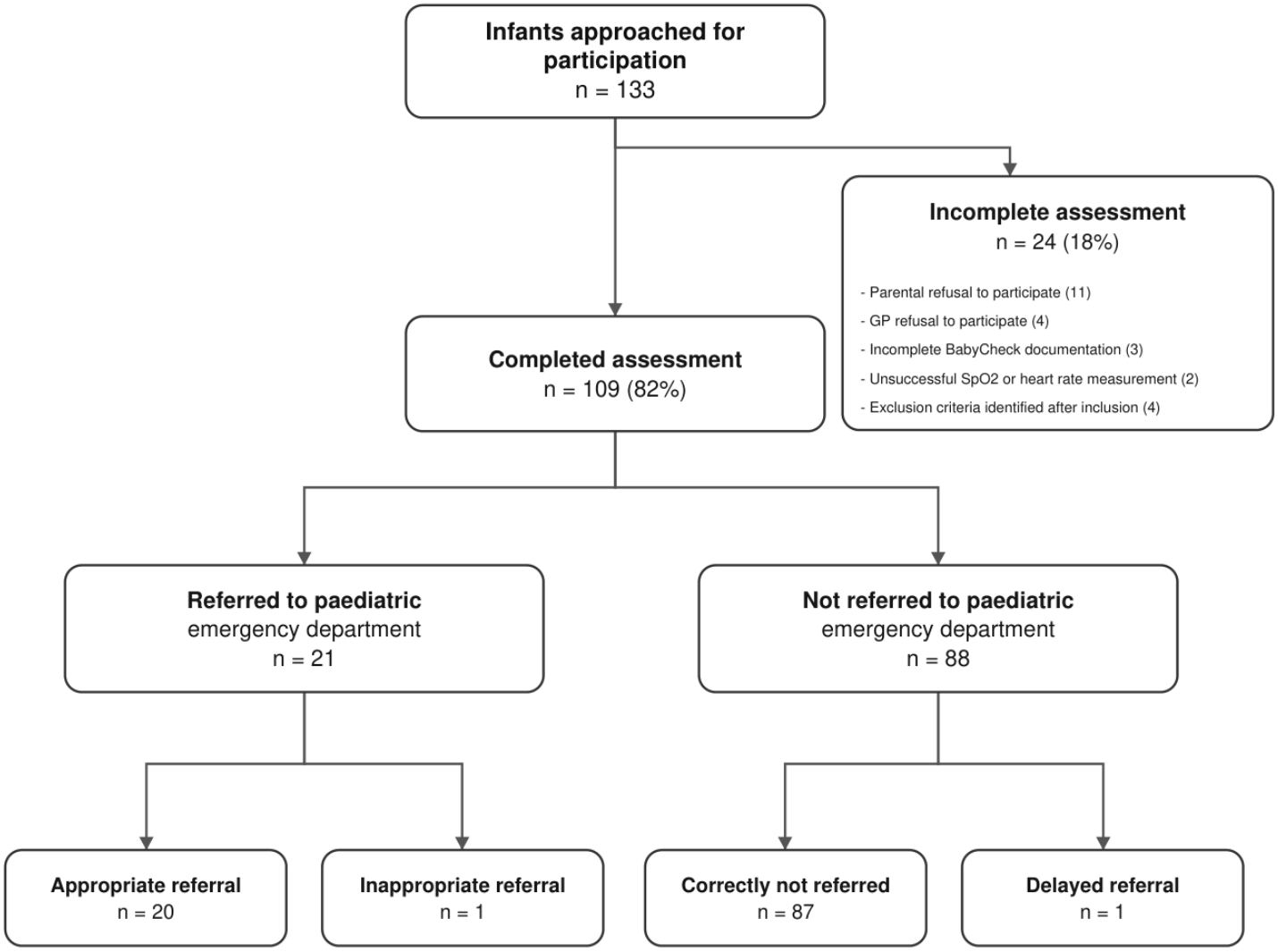
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380 **Fig.2 Flow diagram of participant recruitment, assessment completion, and referral outcomes**

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