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ORIGINAL ARTICLE

Multicentre Delphi study of physicians resulted in quality indicators for young infants with fever without source in emergency departments

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Abstract

Aim: Managing febrile infants has evolved without a generally accepted standard of care. We aimed to design quality indicators for managing infants ≤90 days old presenting to emergency departments (EDs) with fever without source.

Methods: This multicentre Delphi study was carried out by the Febrile Infant Study Group of the Spanish Paediatric Emergency Research Network, from March 2021 to November 2021, and included paediatric emergency physicians from 24 Spanish EDs. A list of care standards was produced, following an extensive literature review and the involvement of all parties. Indicators were essential if they were voted by four panelists and also received a score of ≥4 from at least 95% of the 24 investigators.

Results: We established 20 indicators, including one related to having a protocol, two to triage, nine to diagnostic processes, six to treatment and two to disposition. The following indicators were considered essential: having an ED management protocol, performing urinalysis on every infant, obtaining a blood culture from every infant and administering antibiotics in the ED to any febrile infant who did not appear well.

Conclusion: The Delphi method resulted in a comprehensive list of quality indicators for managing febrile young infants in Spanish EDs.

KEYWORDS
bacterial infection, emergency, fever, infant, quality

1 | INTRODUCTION

A considerable proportion of febrile infants under 3 months of age who present to an emergency department (ED) have a bacterial infection.[1,2] These include invasive bacterial infections such as meningitis, bacteraemia and urinary tract infections. Invasive bacterial infections have a prevalence of between 2% and 3% in this age group, although this rate is even higher in the first weeks of life. The traditional approach taken with these patients consisted of extensive evaluations, hospitalisation and antimicrobial treatment. However, the way that febrile infants under the age of 3 months are managed has changed considerably over the last two decades.

Abbreviations: ED, emergency department; IQR, interquartile range.

Nowadays, not all patients require admission and antibiotic treatment and those who have a very low risk for invasive bacterial infections can be identified and receive outpatient management.

The current management of young febrile infants varies widely, particularly in patients between 29 and 90 days of age.[3] These variations provide an opportunity to modify diagnostic and management strategies based on current epidemiologic research and safely decrease invasive testing and hospitalisation.[4]

Variations are an inherent part of clinical practice.[5] Some degree of variation, including that resulting from patient or family preferences, is considered appropriate. In contrast, inappropriate variations can have multiple causes and are not a by-product of patient and family centred care.[6] The aim of quality improvement initiatives is to learn from, and reduce, inappropriate variations.

Nearly all of the current protocols agree on certain aspects of managing febrile young infants, which are derived from evidence-based medicine. These include the need for complementary tests and admitting younger patients. However, even the most recent clinical tools show some discrepancies, as the 2021 guideline of the American Academy of Paediatrics has pointed out.[7] These differences can be detrimental to the quality of care delivery.[8] Research has highlighted the importance of identifying impediments in translating evidence-based recommendations into practice.[9] The development of quality indicators for managing young febrile infants in the ED could help to improve this situation.

The aim of this Spanish study was to design a series of quality indicators for managing infants ≤90 days old with fever without a source who presented to EDs.

Key notes

- This Delphi multicentre study aimed to design quality indicators for managing infants ≤90 days old presenting to emergency departments (EDs) with fever without source.
- It was carried out by the Febrile Infant Study Group of the Spanish Paediatric Emergency Research Network Febrile Infant Study Group, which included paediatric emergency physicians from 24 Spanish EDs.
- We established 20 indicators that covered such areas as having a protocol, triage, diagnostic processes, treatment and admissions.

2 | METHODS

We conducted a multicentre study of paediatric emergency physicians from 24 Spanish EDs from March 2021 to November 2021. The study was endorsed by the Spanish Paediatric Emergency Research Network, which is part of the Spanish Paediatric Emergency Society. By the time the study was carried out, RISeuP-SPERG comprised 127 investigators from 54 emergency departments. The Network aims to foster high-quality multi-institutional research on the prevention and treatment of diseases and acute injuries in children and adolescents.[10] It is also one of the multicentre research networks affiliated with Paediatric Emergency Research Networks.[11]

First, we formed a main working group comprising five panelists with expertise in research on febrile infants.[12–15] They conducted a literature search and a reading of the most relevant papers published since 2010 on febrile infants,[2,7,16–23] with special interest in the practice guidelines of the American Academy of Pediatrics.[7] Then, after this literature review, the group of panelists held two online meetings to draft an initial list of care standards for managing young infants, focusing on patients with fever without source. The list included standards that applied to the entire population of infants between 0 and 90 days of age with fever without source. Other standards only applied to certain age groups: ≤21, 22–28, 29–60, and 61–90 days. Standards that were accepted unanimously by all the panelists were included in the list.

The Delphi method was used during the second phase. Prior to the start of the second phase, an invitation to participate in the study was sent to all members of the network, to which researchers from 27 hospitals responded. In those hospitals, where more than one investigator responded, they were asked to choose a champion, preferably the person with the most experience in febrile infants. The investigator from each 27 participating hospitals received access to an online questionnaire containing the list of care standards. The majority responded and 24 (89.9%) were included in the study. They were asked to evaluate the clinical relevance of each item using a 7-point Likert scale. Non-responders were sent email reminders 2, 4 and 8 weeks after the initial request.

After all responses were received, items scoring ≥4 by at least 70% of the site investigators were included in the final list; and items given a score of ≥4 by less than 50% were eliminated. Finally, we computed the median score and interquartile range (IQR) and mean score along with 95% confidence intervals for all importance ratings. In Delphi studies, the IQR serves as an indicator of interrater consensus. An IQR ≤1 is considered a strong consensus between raters, while an IQR ≤2 is considered a consensus for items rated on a 7-point scale.[24] The latter cut-off is considered acceptable for studies where outcomes do not represent an immediate threat to life.[25] As in other Delphi studies, we established cut-offs for the IQR (<2) and median importance score (≥6) to identify indicators rated as highly important by consensus.[24,25]

In the final phase, the five panelists, in collaboration with a quality expert from one of the participating hospitals (EI) designed a quality indicator for each standard in the final list. For standards that were common to more than one age group, the working group tried to merge them into a single indicator. The indicators were designed to cover the six domains of Health Care Quality: Safe, Effective, Patient-centred, Timely, Efficient and Equitable.[26] Finally, each panelist chose, among those standards that received a score ≥4 in the Delphi by at least 95% of the participants, the eight indicators that

TABLE 1 List of standards of care for young febrile infants included in the Delphi questionnaire ($n = 24$ respondents).

Age group (days old)	Standard	Mean score (95% CI)	Median score (IQR)	Respondents with score ≥4
0–90	G1—The emergency department must have a management protocol for febrile infants up to 60/90 days old	6.73 (6.44–7)	7 (7–7)	100%
	G2—The appearance of every infant must be registered	6.85 (6.70–6.99)	7 (7–7)	100%
	G3—Rectal temperature must be registered in every infant	5.73 (5.19–6.27)	6 (5–7)	88.5%
	G4—Urinalysis must be performed in every febrile infant	6.65 (6.23–7)	7 (7–7)	96.2%
	G5—Antibiotic therapy must be given if the urinalysis is positive for leukocytes and/or nitrites	6.04 (5.47–6.60)	6.5 (6–7)	96.2%
	G6—Antibiotic therapy must be given if any biomarker is found to be abnormal	5.62 (5.08–6.15)	6 (5–7)	92.3%
	G7—Lumbar puncture (LP) must be performed in every patient not appearing well or those with clinical suspicion of sepsis/meningitis/encephalitis	6.69 (6.44–6.94)	7 (7–7)	100%
	G8—Parenteral antibiotic therapy must be given to every patient not appearing well or those with clinical suspicion of sepsis/meningitis	6.92 (6.81–7)	7 (7–7)	100%
	G9—Blood enterovirus polymerase chain reaction testing must be performed in epidemic season	5.35 (4.71–5.98)	5 (4–7)	88.5%
	G10—A rapid test for influenza should be performed in epidemic season	5.73 (5.21–6.25)	6 (5–7)	96.2%
0–21	A1—A urine sample must be obtained by catheterisation or suprapubic aspiration of the bladder in every febrile infant ≤21 days old	6.73 (6.52–6.95)	7 (7–7)	100%
	A2—A blood biomarker value must be obtained for every febrile infant ≤21 days old	6.54 (6.12–6.95)	7 (7–7)	96.2%
	A3—Blood culture must be obtained for every febrile infant ≤21 days old	6.88 (6.75–7)	7 (7–7)	100%
	A4—LP must be performed in every febrile infant ≤21 days old	6.27 (5.88–6.66)	7 (6–7)	100%
	A5—Parenteral antibiotic therapy must be given to every febrile infant ≤21 days old	6.12 (5.60–6.63)	7 (5–7)	92.3%
	A6—Every febrile infant ≤21 days old must be admitted	6.69 (6.40–6.99)	7 (7–7)	100%
22–28	B1—A urine sample must be obtained by catheterisation or suprapubic aspiration of the bladder in every febrile infant 22–28 days old with a positive leukocyte esterase (LE) or nitrite test	6.85 (6.70–6.99)	7 (7–7)	100%
	B2—A blood biomarker value must be obtained in every febrile infant 22–28 days old	6.73 (6.52–6.95)	7 (7–7)	100%
	B3—Blood culture must be obtained in every febrile infant 22–28 days old	6.85 (6.70–6.99)	7 (7–7)	100%
	B4—LP must be performed in every febrile infant 22–28 days old with altered biomarkers	5.85 (5.39–6.30)	6 (5–7)	100%
	B5—Parenteral antibiotic therapy must be administered to every febrile infant 22–28 days old with pleocytosis	6.50 (6.15–6.85)	7 (6–7)	100%
	B6—Every febrile infant 22–28 days old with pleocytosis must be admitted	6.65 (6.40–6.91)	7 (6–7)	100%
	B7—Antibiotic therapy must not be given in well-appearing febrile infants 22–28 days old with negative urine dipstick, normal biomarkers, and without pleocytosis (or LP not performed)	6.46 (6.20–6.72)	7 (6–7)	100%
29–60	C1—A urine sample must be obtained by catheterisation or suprapubic aspiration (SPA) of the bladder in every febrile infant 29–60 days old with a positive LE or nitrite test	6.88 (6.75–7)	7 (7–7)	100%
	C2—A blood biomarker value must be obtained in every febrile infant 29–60 days old	6.50 (6.15–6.85)	7 (6–7)	100%
	C3—A blood culture must be obtained in every febrile infant 29–60 days old	6.65 (6.40–6.91)	7 (6–7)	100%
	C4—Parenteral antibiotic therapy must be given to every febrile infant 29–60 days old with pleocytosis	6.46 (6.13–6.79)	7 (6–7)	100%
	C5—Every febrile infant 29–60 days old with pleocytosis must be admitted	6.27 (5.74–6.80)	7 (6–7)	96.2%
	C6—Antibiotic therapy must not be given in well-appearing febrile infants 29–60 days old with negative urine dipstick, normal biomarkers and without pleocytosis (or LP not performed)	6.38 (5.94–6.83)	7 (6–7)	96.2%

TABLE 1 (Continued)

Age group (days old)	Standard	Mean score (95% CI)	Median score (IQR)	Respondents with score ≥4
61–90	D1—A urine sample must be obtained by catheterisation or SPA of the bladder in every febrile infant 61–90 days old with a positive LE or nitrite test	6.85 (6.70–6.99)	7 (7–7)	100%
	D2—A blood biomarker value must be obtained in every febrile infant 61–90 days old	6.08 (5.67–6.49)	6 (5–7)	100%
	D3—A blood culture must be obtained in every febrile infant 61–90 days old	6.23 (5.83–6.63)	6.5 (6–7)	96.2%
	D4—Parenteral antibiotic therapy must be given to every febrile infant 61–90 days old with pleocytosis	5.92 (5.32–6.53)	7 (5–7)	92.3%
	D5—Every febrile infant 61–90 days old with pleocytosis must be admitted	6.11 (5.48–6.75)	7 (5–7)	92.3%
	D6—Antibiotic therapy must not be administered to well-appearing febrile infants 61–90 days old with negative urine dipstick, normal biomarkers, and without pleocytosis (or LP not performed)	6.58 (6.16–6.99)	7 (6–7)	96.2%

they considered most relevant. Those selected by at least four panelist were considered essential.

Although the study did not include patient participation, we obtained the approval of the Ethics Committee of the Basque Country. Completion of the questionnaire was considered an indication of consent to participate.

3 | RESULTS

After the first phase, we drafted a list of 35 standards of care: 10 were related to the entire population of febrile infants, six to those ≤21 days of age, seven to patients 22–28 days old, six to those

TABLE 2 Final list of care-quality indicators for young febrile infants after the last phase of the study.

Protocol

- **Existence of a management protocol for febrile infants ≤ 90 days old**

Triage

- Febrile infants ≤ 90 days old with a record of their appearance on arrival at the emergency department
- Febrile infants ≤ 90 days old with rectal temperature measurement

Diagnosis

- **Febrile infants ≤ 90 days old screened for leukocyturia/nitrituria**
- Febrile infants ≤ 90 days old with a urine culture
- Febrile infants 22–90 days old with blood biomarkers levels obtained
- **Febrile infants ≤ 90 days old with blood culture**
- Febrile infants ≤ 90 days old not appearing well with lumbar puncture
- Febrile infants ≤ 21 days old with lumbar puncture
- Febrile infants 22–28 days with abnormal biomarkers and lumbar puncture
- Febrile infants 22–90 days old with a blood polymerase chain reaction for enterovirus performed during the epidemic season
- Febrile infants ≤ 90 days old with a rapid diagnostic test for influenza performed during the epidemic season

Treatment

- **Febrile infants ≤ 90 days old not appearing well with antibiotic therapy**
- Febrile infants ≤ 90 days old with a suspected urinary tract infection and antibiotic therapy
- Febrile infants ≤ 21 days old administered antibiotic therapy
- Well-appearing febrile infants 22–90 days old with normal urine dipstick and altered blood biomarkers with antibiotic therapy administered
- Well-appearing febrile infants 22–90 days old with normal urine dipstick and pleocytosis with antibiotic therapy administered
- Febrile infants ≤ 90 days old with low-risk criteria and no antibiotic therapy

Disposition

- Febrile infants ≤ 21 days old admitted to ward/intensive care unit
- Febrile infants 22–90 days old with pleocytosis admitted to ward/intensive care unit

Note: Indicators considered essential appear in bold.

29–60 days of age, and six to febrile infants between the ages of 61 and 90 days. We forwarded a questionnaire compiled from the entire list to one investigator from each of the 27 participating hospitals and received 24 (88.9%) responses (Table 1). Among the 24 hospitals from which responses were received, there was at least one from 11 of the 17 Spanish regions. All were secondary or tertiary, with a range of volume of patients from 4300 to 65 000 patients/year. All the proposed standards obtained a score of ≥4 from more than 70.0% of the participants. All but one item were deemed highly important by consensus. As Table 1 shows, pandemic-season blood enterovirus polymerase chain reaction testing was the only standard given a median score of 5 (IQR 3).

We merged standards that were common to more than one age group, establishing a final list of 20 standards. Following this, a quality indicator was created for each standard. Table 2 contains the entire list of indicators. Of these, one was related to having a protocol or an adapted guide, two to triage, nine to the diagnostic process, six to treatment and two to disposition, thus covering the six domains of healthcare quality. Table 3 shows the four essential indicators: having an ED management protocol, performing urine analysis in every infant, obtaining a blood culture in every infant and administering antibiotics in the ED to any febrile infant who appeared ill.

4 | DISCUSSION

This three-phase consensus study of 30 experts (five panelists, one investigator of each participant hospital and one quality expert) resulted in a 20-item set of quality indicators established with a high level of expert consensus. These indicators represent five clinical domains for infants ≤90 days old with fever without source, and four of the standards were deemed essential.

Previous research has found variation in the management of the febrile infant.[4,8] One reason for this lack of uniformity is the absence of validated standards of care. The clinical guideline published in 2021 by the American Academy of Pediatrics aimed to organise the recommendations of the institution into key action statements, which are a good proxy for standards of care.[7] Here, we aimed to take this idea one step further by developing a series of

TABLE 3 List of the essential care-quality indicators for young febrile infants.

Indicator	Existence of a management protocol for febrile infants ≤ 90 days old	Febrile infants ≤ 90 days old with a performed screening of leukocyturia/nitrituria
Dimension	Effectiveness, safety, patient-centredness, timeliness, efficiency, equity	Effectiveness, safety
Justification	Good clinical practice is facilitated by standardised processes in accordance with existing scientific evidence through regularly updated protocols. Protocols must adapt management guidelines to the diagnostic and therapeutic possibilities of the local environment to homogenise clinical care and act as a tool that facilitates and expedites decision-making.	Urinary tract infection (UTI) is the most common serious bacterial infection in febrile young infants. For this reason, UTI should be considered in all these patients. Urine dipstick testing for leukocyturia/nitrituria has adequate sensitivity for the diagnosis of UTI
Formula	Existence of a clinical protocol in the ED for the management of febrile infants ≤ 90 days old based on current evidence and updated over the last 5 years YES/NO	$\frac{\text{Febrile infants} \leq 90 \text{ days old screened for leukocyturia / nitrituria in the ED}}{\text{Febrile infants} \leq 90 \text{ days old presenting to the ED}} \times 100$
Explanation of terms	Minimum protocol contents: diagnostic and therapeutic methods and a decision-making aid. The existence of a protocol making reference to febrile infants ≤ 60 days old will also be considered valid	Screening for leukocyturia/nitrituria either by urine dipstick (at the bedside or in the laboratory) or microscopic analysis is considered valid
Population	List of ED protocols	All febrile infants ≤ 90 days old presenting to the ED during the study period
Type	Structure	Process
Data source	ED protocols	Review of discharge forms in the electronic medical record or, failing that, on paper, corresponding to febrile infants ≤ 90 days old presenting to the ED during the period studied
Standard	100%	Higher than 95%
Remarks	Each ED must have its own protocols or adapt protocols designed by other EDs or scientific societies. Protocols must be based on current evidence and be updated every five years at the latest	

ED care-quality indicators, possibly benchmarking these indicators against others like it.

Variability is inherent to clinical practice and is not necessarily harmful. However, there exists a so-called unjustified variability, when medical care disregards patient preferences or current scientific knowledge of the underlying disease.[27] Unjustified variability is always multicausal and depends on factors such as the increasing complexity of health care, lack of valid clinical knowledge, or overconfidence in subjective judgements.[6]

One strength of our quality indicators was that they were designed by expert panelists with deep knowledge of research on the febrile infant. Furthermore, the indicators were externally validated through a Delphi process. The Delphi method was specifically designed to achieve group consensus and has been successfully applied to clinical best practices.[28] The method is based on iterative, controlled interaction between diverse respondents across geographic locations. Unlike other exploratory qualitative methods such as interviews and focus groups, respondents are blinded to each other, and no individual can dominate or influence group thinking. Furthermore, panelists are privy to the responses of their fellow experts and can reconsider their own position in the light of group patterns. Thus, the Delphi process facilitates consensus through anonymous communication without confrontation.[28]

Another strength of our study was that our list concerns infants from birth to 90 days of age. Although patients ≤7 days old were excluded from the current American Academy of Pediatrics guideline, we believed that there was ample evidence in favour of managing these patients in the same way as patients between 8 and 21 days of age.[15,16,20] Although some authors recommend a different approach for febrile infants >60 days old, given the prevalence of urinary tract infection and bacteraemia among these patients,[19] we considered it appropriate to include this group.

One of the most difficult steps in the process involved selecting which indicators should be considered essential. By way of example, 15 of the 20 indicators were believed to be essential by at least one panelist. Finally, a majority of panelists believed it essential for every febrile infant to be managed in accordance with a current evidence-based protocol; that the two most frequent bacterial infections, urinary tract infection and bacteraemia, be ruled out in every infant;

Febrile infants ≤ 90 days old with blood culture	**Ill-appearing febrile infants ≤ 90 days old with antibiotic administered**
Effectiveness, safety	Effectiveness, safety
The prevalence of bacteraemia in febrile infants ≤ 90 days old is higher than 2%. Many of these patients are well appearing and have a normal physical examination on arrival to the emergency department (ED). For this reason, all patients should have a blood culture.	The main risk factor associated with the diagnosis of invasive bacterial infection in a febrile infant ≤ 90 days old is appearing unwell. For this reason, empirical antibiotic therapy should be administered to all such febrile infants in the emergency department (ED)
$\frac{\text{Febrile infants} \leq 90 \text{ days old with a blood culture obtained in the ED}}{\text{Febrile infants} \leq 90 \text{ days old presenting to the ED}} \times 100$	$\frac{\text{Febrile infants} \leq 90 \text{ days old with an unwell appearance were administered antibiotics in the ED}}{\text{Febrile infants} \leq 90 \text{ days old presenting to the ED with an unwell appearance}} \times 100$
	A patient is considered to appear unwell when expressions such as "poor general condition", "unresponsive", "toxic appearance", or similar appear in the medical record. If the Paediatric Assessment Triangle is used in the ED, patients with abnormal findings on any side of the triangle are considered to appear unwell.
All febrile infants ≤ 90 days old presenting to the ED during the study period	All febrile infants ≤ 90 days old present to the ED during the period studied
Process	Process
Review of discharge forms in the electronic medical record or, failing that, on paper, corresponding to febrile infants ≤90 days old presenting to the ED during the study period	Review of discharge forms in the electronic medical record or, failing that, on paper, corresponding to febrile infants ≤90 days old presenting to the ED during the study period
Higher than 95%	Higher than 95%

and that all infants who appeared will be given early parenteral antibiotics, as they are at high risk for invasive bacterial infection.

Our study had certain limitations. As explained above, it must be noted that the standards of care designed in this study are focused on the management of young infants with fever without a source, in contrast to different guidelines or recommendations that include all young febrile infants. Thus, this should be considered for external validation, and, if so, should be very cautiously applied to young febrile infants with fever with a source. Aside from this, a significant limitation was the number of participants in the Delphi process. To avoid the overrepresentation of larger institutions in our network, only one investigator per hospital completed the questionnaire, preferably the researcher with the most expertise. As a result, the number of participants may appear small. However, the study included half of the member hospitals of the Spanish Pediatric Emergency Research Network, therefore, lending sufficient validity to our findings. Second, the quality indicators were developed in a single country, which could limit their external validity. In any case, the Spanish public healthcare system is controlled on the regional level, that is by 17 regional ministries of health. We obtained responses from EDs in 11 of the 17 Spanish regions; these included EDs that are secondary and tertiary, paediatric and mixed-age, rural and urban, and with both small and large patient volumes. We therefore believe that this broad inclusion of participating centres partially mitigates the impact of this limitation. Furthermore, the indicators are being validated in a subsequent study in the same participating hospitals, and it would be ideal to culminate the process with an international multicentre validation. An additional limitation was the fact that the consensus-based indicators have not been validated in real clinical practice. However, this was the first phase of a larger study examining the application of the indicators. Fourth, these indicators focused on bacterial infections, which eliminated other possible aetiologies, such as viruses. Since some of these viruses can develop into sepsis-like illnesses, this aetiology must also be taken into account. However, as most severe illnesses are bacterial, the list of indicators was adequate for the vast majority of febrile infants. Lastly, some of the indicators included blood biomarker determinations, although biomarkers such as procalcitonin and C-reactive protein are scarcely used in some countries. The working group set out to use the most robust, current evidence to create the standards, and therefore the indicators must mention those biomarkers with the best performance. However, we aimed to provide a valid alternative to all indicators for EDs with more limited resources. For example, in hospitals without access to procalcitonin, C-reactive protein, and absolute neutrophil count, we recommend procalcitonin in conjunction with one of the other two.

5 | CONCLUSION

Using a standardised method, we created a comprehensive list of quality indicators for ED management of febrile young infants. Our findings may form the basis for implementation of corrective measures and continuous quality improvement.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

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