Journal of Paediatrics and Child Health

doi:10.1111/jpc.16328

ORIGINAL ARTICLE

Time to change the reference ranges of children's physiological observations in emergency care? A prospective study

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Aim: High heart and respiratory rates are key indicators in many published guidelines to identify and treat serious bacterial infection and sepsis in children, but the credibility of evidence underpinning what is considered abnormal is questionable. This study established the distribution of heart and respiratory rates of children using a large data set to inform debate on what the 'normal' range of these should look like. The primary aim was to compare the distribution of heart and respiratory rates measured in children recruited from non-tertiary emergency care settings with those published by Advanced Paediatric Life Support (APLS). The secondary aim was to compare the distribution of this study's data set to other national guidance on what constitutes a severe (high-risk) measurement and previously published data sets.

Method: Prospective study using anonymised patient data, extracted from electronic patient records of children and young people 0–16 years, recruited from three Emergency Departments and one Urgent Care Centre in Northwest England, UK.

Results: Heart and respiratory rates, including the reporting of values at certain centiles and comparisons of averages. Distribution of heart and respiratory rate were consistently higher than those used by the APLS guidance, resulting in a large proportion exceeding the 'severe' cut-offs proposed. This varied greatly by age.

Conclusions: This study's data set suggests normal heart rate ranges proposed by the APLS and others is too low and therefore 'abnormal' measurements encompass too large a proportion. The respiratory rate of this data set was more consistent with the guidelines and other published data sets.

Key words: emergency medicine; general paediatrics; infectious diseases; intensive care.

What is already known on this topic

1 Heart and respiratory rates are accepted to be critical early indicators in sepsis detection.
2 Clinicians should have evidence-based references ranges for 'normal' and 'abnormal' heart and respiratory rates to make meaningful and accurate assessments of acutely unwell children.
3 Inconsistencies between reference ranges could lead to misclassification of children as having either normal or abnormal heart rates.

What this paper adds

1 Current sepsis guidelines are likely to lead to an over classification of children at 'severe' risk based on heart rate, but not respiratory rate.
2 The younger the child, the greater the chance of misclassification; for children aged 12 years and over, this study's data reflect current guidelines/published work
3 This study suggests that the reference ranges used in UK and other sepsis guidelines should be reviewed.
4 This study demonstrates the potential use of large, anonymised hospital data sets in advancing public health research into addressing inequalities within hospital settings.

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Conflict of interest: None declared.

Author contributions: CH, AR and DR devised the study and sought the necessary information governance approvals. SB extracted and cleaned the data. CH analysed the data. All authors contributed to the preparation of the manuscript. All authors approved the final manuscript before submission.

Accepted for publication 23 December 2022.

Sepsis is a rare but serious medical condition that results from the body's immune system overreacting to an infection or injury.[1] If left untreated, sepsis can lead to septic shock, organ failure and death.[2] In 2019, 156 deaths in children were attributed to infection in England and Wales.[3] The impacts of sepsis can be devastating with effects such as post-traumatic stress disorder (PTSD), chronic pain and fatigue, organ dysfunction and/or limb amputations.[4] An action plan,[5] together with guidelines and toolkits which aim to ensure health-care clinicians have a consistent evidence-based way to assess acutely unwell children, has been published. The most commonly used guidelines in the UK are summarised in Table 1.

Methods

Heart and respiratory rates are accepted to be critical early indicators in sepsis detection. It is important that clinicians have evidence-based references ranges for 'normal' and 'abnormal' heart and respiratory rates to make meaningful and accurate assessments of acutely unwell children.[9] In extreme cases, inaccurate reference ranges could lead to under-detection of sepsis or unnecessary intervention for children.

Advanced Paediatric Life Support (APLS)[6] provides the basis for reference ranges underpinning risk ratings and actions advised for children who are unwell (including those who may have sepsis) in the UK (Table 1). However, previous studies have questioned the evidence supporting the reference ranges published in the APLS guidance. Three previous studies have compared APLS with their own and other published ranges. In a systematic review of normal ranges of heart and respiratory rates in children birth to 18 years, 143 346 heart and 3881 respiratory rates were included.[10] Fleming *et al.* found that heart rates measured in community settings were significantly higher than in clinical or laboratory settings. They concluded that inconsistencies between reference ranges could lead to misclassification of children as having either normal or abnormal heart rates, and their percentiles and reference ranges were more appropriate for hospitalised children.[10] Bonafide *et al.* conducted a cross-sectional study, comparing the heart and respiratory rates from the electronic records of 14 014 hospitalised children with the APLS reference ranges. They too reported differences between distributions of vital signs in their hospitalised population and published reference ranges obtained from well-children.[11] Finally, O'Leary *et al.*[9] produced a set of centile charts derived from low-priority patients attending a paediatric emergency department (PED) in Australia. Their rates were different from Fleming's,[10] yet there was good agreement with the 50th centiles from the Bonafide[11] data set. They suggest that the similarity between Bonafide's and their own data set indicates their 50th centiles are valid and robust for a hospital setting. When compared to the APLS[6] data set, a good fit with heart rates was observed; however, respiratory rates were significantly different. This study concluded that current APLS reference respiratory ranges should be reviewed, and further studies are required to explain the differences found between Fleming's community-derived data and the hospital-derived data.[10]

The aforementioned studies have often occurred in Children's Emergency Departments; however, the majority of children seen in the UK (and around the world) are not seen in paediatric specialist centres (i.e. children's only emergency departments in specialised children's hospitals) but general emergency department and treatment centres (i.e. mixed adults and children's departments where clinicians are experts in emergency and urgent care to all ages). It is possible that there are differences in vital signs between specialised and general Children's Emergency Departments, as has been demonstrated between community and hospitalised populations, and this would warrant further investigation in a future study.

In this study, a large data set of heart and respiratory rates derived from a UK paediatric population attending an urgent or emergency care setting was used to compare to published percentile curves.

This study had three primary aims (Table 2).

Ethical approval

In the UK, clinical audit and service evaluation studies are not subject to review by a research ethics committee. Data in this study were amalgamated when indicated to ensure that no

Table 1 UK guidelines and toolkits for the identification of an unwell child

Advanced Paediatric Life Support (APLS)

APLS[6] is the internationally renowned manual on emergency paediatric care. Now in its sixth edition, APLS It is used by healthcare professionals, both for training and in the event of an emergency. Using its structured approach, APLS is used by healthcare professionals during the crucial first few hours of a life-threatening illness or injury. The manual contains reference ranges for 'normal' and 'abnormal' respiratory and heart rates that are used to underpin many national and international guidelines.

NICE guideline 51[7]

These guidelines cover the recognition, diagnosis and early management of sepsis in all populations, including paediatric populations in and out of the hospital setting. Toolkits and algorithms support the guidelines and outline criteria for risk including heart and respiratory rates (based on APLS reference ranges). Risk is stratified into 'low', 'moderate to high' or 'high'. Any patient with one or more high risk, or two or more moderate to high-risk criteria require blood tests and clinical review.

UK Sepsis Trust guidelines 'Sepsis six'[8]

The UK Sepsis Trust produces operational toolkits for use in all healthcare settings. The tools are endorsed by NICE and provide checklists for identifying and managing signs of sepsis. Checklists of possible signs and symptoms include heart and respiratory rates, which are categorised into 'severe' (red) and 'moderate' (amber), based on readings above the 'normal' APLS reference ranges. Guidance is given on actions to take if either (or any other signs/ symptoms) are present. In the case of either being classed as 'severe' six actions are outlined that must be completed within one hour. If classified as 'moderate' bloods and senior clinical review is required within one hour.

Table 2 Aims of this study

Aim one
To determine and interpret how the distribution of heart rates and respiratory rates measured in a large number of children recruited from emergency care settings, compared to those published within the Advanced Paediatric Life Support (APLS) course documentation.[6]
Aim two
To determine the proportion of this study's data set that would cross the 'severe' cut-off in the guidelines from the UK Sepsis Trust,[8] and the National Institute for Health and Care Excellence (NICE) in its guideline 51.[7]
Aim three
To compare this study's data set to similar, previously published, large data sets.[9–11]

individual child or family could be identified from this publication. Anonymised patient data were used in this study, which were extracted from the electronic patient record of one data controller. No identifiable patient information was shared. Following discussion with the data controller's research and innovation department, approval was sought to proceed with this study from the data controller's Caldicott Guardian and Data Protection Officer in the Information Governance Department. Approval was given by both office-holders to proceed with this study without seeking formal research ethics committee approval.

Sample

The sample was recruited consecutively from three Emergency Departments and one Urgent Care Centre, serving populations with significant inequalities in health and life expectancy, in the North West of England, UK. Data collection was prospective over all seasons of the year to avoid potential bias from seasonal variability (1 October 2017 to 30 September 2020). Eligible cases were children and young people 0–16 years of age who attended one of four hospital sites within one large, multi-site NHS organisation in Greater Manchester, UK. Access was granted to anonymised data from the Emergency Departments' and Urgent Centre's electronic patient records, to extract the physiological data necessary for this study (as well as the sex, and date of birth and date of attendance). From the demographic data supplied and the date of attendance, the exact age of the child was calculated. Data were cleaned and anonymised by a data manager in the Research and Innovation Department before passing the data onto the study statistician. As it was the intention to summarise the characteristics from the set of hospitals collectively, as opposed to describing them individually, the data from all four hospitals were combined into one data set.

Statistical analyses

Analysis was conducted in Stata 14 MP. All statistics are descriptive. Descriptive statistics do constitute formal statistics, as they can be used to evaluate central tendency and spread of data, especially given the size of the sample in this study. Despite both heart rate and respiratory rate being positively skewed their distribution was considered, by the research team, to be 'normal enough' to represent with mean and standard deviation.

Aim 1

To descriptively compare the 5–95th heart rate and respiratory rate centiles from the APLS guidelines[6] were descriptively compared with the same in this study's data set. The APLS centiles are also compared to the 1–99th, 10–90th and 50th centiles from this study's data set.

Aim 2

To describe this study's data set, alignments with the reference severe (high risk) heart rate cut-offs from the UK Sepsis Trust (UKST)[8] and NICE[7] (these are equivalent cut-offs, and for convenience are therefore referred to as simply being from NICE) were described. The centile at which NICE's proposed cut-offs were found in this study's data set was calculated. With this it was possible to determine what per cent of this study's data set would be considered in the high-risk category by NICE.

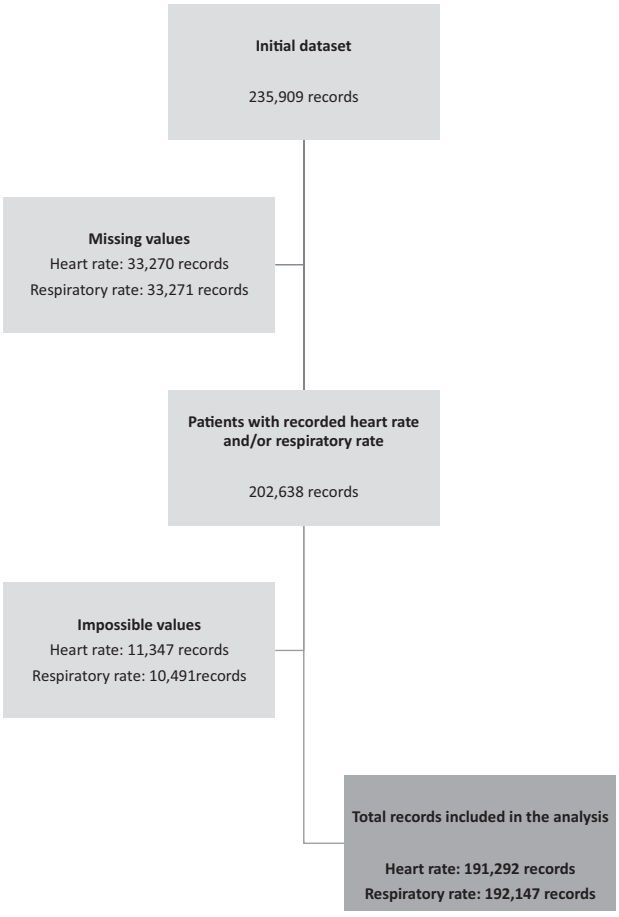

Fig. 1 Flow chart from initial data set to records included in analysis.

Aim 3

For heart rate and respiratory rate, the value at each of the following centiles was listed: 1, 5, 10, 25, 50, 75, 90, 95 and 99. These were compared to reference values from three sources.[9–11] These comparisons were thoroughly explored by calculating the average of the absolute differences between this study's data set and the other sources for each age range, and also over all age ranges. The absolute difference, rather than the difference, was chosen because the primary purpose of the comparison was to determine how different this study's centile values were from the alternatives, not the direction of the differences.

Results

Data on 235 909 records were received. After removing the missing and values deemed impossible, there were 191 292 records with a heart rate measurement and 192 149 records with a respiratory rate measurement (Fig. 1). 'Impossible' values were heart rates below 50, and respiratory rates below 9 or above 90.

The median age of the patients included in this study was 5 years (interquartile range 1–10) and the sample was recorded as being 45% female. Site 1 (Type 1 Emergency Department) provided 35.7% of the records; Site 2 (Type 1 Emergency Department and trauma unit) 34.2% of the records; Site 3 (Type 1 Emergency Department but not receiving acutely unwell children by

Table 3 A comparison of centiles between this study and APLS,[6] for both heart and respiratory rate

Rate	Age	5–95 percentile APLS, range	5–95 percentile in this study, range	10–90 percentile in this study	1–99 percentile in this study	Median in this study
Heart rate	Birth	90–180, 90	118.5–180, 62.5	126–172	106–195	148
	1 month	110–180, 70	122–181, 59	128–174	110–197	149
	3 months	110–180, 70	114–180, 66	120–171	102–197	143
	6 months	110–180, 70	111–181, 70	116–172	100–199	139
	1	80–160, 80	106–183, 77	112–174	94–200	138
	2	80–140, 60	95–168, 73	100–159	84–185	123
	3					
	4	80–120, 40	85–151, 66	90–142	76–168	110
	5					
	6	75–115, 40	77–139, 62	81–130	70–157	101
	7					
	8	70–110, 40	72–131, 59	77–121	65–150	95
	9					
	10	70–110, 40	70–126, 56	74–117	62–146	91
	11					
	12	60–110, 50	67–120, 53	71–112	60–140	89
	13					
	14	60–100, 40	64–120, 56	68–110	58–138	87
	15					
Respiratory rate	Birth	40–60, 20	30–60, 30	32–52	26–72	40
	1 month	30–50, 20	30–60, 30	32–52	26–70	40
	3 months	30–45, 15	26.1–59.9, 33.8	28–50	24–68	36
	6 months	25–35, 10	26–52, 26	27–47	22–64	32
	1	20–30, 10	24–48, 24	26–41	22–60	30
	2	20–28, 8	22–41, 19	22–36	20–55	28
	3					
	4	20–26, 6	20–34, 14	22–30	18–47	25
	5					
	6	18–24, 6	20–29, 9	20–28	18–40	24
	7					
	8	18–22, 4	19–28, 9	20–26	17–36	22
	9					
	10	16–20, 4	18–26, 8	19–25	16–32	22
	11					
	12	16–20, 4	16–24, 8	16–24	15–30	20
	13					
	14	16–20, 4	16–24, 8	16–22	14–28	19
	15					

APLS, Advanced Paediatric Life Support.

ambulance) 13.1% of the records and Site 4 (Urgent Care Centre) 17.0% of the records. The number of patient records providing data on heart rate and respiratory rate was 191 292 (81.1%) and 191 256 (81.1%), respectively. A summary of the data set is provided in Supplementary file S1.

Aim 1

All results for this aim are displayed in Table 3.

The heart rate 95th centile in this study's data set closely matches those from APLS for children under 1 year but is then considerably higher for all other age ranges (minimum of 10 beats per minute (bpm) higher at 12–13 years, maximum of 31 bpm higher for 4–5 years). This study's 5th centile is higher at nearly every age than the equivalent APLS centile, most prominently at birth (28.5 bpm higher) and at 1 year (26 bpm higher). The range of the 5–95th centile in this study's data set, as compared to the APLS, is overall smaller for those under 1 year old and larger for those older.[9]

Regarding respiratory rate, this study's 95th centile is equal to the APLS equivalent at birth but is consistently higher at all other age ranges, more so for those under 4 years of age. This study's 5th centile is broadly similar to those from the APLS, the only meaningful departure is at birth (10 breaths per minute lower). The range of the 5–95th centile is consistently higher in this study's data set.

Of the three centiles ranges considered (1–99th centile, 5–95th centile, 10–90th centile), this study's 5–95th range is the one that most closely matches the APLS guidelines for heart rate, whereas the 10–90th range is the one that most closely matches the APLS guidelines for respiratory rate.[6]

Aim 2

The percentage of children in this study's data set that would cross the high-risk heart rate cut-offs set by NICE[7] differed greatly depending on age. For those children below 1 year of age, 23.3% of this study's data set had what NICE[7] considers to be a high-risk heart rate; this percentage decreases as age increases up until those aged 12 and older, for whom only 2.2% crossed this threshold (Table 4). Across all age groups, the percentage whose heart rate would be considered in the high-risk category under NICE[7] was 17.5%.

For respiratory rate, the pattern is quite different, with a much lower percentage of this study's data set crossing the high-risk threshold. Only 9% or lower exceeded the threshold for all ages except in those aged 6–11 years. Across all age groups, the percentage whose respiratory rate would be considered high risk under NICE[7] was 7.4%.

Aim 3

The mean difference at each age range, averaged over the centiles, for each variable of interest is listed in Supplementary file S2.

For heart rate, the recommended centile values differ from those of O'Leary[9] and Bonafide[11] by a very similar amount, mean 7.9 (sd 7.9) and 7.9 (sd 6.5), respectively. The mean difference between this study and Fleming's[10] values was considerably greater at 15.2 (10.6). The pattern of differences varied considerably between the three reference values. This study's values were more similar to those found by O'Leary for the lower centiles and increasingly different for the higher centiles. The difference between this study's and Bonafide's values was more consistent across the centiles. These patterns held true for the respiratory rate also, though the overall difference was more consistent across the three studies, 3.6 (4.2), 3.7 (3.6) and 3.5 (2.1) for O'Leary, Fleming and Bonafide, respectively. In broad terms of the direction of the difference, this study generally had centile values slightly higher than the three comparator studies, regardless of age group.

Table 4 The centile in this study that would cross the NICE guidelines 'high-risk' cut-off[7]

Rate	Age (years)	High-risk cut-off Sepsis Trust/NICE	Equivalent percentile in this study	Percentage in this study that would be considered 'high risk'
Heart rate	<1	≥160	76.7	23.3%
	1–2	≥150	71.3	28.7%
	3–4	≥140	81.2	18.8%
	5	≥130	83.0	17.0%
	6–7	≥120	81.3	18.7%
	8–11	≥115	86.0	14.0%
	12+	≥130†	97.8	2.2%
Respiratory rate	<1	≥60	95.8	4.2%
	1–2	≥50	96.5	3.5%
	3–4	≥40	95.2	4.8%
	5	≥29	91.0	9.0%
	6–7	≥27	87.5	12.5%
	8–11	≥25	85.7	14.3%
	12+	≥25†	96.7	3.3%

NICE, National Institute for Health and Care Excellence. † The guidelines present these as 'red flags' rather than 'high-risk' scores.

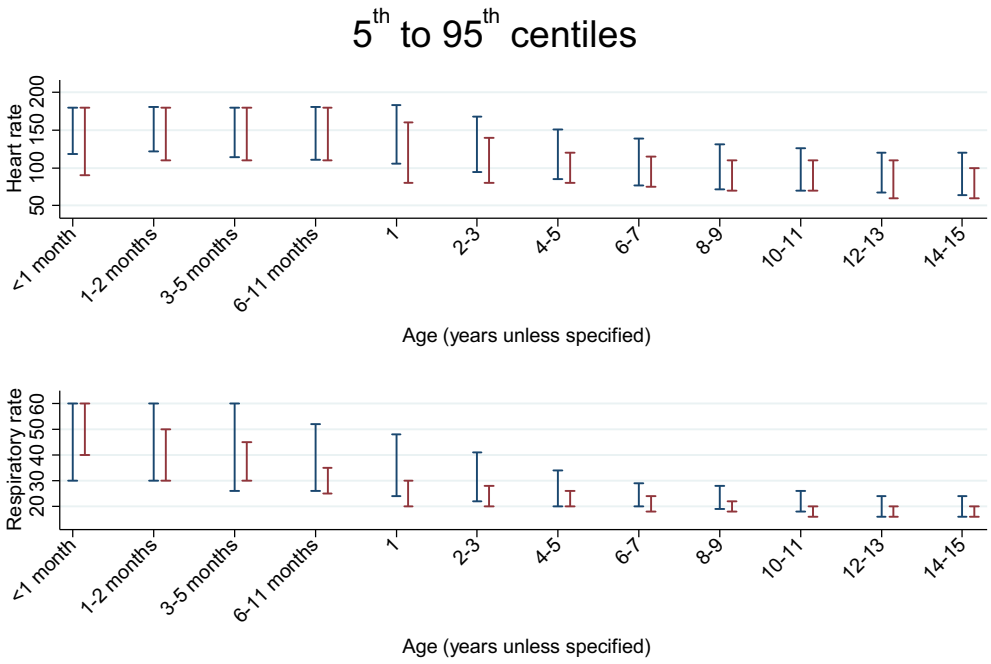

Fig. 2 5th to 95th centiles of this study and APLS, for heart and respiratory rate. APLS, Advanced Paediatric Life Support. (⟵⟶), This study; (⟵⟶), APLS.

Discussion

Reference ranges used in the detection of sepsis must be accurate for the setting in which they are used. The findings from this study of non-tertiary emergency departments (those general departments treating both adults and children), representative of where the majority of acutely unwell children seen in the UK would initially attend, suggest that the heart and respiratory rates used in the current APLS[6] guidelines are too low, meaning that higher than necessary proportions of children are being classed as severe or high risk, and therefore perceived to be at risk of sepsis.

Sepsis is a serious medical condition in children, with potential long-term health consequences. NICE wished to provide guidelines on use of heart rate and respiratory rate in assessment of people with sepsis. Heart rate and respiratory rate vary by age, so it was argued that recommendations across a large age range needed to take this into account. The available information on normal ranges for heart rate and respiratory rate in children of different ages, including neonates, was reviewed by NICE. It was recognised that the most used scale in the UK is from the APLS course guideline,[6] which was also used in NICE's Fever in children under the age of 5 years (Clinical Guideline 160). In reviewing normal heart and respiratory rates, the NICE's Guideline Development Group also considered the findings of a systematic review[10] and of a retrospective cross-sectional study.[9] NICE and the UKST developed a sepsis management guideline to improve sepsis care, which incorporated the so-called Sepsis Six as a practical tool said to help health-care professionals deliver the basics of care rapidly and reliably. Sepsis Six and the UKST guideline are reported to be used in 96% of British hospitals and in 37 other countries world-wide.

The Sepsis Guideline Development Group noted that comparing data from APLS guideline, Fleming *et al.*[10] and O'Leary *et al.*[9] studies highlight that there is still controversy on what represents a normal respiratory and heart rate in infants and children of different ages.

In particular, this study's 5th centile is higher at *every age* than the equivalent APLS centile, most prominently at birth (28.5 bpm higher) and at 1 year (26 bpm higher). This study also found, compared to the NICE guidelines, the younger age groups' heart rate values were higher than pre-defined normal ranges with 23.3% of children below 1 year of age having a heart rate consistent with a potentially severe infection. This percentage decreased as age increased up until those aged 12 and older, for whom only 2.2% crossed this threshold (Fig. 2). It is important to note though that the NICE guideline advises that patients crossing these thresholds are assessed by a senior clinical decision maker who will likely rule out false positives. This additional burden on the service was never quantified or evaluated prior to the release of the guidance.

In broad terms of the direction of the difference, this study generally had centile values slightly higher than the three comparator studies, regardless of age group. An important caveat to these comparisons is that O'Leary had attempted to remove patients with fever from their data set, whereas this study did not. Also, the data from Bonafide's study were from an in-patient population. These will likely account for some of the observed differences.

The findings of this study raise a number of questions regarding the current use of age-banded vital signs for the detection of serious illness in children. Previous criticism of sepsis guidelines has centred on their poor specificity in Emergency Department settings with two recent studies demonstrating high prevalence of children meeting sepsis concern criteria, but very low numbers of children discharged with a diagnosis of sepsis.[12,13] Two of the Emergency Departments in these studies were also based at tertiary children's hospitals. This study adds to the evidence

demonstrating it is highly likely that poor specificity of sepsis screening is present in all emergency settings.

The consequences of poor detection can lead to so-called alarm fatigue, where clinicians become de-sensitised to tools which trigger constantly and therefore are at risk of missing children with serious illness when they do trigger appropriately. This presents a significant patient safety risk.

The risks associated with over detection include unnecessary stress for parents and children, additional tests, unrequired treatment and potential adverse reactions such as fluid overload, anaphylaxis or extravasation injuries.[12] Further investigation into the public health consequences of over detection is warranted, as it has been evidenced that the patients requiring emergency admissions are more likely to be from deprived areas,[14] and those using Emergency Departments on a regular basis are also more likely to be from areas of higher deprivation.[15–17] The unintended stress and consequences associated with the over detection of sepsis indicators has the potential to widen inequalities in child health.

It is perhaps surprising that deviation in this study's cohort was more pronounced for heart rate than it was for respiratory rate. The reasons for this are not clear. The data in this study are representative of typical emergency departments in the UK where children attend and would be representative of other countries with a similar socio-economic profile to the UK. The data in this study may be different from other centres, and previously published results for a number of reasons. This study included only initial vital signs collected at assessment (as repeated vital sign measurements were not recorded electronically). There has also not been control for other influences on heart rate and respiratory such as fear or temperature. It is known that temperature does impact on heart rate[18] but this potential confounder applies across all patient groups. As this study did not specifically look at outcomes per patient, the deviation from 'normal' to a specific outcome cannot be linked (this was not *a priori* method). It is possible that certain deviation from normal values does increase risk of sepsis significantly and this would be an area for further study.

Conclusions

The findings in this study suggest that the heart and respiratory rates used in the current APLS guidelines are too low, meaning that higher than necessary proportions of children are being classed as 'severe', and therefore perceived to be at risk of sepsis, the more so the younger the child is. Heart rate centiles in this study's data set had a greater variation with guidelines and other published data sets than the respiratory rate centiles.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1. Supporting Information