NICE National Institute for Health and Care Excellence

May 2026 exceptional surveillance of anaphylaxis: assessment and referral after emergency treatment (NICE guideline CG134)

Surveillance report
Published: 27 May 2026

www.nice.org.uk

Contents

Surveillance proposal

The topic areas considered in this surveillance were:

- Number and timing of blood samples for measurement of mast cell tryptase levels following successful emergency treatment of suspected anaphylaxis.
- Duration of the post-anaphylaxis observation period.

Following consultation with topic experts we propose to:

- replace recommendations about post-anaphylaxis observation periods in adults aged 16 years and older and children, with the Resuscitation Council UK's (RCUKs) recommendations about a risk-stratified approach to the length of in-hospital observation following anaphylaxis
- not update recommendations about the timing and frequency of blood sampling.

Trigger for the exceptional review

We were contacted by a member of the RCUK to say that their Emergency treatment of anaphylactic reactions: Guidelines for healthcare providers was updated in 2021. It was suggested that NICE's guideline on anaphylaxis needed updating as it now does not align with the RCUK guidance.

Context

The scopes of the 2 guidelines

NICE's guideline is intended to complement the RCUK's guidance and cross references it. The aim of NICE's guideline is to improve identification, diagnosis and referral of anaphylaxis following emergency treatment. Initial assessment, diagnosis of anaphylactic episode before emergency treatment and emergency treatment are out of scope.

The RCUK guideline is for healthcare providers who are expected to treat anaphylaxis during their usual clinical role (for example, doctors, nurses, and paramedics) in hospital or

out-of-hospital settings. It provides recommendations and care algorithms about the recognition and emergency treatment of anaphylaxis and refractory anaphylaxis.

Overlap between both guidelines

There is overlap between some recommendations in NICE's guideline and section 7 on investigations in the RCUK guideline. There are now notable differences which are based on evidence not considered during the development of NICE's guideline and that add to evidence identified during 2016 surveillance.

RCUK guideline methodology

The methodology underpinning the update of the RCUK guideline is detailed in Dodd et al. (2021). Development consisted of using the GRADE evidence to decision (EtD) framework, also known as recommendation adoption, adaption or development (for example, GRADE-ADOLOPMENT). This comprised:

- Identifying systematic reviews and international guidelines (including NICE's guideline on anaphylaxis) published or updated after the last RCUK guideline.
- Completing an EtD table using the GRADE EtD framework for each research question underpinning the extant RCUK 2012 guideline.
- Convening a working Group (numbering 16 medical and healthcare professionals and 1 patient advocate), who reviewed the EtD tables, considered the new evidence, and reached a consensus as to:
  - the certainty of the available evidence;
  - whether it still supported the previous recommendation (if yes, the recommendation was adopted) or
  - whether it indicated a need to update the recommendation (if yes, the recommendation was adapted) or
  - whether development of an entirely new recommendation was warranted (a new recommendation was developed).

Methods

This exceptional surveillance process consisted of:

- Identifying inconsistencies between NICE's guideline on anaphylaxis and the RCUK's guideline and where the content overlaps.
- Considering the evidence used to develop NICE's guideline on anaphylaxis and the RCUK's guideline.
- Assessing the new evidence against current recommendations to determine whether or not to update sections of the guideline, or the whole guideline.
- Consulting with NICE's Consultant Clinical Advisers (CCAs).
- Consulting with topic experts from NICE's expert adviser's database about the proposals.

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Comparison of NICE's guideline on anaphylaxis with the Resuscitation Council's guideline

Timing and frequency of blood sampling for measuring mast cell tryptase

New evidence

Section 7 of the RCUK's guideline recommends that:

'Mast cell tryptase should be measured in all patients with suspected anaphylaxis where the diagnosis is uncertain.'

With regards to sample timing, it recommends:

'a) Minimum: one sample, ideally within 2 h (when peak tryptase levels generally occur) and no later than 4 h after onset of symptoms.

b) Ideally: take three timed samples:

1) An initial sample as soon as feasible – but do not delay treatment to take sample.

2) A second sample 1 – 2 h (but no later than 4 h) after onset of symptoms.

3) A third sample at least 24 h after complete resolution, or in convalescence.'

These recommendations are largely consistent with NICE's guideline on anaphylaxis which recommends:

'Record the time of onset of the reaction.

After a suspected anaphylactic reaction in adults or young people aged 16 years or older,

take timed blood samples for mast cell tryptase testing as follows:

- a sample as soon as possible after emergency treatment has started
- a second sample ideally within 1 to 2 hours (but no later than 4 hours) from the onset of symptoms.'

NICE's guideline on anaphylaxis makes the same recommendations for children aged less than 16 years but they are consider recommendations, due to extrapolation from studies of adult populations about mast cell tryptase utility in diagnosing anaphylaxis.

NICE's guideline differs from the RCUK's guideline because it is less directive and explicit.

It recommends:

'Inform the person (or, as appropriate, their parent and/or carer) that a blood sample may be required at follow-up with the specialist allergy service to measure baseline mast cell tryptase.'

Impact assessment

The RCUK recommend a third sample at 24-h 'because it provides a baseline tryptase value (as)...some individuals have an elevated baseline level and may be at greater risk of anaphylaxis in response to some triggers.' This is therefore a risk management recommendation that acts to identify people who may be at higher risk of a subsequent anaphylactic episode or who may have raised levels due to another condition.

The NICE guideline recommendations about the timing of blood samples are based on 13 studies that investigated mast cell tryptase's utility to confirm anaphylaxis in adults, no studies in children were identified. No information on the optimal timing of baseline measurement of mast cell tryptase was identified. Very low quality evidence from 7 observational studies (n=178 patients) reported that the timing of peak levels ranged from 1 minute to 6 hours (median 30 minutes).

The committee noted that 'some patients had unexplained high levels of mast cell tryptase (for example, in mastocytosis), and therefore in order to interpret the results correctly it was important for a baseline sample to be taken. To aid the interpretation of the results it was agreed that this baseline sample would need to be taken at least 24 hours after the onset of symptoms, probably during specialist follow-up (full guideline pages 25 to 26)'

This is the origin of the recommendation, which accommodates a third sample after at least 24 hours, although it is far less specific and directive than the RCUK's recommendation.

The RCUK's recommendation is based on that from the World allergy organization anaphylaxis guidance 2020 which states: 'It is recommended to evaluate baseline serum tryptase at least 24 h after resolution of anaphylaxis symptoms, even when tryptase concentration during episode remains within normal range'. This is a consensus recommendation that is taken from another consensus recommendation from the 2010 Mast cell activation working conference (Valent et al. 2011). This attempted to define mast cell activation (MCA) using 'accepted, objective, easily measurable, and commonly applicable parameters and criteria.' This is a goal predicated on knowing a person's baseline mast cell tryptase levels. The report states that 'the following criteria were regarded as indicative of systemic MCA: (1) typical clinical signs and symptoms, (2) substantial and transient increase in an MC-derived mediator in biological fluids…during or shortly after the acute event compared to a baseline level recorded either before the acute event or at least 24 h after all clinical signs and symptoms of the event have completely resolved.'

NICE's recommendation, accommodates taking a third post-anaphylaxis blood sample in a specialist allergy service. Feedback from a clinical colleague at NICE with experience in this area suggests this remains standard NHS practice. Considering this and that the evidence underpinning the RCUK's guideline is based on consensus, we do not propose to update the NICE guideline recommendations about blood sampling at this time.

April 2026: update to the timing and frequency of blood sampling for measuring mast cell tryptase

Background

Following the conclusion of this surveillance report we met with an anaphylaxis expert from the RCUK who commented that NICE's guideline recommendations about the use of MCT should not differ based on an individual's age. They also highlighted that the NICE guideline recommendations about MCT are different strengths and are conditional based on age as follows:

- NICE's guideline recommends measuring MCT for all people aged over 16 years with suspected anaphylaxis.

- NICE's guideline recommends considering measuring MCT in people aged less than 16 years only if it is thought to be venom-related, drug-related or idiopathic.

They commented that this is based on an erroneous interpretation of limited and dated evidence and that NICE's recommendations differ from those made by some other centres including the RCUK. The RCUK colleague pointed us to the evidence review underpinning the US's Joint Task Force on Practice Parameters (JTFPP)'s Anaphylaxis: A 2023 practice parameter update as a good source of up to date evidence about MCT utility.

Like the RCUK, the JTFPP do not make a distinction by age about the circumstances of when MCT should be measured in cases of suspected anaphylaxis. We therefore carried out a second surveillance review that investigated the utility of MCT measurement in children aged less than 16 years.

Methods

- Re-considering evidence underpinning the RCUKs guidelines about measuring MCT in children included in the Emergency treatment of anaphylactic reactions: Guidelines for healthcare providers.
- Considering the evidence underpinning the JFTPP's 2023 recommendations about measuring MCT in Anaphylaxis: A 2023 practice parameter update and the overall quality of the practice parameter.
- Considering recommendations about the use of MCT for anaphylaxis diagnosis from other centres including the World Allergy organization (WAO), the Royal College of Paediatrics and Child Health (RCPCH) and European Academy of Allergy and Clinical Immunology (EAACI).
- Re-considering the evidence about the use of MCT in children included in NICE's guideline.
- Consulting with a NICE Consultant Clinical Adviser.
- A search for studies about the utility of MCT for the identification of anaphylaxis in children and adults, that post-date the Anaphylaxis: A 2023 practice parameter update evidence review.

Impact assessment

We assessed the impact of evidence and intelligence gathered from the sources listed above and made the following impact assessment:

Recommendations about MCT testing in children from other guideline producers largely make no distinction between when to test in children compared with when to test in adults. However, like NICE's guideline, the recommendations are largely consensus informed by low quality evidence. While there is evidence post-dating NICE's guideline development about MCT use in children that is referenced by the JFPTT, there remains a paucity of evidence in children and experts are often limited to extrapolating data from adults to make recommendations about children.

New evidence post-dating the JFPTT practice parameter suggests clinical utility for MCT for diagnosis in children (sensitivity 53% to 72%) may be comparable with that in adults (sensitivity 73%). However, some of this evidence is mixed in its conclusions. For example, 1 study in children suggests MCT is only elevated in severe reactions while another reports no correlation between severity and tryptase level.

We did identify some evidence that is limited in volume and quality that milk-related anaphylaxis causes elevated tryptase levels and that MCT may be useful for diagnostic work up in these cases. There is recent evidence from epidemiological studies that milk is the most common cause of food-related anaphylaxis fatality in children less than 16 years old. However, this evidence is not enough on its own to warrant amending recommendations about when to measure MCT in children.

While organisations including the WAO, The EAACI, the RCUK and the RCPCH do not make separate recommendations for children and adults, their recommendations are largely consensus. They are informed by very low quality evidence for children which is limited in volume resulting in experts relying on extrapolation from evidence from adult populations. Due to the poor quality and sometimes mixed evidence for children about MCT utility, NICE's guideline is assessed as being correct in making a separate weaker 'consider' recommendation for children and a stronger 'offer' recommendation for adults.

Conclusions

NICE's guideline having separate recommendations about MCT testing for people older and people younger than 16 years who have been treated for suspected anaphylaxis, remains valid. While other guideline producers do not do this, the weaker

recommendations in NICE's guideline for children more appropriately reflect the greater uncertainty around the utility of MCT testing in children resulting from a lower volume of evidence.

We will add the topic of anaphylaxis caused by cow milk allergy in children to the issues log for NICE's guideline.

Duration of the post-anaphylaxis observation period

Anaphylaxis can be followed by a biphasic reaction (BR); a repeat episode at a relatively short interval after the first in the absence of any further obvious exposure to a causal allergen.

New evidence

To mitigate BRs theRCUK's Emergency treatment of anaphylaxis guideline (page 43) recommends observation periods stratified by risk of 2 hours, at least 6 hours and at least 12 hours. The latter duration is longer than the NICE guideline currently recommends, and NICE's guideline does not explicitly stratify by defined risk criteria other than suggesting that the response to treatment may indicate risk of BR.

NICE's guideline recommends that 'Adults and young people aged 16 years or older who have had emergency treatment for suspected anaphylaxis should be observed for 6 to 12 hours from the onset of symptoms, depending on their response to emergency treatment. In people with reactions that are controlled promptly and easily, a shorter observation period may be considered provided that they receive appropriate post-reaction care prior to discharge.'

NICE's guideline also recommends that 'Children younger than 16 years who have had emergency treatment for suspected anaphylaxis should be admitted to hospital under the care of a paediatric medical team.'

NICE's guideline recommendations about post-anaphylaxis observation periods are based on expert opinion as no studies were identified investigating an optimal observation period (full guideline page 34 section 3.2.3). As a result, the committee made a recommendation for research on length of observation period following emergency treatment for

anaphylaxis. This recommends an RCT that compares differing observation durations.

The RCUK guideline recommends 12 hours or more in the following circumstances:

- Severe reaction requiring >2 doses of adrenaline.
- Patient has severe asthma or reaction involved severe respiratory compromise.
- Possibility of continuing absorption of allergen, for example, slow-release medicines.
- Patient presents late at night, or may not be able to respond to any deterioration.
- Patients in areas where access to emergency care is difficult.

This is a 'weak' recommendation because it is based on what the RCUK assessed as very low certainty evidence. The new evidence for stratification of observation by risk identified by the RCUK that is in scope for NICE's guideline, includes 3 studies: Kraft et al. 2020, Lee et al. 2015, and Kim et al. 2019. The RCUK guideline's Evidence to Decision Framework (page 29) describes the rationale for this stratified approach (this is a supplement to Dodd et al. 2021).

Lee et al. 2015 is a meta-analysis of 27 observational studies (n=4,112, 192 BRs, including 10 studies of paediatric patients n=1,473, 54 BRs). The study reports that the median onset of a BR is 11 hours with a range of 0.2 to 11.0 hours. The ages of the participants included are not described in the abstract. The study reports that food as the allergen lowers the risk of BR (odds ratio [OR] 0.62, 95% confidence interval [CI], 0.4 to 0.94). Unknown triggers were associated with an increased risk of a BR (pooled OR 1.72, 95% CI, 1.0 to 2.95). Initial presentation with hypotension was also associated with the development of a BR (pooled OR 2.18, 95% CI, 1.14 to 4.15). Results for children are not reported separately. The study is included in the 2016 surveillance of NICE's guideline, which assessed it as not being enough on its own to warrant updating recommendations. The surveillance review reported that topic experts (TEs) said that new evidence was available about post-anaphylaxis observation periods but that they provided no references.

Kraft et al. 2020 is an analysis of registry data from n=9,171 cases from 11 countries, 10 European, not including the UK, and includes 2,187 children (<17 years). It reports a BR rate of 4.7% (n=435) with 60.5% (n=225) occurring within 12 hours after initial anaphylaxis; 23.9% (n=89) between 12- and 24-hours; and 15.6% (n=58) occurring after 24-hours. The rate of biphasic reactions did not significantly differ between children (5.1% [4.3% to 6%])

and adults (4.6% [4.1% to 5.1%]). The study reports that the following factors increased the risk of BR: reaction severity (grade III/IV versus grade II (OR 1.34; 95% CI: 1.1 to 1.62); multiorgan involvement; skin, gastrointestinal, severe respiratory, and cardiac symptoms; anaphylaxis caused by peanut/tree nut (OR 1.78; 95% CI: 1.38 to 2.23) or an unknown elicitor (OR 1.96; 95% CI: 1.41 to 2.72); and exercise as a cofactor (OR 1.44; 95% CI: 1.17 to 1.78).

Kim et al. 2019 is a meta-analysis of 12 studies (n=2,890 anaphylactic episodes, with 143 BRs) including adults and people of 'unidentifiable' age. It reports that 1-hour of observation achieved a 95% negative predictive value (NPV) and 6-hour or more, 97%. The NPV increased with longer observation periods with the trend of increasing NPV slowing after 6-hours. Incidence at 1- and 4-hours was 0.45 (95% CI 0.20 to 1.04) and 0.41 (95% CI 0.19 to 0.87) per 100 person-hours. After 8-hours an NPV > 98% was reported (incidence <0.10/100 person-hours). The authors conclude that although longer observation duration identified more people, a decreasing incidence is observed and a 6 to 12-hours observation window is probably practical.

Evidence provided by topic experts

A TE highlighted Dribin et al. 2025, a retrospective cohort study of children (n=5,641, median age 7.9 years, IQR 3.3 to 13.1) which investigated the incidence and timing of repeat adrenaline dosing based on initial reaction severity. The primary outcome was time from first dose to last dose of intramuscular or intravenous adrenaline administered before or during the emergency department stay. The study aimed to estimate the time threshold when there was <2% increase in the cumulative incidence in repeat adrenaline dosing as the observation time increased by 1-hour. The authors comment that <2% was 'a clinically acceptable risk' of receiving adrenaline after discharge.

Time to last repeat adrenaline dose

Time from first to final repeat dose of adrenaline	2 hours	4 hours	6 hours	8 hours	<2% incidence threshold (mins) (95% CI)	Proportion receiving a repeat dose after the <2% incidence threshold
Whole group (n=5,641)	4.7%	1.9%	1.1%	0.8%	115 (105, 122)	5.0%
Anaphylaxis without respiratory or cardiovascular involvement (n=1,070)	3.8%	1.3%	0.3%	0.1%	105 (54, 135)	4.1%

Time from first to final repeat dose of adrenaline	2 hours	4 hours	6 hours	8 hours	<2% incidence threshold (mins) (95% CI)	Proportion receiving a repeat dose after the <2% incidence threshold
Anaphylaxis with respiratory involvement but not cardiovascular (n=4,070)	4.5%	2.0%	1.3%	1.0%	109 (98, 118)	5.2%
Anaphylaxis with cardiovascular involvement (n=495)	7.5%	2.8%	1.2%	0.8%	161 (125, 249)	4.4%

This study suggests only a small proportion of children required repeat adrenaline doses, and that most received their last dose within a 2-hour window except for those with anaphylaxis with cardiovascular involvement. Risk factors for repeat adrenaline were severe respiratory (OR 1.47, 95% CI 1.16 to 1.84) or cardiovascular involvement (OR 3.18, 95% CI 2.35 to 4.17).

Following discharge 1.5% (n=83) had an emergency department (ED) revisit within 72-hours related to the original episode of which 33 of 83 received adrenaline. Of 2,562 patients who received pre-ED adrenaline 84.2% did not receive repeat adrenaline in the ED.

Some limitations of this study are that it uses final dose as a proxy for stability rather than the timing and rates of BR; it was conducted in the US healthcare system so it's relevance to a UK population may be questionable; and it excludes people transferred from other healthcare providers and those with MCA disorders. The latter criteria may both have led to the exclusion of more severe anaphylaxis cases that are more likely to require longer observation periods.

Further searches (Elicit, PubMed, Google Scholar) identified Short et al. (2024) a retrospective cohort study of children (n=292, mean age 8.8 years SD +/-5.7) investigating the frequency and timing of BRs. Participants were observed for an average of 233.1 minutes in line with NIAID (United States National Institute of Allergy and Infectious Diseases) recommendations of 4 to 6 hours. N=10 experienced a BR, 6 within an average of 96.3 minutes after initial symptom resolution and 4 between 10 and 33 hours after resolution. It reports no significant difference in the number of symptoms at anaphylaxis onset (cardiac, respiratory, GI, mucosal) or time to first adrenaline dose between groups. This suggests it is very difficult to definitively predict those at risk of a delayed BR, although n=10 is a very small number of events from which to make generalisations.

Impact assessment

Adults aged 16 years and above

NICE's guideline recommendations about duration of observation period are based on consensus. The RCUK's guideline is informed by new evidence, some of which was highlighted during the 2016 surveillance review along with a small signal of change from TEs. Although the RCUK considered the new evidence to be of low certainty, they considered it sufficient to warrant a change in recommendations.

The RCUK note in Emergency treatment of anaphylaxis (section 8.2) that the 'previous RCUK guideline referred to the NICE 2011 recommendation that patients over 16 years of age should be observed for 6 to 12 hours from the onset of symptoms. However, recent evidence suggests that this strategy may miss over 50% of biphasic reactions in the 5% of patients who experience them.'

The figure of 50% is likely taken from Lee et al. 2015 that reports that the median onset of a biphasic reaction is 11-hours. Additionally, Kraft et al. 2020 reports that 40% of BRs happened >12-hours after onset of symptoms.

In addition to duration of observations, the RCUK, also based on this new evidence, have recommended stratifying duration according to the presence of risk factors which are additional to those in NICE's guideline, which includes only response to treatment. Furthermore, the RCUK provide some indication of the level of risk from these factors by basing the duration of post-anaphylaxis observation on their presence or absence. It has been noted by a clinical colleague at NICE that in their experience, a 6-hour observation period is often promoted to staff. However, they also noted that a stratified approach with a clear rationale, may enable observation periods to be reduced in some people, and will also enable clearer communication with patients about the duration of observation periods.

Eight out of 9 TEs consulted as part of this exceptional review agreed with this proposal, noting that stratification by risk is a clinically sound strategy and consistent recommendations between the RCUK and NICE are welcome. We therefore propose that NICE's recommendation is replaced with the RCUK's Emergency treatment of anaphylaxis recommendations about a risk-stratified approach to the length of in-hospital observation following anaphylaxis (page 43).

Children aged less than 16 years

The RCUK's recommendations for a stratified approach includes infants, children and adults, although it acknowledges that children less than 16 years old should be subject to 'additional consideration' (see RCUKs EtD table 10 page 29). Two of the 3 pieces of new evidence that were not considered during NICE's guideline development include a significant proportion of children. Additionally, new evidence from a large US cohort provided by a TE during consultation on this exceptional surveillance, reports that most children with suspected anaphylaxis are stabilised within 2-hours following their last dose of adrenaline.

We consulted with TEs about only applying a stratified approach to adults; 3 TEs disagreed with this and 5 agreed. Several commented that there is an increase in cases of anaphylaxis which is largely driven by children, a claim supported by evidence (Bassegio et al. 2018). A TE noted that there is no rationale to justify not stratifying observation duration by risk factor for children as the RCUK recommends this approach. They commented that to not do so misses the opportunity to improve patient experience and make cost-savings. Another TE noted that some paediatric wards already have short stay observation units.

Based on this, it proposed that NICE's recommendation is also replaced with that from the RCUK about a risk-stratified approach to the length of in-hospital observation following anaphylaxis.

Previous surveillance reviews

Lee et al. 2015 about post-anaphylaxis observation periods is included in the 2016 surveillance of NICE's guideline. It was assessed as having not being enough on its own to warrant updating recommendations. The review reported that TEs said that new evidence was available about post-anaphylaxis observation periods.

The 2014 evidence update did not identify any impacting evidence.

System intelligence

We received information from a member of the RCUK notifying us of their updated guidelines. They suggested NICE's guideline was out of date because of new RCUK recommendations about blood sampling and post-anaphylaxis observation.

We consulted with topic experts (TEs) about the proposals to adopt the RCUK's recommendations about stratifying observation period, based on the presence of risk factors.

Consultation with topic experts

We consulted with TEs about the proposal to replace the NICE guideline recommendations about post-anaphylaxis observation periods for people 16 years or older with the RCUK's recommendations, and about the wording of the proposed recommendations. We provided TEs with draft wording adapted from the table on page 43 of the RCUK's Emergency treatment of anaphylaxis. We had responses from 9 TEs that included: a GP with an extended role in allergic medicine; a matron with an extended role in emergency and acute medicine; a nurse adviser and health visitor; a consultant in paediatric emergency medicine; a consultant nurse in adult immunology and allergy; a consultant paediatrician; a consultant paediatric allergist; 2 consultants in emergency medicine; and a professor of paediatric allergy.

Eight of 9 respondents agreed with the proposal to replace NICE's recommendation about people aged over 16 years with the RCUK's recommendations. TEs commented that the proposal made practical sense and would ensure clarity. They commented that the RCUK's guidelines are robust, evidence-based, and that there is a good clinical rationale for stratifying observation period durations according to risk. One TE noted that the proposal would address a current gap in NICE's guideline about observing people who are at increased risk for longer than 12 hours. One TE did not disagree per se but had concerns that the proposed amendment fails to adequately highlight the information needs for safe discharge as per section 8.3 of the RCUK guidance. The latter includes a bulleted list of recommendations taken from NICE's guideline about steps to take before discharge, so is assessed as being largely consistent with NICE's guideline.

However, 2 other TEs also commented that the draft wording provided would benefit from

the addition of wording that recommends that a patient should be assessed by a senior clinician before a decision is made about length of observation period, further treatment and discharge. One TE commented that this was particularly important if fast track discharge is being considered for people who required 2 doses of adrenaline, but who have had a successful (negative) allergy challenge test. We will therefore amend the draft wording to ensure that it recommends that a patient should be reviewed by a suitably qualified and experienced clinician before a decision about length of observation period and discharge is made.

Another TE commented that the wording 'in some circumstances, it may be reasonable for some patients to be discharged after 2 hours despite needing 2 doses of intramuscular adrenaline, for example, following a supervised allergy challenge' has the potential to lead to wrong decisions. They commented that it should be modified to clarify that this is only the case if the other requirements for fast track discharge are met and the patient has been subject to senior review prior to discharge. We will amend the draft wording to reflect these comments and ensure clarity.

We asked TEs if they agreed with the proposal to retain the existing recommendation about observation periods for children; 5 agreed, 3 disagreed, and 1 was unable to comment on the treatment of children. The 3 who disagreed commented that the RCUK makes no distinction between the approach to the discharge of adults versus younger children. They commented that a risk-stratified approach would be of great benefit to low-risk children and their families, as well as to busy paediatric emergency departments who are seeing increasing anaphylaxis admissions. This comment is backed up by evidence provided by another TE.

The second TE noted there is no evidence to suggest children should be treated differently; another TE noted that it makes little sense to amend guidance for adults and not for children as the increase in cases is being driven 'almost wholly' by children. They noted that children are at lower risk of biphasic reactions (BRs) and provided new evidence (Dribin et al. 2025, see impact assessment in evidence provided by topic experts) that suggests for most children treated for anaphylaxis without cardiac involvement a 2-hour observation window is appropriate.

The TEs who agreed with our proposal to not use a risk-based approach with children emphasised that children may not be able to verbalise the signs of BRs. They noted that longer observation periods will allow time to check on children's carers' knowledge of anaphylaxis management. This issue is covered by NICE's guideline recommendations

about discharging patients which includes a recommendation about educating parents and carers of children treated for anaphylaxis. One TE highlighted that some paediatric departments already have short stay observation units and suggested the wording could be amended to reflect this.

Budget impact and economic considerations

Recommending a stratified approach to post-anaphylaxis observation periods should act to reduce resource as evidence suggests the majority of people would be discharged after shorter observation times.

System impact

There are system benefits of having consistent and complimentary recommendations between NICE's guideline and the RCUK's guideline. The current inconsistency between 2 respected recommendation producing centres may result in confusion and uncertainty in the system.

Population impact

BMJ Best Practice describes anaphylaxis as a severe, generalised or systemic hypersensitivity reaction, characterised by rapidly developing life-threatening airway and/or breathing and/or circulation problems usually associated with skin and mucosal changes. The lifetime prevalence of anaphylaxis is estimated at approximately 1 in 1,333 people.

The prevalence of BRs is estimated at about 5% of anaphylaxis cases. The RCUK suggest fatality from BRs is 'very rare' and quote data from the European anaphylaxis registry from 2011 to 2019 (Kraft et al. 2020). This reports that 9,000 cases of anaphylaxis resulted in 28 deaths of which none were attributable to the 435 BRs recorded.

Health inequalities

None identified relating to the issues covered by this surveillance review.

Overall proposal

Following consultation with topic experts we propose to:

- replace NICE's guideline recommendations about post-anaphylaxis observation periods in adults aged 16 years and older and children, with the Resuscitation Council UK's (RCUKs) recommendations about a risk-stratified approach to the length of in-hospital observation following anaphylaxis.
- not update recommendations about the timing and frequency of blood sampling.

Addendum – Updating NICE's guideline with the RCUK's recommendations about post-anaphylaxis observation periods

Introduction

This surveillance report's proposal to replace NICE's guideline recommendations about post-anaphylaxis observation periods in adults aged 16 years and older and children with the RCUK's recommendations about a risk-stratified approach to the length of in-hospital observation following anaphylaxis was approved in July 2025. Risk-stratified recommendations as recommended by the RCUK were assessed by NICE as having the potential to improve patient care by ensuring that people are not unnecessarily detained while those at greater risk of biphasic reaction (BR) are observed for a safe duration of time. They were also assessed as having the potential to be cost saving for the NHS by freeing up emergency department capacity.

As the proposed wording of new recommendations was to be based on RCUK recommendations with clarifications agreed with an RCUK topic expert, the update was carried out by NICE's surveillance team and publishing team without the need of a full evidence review. Work began in August 2025.

Update methods

- Working closely with a topic expert at the RCUK, who is part of the RCUK's anaphylaxis working group and co-author of the RCUK's emergency treatment of anaphylactic reactions, to approve adapted wording and clarify RCUK recommendations as required.
- Consulting with a NICE CCA with expertise in the management of anaphylaxis about additions and amendments to NICE's guideline.
- Working with a NICE senior guidance content designer to ensure new recommendations are coherent with existing recommendations and meet with NICE's writing and presentational standards.

- Consulting with NICE's guideline stakeholders about all substantive changes to the guideline (see stakeholder consultation).
- Sign-off on the recommendations for publication after consideration by NICE's Guideline Executive.

The areas updated

- Recommendations 1.1.7 to 1.1.10 have been added. These are adapted from the RCUK's guidance and recommend a risk-stratified approach to the duration of the period of observation following treatment for suspected anaphylaxis in the emergency setting prior to discharge. They apply to all age groups.
- Recommendation 1.1.11 has been created which recommends admitting children aged less than 16 years if they cannot be discharged after 2 hours of observation in accordance with the criteria in recommendation 1.1.7. This is to ensure children access the most appropriate care pathway if a longer period of observation is required.
- Recommendations 1.1.15 and 1.1.16 have been updated and restructured to make it clear that at discharge, prescribers should offer 2 in-date adrenaline auto-injectors (AAIs), with a brand-specific demonstration of their use and advice to always carry them, in line with MHRA and RCUK guidance.
- Recommendation 1.1.15 has also been updated to recommend not offering AAIs to patients with anaphylaxis resulting from a drug allergy, where the drug has been identified and can be subsequently easily avoided. This is to align NICE's guideline with RCUK and BSACI (British Society for Allergy & Clinical Immunology) guidance.
- The use of 'anaphylaxis' has been used in place of 'anaphylactic reaction' throughout the recommendations in line with current best practice.

Stakeholder consultation

We carried out a 2 week consultation on the draft recommendations, which focussed on substantive changes. Full stakeholder questions, their comments and our responses can be seen in appendix A, but in brief we received 8 responses from the following organisations: RCUK, Royal College of Anaesthetists, General College of Dentistry, South Eastern Health and Social Care Trust, Royal College of Pathologists, Association of Paediatric Emergency Medicine, British Paediatric Allergy, Immunity and Infection Group,

and NHS England.

We asked 4 questions about the substantive changes to NICE's guideline and 1 question about whether there was any health inequalities associated with anaphylaxis that NICE's guideline could better address. There was strong support from stakeholders for NICE's guideline adopting the RCUK's recommendations (7 agreed, and 1 thought 6 to 12 hours of observation was adequate) about post-anaphylaxis observation periods. Stakeholders welcomed the consistency with the RCUK guidance.

There was also strong support for amending discharge recommendations to make it clearer that 2 AAIs should be offered to people who need it prior to discharge and that this was not needed in cases of a drug-induced anaphylaxis where the drug allergen was known and could be subsequently easily avoided; 7 stakeholders agreed and 1 disagreed. The latter noted the provision of AAIs may be difficult for smaller services out of hours. No stakeholder disagreed with the update to not offer AAIs in cases of drug-induced anaphylaxis where the drug can be easily avoided.

There were several suggestions made by stakeholders about the wording and structure of the recommendations that improved their clarity and which we adopted, briefly these were:

- 2 stakeholders commented that not all children require admission following treatment for suspected anaphylaxis. They commented that many families are experienced in dealing with the post-anaphylaxis period following resolution of symptoms after treatment, and the appropriate period of in-hospital observation. We amended recommendation 1.1.7 to say only those children who could not be discharged after 2 hours of observation should be admitted based on these responses, and on comments from a NICE clinical colleague with anaphylaxis expertise.
- We added the word 'when' to recommendation 1.1.7 bullet 3 based on stakeholder feedback, for example, 'the person already has 2 in-date adrenaline auto-injectors and knows how and when to use them.'
- Stakeholders highlighted that the 2011 version of NICE's guideline was confusing and unclear with respect to the number of AAIs that should be offered to patients. They noted that NICE's guideline seemed to be suggesting a clinician should offer 3 AAIs. Offering 2 AAIs is in line with current MHRA guidance. We amended recommendation 1.1.15 to make it explicit that patients should be offered 2 AAIs before discharge.

- Stakeholders commented that intranasal adrenaline (EURNeffy) has been licensed for people weighing 30 kg or more and that recommendations should be amended to reflect this event. EURNeffy licensing was also raised by RCUK colleagues, however, currently there is limited evidence for EURNeffy's effectiveness. We are tracking an ongoing trial about EURNeffy which we will assess when it publishes, and we will continue to monitor for other emerging evidence about intranasal adrenaline. We have also highlighted this area to the NIHR.

Conclusion

NICE's Guideline Executive agreed publication of the updated recommendations. In addition, for final publication, it was decided that the changes were substantive enough to warrant replacing NICE's existing guideline (CG134) with the new NICE guideline (NG258).

ISBN: 978-1-4731-9534-9