National Institute for Health and Care Excellence

4-year surveillance (2016) – Anaphylaxis (2011) NICE guideline CG134

Appendix B: stakeholder consultation comments table

Consultation dates: 19 August 2016 to 9 September 2016

Do you agree with the proposal not to update the guideline?

Stakeholder	Overall response	Comments	NICE response
Department of Immunology & Allergy Royal Victoria Infirmary Newcastle upon Tyne	None	None	Thank you.
Sunderland Royal Hospital	Agree	None	Thank you for your response.
Guy's and St Thomas NHS	Agree	None	Thank you for your response.
Royal College of Anaesthetists	Agree	No current reason to update, but results from a major national on-going study relating to Perioperative Anaphylaxis "NAP6" will become available during 2017 and 2018. Please see the following URL for more detail: http://www.nationalauditprojects.org.uk/NAP6home	Thank you for your comment. The NAP6 study falls within the scope of CG134. Although no specific recommendations about perioperative anaphylaxis after administration of anaesthesia are made in the clinical guideline, we anticipate that the results of this study may inform future surveillance review decisions. As no data from the national audit are currently available to determine whether it will have any impact on guideline recommendations, we will monitor the progress of this study and the results will be considered at the next surveillance time point.
Association of Anaesthetists of Great Britain and Ireland (AAGBI)	Disagree	The Royal College of Anaesthetists along with relevant stakeholders which includes the AAGBI and the British Society of Allergists and Clinical Immunologists, BSACI) are undertaking a national audit of anaphylaxis associated with anaesthesia, NAP6. This national audit	Thank you for your comment. The NAP6 study falls within the scope of CG134. Although no specific recommendations about perioperative anaphylaxis after administration

		project will review over 3 million anaesthetics given across the UK over a one-year period and thereby identify as accurately as possible the true incidence or perioperative anaphylaxis. Adherence to current standards of care (acute management and subsequent allergy clinic referral) will be assessed. The project is scheduled to publish its finding in 2018 (within the next 3 years). Detail of clinical presentation, management, initial investigation, immediate and long term outcomes and referral for allergist review will be made known for the first time in the UK population. Ability to adhere to current guidance will also be demonstrated. This large national audit will have a great deal of information with which to advise the NICE guideline review.	of anaesthesia are made in the clinical guideline, we anticipate that the results of this study may inform future surveillance review decisions. As no data from the national audit are currently available to determine whether it will have any impact on guideline recommendations, we will monitor the progress of this study and the results will be considered at the next surveillance time point.
NHS England	Agree	No comments	Thank you for your response.

Do you agree with the proposal to put the guideline on the static list?

Stakeholder	Overall response	Comments	NICE response
Department of Immunology & Allergy Royal Victoria Infirmary Newcastle upon Tyne	None	None	Thank you.
Sunderland Royal Hospital	Agree	None	Thank you for your response.
Guy's and St Thomas NHS	Agree	None	Thank you for your response.
Royal College of Anaesthetists	Disagree	Results from a major national on-going study relating to Perioperative Anaphylaxis "NAP-6" will become available during 2017 and 2018. Whilst NAP6 is an observational study, the scale and scope of the study may produce data that is of direct relevance to this guideline. Please see the following URL for more detail: http://www.nationalauditprojects.org.uk/NAP6home	Thank you for your comment. The NAP6 study falls within the scope of CG134. Although no specific recommendations about perioperative anaphylaxis after administration of anaesthesia are made in the clinical guideline, we anticipate that the results of this study may inform future surveillance review decisions. Since the study is ongoing, and will be published within the next few

			years, we propose not to place CG134 on the static list and the guideline will continue to undergo regular surveillance.
Association of Anaesthetists of Great Britain and Ireland (AAGBI)	Disagree	NAP6 will report in two years' time. If CG134 is placed on the static list, the timely-ness of the NAP6 data and its interpretation will be lost to NICE and their readership. Prospective audits of care on such a large scale provide valuable insights to current care and help shape future guidance.	Thank you for your comment. The NAP6 study falls within the scope of CG134. Although no specific recommendations about perioperative anaphylaxis after administration of anaesthesia are made in the clinical guideline, we anticipate that the results of this study may inform future surveillance review decisions. Since the study is ongoing, and will be published within the next few years, we propose not to place CG134 on the static list and the guideline will continue to undergo regular surveillance.
NHS England	Agree	No comments	Thank you for your response.

Do you agree with the proposal to remove the research recommendation:

Aside from mast cell tryptase, which other chemical inflammatory mediators offer potential as indicators of anaphylaxis?

Stakeholder	Overall response	Comments	NICE response
Department of Immunology & Allergy Royal Victoria Infirmary Newcastle upon Tyne	None	None	Thank you.
Sunderland Royal Hospital	Agree	There is no progress in this area and no new markers have been suggested but more work is done to look at the timing of the Mast cell tryptase testing, the evidence available till date as per the review evidence, the evidence support the NICE recommendations.	Thank you for your comment. A clinical question specific to the timing of mast cell tryptase testing is included in NICE CG134: "134–02 Should mast cell tryptase testing be performed in patients with suspected anaphylaxis? If so, what is the optimal timing for testing?" No randomised controlled trials or systematic reviews were identified in the evidence update and during the 4-year surveillance review. Observational studies proffered by topic experts were mainly in line with guideline recommendations. As a result, this clinical question will be

			reviewed during the next surveillance review.
Guy's and St Thomas NHS	Agree	None	Thank you for your response.
Royal College of Anaesthetists	Agree	None	Thank you for your response.
Association of Anaesthetists of Great Britain and Ireland (AAGBI)	Agree	IgE specific tests are not sufficiently reliable.	Thank you for your comment. No new studies evaluating chemical inflammatory mediators, other than mast cell tryptase, were identified at any surveillance time point. Furthermore, IgE testing to confirm the suspected cause of the anaphylactic reaction is currently outside the scope of NICE CG134.
NHS England	Agree	No comments	Thank you for your response.

Do you agree with the proposal to remove the research recommendation:

For how long should a person who has received emergency treatment for anaphylaxis be observed?

Stakeholder	Overall response	Comments	NICE response
Department of Immunology & Allergy Royal Victoria Infirmary Newcastle upon Tyne	None	None	Thank you.
Sunderland Royal Hospital	Agree	None	Thank you for your response.
Guy's and St Thomas NHS	Agree	None	Thank you for your response.
Royal College of Anaesthetists	Disagree	There is a major national on-going study relating to Perioperative Anaphylaxis "NAP-6" that may provide evidence that addresses this research question. Whilst NAP6 is an observational study, the scale and scope of the study is such that it is likely to produce data that is of direct relevance to this guideline. Please see the following URL for more detail:	Thank you for your comment. In light of the ongoing study you have highlighted, we propose not to remove this research recommendation from the NICE version of the guideline and the NICE research recommendations database.

		http://www.nationalauditprojects.org.uk/NAP6home	
Association of Anaesthetists of Great Britain and Ireland (AAGBI)	Agree	NAP6 will collect data on length of hospital admission following anaphylaxis. Levels of compliance with current guidance on length of stay will be reported.	Thank you for your comment. In light of the ongoing study you have highlighted, we propose not to remove this research recommendation from the NICE version of the guideline and the NICE research recommendations database.
NHS England	Agree	No comments	Thank you for your response.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Department of Immunology & Allergy Royal Victoria Infirmary Newcastle upon Tyne	Yes	It would be helpful to update the Guideline in respect of the number and strength of the adrenaline autoinjectors issued. There are now 3 available autoinjectors, one of which is marketed as a 500 mcg strength. It is unclear that for self-treatment more than 300 mcg is required for an adult, although this can be repeated. The company marketing the 500 mcg pen cites the Resuscitation Council Guidelines for anaphylaxis as the justification for using 500 mcg but these guidelines are designed for health professionals not for self-administration. GPs are beginning to prescribe these pens. I understand that the issue is still under MHRA/EMEA review, so it would be helpful if the NICE Guidelines could give authoritative advice.	Thank you for highlighting this issue. Approval of specific medications or medical device falls under the jurisdiction of the MHRA and the European Medicines Agency. As a result, NICE will wait for completion of MHRA and European reviews to establish whether the guideline could be impacted.
Sunderland Royal Hospital	Yes	I would like to point out couple of issues I have observed when the guidelines have been used / or discussed in teaching sessions: 1.1.4 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 1–2 hours (but no later than 4 hours) from the onset of symptoms.	Thank you for your comment. Many thanks for highlighting this. NICE has produced implementation tools that aim to help organisations put guidance into practice. In particular, there is a slide set available which provides key points to note about the guideline recommendations. Furthermore, the full guideline provides additional detail about the recommendations including an 'evidence to recommendations section' which describes how the Committee developed the recommendations and the links between the evidence and the recommendations. We have noted your

		The statement in red is not easily understood by some. If this was worded 'if the first sample was taken with in the first hour of the starting of the symptoms, a second sample ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms. 1.1.5 After a suspected anaphylactic reaction in children younger than 16 years, consider taking blood samples for mast cell tryptase testing as follows if the cause is thought to be venom-related, drug-related or idiopathic: • a sample as soon as possible after emergency treatment has started • a second sample ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms. The statement in red is not easily understood by some. If this was worded 'if the first sample was taken with in the first hour of the starting of the symptoms, a second sample ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms. Also in this recommendation, using the word specially … After a suspected anaphylactic reaction in children younger than 16 years, consider taking blood samples for mast cell tryptase testing as follows, especially if the cause is thought to be venom-related, drug-related or idiopathic:	feedback and will monitor this at the next surveillance review of the guideline.
Guy's and St Thomas NHS	No	None	Thank you.
Royal College of Anaesthetists	No	None	Thank you.
Association of Anaesthetists of Great Britain and Ireland (AAGBI)	No	None	Thank you.
NHS England	No Answer	None	Thank you.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
Department of Immunology &	Yes	It would be helpful to update the Guideline in respect of the number	Thank you for highlighting this issue.

Allergy Royal Victoria Infirmary Newcastle upon Tyne		and strength of the adrenaline autoinjectors issued. There are now 3 available autoinjectors, one of which is marketed as a 500 mcg strength. It is unclear that for self-treatment more than 300 mcg is required for an adult, although this can be repeated. The company marketing the 500 mcg pen cites the Resuscitation Council Guidelines for anaphylaxis as the justification for using 500 mcg but these guidelines are designed for health professionals not for self-administration. GPs are beginning to prescribe these pens. I understand that the issue is still under MHRA/EMEA review, so it would be helpful if the NICE Guidelines could give authoritative advice.	Approval of specific medications or medical device falls under the jurisdiction of the MHRA and the European Medicines Agency. As a result, NICE will wait for completion of MHRA and European reviews to establish whether the guideline could be impacted.
Sunderland Royal Hospital	Yes	I would like to point out couple of issues I have observed when the guidelines have been used / or discussed in teaching sessions: 1.1.4 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 1–2 hours (but no later than 4 hours) from the onset of symptoms. The statement in red is not easily understood by some. If this was worded 'if the first sample was taken with in the first hour of the starting of the symptoms, a second sample ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms. 1.1.5 After a suspected anaphylactic reaction in children younger than 16 years, consider taking blood samples for mast cell tryptase testing as follows if the cause is thought to be venom-related, drug-related or idiopathic: • a sample as soon as possible after emergency treatment has started • a second sample ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms. The statement in red is not easily understood by some. If this was worded 'if the first sample was taken with in the first hour of the starting of the symptoms, a second sample ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms. Also in this recommendation, using the word specially … After a	Thank you for your response. Many thanks for highlighting this. NICE has produced implementation tools that aim to help organisations put guidance into practice. In particular, there is a slide set available which provides key points to note about the guideline recommendations. Furthermore, the full guideline provides additional detail about the recommendations including an 'evidence to recommendations' section which describes how the Committee developed the recommendations and the links between the evidence and the recommendations. We have noted your feedback and will monitor this at the next surveillance review of the guideline.

		suspected anaphylactic reaction in children younger than 16 years, consider taking blood samples for mast cell tryptase testing as follows, especially if the cause is thought to be venom-related, drug-related or idiopathic:	
Guy's and St Thomas NHS	No	None	Thank you.
Royal College of Anaesthetists	No	None	Thank you.
Association of Anaesthetists of Great Britain and Ireland (AAGBI)	No	None	Thank you.
NHS England	No Answer	None	Thank you.