Proposal for a tryptase lateral flow device

By Vanessa Ankude, PhD
Immunology & Immunotherapy
(Clinical Immunology Services)

Supervisors – Dr Jennifer Heaney
and Professor Alex Richter

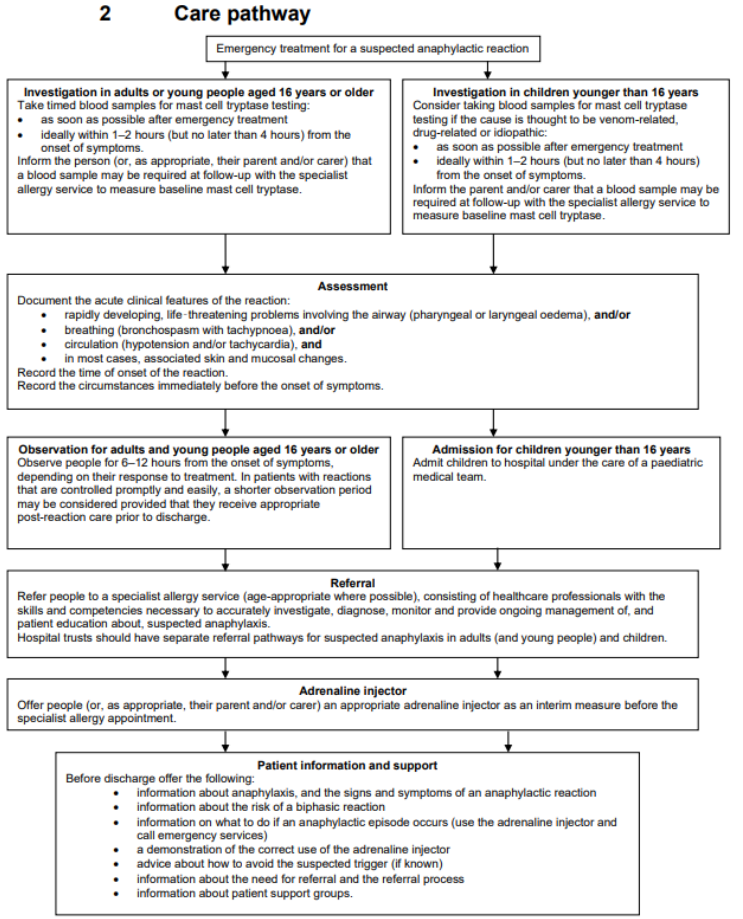
UNIVERSITY OF BIRMINGHAM

Why?

- **Current practice for diagnosing anaphylaxis (severe allergic reaction)**
  - NICE recommends at least 2 serial blood tryptase tests
  - Currently all performed in secondary care
  - Test uses laboratory automation
  - Only one commercially available test in UK at present

BUT!

- We don't follow guidelines!
- Samples are drawn at inappropriate times and 31% of patients have serial samples
- Only 54% of patients get referred for definitive care



2 Care pathway

Emergency treatment for a suspected anaphylactic reaction

Investigation in adults or young people aged 16 years or older
Take timed blood samples for mast cell tryptase testing:
- as soon as possible after emergency treatment
- ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms.

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.

Investigation in children younger than 16 years
Consider taking blood samples for mast cell tryptase testing if the cause is thought to be venom-related, drug-related or idiopathic:
- as soon as possible after emergency treatment
- ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms.

Inform the 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.

Assessment
Document the acute clinical features of the reaction:
- rapidly developing, life-threatening problems involving the airway (pharyngeal or laryngeal oedema), **and/or**
- breathing (bronchospasm with tachypnoea), **and/or**
- circulation (hypotension and/or tachycardia), **and**
- in most cases, associated skin and mucosal changes.

Record the time of onset of the reaction.
Record the circumstances immediately before the onset of symptoms.

Observation for adults and young people aged 16 years or older
Observe people for 6–12 hours from the onset of symptoms, depending on their response to treatment. In patients 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.

Admission for children younger than 16 years
Admit children to hospital under the care of a paediatric medical team.

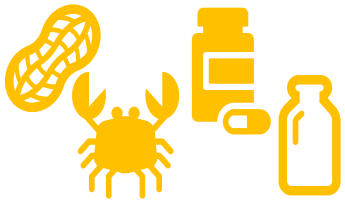
Referral
Refer people to a specialist allergy service (age-appropriate where possible), consisting of healthcare professionals with the skills and competencies necessary to accurately investigate, diagnose, monitor and provide ongoing management of, and patient education about, suspected anaphylaxis.
Hospital trusts should have separate referral pathways for suspected anaphylaxis in adults (and young people) and children.

Adrenaline injector
Offer people (or, as appropriate, their parent and/or carer) an appropriate adrenaline injector as an interim measure before the specialist allergy appointment.

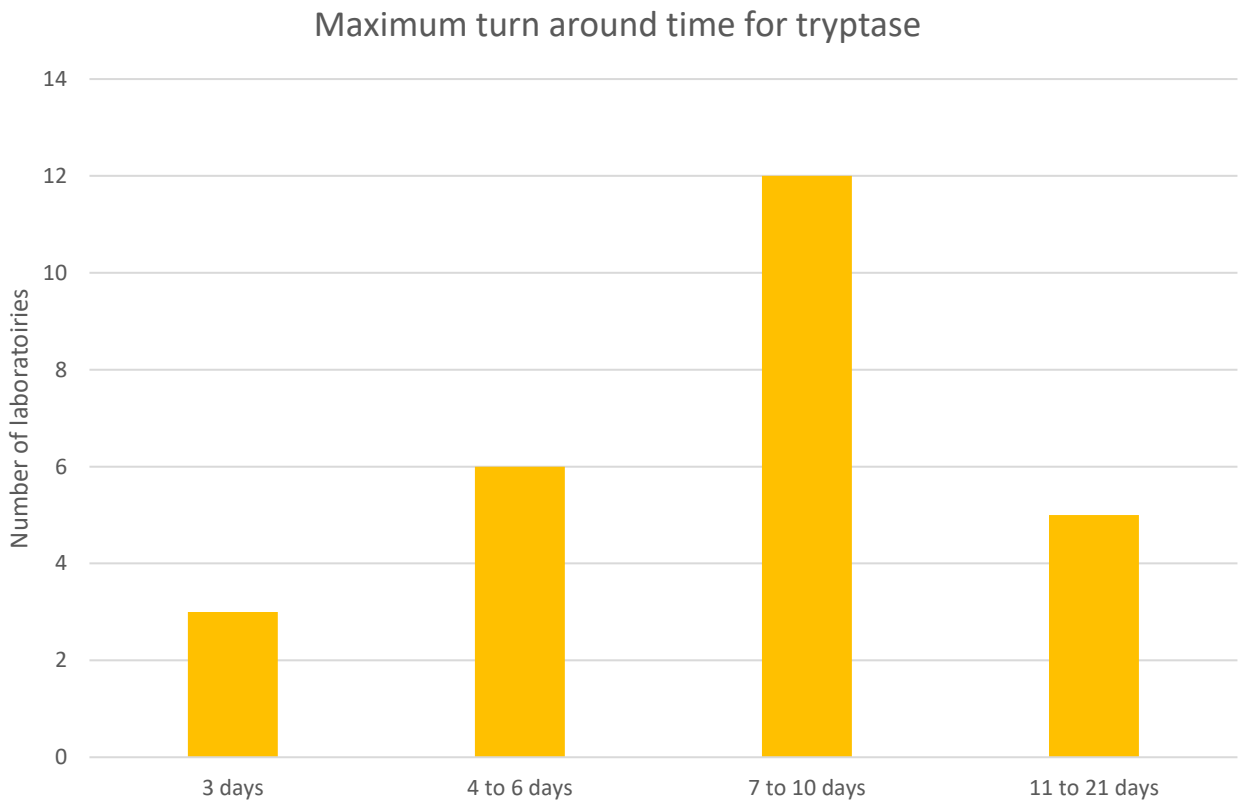
Patient information and support
Before discharge offer the following:
- information about anaphylaxis, and the signs and symptoms of an anaphylactic reaction
- information about the risk of a biphasic reaction
- information on what to do if an anaphylactic episode occurs (use the adrenaline injector and call emergency services)
- a demonstration of the correct use of the adrenaline injector
- advice about how to avoid the suspected trigger (if known)
- information about the need for referral and the referral process
- information about patient support groups.

Buka RJ et al. Anaphylaxis and clinical utility of real-world measurement of acute serum tryptase in UK emergency departments. *J Allergy Clin Immunol: Pract.* 2017;5(5):1280-1287.

Srivastava S et al. Systemic reactions and anaphylaxis with an acute serum tryptase ≥14 µg/L: retrospective characterisation of aetiology, severity and adherence to National Institute of Health and Care Excellence (NICE) guidelines for serial tryptase measurements and specialist referral. *J Clin Pathol.* 2014;67(7):614-9.

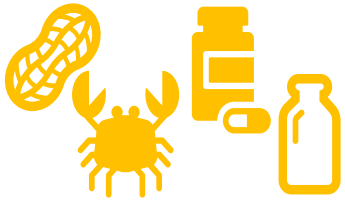


Given tryptase is the main test for diagnosis and guiding future management…



…there is a disconnect between the laboratory turn around time and clinical pathway and decision making

Busy acute clinicians must remember to act on results up to 3 weeks in the future – this may explain the low referral rate to specialist allergy services



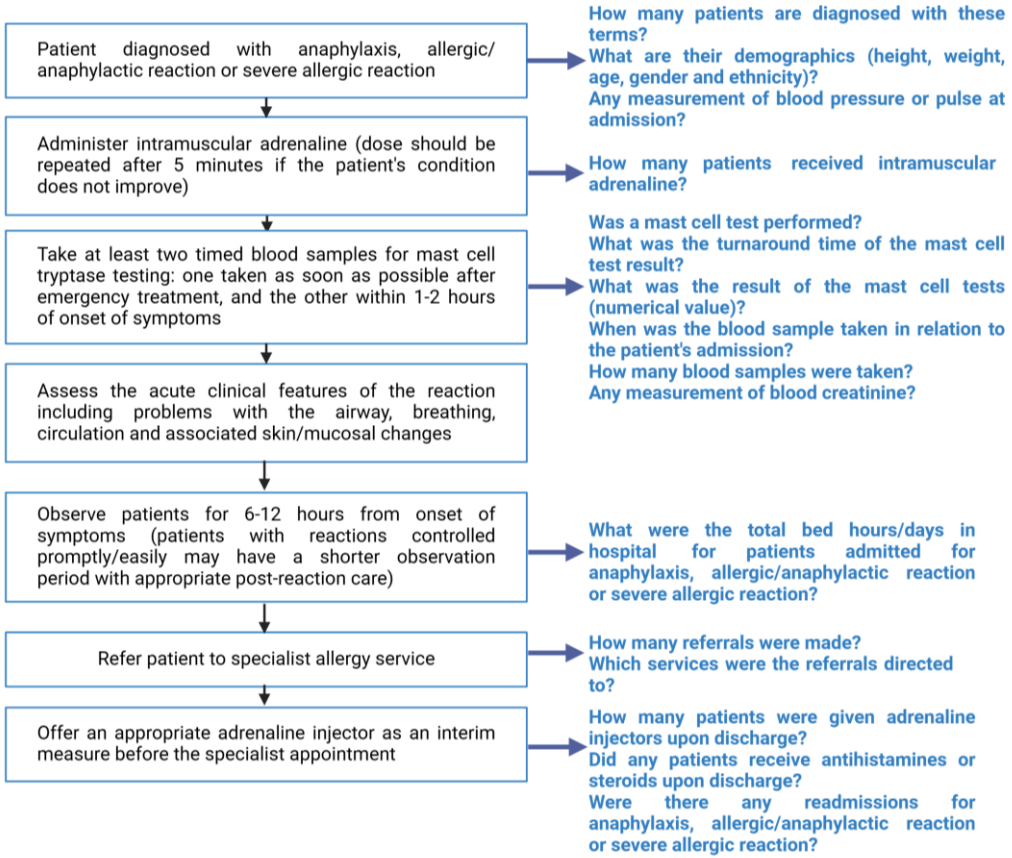
Is tryptase a useful test?

- Does the current test change the clinical pathway (is it useful)?

- Would a novel lateral flow device accelerate the clinical pathway and make it more compliant with NICE guidelines (and be more useful)?

Using real world data to explore clinical care pathways as a tool

Interrogating the role of the tryptase test in the acute anaphylaxis pathway



- Retrospective study using clinical data collected by PIONEER
- Examining the anaphylaxis pathway in Queen Elizabeth Hospital Birmingham from 2022-2024
- Using real world data rather than designing new trials
  - Cheaper
  - Quicker analysis and results

PIONEER
Health Data Research Hub

Establishing potential demand for a lateral flow from one hospital

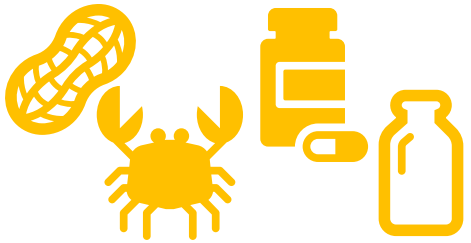
Anaphylactic incidences across UHB acute hospitals
UHB = University Hospitals Birmingham, QEHB = Queen Elizabeth Hospital Birmingham.

Year	Total number of cases	Total number of patients	QEHB number of cases	QEHB number of patients
2022	377	342	101	93
2023	386	373	113	109
2024	310	295	83	81

- QEHB had ~100 anaphylaxis cases a year from 2022-2024

PIONEER Health Data Research Hub

Situation Report



✓Establishing Pioneer model

✓Building prototype tryptase lateral flow

- Next steps:
  - Identify routes for funding to scale up and produce prototype
  - Establish the need and value from end users