

## DRUG ALLERGY LABELS IN THE ELECTIVE SURGICAL POPULATION



## DALES STANDARD OPERATING PROCEDURE

**This document concerns the practical aspects of conducting the pre-operative Patient Survey, its targeted follow-up and the Anaesthetist Survey.**

**\*Adult patients  $\geq 18$  years undergoing elective surgery are eligible\***

**\*The Patient Survey **must** be completed online\***

**\*You will **not** require the patient notes when surveying patients\***

**\*Pseudoanonymiser filled in = follow-up required; check your Junk Mail\***

**\*Anaesthetists on elective lists on study days must be surveyed\***

**\***All** consenting subjects, anaesthetists and patients, are accrued\***

**\***All** investigators must hold valid GCP training\***

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## DAILY ROUTINE

**All** investigators will need to have previously completed the [NIHR Good Clinical Practice](#) or [MRC Good Research Practice](#) (valid for 2 years) before they can sign up to collect data using the links provided to them by their Local Site Leads.

For study purposes most investigators will be anaesthetic trainees but they may be any doctor (FY1+), research nurse / practitioner or medical student (if supported by the local Principal Investigator).

On each day each investigator will need:

- A device capable of receiving NHS emails (either your own or the hospital's)
- A connection to hospital Wi-Fi (public or private) or to 3G / 4G
- Your personal sign-up email containing your personal weblink to the survey
- Theatre lists for all areas undertaking elective surgical work
- A copy of your local antibiotic prophylaxis guidelines and BNF

Each study day will involve:

-Patient Data Collection:

- Surveys the evening before for elective cases admitted the day prior e.g. cardiac
- Pre-op surveys of **all** remaining patients in your admissions unit / outside areas
- Targeted post-op follow-up for:
  1. Patients with  $\beta$ -lactam allergy labels who would otherwise be due these antibiotics as part of Trust antibiotic prophylaxis guidelines
  2. Patients with opioid allergy labels likely to be receiving opioids

-Anaesthetic Data Collection:

- Ensuring **all** anaesthetists working in elective theatres that day complete the survey once each

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## 1. STUDY WINDOW

Patient data collection runs on 3 locally-agreed days within the overall 6-week study period; these may be non-consecutive days.

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## 2. INCLUSIONS / EXCLUSIONS

Include:

- Adult patients  $\geq 18$  years undergoing **any elective surgical procedure** are included
- This includes procedures performed by: **surgeons, anaesthetists or interventional radiologists regardless of anaesthetic performed**, e.g. Caesarian section but also cataract surgery, EVAR or chronic pain interventions
- Under-18s, patients not consenting, patients in custody and patients without capacity are excluded

Exclude:

- Please **do not include** elective non-surgical procedures carried out by other specialties e.g. endoscopic procedures by gastroenterologists, cath lab procedures by cardiologists or flexible bronchoscopies by respiratory physicians
- **Do not include** any emergency / urgent / non-elective surgical procedures

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## 3. LOCATIONS AND TIMING FOR DATA COLLECTION

The priority is completing the initial patient surveys; follow-up data is 'same-day' but does **not** involve patient contact and is completed entirely from the notes.

Please consider that your hospital may have multiple areas where elective surgical patients are admitted (e.g. admission lounges, day units, wards). In addition, admission may not be on the day of surgery.

If patients are admitted the day before surgery e.g. for cardiac surgery or other complex cases they can be surveyed that day; this will save time the following day and help to avoid missing the first patients on the list.

Patients can only be approached after they have had their admission wristbands applied, i.e. identity + / - any allergy wristbands.

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#### 4. GETTING ONLINE / WI-FI & 3G / COMPUTERS ON WHEELS / NHS EMAILS

As part of the pre-sign-up process the Local Site Lead for each site will be sent a **site-specific** sign-up link once all R&D approvals for that site are in place.

This link is then distributed to all local data collectors who use it to generate their own custom online survey links; **these links are re-usable but each local investigator completes this sign-up process once per site using their NHS email.**

The primary patient survey can **only** be completed in real-time using the online tool provided. This must be on a device that can access your NHS email. You can use hospital Wi-Fi (public or private) or cellular (3G / 4G).

We suggest using an iPad or other portable device but the survey can also be done using an NHS computer on wheels (CoW). If using a personal portable device please ensure you have run system updates prior to collecting data.



Don't forget to check your Junk Mail folder when signing up and to add [Anaesthesia.Audit](#) to your safe list; you may need to repeat this step for the follow-up emails.

Signing up via NHS.net ([you@nhs.net](#))? Access NHS.net either via your [mobile web browser](#) OR by setting up NHS.net under mail accounts ([iPhone](#) or [Android](#)).

Signing up via Trust / Board emails ([you@trust.nhs.uk](#))? Depending on your hospital you may be able to access your Trust / Board email on your personal device. Your local eHealth department can advise.

If your hospital firewall is blocking our website you may also need to get eHealth to add our domain to their internet 'safe' list: <https://anaesthesia-audit.scot.nhs.uk/>

For infection control reasons, please don't forget to wipe down your device between patients.

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## 5. DIFFICULT INTERNET ACCESS

If access is difficult in one area consider using [personal hotspots](#) on devices from team members with better reception. It is possible to collect data on a form before moving to an area with reception to submit it but this is not recommended.

'Hotspots' are also a useful approach if you wish to use iPads that do not have built-in 3G / 4G.

It may be worth approaching your R&D department in advance to see if they can provide dedicated portable devices and / or access to hospital private wi-fi.

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## 6. ALLERGY VS ALLERGY LABEL VS SENSITIVITY

We seek to explore allergy labels. **An 'allergy label' is any reaction reported by the patient or noted on their wristband.** We appreciate that not all allergy labels represent an IgE-mediated reaction and that patients may use terms such as 'allergy' and 'sensitivity' inaccurately.

You should specifically **not** try to determine the true nature of these labels; the focus is on recording the reaction as described by the patient.

Please document anything the patient refers to as an allergy as 'allergy' and anything the patient refers to as a sensitivity as 'sensitivity'. A patient is considered to carry an allergy label if they report one or have been given a red allergy wristband (or Trust equivalent).

**We want to record all reactions** (both patient-reported and those recorded on wristbands); there are additional facilities in the survey to record non-drug allergy labels e.g. to pollen, needle phobia etc. as well as for any drugs not listed within the survey.

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## 7. CONSENT

This is a consenting research study. Consent is taken within the online survey (and the patient themselves should click the 2 buttons covering the consent agreement).

Onscreen the investigator is prompted to ask the patient:

**'I would like to ask you some questions about allergies and review your notes. Is that OK?'**

and

**'This will involve sharing non-identifiable data with other medical staff at other hospitals to help understand these kinds of problems. Is that OK?'**

If the patient answers 'Yes' to both of the above questions, this is recorded in the survey and constitutes the consent process. Then the patient hands the device back to the investigator and then the investigator continues the survey directly on the device **-the patient does not complete the survey themselves on the device.**

If the answer to either of these 2 questions is 'No' you will be prompted by the survey to confirm this response. Once confirmed the survey will end, i.e. no further questions can be asked to that patient.

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## 8. PRE-SURVEY QUESTIONS

All eligible consenting patients surveyed during the study are included regardless of allergy status, **i.e. patients without allergy labels / who answer 'No allergies' must still be asked the initial screening questions and have their data submitted.**

This is essential to provide denominator data and baseline demographics.

As well as standard demographics the following question is asked to all patients regarding atopy and urticaria:

**'Do you have hay fever, rhinitis, asthma, eczema or dust allergy and/or hives, urticaria, angioedema or a general tendency to itchy rashes or facial swelling?'**

This is included to collect information regarding possible predisposition to allergy.

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## 9. FOLLOW-UP: GENERAL POINTS

Follow-Up is targeted and **only** for patients with  $\beta$ -lactam and opioid allergies likely to be receiving these drugs; it's also from the patient's notes only.

If (and only if) patients are appropriate for Follow-Up, the REDCap system will prompt you to enter a pseudoanonymiser; this is standardised to help you keep track of which patients to follow up via theatre and list order (see below).

**Links to complete the follow-up surveys arrive via email (don't forget to check your Junk Mail and 'Mark as not junk'.**

If you don't have access to your NHS emails via a mobile device or are short on CoWs, it may be easier to take the notes to an NHS desktop computer in the post-op area rather than visa-versa.

If you do not complete Follow-Up on the study day the system will send reminders.

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## 10. THE PSEUDOANONYMISER

As above, follow-up is automatically targeted based on the data you input. **If you are asked for a pseudoanonymiser then the patient requires follow-up; if you can't see the follow-up email then check your Junk Mail.**

The pseudoanonymiser details you will be asked for are:

1. *Study Day* (D1, D2 or D3)
2. *Theatre* (select theatre number)
3. *Theatre Complex*. Select 'A' if your hospital has only 1 complex; if your hospital has more than 1 theatre complex, please agree with your data collector team which complex is designated as A, B, C etc. This also needs to include any non-theatre areas that you survey.
4. *Patient order on the list*. This must match the information on your copy of the list which will serve as the reference for later.

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## 11. B-LACTAM ALLERGY LABEL FOLLOW-UP

If a patient has a  $\beta$ -lactam allergy label and would otherwise be due  $\beta$ -lactam antibiotic prophylaxis under your Board / Trust guidelines you will be asked to follow them up to see what they have received; this can be completed at any point after the patient has received their antibiotics.

This is targeted follow up via email with a brief survey to be completed with the notes rather than face-to-face with the patient.

## 12. OPIOID ALLERGY LABEL FOLLOW-UP

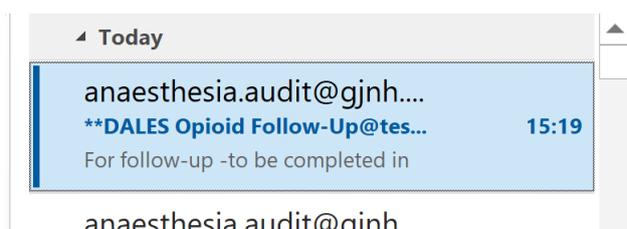
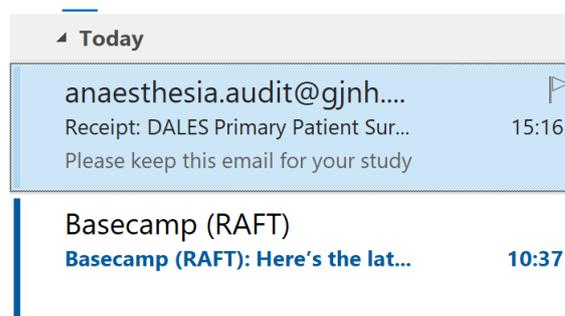
If a patient has an allergy label to opioids and is likely to be receiving them as part of their treatment you will be asked to follow up the patient. We consider any surgery other than cataract surgery a possibility for receiving opioid. This should be done on the day of surgery, i.e. the same day as the initial data collection has been carried out.

This is again targeted follow up via email with a brief survey to be completed with the notes rather than face-to-face with the patient.

## 13. ACCRUALS / SURVEY RECEIPTS

DALES is a [National Institute of Health Research Portfolio study](#); each consenting subject, anaesthetist or patient with or without allergies, counts for an accrual.

After **each** Anaesthetist Survey and Primary Patient Survey you complete you will receive an email receipt from Anaesthesia.Audit; this also includes receipts for patients who do **not** consent; this is clear in the receipt and such patients do not count for accruals.



Also look out for Follow-Up emails in between these emails; you will **not** receive a receipt after completing Follow-Up but you can re-open the link to confirm completion.

**As always, if you are not receiving any emails check your Junk Mail; receipts and the Follow-Up come from the same system so make sure you 'Mark as not junk'.**

You can use the email tester system below to ensure you can receive all the project emails; you should expect to receive two survey links in succession as well as a receipt for the second survey:

[https://anaesthesia-audit.scot.nhs.uk/mf/view.php?id=101162&element\\_1=DALES](https://anaesthesia-audit.scot.nhs.uk/mf/view.php?id=101162&element_1=DALES)

## HOW TO COLLECT ANAESTHETIST SURVEY DATA

- The Anaesthetist Survey runs concurrently with the Patient Survey, **i.e. the anaesthetists surveyed will be the ones working in elective theatres on the same 3 days as the Patient Survey**
- Anaesthetists will need to be identified ahead of schedule e.g. via theatre lists to avoid missing anyone; please don't omit your outside areas
- Intensive Care staff are **not** eligible
- If it is not possible to survey an eligible anaesthetist on the day for practical reasons then they may be surveyed at a more convenient time (provided it is completed within the 6-week overall DALES window)
- **The Anaesthetist Survey is best completed on paper** to allow simultaneous completion by multiple anaesthetists; paper copies can then be collected and bulk uploaded to Anaesthesia.Audit (REDCap) by data collectors
- Anaesthetists will complete the survey once only during study period, i.e. if they are at work on 2 or more of the study days they will not be re-surveyed
- All anaesthetists on a list are to be surveyed; if a more junior anaesthetist is assigned to a list or area, please survey them too
- Prescribing anaesthetic physicians assistants (PA(A)s) are included; if they are not prescribers, please do not survey them
- **Try to target the Anaesthetist Survey towards the end of the day;** data collection for the Patient Survey will take precedent at the start of the day but as lists get underway, more data collector time will become available to run the Anaesthetist Survey (this will also help to reduce any bias)

## HOW TO COLLECT DENOMINATOR SURVEY DATA

- **This is only made available to Local Site Leads** and should be a 'one-time' upload once **all** data collection at the site in question is complete.
- This survey covers survey numbers and background info on your centre regarding the availability of certain drugs and protocols / guidelines.

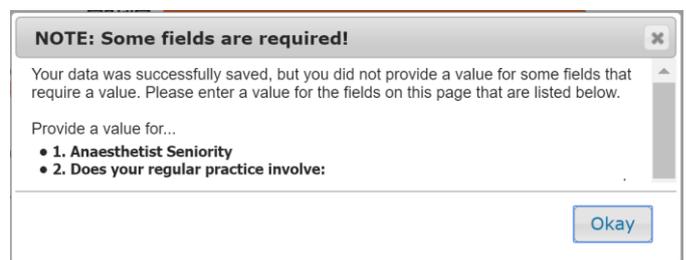
## AN IMPORTANT NOTE ON WARNINGS AND UPLOADING ENTRIES

We have tried to make the surveys as user-friendly as possible but there is still some inevitable complexity; the system will try to warn you if you are entering unusual data but will not stop you from doing so, e.g.:

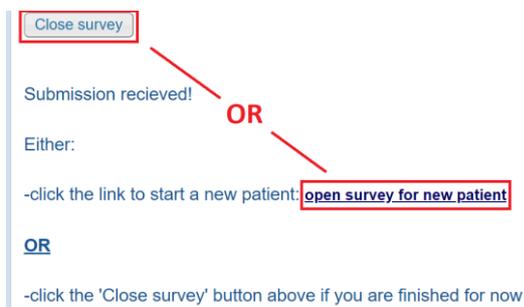
### \*MATRIX ERROR - PLEASE RE-CHECK INPUT\*

**\*WARNING!\*** You have ticked that the patient gives no history of allergy but have checked a +ve history of allergy and / or sensitivity in the Matrix.

Regarding incomplete data, if you have hit 'Submit' on a form and the system reports incomplete data **DO NOT** close the window; instead click 'Okay' to acknowledge the error pop-up and complete the missing fields(s) before submitting again. This will avoid data duplication / lost entries.



Regarding survey completion, when you have finished entering an individual patient or anaesthetist survey you **MUST** either:



-click the 'open survey for new...' link to start the next case

OR

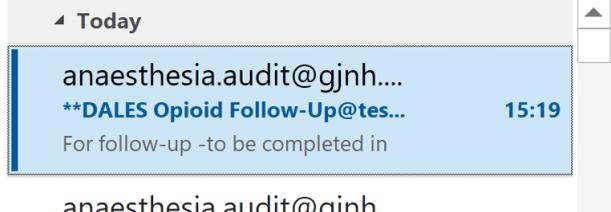
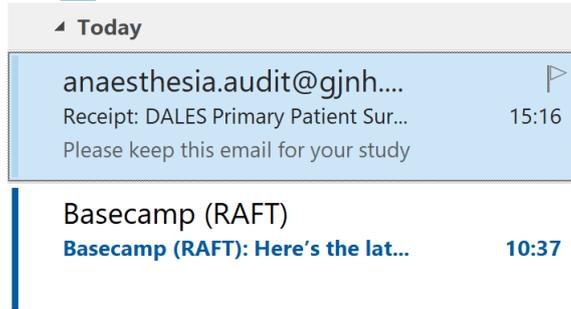
-close the window using 'Close survey'

Do **NOT** click the 'Back' button in your browser to start the next case, you risk corrupting your data and we will likely not be able to recover it, you have been warned...

If you are starting a new data collection session and need to open up either survey from afresh then use the links in your Sign-Up email.

## AN IMPORTANT NOTE ON DATA STORAGE

Sites are required to undertake some data storage locally for a defined period:

- i) the rotas and theatre lists used to identify eligible anaesthetists and to identify patients for Follow-Up post-op should be kept securely in a locked office until Follow-Up data is uploaded; **this arrangement must be for no longer than 3 months after the final study day at your site by which time all Follow-Up must be completed**
- ii) at this time all Follow-Ups emails must also be permanently deleted because they contain the pseudoanonymiser information  

- iii) all patients recruited will generate a receipt email to the local investigator; this contains no identifiable information and may be kept for your records (this may also be useful if / when your R&D wishes to upload accrual information to EDGE)  

- iv) the paper copies of the Anaesthetist Survey and the site file should be stored locally under secure arrangements for five years

Many thanks for all your time and effort with DALES!