AuSCR
Australian Stroke Clinical Registry

FACT SHEET
Informing patients about the Registry – the opt-out approach

- The Australian Stroke Clinical Registry (AuSCR) is designed to collect standardised data to improve hospital care for patients admitted with stroke and transient ischaemic attack (TIA).
- Since the data are used to compare hospitals, it is important that all eligible patients are included to reduce the potential for biased data.
- Best practice for national Clinical Quality Registries (CQR) is to use an opt-out approach because this method reduces response bias. With this approach, potential registrants are provided information about the CQR and their participation is presumed unless they take action to decline involvement.[1]
- Since 2009, the AuSCR has used the opt-out approach and has a waiver of consent for patients who die in hospital or for those with cognitive impairment who have no declared proxy.
- The acceptability of this approach to people who have experienced stroke/TIA who are in the Registry (over 140,000 registrants) is supported by a very small opt-out rate of less than 2.5%.
- The opt-out process applies in all AuSCR hospitals through either a research ethics/governance approval or a quality assurance pathway.

AuSCR Patient Information Sheet

Each hospital participating in the AuSCR has an approved hospital-specific Patient Information Sheet to explain the purpose of the AuSCR, specifying:

- Patient personal identifying data will be provided to the Registry.
- Patients will be contacted to complete a survey about their health status three to six months after their hospital admission.
- The patient or their next of kin may use one of the cost-free options to opt out of the registry, i.e. request their personal information be removed.
- Important contact details including the principal investigator at your hospital, AuSCR Office contact and the ethics committee or equivalent for queries or complaints.

The AuSCR Patient Information Sheet should be provided to patients or their next of kin during admission and should be accompanied by a verbal explanation (see example script). Provision of the Patient Information Sheet should be documented in the medical record.

Where it is not possible to provide the Patient Information Sheet during the patient admission, it should be sent to the patient with your approved, hospital-specific, Post-Discharge Contact Letter as soon as possible after discharge. Ensure you keep documentation of this.

The Patient Information Sheet should be provided to the patient or next of kin prior to entering the patient's details in the Registry.

Example verbal explanation of the Registry:

Our hospital participates in the Australian Stroke Clinical Registry. We enter some information about you and your stay in hospital to a registry. We use this data to monitor our stroke care and to ensure we are providing the best care possible. The registry staff will contact you with a survey in about three months to see how you are going after your stroke/TIA. You can choose to opt out of having your personal details stored on the registry – just let me know, or contact them directly. Here is a patient information sheet with more information.

The AuSCR Office also posts out the Patient Information Sheet to registrants with the follow-up survey, which provides another opportunity to inform patients about their data being in the Registry.

Other methods of informing patients of the Registry

A generic patient pamphlet and site-specific poster are available for you to place throughout your hospital or Stroke Unit/wards to inform patients that your hospital is participating in the Registry.

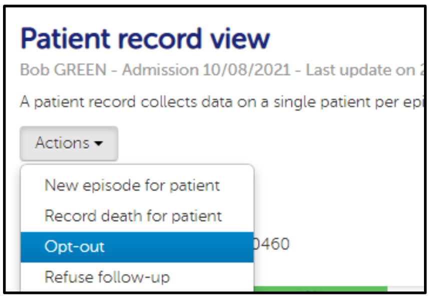
PROCEDURES

How to opt out a patient

Patients may choose to opt out of having their personal details stored in the registry in the following ways:

- Informing hospital staff
- Completing the opt-out form at the bottom of the Patient Information Sheet
- Notifying the AuSCR office by 1800 number, mail or email.

Hospital staff and AuSCR Office staff can opt patients out of the registry in the AuSDaT by using the Actions button in the Patient record view screen.


Patient record view

Bob GREEN - Admission 10/08/2021 - Last update on

A patient record collects data on a single patient per epi

There are two opt-out options: ‘Personal information’ or ‘Personal and clinical information’. The AuSCR has ethical approval to retain the anonymised clinical information from patients who opt out, so the ‘Personal information’ option should be selected unless the patient specifically requests all information be removed. This option removes their name, date of birth, gender, address, telephone number/s, Medicare number, hospital UR number, contact details for next of kin, country of birth, language spoken, interpreter needed and whether they are of Aboriginal or Torres Strait Islander origin. This allows the patient’s clinical information to be included in processes of care calculations.

Where patients are involved in multiple AuSCR programs, such as AuSCR-Red and AuSCR-FeSS, they will need to be opted out of both programs (i.e. complete this step twice), to ensure all personal details are removed.

Hospitals should keep a record of when a patient has chosen to opt out of the registry, to avoid re-entering their details. The AuSCR Office will periodically inform hospital staff of patients that the office have opted out, following patient or next of kin requests.

Refuse follow-up

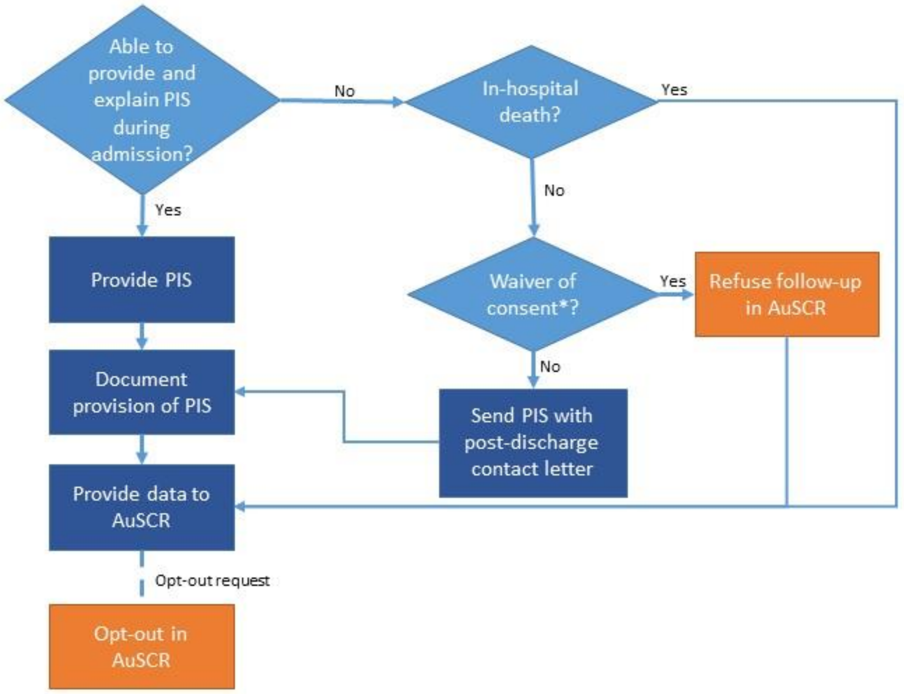
Patients also have the option of choosing not to be contacted by the registry after discharge. This can also be actioned by hospital staff or AuSCR staff via the Actions button in the Patient record view screen. Personal details will be retained in these instances.

If patients are deemed in the medical record of being incapable of understanding written information and no next of kin or responsible person is able to receive the information about the AuSCR they are not required to receive information about the AuSCR, and can still entered in the registry. In these instances, refuse follow-up should be selected so follow-up is not generated for these patients.

In-hospital deaths

Patients who die in hospital should be entered in the registry (excluding those that die in the Emergency Department), and there is no need to provide the Patient Information Sheet to their next of kin. No follow-up survey will be sent where the death is recorded in the registry under item 14.00 ‘Patient deceased during hospital care’ or via the Actions button.

Figure 1: Flowchart for provision of AuSCR Patient Information Sheet (PIS) and data



*All patients who are deemed, in their medical record, as being incapable of understanding written information and do not have a next-of kin or responsible person who is able to receive the information are not required to receive information about the AuSCR and no follow-up information will be needed.

For more information please contact your AuSCR State Coordinator or visit www.auscr.com.au

References:

1. National Health and Medical Research Council. *National Statement on Ethical Conduct in Human Research* (updated 2018)

Frequently Asked Questions: The Opt-out Process

I have spoken to a patient who is happy to be registered in the AuSCR but doesn't want their personal details recorded. Should I use the "opt out" or "refuse follow up" option?

Select the 'opt out' option from the 'Actions' button. This will remove their personal details from the registry, but retain their de-identified clinical information for analysis. If the patient is in more than one program, complete this step for each program they are participating in (e.g. AuSCR Red and AuSCR FeSS).

Select 'refuse follow-up' if the patient is happy for their details to be included in the registry, but does not wish to be contacted by the AuSCR Office to complete the follow-up survey at three to six months after admission.

Our team was not able to provide a Patient Information Sheet to the patient before they were discharged, can I still enter their details in the registry?

A Patient Information Sheet must be provided to patients prior to entering their data in the registry. Send the Patient Information Sheet in the mail with your approved Post-Discharge Contact Letter prior to adding their data to the registry.

The exceptions to this are where the patient died in hospital or where it is documented in the medical record that the patient is incapable of understanding written information and no next of kin or responsible person is able to receive the information about the AuSCR. Data may be provided to the AuSCR without having provided the Patient Information Sheet in these circumstances.

Should I select the 'Personal Information' or 'Personal and clinical information' opt-out?

Where not specified by the patient, select the 'Personal Information' level of opt-out, as the registry has approval to retain the de-identified clinical information in these circumstances. Where a patient wishes all their information to be removed, select 'Personal and clinical information' level of opt-out, which will remove all details from the registry.

A patient has informed hospital staff that they would like to opt out of the registry while in hospital, do we still enter their data in AuSCR?

The standard level of opt-out is to remove the patient's identifying details and retain the de-identified clinical information. If the patient is happy for the registry to retain the clinical information, enter their details into AuSCR. First name, last name, date of birth and gender will be required to generate the unique episode code. As soon as entered, select 'opt-out' via the Actions button.

If a patient does not want any of their details in the registry, there is no need to enter them in AuSCR. We recommend you keep a note of this so they are not entered in future and can be accounted for during case ascertainment.

Version 1.2, May 2025

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