

1. Introduction

- 1.1 Intracranial vascular malformations (IVMs) cause over one third of spontaneous (non-traumatic) intraparenchymal brain haemorrhage in young adults, making them the leading cause in this age group. IVMs can cause recurrent intracranial haemorrhage, epilepsy and chronic disability.
- 1.2 Despite their importance, there is uncertainty about the untreated clinical course of IVMs and the prognosis they carry for specific individuals. Furthermore, the evidence supporting existing interventions for IVMs is composed of case series (usually without a control group), which makes treatment decisions extremely difficult.
- 1.3 Because of the potential for variation in patient management, the priorities for the evaluation of health services for patients with IVMs are to:
 - monitor equity of access to treatment
 - monitor patterns of intervention
 - monitor the outcomes of patients who do and do not receive interventional treatment (and thereby monitor the beneficial and adverse effects of these interventions)
 - assess the health economics of treatment use
 - strive for quality improvement in clinical services in Scotland
- 1.4 Therefore, a multidisciplinary collaborative steering committee, representative of the four neuroscience centres in Scotland, patients, and general practitioners (GPs), is conducting a nationwide, prospective, population-based register of IVMs: the Scottish Audit of Intracranial Vascular Malformations (SAIVMs).
- 1.5 SAIVMs is a continuation of the audit core of a preceding project, called the Scottish Intracranial Vascular Malformation Study (SIVMS). SIVMS continues as an observational epidemiological project, which uses anonymised data extracted from SAIVMs.

2. Objectives

- 2.1 **Continue to recruit and follow-up a cohort of adults, resident in Scotland, who are newly-diagnosed with an IVM.** This will use an existing nationwide collaborative network, and surveillance via medical records and annual postal GP follow-up assessments.
- 2.2 **Observe current clinical practice.**
- 2.3 **Measure current practice** (with reference to the SAIVMs audit standards).
- 2.4 **Ultimately, aim to improve practice** and continue the audit alongside any changes/improvements (which are likely to be gradual), to complete the ‘audit loop’

3. Inclusion criteria

- 3.1 Diagnosis of any of the principal sub-types of IVM:
 - Brain arteriovenous malformation (AVM)
 - Dural arteriovenous fistula (AVF), including carotid-cavernous fistulae
 - Cavernous malformation (CM), with or without an associated venous malformation
- 3.2 Age 16 years or over at the time of diagnosis
- 3.3 Permanently resident in Scotland at the time of diagnosis
- 3.4 Date of diagnosis (by imaging or histology) 1st January 1999 – 31st December 2003, or 1st January 2006 onwards
- 3.5 For the purposes of SAIVMs, a participant is defined an ‘incident case’ at the time a diagnostic image (computed tomography (CT), magnetic resonance (MR), or catheter angiogram) or diagnostic pathological examination (biopsy or autopsy) is performed. If there was a clinical suspicion of an IVM prior to this time, or symptoms antedated diagnosis by many years, the time of the diagnostic image or histology is still the time at which someone is ‘incident’ for this register. Certainty of diagnosis is established by our register’s consultant neuroradiologist(s) who review the diagnostic imaging, thereby creating ‘definite’ / ‘probable’ / ‘possible’ subsets of included participants.
- 3.6 Participant does not opt out of data collection for this audit

4. Exclusion criteria

- 4.1 Incorrect diagnosis of an IVM *
- 4.2 Certain other types of vascular malformation:
 - Venous malformation (developmental venous anomaly)
 - Vein of Galen malformation
 - Capillary malformation/telangiectasis
 - Spinal vascular malformation
- 4.3 The participant opts out of the audit data collection.

* If any participant is found to have received an incorrect diagnosis of an IVM after review of their CT/MR/angiogram by the register’s neuroradiologist(s), they are excluded, and their consultant and GP are informed. However, less than ‘definite’ certainty, as above, does not necessarily exclude a participant, because their management may proceed with this working diagnosis, without further investigation.

5. Design

- 5.1 SAIVMs recruits a longitudinal, concurrent cohort of newly-diagnosed (‘incident’) participants, using multiple overlapping sources of case ascertainment, in order to give a representative picture of what happens to adults with IVMs across NHS Scotland (see appended flowchart).

Case ascertainment

5.2 Primary sources of case ascertainment are:

- neuroradiologists at the four Scottish Neuroscience centres
- radiologists working at other departments in Scotland, and hospitals in England occasionally serving the Scottish population, with CT and/or MR brain imaging
- all neurologists, neurosurgeons, stroke physicians, neuropathologists, and relevant clinical nurse specialists in Scotland, and hospitals in England occasionally serving the Scottish population

5.3 **Secondary source of case ascertainment:** With the approval obtained from the Privacy Advisory Committee on 3rd August 2007, the Information Services Division (ISD) runs electronic searches of hospital discharge (SMR01) and death certificate data on a six-monthly basis, seeking adults meeting our inclusion criteria (we have evaluated the accuracy of the limited ICD-9 and ICD-10 codes available for IVMs, and found the only worthwhile codes to use are those for brain AVMs).

5.4 Notification of the diagnosis of a potentially eligible adult may be received by post, fax (to a designated NHS office, which is locked when unoccupied), email (to a secure NHS.net email address), or via the SAIVMs website. The website uses Secure Sockets Layer (SSL) 128-bit encryption, which is the strongest encryption supported by the current web browsers, giving the highest level of protection for confidential transactions over the internet. The online notification form can only be accessed by collaborators, who receive a unique URL (incorporating their identity) in emails sent to them to remind them about recruitment to the register.

Opt out consent

5.5 **Information for patients:** Posters and information leaflets about SAIVMs are distributed to all brain imaging facilities and outpatient and inpatient areas served by neurologists, neurosurgeons, and stroke physicians throughout NHS Scotland. Therefore *any* patient (their family and carer) has access to information about SAIVMs at the point of diagnosis. The leaflet and poster are freely available on the SAIVMs website (www.saivms.scot.nhs.uk). At the time of case validation (see 5.8 below), a SAIVMs leaflet is sent to every patient's consultant (who is usually a collaborator, participating in the national audit) for them to forward on to the patient in case the patient is not already aware of their inclusion in the register. Health Rights Information Scotland (HRIS) also provides leaflets to inform patients about the uses of their data for audit.

5.6 If an adult wishes to opt out of this audit, SAIVMs honours that request, and they are excluded from the register (see 4.3 above).

5.7 The Confidentiality and Security Advisory Group for Scotland (CSAGS) considered categories where implied (opt out) consent would be acceptable, and these include the objectives of SAIVMs, "planning, managing, funding and auditing, where identifiable data cannot be anonymised" and, "Multiple uses (if cannot be anonymised) e.g. registries, epidemiology, national data banks."¹

¹ Confidentiality and Security Advisory Group for Scotland (CSAGS). Protecting patient confidentiality. Scottish Executive Health Department, 2002.

Case validation

- 5.8 **Contact with responsible clinicians:** Four weeks after an adult's notification to SAIVMs, the register approaches the GP and hospital consultant by post to check the adult's demographic details and diagnosis. If these data are correct, confirming the adult's inclusion in SAIVMs, the register's administrator obtains and/or creates anonymised digital copies of their diagnostic CT scans, MR imaging, and catheter angiograms in DICOM format. At this stage, we also ask the GP and hospital consultant if the participant is still alive and aware of their diagnosis. We ask hospital consultants to inform patients of their diagnosis, if they have not been informed already, and to inform the patient of the passage of their details to this nationwide audit project.
- 5.9 **Review of brain imaging:** One or both of the register's neuroradiologists reviews each participant's anonymised diagnostic imaging via a secure web-based reviewing system, to further validate their IVM diagnosis. The digital images are stored on password-protected NHS computers and external hard drives (for back up), both in the Institute of Neurological Sciences in Glasgow and in the Department of Clinical Neurosciences in Edinburgh. Any hard copies of participants' brain imaging (from hospitals that have not provided imaging in digital format) are kept in a locked filing cabinet in Dr Jo Bhattacharya's office at the Institute of Neurological Sciences, Glasgow, or in a secure storage area in the Department of Clinical Neurosciences, Edinburgh.

Medical records review

- 5.10 Patient identifiable data are needed to obtain the correct sets of medical records.
- 5.11 SAIVMs staff with NHS contracts (or CRA authorisation) collect data on clinical presentation and outcome, as well as markers of the process of care, from GP and hospital medical records. Co-workers who are affiliated to SAIVMs (for example, medical students), are asked to sign assurances of confidentiality.
- 5.12 Stickers are put on these medical records, so that they are not destroyed and GPs/consultants are reminded to send SAIVMs copies of correspondence about the participant during follow-up.
- 5.13 Copies of medical records are stored in case notes that are only labelled with a patient's SAIVMS number, in locked filing cabinets, in a notes storage area secured by keypad access.

Follow-up

- 5.14 SAIVMs sends each participant's GP a questionnaire a few weeks before the anniversary of the participant's diagnosis to check the participant's demographic details and check they are still alive, to obtain information about any hospital admissions/investigations/appointments, and to obtain important outcome data (brain haemorrhage, epilepsy and the GP's rating of the participant's level of dependence on the Oxford Handicap Scale).
- 5.15 Every participant is followed-up via their GP and hospital case notes on an annual basis in order to collect data that are not reliably coded in ISD SMR01 hospital discharge data (e.g. epilepsy), or are not coded at all (e.g. outpatient attendances, prescriptions). These outcome data on process

and outcome underpin SAIVMs as a high-quality clinical audit: survival and morbidity are two of the most meaningful outcomes for neurological disorders and their treatment, and dependence/disability are impossible to extract from the Scottish Morbidity Record (SMR01), which only codes the diagnoses listed on a discharge summary.

- 5.16 During the annual follow-up process, the GP becomes the principal point of contact about each participant because adults with IVMs may not be followed-up for long by their hospital consultant. GP follow-up is essential to document outcome for the whole cohort at uniform time points, especially because many patients are discharged from secondary care, and morbidity is a far more meaningful measure of outcome for neurological conditions than death.
- 5.17 The primary outcome in SAIVMs is a composite outcome of dependence/disability/death rated annually by the GP on the Oxford Handicap Scale. Other important outcomes are the occurrence and/or recurrence of intracranial haemorrhage, seizure(s) after presentation, and time to being 1 or 2 years seizure-free (for those patients with a history of seizure(s)).
- 5.18 All clinical and radiological data are stored in databases on secure servers in the Department of Clinical Neurosciences in Edinburgh; these databases are password protected with access controlled by allocating users restricted permissions. An anonymised extract of the radiological data is kept in a password-protected database in Dr Bhattacharya's office in the Institute of Neurological Sciences in Glasgow. Identifiable data are not shared with any external agency, but they are required for communication with medical records departments at hospitals where participants have been seen and with participants' GPs, in order to collect essential outcome data for the clinical audit.

6. Approval of SAIVMs

- 6.1 SAIVMs is part of the NHS Scotland National Audit Programme. The National Audit Manager (Diana Beard) and/or the National Services Scotland Caldicott Guardian (Rod Muir) attend the SAIVMs Steering Committee meetings, and have assessed the methods of the register.
- 6.2 The register employs a very similar design to several other national audits, and in particular it uses the same mechanism of information provision and opt out consent employed by other audits (such as the Scottish Renal Register).
- 6.3 The audit core of SIVMS – which preceded SAIVMs – had ethical approval from the MREC for Scotland (MREC/98/0/48), and approval from the Privacy Advisory Committee of NHS National Services Scotland.
- 6.4 SAIVMs has also been considered and approved by a variety of other organisations:
 - The Chief Medical Officer of NHS Scotland
 - NHS Quality Improvement Scotland
 - Scottish Association of Neurological Sciences
 - Stroke Association
 - Chest Heart and Stroke Scotland
 - AVM Support UK
 - Angioma Alliance UK

