



The Australian Group on Antimicrobial Resistance
<http://antimicrobial-resistance.com>

Data Governance and Management Plan

Operation of the 2020 Australian Group on Antimicrobial Resistance (AGAR) Surveillance Programs

06 July 2020

1. Introduction

The Australian Group for Antimicrobial Resistance (AGAR), which is operated by the Australian Society for Antimicrobials (ASA), is a unique collaboration of clinicians and scientists from major microbiology laboratories around Australia.

AGAR tests and gathers information on the level of antibiotic resistance in bacteria causing important and life threatening infections. The group started in 1985 and at that time involved 13 teaching hospitals. It has subsequently grown to involve 40 institutions including five private laboratories. The broadening of the group has meant that not only does the group have good information as to what is happening with major pathogens in the larger teaching hospitals in each State and Territory, but now also has the ability to monitor what is happening with resistance rates in private hospitals.

AGAR primarily focuses on bloodstream infections and has three major antimicrobial resistance (AMR) surveillance programs:

- Australian Staphylococcal Sepsis Outcome Program (ASSOP)
- Australian Enterococcal Sepsis Outcome Program (AESOP)
- Gram negative Sepsis Outcome Program (GNSOP)

The Australian Commission on Safety and Quality in Health Care (Commission) has engaged ASA for the continuation of AGAR, to perform its surveillance programs and in doing so, within the period of the contract, maintain its data collection, analyses and reporting, along with the integration of its data as part of the Commission's Antimicrobial Use and Resistance in Australia (AURA) Surveillance System. Under the current contract, funding support for AGAR is available for its operation from 1 July 2020 to 31 December 2020 for the conduct of the 2020 ASSOP, AESOP, and GNSOP.

As per the contract with the Commission, AGAR is required to develop a comprehensive data management plan that sets out, among other things, the structures and roles for data governance, including the roles and responsibilities of the AGAR Executive and data officers. The plan identifies the Chair of the Data Management Committee as a steward (see definition at Appendix 1) for the AGAR data and addresses the following:

- arrangements for ethics and jurisdictional approval for the collection, containment, release, use and publication of any data consistent with current data sets
- privacy requirements for personal information (patient date of birth, sex, postcode of residence, hospital admission and discharge date, 7 and 30 day mortality and the originating laboratory) consistent with the Privacy Act and the Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Cth) (Amending Act)
- arrangements to prevent re-identification of patients and arrangements for storing the data to prevent re-identification of personal data or matching with data in another data set

- data custodian, contributor and user authorisation protocols and mechanisms for monitoring access to the database
- systems and processes used for collection, analysis and storage of data on the Nexus 6 server

2. Governance Arrangements

ASA, Australian Business Number 31 081 739 370, is a government endorsed charitable institution incorporated in Western Australian in 1999 (Registration Number A10076082).

Although AGAR is a working group of the ASA, the ASA Committee has delegated the authority of running AGAR to the AGAR Executive. The AGAR Executive manages the activities and operations of AGAR. ASA administers the AGAR finances, coordinates the AGAR Executive and Committee meetings, and funds the maintenance of the AGAR website. An AGAR representative, as recommended by the AGAR Executive, is co-opted onto the ASA Committee to provide a report on AGAR activities. The AGAR representative is also chair of the AGAR Data Management Committee.

AGAR Executive

The AGAR Executive is composed of eight elected AGAR Committee members and two AGAR Scientific Officers.

2017 – 2020 AGAR Executive Members

Position	Name	Institution
Elected Members (Voting)		
Chair	Prof Geoffrey Coombs	PathWest Laboratory - WA Fiona Stanley Hospital, WA
Deputy Chair	Prof Graeme Nimmo	Queensland Pathology Central Laboratory, Qld
Scientific Convenors	A/Prof Thomas Gottlieb	Concord Hospital, NSW
	Prof Peter Collignon	The Canberra Hospital, ACT
	Prof Jon Iredell	Westmead Hospital, NSW
	Ms Despina Kotsanas	Monash Medical Centre, Vic
	Dr Jenny Robson	Sullivan Nicolaides, Qld
	Dr Louise Cooley	Royal Hobart Hospital, Tas
Co-opted Members (Non-Voting)		
Scientific Officers	Ms Denise Daley – SO1	PathWest Laboratory - WA Fiona Stanley Hospital, WA
	Ms Jan Bell – SO2	

The eight elected members of the AGAR Executive are responsible for the management of the three permanent ongoing programmes:

- Australian Staphylococcus Sepsis Outcome Programme (ASSOP)

- Australian Enterococcus Sepsis Outcome Programme (AESOP)
- Australian Gram-negative Sepsis Outcome Programme (GNSOP)

One AGAR Scientific Officer (SO1) acts as data custodian (see Appendix 1), collates the data collected from the three programmes and provides de-identified data for analysis as below

- SO1 is also responsible for all data checking, cleaning and extraction and for data analysis of
 - Australian Staphylococcus Sepsis Outcome Programme (ASSOP)
 - Australian Enterococcus Sepsis Outcome Programme (AESOP)
- A second scientific officer (SO2) is a data user (see Appendix 1) responsible for analysis of de-identified data from the
 - Australian Gram-negative Sepsis Outcome Programme (GNSOP)

AGAR observes high ethical standards in the conduct of its activities and in its performance.

AGAR does not engage in:

- Conduct that is misleading, fraudulent or deceptive
- Conduct that is illegal
- Conduct that amounts to bribery or corruption or assists or supports bribery or corruption
- Conduct that amounts to terrorism or that supports or assists terrorism

3. Data Management

The AGAR Database Management Committee is a subcommittee of AGAR and reports to the AGAR Executive. The subcommittee consists of a chair appointed by the AGAR Executive and the two AGAR Scientific Officers. The chair acts as data steward.

Although AGAR is administered by ASA, the AGAR data with patient details are not available to the ASA Committee or its members. Only the AGAR SO1, and the data custodians, including Nexus6 staff, can access the AGAR data with patient details.

As per the guidelines issued under section 95A of the Privacy Act AGAR collects health data for the purposes of compiling and analysing statistics. AGAR discloses aggregated de-identified health data to the Commission for the purpose of compiling and analysing statistics and not for the purpose of the management, funding or monitoring of a health service.

The data collected by AGAR has received ethics approval by each AGAR institution's ethics review committee. The institution's ethics approval includes the release of the data to AGAR. Once ethics approval has been provided documentary proof is submitted to the AGAR SO1. An institution's ethics status is maintained and reviewed by SO1, who reports the ethic status for each institution to the AGAR Database Management Committee and the AGAR Executive. Each AGAR institution has consented to the containment and release of the data to AGAR and the proposed use of the data i.e. the de-identification of the data for use and publication of aggregated data derived from the current data sets.

AGAR data may include patient's date of birth, sex, postcode of residence, hospital admission and discharge date, 7- and 30-day all-cause mortality and the originating laboratory (see Appendix 2 for data definitions). Only aggregated data are published and this does not allow access to any patient data fields. Privacy requirements for all personal information are consistent with the Privacy Act and the Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Cth) (Amending Ac). The two AGAR Scientific Officers do not have access to each AGAR institution's laboratory information systems, which may include additional identifiers such as names and addresses. AGAR aims to ensure personal information is managed in accordance with the Australian Privacy Principles contained in the Privacy Act.

The AGAR data is stored on a server hosted by Bulletproof which has been reviewed by the Commission as being security compliant.

The AGAR data is submitted by AGAR institutions using a web application that has been developed and is managed, under a service agreement, by Nexus6 Software Pty Ltd (CAN 096 841 244). While maintaining the database Nexus6 Software personnel can access the database. The Systems Administrators have service contracts that include obligations related to compliance with privacy legislation. The System Administrators are aware of their responsibilities with respect to data security and privacy policies. For the

Nexus6 staff their responsibilities have been reinforced over many years of providing web application and data management services for the Queensland Police Service, The Australian Electoral Commission, the Victorian State Revenue Office, and many large corporate clients. In the provision of services to ASA, as per the service agreement, Nexus6 Software is committed not to engage in any practice that would result in either ASA or Nexus6 breaching the Australian Privacy Principles contained in schedule 1 of the Privacy Act 1988 and the Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Cth) (Amending Act). Nexus6 Software's privacy, ethical and data security obligations are consistent with AGAR.

The AGAR SO1 extracts data from the AGAR Nexus6 database via a secure portal. The portal is password protected and only strong passwords are accepted by the system. All files are transferred from the server via the HTTPS protocol, and therefore are encrypted in transit. Extracted data are stored on secure servers hosted by the Western Australian Department of Health and the Commission.

ASSOP and AESOP: (Server hosted by the Western Australian Department of Health). The Department of Health Western Australia uses best practice to maintain security. Data are secured on physically secure file servers that are configured in such a way that password protection is universally enforced and only strong passwords are accepted by the system. The Public Sector Management Act binds the Department of Health Western Australia, and the Public Sector Code of Conduct binds all Health staff. As part of the service contract with the Health Department the AGAR SO1 must complete annual on-line training modules related to compliance with privacy legislation and the Public Sector Code of Conduct. Online training is monitored by the Department of Health Western Australia.

GNSOP: Server hosted by the Commission. De-identified data are stored in a secure fashion at all times; password protection is enforced and only strong passwords are accepted by the system. The GNSOP data are managed within the framework of the Commission's [Data Plan 2016–19](#) and the data management procedures. The AGAR SO2 is engaged by Commission under a service contract that includes obligations related to compliance with privacy legislation and the Commission's data security policies and procedures. The AGAR SO2 does not have access either to the AGAR data base or to personal information. The de-identification protocol is as follows: data is downloaded by SO1 from the web portal and checked for mismatches, errors and incorrect dates. The laboratory accession number and postcode are deleted. Onset and outcome parameters are calculated from dates of onset, admission and death (if applicable) and the dates themselves are deleted. Date of birth is also deleted once age has been calculated.

The Western Australian Health Department's and the Commission's servers record information on data contributor, user authorisation protocols and mechanisms for monitoring access to the database.

4. Compliance

AGAR complies with all relevant privacy legislation and data security provision outlined in the Commission's contract.

The following subcontractors have been engaged by ASA to support the performance of services related to the contract

- PathWest Laboratory Medicine – WA (Denise Daley [ASSOP, AESOP])
- The Westmead Institute for Medical Research [GNSOP, molecular characterisation and storage of isolates])
- Nexus6 Software Pty Ltd (Kirk Holland [Web portal development and maintenance])
- Murdoch University (ASSOP and AESOP molecular characterisation and storage of isolates)
- Ms Jan Bell, AGAR SO2 (GNSOP data analysis and reporting)

ASA has a formal contract or agreement in place with those subcontractors and they have agreed to comply, where relevant, with the same obligations as the Commission's contract in relation to: ethical conduct, privacy legislation and provisions; restrictions on data use, collection, storage and security and intellectual property.

Data breach prevention and response protocol info to be added

The link below has helpful info on what organisations need to comply with the Notifiable Data Breaches (NDB) scheme that commenced on 1 February 2017:

<https://www.oaic.gov.au/agencies-and-organisations/guides/data-breach-preparation-and-response>

Appendix 1 –Information on the roles of various roles in the data governance framework

AGAR Data Management Committee (DMC)

As part of its role to develop and oversee the implementation of this framework the DMC will assume responsibility for:

- Developing, implementing and maintaining the AGAR data management plan.
- Establishing and reviewing the data management plan and its implementation, which includes:
 - Ensuring data holdings are allocated to Data Steward and Data Custodians;
 - Setting, implementing and monitoring standards for:
 - the storage and use of data holdings (including reference and master data sets);
 - security of data holdings;
 - data quality;
 - metadata requirements and solutions; and
 - other data management compliance measures as required.
- Resolving issues raised by data stewards and data custodians.
- Initiating and participating in the development of IT solutions for data management activities.

Data steward

A data steward manages the usage and quality of one or more data collections from a management perspective. A data steward is often a subject matter expert, though not necessarily highly technically literate. A data steward will understand the business requirements for collecting and holding data, as well as its permitted uses, publication and dissemination.

Data stewards have dual roles in education and training. For each of the data holdings under their care, Data Stewards also have a responsibility to ensure that their users have access to the information (mostly in the form of metadata) and skills they require to correctly access and use that data.

A data steward will provide clear delegation and instructions to data custodians so that access and security privileges to their data holdings are maintained and monitored.

Data custodian

A data custodian performs operations management of the collection, storage and use of one or more data collections. Data custodians normally have high levels of data literacy, as well as skills in data management software system and tools.

The data custodian is responsible for:

- ensuring data collections are protected from unauthorised access, alteration or loss;
- provide advice to users of the data, including any caveats on the use of the data;

This means that they may be involved in the design of data acquisition, receipt and storage, processing, analysis, reporting, dissemination and perhaps archival or deletion of data. Data custodians generally have considerable skills in using data and the associated software tools and systems. They are required to follow policies and procedures on the secure storage and transfer of data to external stakeholders.

Where a data custodian is unsure of their authority to access, process, report or disseminate data they should refer issues to the DMC.

Data custodians require IT support tools to allow them to view and monitor their role. This includes access to effective metadata so that they can fully understand the context, definitions, meaning and data quality indicators for the data they are using.

It is possible for the same person to perform the dual roles of data steward and data custodian.

Data users

Data users are those staff who need access to de-identified data for analysis but who are not custodians or stewards of the data. Data users normally have varying levels of data literacy and data management skills. They do not have the authority to update (edit), copy or delete the raw data.

By being provided with access to data, data users are assuming responsibilities for its correct use, analysis, interpretation and reporting.

Where a data user is unsure of their authority to access, analyse, report or disseminate data they should refer issues to the appropriate data custodian in the first instance.

The actions of data users must be visible to the data custodians of the data they are using.

Appendix 2 - Data Definitions

1 AESOP Definitions

Data Item	Definition
LabNo	Lab number, format is a combination of numbers and letters
Secondary Lab Number	Lab number, format is a combination of numbers and letters
DOC	Date of collection, format is dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Genus	Format is text
Species	Format is text
van PCR	van gene PCR result, see list of acceptable values
Polymicrobial	Was this organism isolated with other organisms in the same blood culture set? Y/N or Yes/No
Org2	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
Org3	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
Org4	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
Org5	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
DOB	Date of birth or age, format is dd/mm/yyyy or 0-110 years
Sex	M/F or Male/Female
Postcode	4 digit number, 8888 if outside Australia
Admitted	Was the patient admitted to hospital, Y/N or Yes/No
DOA	Date of admission, format is dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Discharge Date	Date of discharge, format is dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Still Inpatient	Still inpatient after 30 days, Y/N or Yes/No
Device Related Infection	Was the bloodstream infection thought to be device-related, Y/N or Yes/No
Principal Clinical Manifestation	What was the principal clinical manifestation of the bloodstream infection, see list of acceptable values
Outcome 7 Days	What was the patient outcome at 7 days (after date of blood culture collection), died/survived/unknown
Outcome 30 Days	What was the patient outcome at 30 days (after date of blood culture collection), died/survived/unknown
Date of death	Date of death if patient died before 30 days, format dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Comments	Free text

2 ASSOP Definitions

Data Item	Definition
LabNo	Lab number, format is a combination of numbers and letters
Secondary Lab Number	Lab number, format is a combination of numbers and letters
DOC	Date of collection, format is dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Genus	Format is text
Species	Format is text
Manual beta-lactamase	Optional. Format is text - one of positive/pos/negative/neg/not performed
Polymicrobial	Was this organism isolated with other organisms in the same blood culture set? Y/N or Yes/No
Org2	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
Org3	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
Org4	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
Org5	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
DOB	Date of birth or age, format is dd/mm/yyyy or 0-110 years
Sex	M/F or Male/Female
Postcode	4 digit number, 8888 if outside Australia
Admitted	Was the patient admitted to hospital, Y/N or Yes/No
DOA	Date of admission, format is dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Discharge Date	Date of discharge, format is dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Still Inpatient	Still inpatient after 30 days, Y/N or Yes/No
Device Related Infection	Was the bloodstream infection thought to be device-related, Y/N or Yes/No
Principal Clinical Manifestation	What was the principal clinical manifestation of the bloodstream infection, see list of acceptable values
Outcome 7 Days	What was the patient outcome at 7 days (after date of blood culture collection), died/survived/unknown
Outcome 30 Days	What was the patient outcome at 30 days (after date of blood culture collection), died/survived/unknown
Date of death	Date of death if patient died before 30 days, format dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Comments	Free text

3 GnSOP Definitions

Data Item	Definition
LabNo	Lab number, format is a combination of numbers and letters
Secondary Lab Number	Lab number, format is a combination of numbers and letters
DOC	Date of collection, format is dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Genus	Format is text
Species	Format is text
Polymicrobial	Was this organism isolated with other organisms in the same blood culture set? Y/N or Yes/No
Org2	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
Org3	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
Org4	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
Org5	Other organisms isolated from same blood culture set, ASSOP/AESOP/GNSOP/other
DOB	Date of birth or age, format is dd/mm/yyyy or 0-110 years
Sex	M/F or Male/Female
Postcode	4 digit number, 8888 if outside Australia
Admitted	Was the patient admitted to hospital, Y/N or Yes/No
DOA	Date of admission, format is dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Discharge Date	Date of discharge, format is dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Still Inpatient	Still inpatient after 30 days, Y/N or Yes/No
Device Related Infection	Was the bloodstream infection thought to be device-related, Y/N or Yes/No
Principal Clinical Manifestation	What was the principal clinical manifestation of the bloodstream infection, see list of acceptable values
Outcome 7 Days	What was the patient outcome at 7 days (after date of blood culture collection), died/survived/unknown
Outcome 30 Days	What was the patient outcome at 30 days (after date of blood culture collection), died/survived/unknown
Date of death	Date of death if patient died before 30 days, format dd/mm/yyyy, dd-mm-yyyy or dd-mmm-yyyy
Comments	Free text