Vaccination Recording and Reporting to the Australian Immunisation Register (AIR)
GuildCare NG Program

PROTOCOL

This document provides information on conducting a Vaccination Recording Service using GuildCare NG software.

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Program powered by:

Program Information

Use this protocol document for detailed information about the programs content and what to do when using GuildCare NG to record an immunisation. This protocol will also cover the capability to provide patient vaccination statements direct to the **Australian Immunisation Register (AIR)** using GuildCare NG.

Program Objective

To support pharmacies offering immunisation services by assisting in patient assessment, recording consent, recording vaccination statements and for eligible pharmacies the ability to send vaccination statements to the Australian Immunisation Register (AIR).

Program Overview

The GuildCare NG Vaccination Recording Service is up-to-date with all current state legislation and requirements and allows for recording of immunisations done by an employed pharmacist immuniser as well as a third-party provider.

The GuildCare NG Vaccination Recording Service can be used to record the following information;

- Pre-vaccination screening results
- Patient Consent
- Vaccination details (including batch number, expiry and route/site of administration)
- Post Vaccination Care
- Adverse Event Reporting

To utilise the GuildCare NG AIR functionality ensure your pharmacy is registered with the Australian Immunisation Register as an Immunisation Provider. Once registered with the AIR every pharmacy receives a unique **provider number** to use.

A pharmacy that provides their **Australian Immunisation Register (AIR) Provider Number (IPN)** in the GuildCare NG admin settings will fall into an auto-reporting mode. Upon completion of a vaccination case the patient vaccination statement will be sent to the AIR automatically.

GuildCare NG does not support ad-hoc reporting to the AIR and if a pharmacy does not want all immunisation records sent to AIR the pharmacy IPN must be left blank and reporting to the AIR must then be done manually via the AIR portal at the pharmacist's discretion.

Software Information

Activating the GuildCare NG Australian Immunisation Register Integration

To activate the AIR functionality within GuildCare NG enter the pharmacy's AIR provider number in the admin section. This section controls how vaccination cases interact with the GuildCare NG AIR reporting.

If an IPN is entered- All future GuildCare NG Vaccination cases will show an AIR section as part of each case that includes an updated consent form that mentions the AIR. All future vaccination cases will automatically be submitted to the AIR upon case completion.

If IPN is left blank- No vaccination statements will be sent to the AIR via GuildCare NG. The AIR section will not show as part of any vaccination cases.

Checking AIR Status of a Vaccination Case

An AIR claims report is accessible in the GuildCare NG reporting section. Users can sort by date range and case status, noting if a case was successful or failed. To retry sending a case to the AIR the vaccination case must be re-opened and the "retry send to AIR" button clicked.

Program Structure

1. **Enrol Patient:** Create a vaccination case for your patient
2. **Update Patient if Prompted:** Ensure all required patient details are entered and correct
3. **Vaccination Documents:** Select vaccination provider and n the documents being used for the case (GuildCare documents OR Third party)
4. **Vaccine Details:** Complete the vaccine details by selecting the disease you are vaccinating against and the vaccine being administered. You can also print patient FAQ's and CMI for the patient.
5. **Pre-vaccination Screening Checklist:** Fill out the pre-vaccination screening checklist
6. **Patient Suitability and Consent:** Acknowledge the patient suitability and consent section. If an IPN is saved in the admin section for your pharmacy the patient consent form will include information regarding the patients record going to the AIR. Please ensure the patient has signed the correct consent form.
7. **Australian Immunisation Register Detail:** If an IPN is saved in the admin section for your pharmacy the AIR section will appear and must be filled out accurately. Upon patient request, the Ceasing Correspondence and Release of Information Form can also be printed off for the patient here.
8. **Australian Immunisation Register Detail:** If no IPN is saved in the admin section for your pharmacy the AIR section will not appear. If you would like to report the case to the AIR an IPN must be entered in the admin section prior to case completion OR externally access the AIR portal to manually update a patient record on the AIR directly.
9. **Vaccination Details:** Accurately enter all vaccination information including date of vaccination, batch number, expiry, site and route of administration. Print the patient handout here and acknowledge that the patient hand out has been provided to the patient.
10. **Action Taken:** Select if the patient remained in the pharmacy for 15 minutes post immunisation and note any outcomes were observed.
11. **General Practitioner Details:** Enter the patients GP details.
12. **Print:** Print off any required records including vaccination statements for the patient and the GP.
13. **Complete the Case:** If an IPN was saved in the admin section for your pharmacy when the case is completed an AIR claim flag will appear at the top of the case marking if the file was sent successfully or not. If a **retry** is required click the orange retry button at the top of the vaccination case, anytime to retry sending to AIR.
14. **Complete the Case:** If no IPN was saved in the admin section for your pharmacy simply complete the case.

Patient Decline

If the pharmacist or patient does not wish to continue after a Vaccination Recording Service case has been created, the pharmacist should select 'Declined' as the case status.

Clinical Recording Information

This recording service assists pharmacies to record all details of their vaccination administration service as per the *Australian Immunisation Handbook and QCPP T3M - Hosting Vaccination Services in the Pharmacy Checklist*. It also provides documentation and handouts that are required before and after vaccination. It is the pharmacy's responsibility to discuss this with their chosen accredited vaccine administrator and they may wish to document this by using the GuildCare NG Third Party Declaration Form. All equipment/therapeutic devices used for service delivery must comply with the QCPP Standards/Checklist requirements.

Documentation

Prior to vaccination, the vaccine administrator:

- Provides an FAQ document to the patient, individual to the vaccine that patient is receiving

- Uses a pre-vaccination screening checklist to assess patient's suitability for vaccination; and if suitable, obtain patient's consent for vaccination (and where applicable, obtain consent to send the vaccination record to the Australian Immunisation Register).

If patient is not suitable for pharmacy vaccination, the pharmacist can use the GP Referral printout from the program to refer patient back to their GP or simply decline the service.

Following vaccination, the vaccine administrator or trained staff:

- Records details of vaccine administered including brand, site and route of administration, batch number and accredited vaccine administrator details
    - Where applicable, vaccine dose number, expiry date and next vaccination due date should also be recorded.
    - Where applicable, acknowledge the patient details are correct and that that case with be sent to the AIR upon completion.
- Provides patient with Patient Handout (Record of Immunisation), including details of vaccine administered and possible side effects
- Monitors the patient for 15 minutes, records details of any outcomes observed.
    - Any observed adverse events should be reported to the TGA using either the GuildCare NG Adverse Event Recording module or other methods listed in Appendix A, unless the state guidelines require the pharmacy to report directly to the relevant state Health Department.
- Provides the patient's nominated GP the details of the vaccination for their records

Staff Roles

The vaccine administrator (pharmacist or nurse immuniser) must assess the patient's suitability for vaccination and obtain the patient's consent to be vaccinated. This can be done by either using the GuildCare NG screening checklist and patient consent form, or third-party documents.

If the vaccine administrator is not the person who collects the patient's screening checklist and consent, they should review the form and verify with the patient that consent has been obtained and patient is suitable for vaccination. Only an accredited and approved vaccine administrator, such as an accredited vaccination nurse or accredited pharmacist immuniser, may administer vaccines to patients. Then the vaccine administrator, pharmacist or trained staff can enter details of the vaccination into the GuildCare NG software.

If sending vaccination statements to the Australian Immunisation Register within GuildCare NG or manually direct to AIR, staff will also need to ask if patients consent to their information being sent to the Australian Immunisation Register.

As part of providing access to this service and recording the details of administration, pharmacists are under obligation to adhere to the relevant professional practice standards. This includes but is not limited to applying professional judgement to identify and record any potential or actual medication related problems that are likely to be clinically significant for the patient (e.g. interactions, contraindications, incompatibilities, allergies, adverse drug reactions). Pharmacists should also ensure that these problems are reported by either the vaccine administrator or the pharmacist themselves; to the patient's Medical Practitioner, the Therapeutic Goods Administration (see Appendix A) and any other relevant entity.

Resources

The platform contains a comprehensive list of resources such as:

- Emergency response protocol
- Vaccine consumer medicine information (CMI)
- Vaccine-specific frequently asked questions
- Vaccine suitability checklist
- Patient consent form
- Third party declaration form
- Patient report, GP report or referral

Appendix A: How to report a problem with a medicine or medical device to the Therapeutic Goods Administration

Information for health professionals

Source: http://www.tga.gov.au/hp/problem.htm

The Therapeutic Goods Administration (TGA) is a division of the Australian Government Department of Health and Ageing and is responsible for regulating medicines and medical devices. The work of the TGA is based on applying scientific and clinical expertise to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices. The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices so that the TGA can identify and respond to safety matters.

When to report

If a patient has experienced or you suspect they may be experiencing an adverse event relating to a medicine or medical device, report the adverse event to the TGA. Suspected adverse events should be reported the first time they occur, as well as any time they occur thereafter.

What to report

Please report any suspected adverse event that your patient(s) may be experiencing, in particular:
- serious reactions (e.g. resulting in hospitalisation)
- unexpected reactions (reactions not consistent with consumer medicine information or labelling)
- all suspected reactions to medicines recently introduced in Australia
- all suspected adverse events that may be caused by combinations of medicines (drug interactions)
- faults with medical devices resulting in an adverse event (keep the faulty equipment until you have contacted the TGA).

What to include in your report

In your report include (if applicable):
- basic details of the patient experiencing the adverse event – initials, date of birth, gender
- details of the adverse event or reaction – date it occurred, symptoms experienced (including duration), description of device fault resulting in adverse event, treatment required and outcome (if known)
- details of the medicine or device involved – name, description, dose, for a complementary medicine include AUST L number
- details of any other medicine(s) the patient experiencing the adverse event may be taking.

Report a medicine or medical device adverse event to the TGA

How to report

Report a suspected adverse event directly to the TGA using:
- **GuildCare's Adverse Events Recording module**, sent electronically via a web service portal direct to the TGA
- the TGA website - http://www.tga.gov.au/safety/problem.htm

Alternatively:

Medicines

Phone: 1300 134 237 or 1800 044 114

Email: adr.reports@tga.gov.au

Medical devices

Phone: 1800 809 361

Email: iris@tga.gov.au