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COVID-19

Detecting failsafe reporting guidelines

National Immunisation Programme

Version 2.0

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# Document Version Control

### Revision history

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| Version | Date | Section/Appendix |
| V1.0 | 23 May 2022 | First version published and shared |
| V2.0 | 01 August 2022 | * Content table added
* Updated branding and language moving into Te Whatu Ora – Health New Zealand
* Added clarity on the number of days between doses for the detecting failsafe settings (for the Master spreadsheet not the data quality spreadsheet). This will be applied from 1 August 2022.
* New update for the data quality failsafe: From 1 July 2022 onwards, CIR helpdesk will update invalid batch number and boosters recorded as an additional dose on behalf of the locality where the required change meets the existing business rules.
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# Definitions

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| Adverse Event Following Immunisation (AEFI) | An untoward medical event which follows immunisation and does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. |
| Case | CIR record |
| COVID-19 Immunisation Register (CIR) | Electronic register of consumer COVID-19 vaccination event/s. This is an electronic clinical record.  |
| District | District is the new term for the previously named District Health Boards (DHB) |
| Data quality error | A data quality error is when information was incorrectly entered into the CIR. |
| Detecting Failsafe | A detecting failsafe uses the CIR records to detect unverified adverse events and incidents including never events  |
| Incident | Incident means any unplanned event resulting in, or having a potential for injury, ill health, damage or other loss (as defined by Australian/New Zealand Standard AS/NZ 4801:2001). An incident includes an accident. |
| Monitoring failsafe | A monitoring failsafe uses the CIR to monitor vaccination events that may highlight a pattern or trend of procedural errors. |
| Never event | A never event is a serious incident. It is considered preventable because guidance or safety recommendations providing strong systemic protective barriers are available at a national level. These should have been implemented by all vaccinating providers.  |
| Unverified Incident  |  A CIR report which has been identified as a potential incident and needs verification to determine the accuracy to eliminate the possibility of a data quality error. |

# Detecting failsafe reporting

The purpose of a detecting failsafe is to identify an unverified incident which may be the cause of harm to a consumer and or a data entry error. The detecting failsafe is a tool in the National Immunisation Programme’s (NIP) quality assurance framework which contributes to system level incident management and continuous quality improvement.

The quality and safety of the immunisation programme is focusing on preventive actions to assure a safe, quality vaccination experience for all consumers. The detecting failsafes do not detect all NIP incidents or adverse events.

A never event is a serious incident. It is considered preventable because guidance or safety recommendations providing strong systemic protective barriers are available at a national level. These should have been implemented by all vaccinating providers.

Not all NIP incidents are never events. When an incident is a never event, it is considered avoidable when available preventative measures have been implemented. The importance, rationale and good practice use of relevant barriers should be fully understood by and robustly sustained throughout the system, including through the preparation of the vaccinating health workforce.

There are NIP never events such as:

* Vaccination administered outside Medsafe approved or Programme recommended use:
	+ A second primary dose of the Pfizer or Novavax vaccines administered at 21 days or earlier, or the AstraZeneca vaccine administered at 28 days or earlier.
	+ A vaccination administered without prescription to a person younger than the approved minimum age requirement this includes an adult/paediatric dose administered in error.
* A dose of an incorrect vaccine administered to a consumer (eg, consumer wanted the AstraZeneca vaccine, however, was administered a dose of the Pfizer vaccine).

**Note:** For more detail around never events and serious adverse events of COVID-19 vaccines included in the detecting failsafe please see **Appendix A** for more detail.

Detecting failsafe reports identify potential incidents which can be verified upon investigation. Many cases are identified as a data quality error and when corrected will be removed from the detecting failsafe report. Some detecting failsafe cases may identify both a verified incident and data entry error has occurred. Therefore, it is important that each individual case is verified, and the appropriate actions outlined in the below table are followed.

An ‘off label dose’ may be administered when authorised by prescription, the failsafe may detect an unverified incident where a prescription was provided but not recorded in CIR, if so then it is not an incident.

Districts provide their Regional Account Manager (RAM) with a nominated District contact who will be responsible for the failsafe verification process.

Failsafe reports are shared with District via the “COVID Household Contact & Cohort Information” (CHCCI) Microsoft Teams channel. The nominated DHB contact will have access to this channel and the relevant District folder.

1. Weekly detecting failsafe reports (with NHIs) are generated by Te Whatu Ora - Health New Zealand and loaded into the relevant folder in the CHCCI Microsoft Teams channel. It is the responsibility of the District to ensure the providers verify the accuracy of the failsafe report.
2. There are two files:
	1. A “Master” excel file. This will be updated weekly to add new cases.
	2. A new data quality excel file will be uploaded each week.
3. The District should check and verify if the cases on the report are incidents or data errors within 5 working days with the support of the Te Whatu Ora - Health New Zealand CIR helpdesk or Quality Team.
4. The nominated District contact is responsible for ensuring that the relevant actions are completed. These are outlined below and detailed in the detecting failsafe categories section.

Summary of actions:

* 1. If the report is a verified incident **without prescription**:

Notify the Ministry of any incidents (using the NIP Adverse Event Notification form found in the [COVID-19 Vaccine Operating Guidelines](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines) Appendix I). The incident should be investigated through the District’s usual incident channels and processes.

**Note:** Districts should share with the providers the relevant documents and incident toolkits on the [Connex ‘Mahi Tahi’ SharePoint](https://www.connex.health.nz/group/QSLanding/cvip/SitePages/Home.aspx). Currently, available guidance includes incorrect vaccination, missed vaccination and underage vaccination documents. Further documents will be uploaded as they are available.

* 1. For **data quality errors**, please review and provide relevant information to help@c-19imms.min.health.nz for the correction to be made, or correct (if able). Please liaise with the relevant staff member at the site to alert them to errors and provide coaching to ensure correct data entry.

For CIR tips and coaching, please encourage teams to take advantage of the CIR drop in sessions where there is coaching available from one of Te Whatu Ora - Health New Zealand senior support team members, Mon – Fri 1:00pm – 1:30pm. Use this link to connect: [Click here to join the meeting](https://covid-19vaccine.cmail19.com/t/i-i-chrdjjt-l-r/)

## Detecting failsafe categories

The below tables outline the detecting failsafe reporting categories and the relevant actions.

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| Master Excel File |
| **Underage and incorrect vaccinations**Cases related to age and incorrect vaccine administered can be found in the “Master” excel file “Age” tab. For detailed information please see Appendix A. Cases are not classified as an incident if the appropriate prescription was used. |
| **Dose interval gap**Cases related to administering vaccine doses earlier than Medsafe approved use and/or Programme recommended dose interval can be found in the “Master” excel file “Gap” excel tab. For detailed information please see Appendix A. Cases are not classified as an incident if the appropriate prescription was used. |
| **Additional dose**Cases related to administering additional doses can be found in the“Master” excel file “Additional dose” tab. For detailed information please see **Appendix A**. Cases are not classified as an incident if the appropriate **prescription** was used. |
| Actions for the age and gap tabs (records post 1 February 2022):1. Verify if record is accurate (a true incident without prescription) or a data quality error (e.g., wrong DOB).
2. Update verification and status in teams excel sheet under the following columns:
	1. Data quality error (Y/N/NA)
	2. CIR helpdesk contacted (Y/N/NA)
	3. Verified Incident (Y/N/NA)
	4. NIP incident notification form submitted (Y/N/NA)
	5. Prescription (Y/N/NA)
3. If data quality error, correct (if able) or provide relevant information to help@c-19imms.min.health.nz
4. If the report is a verified incident without prescription:
	1. Notify the Ministry of any incidents (using the NIP Adverse Event Notification Form found in the [COVID-19 Vaccine Operating Guidelines](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines) Appendix I). The incident should be investigated through the Districts’s usual incident channels and processes.

Note: To address the incident, the District shares with the incident response lead the relevant documents and incident toolkits on the [Connex ‘Mahi Tahi’ SharePoint](https://www.connex.health.nz/group/QSLanding/cvip/SitePages/Home.aspx).  |

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| Monitoring  |
| **Monitoring failsafe reports** These are records available for Districts to monitor any recurring patterns.1. A second primary dose of the Paediatric Pfizer vaccine administered between 22 days and 8 weeks (56 days) after the first primary dose. If a site is reported as administering multiple Paediatric Pfizer vaccines in this interval, the District may choose to raise as a monitoring observation to check the site is following recommended dose interval process and practice.
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| Data Quality |
| Cases related to data quality errors are in the “data quality failsafe” sub-folder. This includes the following types of data quality:1. Batch vaccination type does not match the vaccine given
2. Invalid batch number

Common items to look out for are:* 1. For Pfizer batch IDs with seven characters, the batch number should start with 1F, not IF (numeral one, not capital I)
	2. Check zero’s (number 0) vs O’s (capital letter o)
	3. Check one’s (number 1) vs I’s or l’s (capital letter i and lower-case L)
1. Booster recorded as additional dose
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| Actions (for records from 1 April 2022): 1. Check records
2. Update verification and status in Teams excel sheet under the following columns:
	1. Data quality error (Y/N/NA)
	2. CIR helpdesk contacted (Y/N/NA)
	3. Verified Incident (Y/N/NA)
	4. NIP incident notification form submitted (Yes/N/NA)
	5. Prescription (Y/N/NA)
3. Provide information for changes required to help@c-19imms.min.health.nz.
4. Liaise with the relevant staff member(s) at the site(s) to alert them to errors and provide coaching to ensure correct data entry.

Note: From 1 July 2022 onwards, the CIR helpdesk will update invalid batch number and boosters recorded as an additional dose on behalf of the locality where the required change meets the existing business rules.  |
| Pre-existing records (for records before 1 April 2022): A process to fix these records is in progress. |

# Appendix A Detecting Failsafe Settings

### The detecting failsafe are set to search for the incidents below.

### Underage vaccination without a prescription include:

1. Any dose of a COVID-19 vaccine administered to a consumer under the age of 5 years[[1]](#footnote-2)
2. An AstraZeneca dose administered to a consumer under the age of 18 years
3. A Novavax dose administered to a consumer under the age of 18 years
4. An adult Pfizer booster dose administered to a consumer under the age of 16 years

### Incorrect vaccination:

1. An Adult Pfizer dose administered to a consumer aged 5-11 years1
2. A Paediatric Pfizer dose administered to a consumer aged 12 years and above. Except: first dose Paediatric Pfizer then Paediatric Pfizer second dose if the consumer turns 12 during the interval.
3. A dose of an incorrect vaccine administered to a consumer (eg, consumer wanted the AstraZeneca vaccine, however, was administered a dose of the Pfizer vaccine)1

### Medsafe approved use and/or Programme recommended early doses without a prescription include:

1. For consumers aged 18 years and over an adult Pfizer booster dose administered earlier than 3 months (when administered ≤87 days, this requires an investigation).
2. For consumers aged 16-17 years an adult Pfizer booster dose administered earlier than 6 months (when administered ≤179 days).
3. For consumers aged 18 years and older a Novavax booster dose administered earlier than 6 months (when administered ≤179 days).
4. A second primary dose of the Paediatric Pfizer vaccine administered ≤21 days
5. A second primary dose of the Pfizer vaccine (12 years and older formulation) administered ≤21 days
6. A third primary dose administered ≤28 days after second primary dose
7. A second primary dose of the AstraZeneca vaccine administered ≤28 days
8. A second primary dose of the Novavax vaccine administered ≤21 days

# Appendix BDetecting Failsafe FAQs

The detecting failsafe are uploaded weekly on Thursdays via the COVID Household Contact and Cohort Information (CHCCI) Microsoft Teams channel.

Each District will have a nominated contact or role, they will be responsible for distributing the data to providers to verify any incidents and correct data quality errors. This is done by using the columns in the failsafe excel spreadsheet (as outlined in the ‘COVID-19 Detecting failsafe reporting’ document).

The District are asked to review the failsafe reports within 5 working days between uploads.

### What is a monitoring failsafe?

A monitoring failsafe uses the CIR to identify vaccination events which highlight patterns or trends of procedural errors. These monitoring failsafe does not require immediate action, however, patterns or trends can be identified, District can check in with the site to see if recommended processes are being followed.

A monitoring failsafe **does not require verification**.

### What is a detecting failsafe?

A detecting failsafe uses the CIR records to detect unverified adverse events and incidents including never events or data entry errors. Detecting failsafe reports identify possible incidents which can be verified upon investigation. Some cases may be both a verified incident and data quality error. Therefore, it is important that each individual case is verified, and the appropriate actions outlined in the table from the COVID-19 Detecting failsafe reporting document are followed.

### Why do we need to correct the CIR database?

Ensuring that the CIR database is correct is important as accurate clinical records are a safety measure for the consumer. Accurate entries into CIR will alert practitioners to previous vaccines or reactions and in case of vaccine or batch recalls. The CIR also records vaccine usage and waste.

### What does “verify” an incident or data quality involve?

There are two Excel spreadsheets filed in the Failsafe folder in each District Teams channel. Districts are responsible to ensure that both detecting failsafe reports are checked weekly for accuracy and to confirm (verify) the failsafes as incidents, data quality errors or requiring a script.

1. “DATE\_DISTRICT\_DETECT\_FAILSAFE\_DQ.xslx”
	1. This is a new file every week for specific data entry issues (eg, invalid batch number)
	2. Corrected records are removed from the following week’s sheet
2. “MASTER\_DISTRICT\_DETECT\_FAILSAFE.xslx”
	1. This is one master file where new cases are added weekly



For a more in depth break down of this process, refer to the ‘COVID-19 detecting failsafe reporting document’.

**Note:** Submitting an AEFI report does not notify the Programme about incidents. It’s important that NIP incident form is completed and sent to NIP.incidentnotification@health.govt.nz. The most up to date NIP incident form can be found in the [COVID-19 Vaccine Operating guidelines](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines#operate).

1. If a verified incident, this a NIP never event [↑](#footnote-ref-2)