MINISTRY OF HEALTH
MANATŪ HAUORA

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Annual Cold Chain Management Guide and Record

Clinic name:

Date:

Designated cold chain staff:

Local immunisation coordinator:

Contact number:

Refrigerator manufacturer:

Contact number:

Released December 2012

www.health.govt.nz

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MANATŪ HAUORA

Contents

Introduction

The *Annual Cold Chain Management Guide and Record* is a quality tool to support your clinic's cold chain management. The guide aims to facilitate you as an immunisation provider in achieving and maintaining Cold Chain Accreditation as endorsed by the Ministry of Health.

The guide has been updated to reflect the information in the *National Guidelines for Vaccine Storage and Distribution 2012* and incorporates the previous Immunisation Advisory Centre guide.

The *National Guidelines for Vaccine Storage and Distribution 2012* is available from the Ministry of Health website at www.health.govt.nz/national-guidelines-vaccine-storage

This guide enables you to:

- have instant access to temperature-recording charts at the vaccine refrigerator site
- use the trouble shooting tips for cold chain problems
- have a self-audit tool to check your clinic is on target for excellence
- keep track of your clinic's cold chain history
- use as an orientation guide for new staff.

How to use this guide

This guide contains the following sections:

- key points for handling and storing vaccines
- what to do if you have a cold chain failure
- National Cold Chain Audit
- self-audit for safe vaccine handling and storage
- temperature control flow chart
- returning vaccines for destruction
- daily temperature recording charts
- clinic cold chain history
- key contacts.

Each of these sections are relevant to your cold chain managment and daily practice.

You must keep this booklet for 10 years as an audit trail of the clinic cold chain.

Contact your local immunisation coordinator when:

- your clinic has a cold chain failure
- purchasing new cold chain equipment (eg, refrigerator)
- you have National Cold Chain Audit queries
- an equipment failure takes place
- daily vaccine refrigerator temperature recordings are outside the recommended +2°C to +8°C range
- there is a significant change in staff.

Key points for handling and storing vaccines

Ordering

- Overstocking your vaccine refrigerator will affect vaccine efficacy.
- To avoid overstocking and to ensure stock rotation, a minimum vaccine stock of two weeks is recommended, but no more than 6 weeks of stock should be held at any given time.
- Providers are entitled to two free deliveries per month from your ProPharma regional store.
- To estimate the volumes of National Immunisation Schedule vaccines for your clinic consider:
  - the calculation tables in the *National Guidelines for Vaccine Storage and Distribution 2012*
  - the number of children enrolled in your clinic aged under 5 years, and 11 and 12 years of age (depending on whether a school-based programme is delivered in your region (as per your cold chain policy)
  - adding a buffer of vaccines for number of casual patients
  - existing stock in refrigerator
  - type and capacity of refrigerator
  - seasonal variations (eg, Annual Influenza Programme)
  - disease outbreaks and special programmes.
- Use vaccines with shortest expiry date first.

For more information refer to the *National Guidelines for Vaccine Storage and Distribution 2012*.

Receiving

Checklist

- ✔ On receipt of vaccines from the distributor check that the ice packs are still cool.
- ✔ Check that the contents match the order form.
- ✔ Check that the vaccine delivery is within the stated delivery window.
- ✔ Check for a ProPharma data logger which may be packed with your vaccine order and follow the instructions attached to your order for the return of the data logger to the ProPharma regional store.
- ✔ Check for National Cold Chain Audit Tag Alert monitors and record cards and complete the card on arrival.
- ✔ Once satisfied with order, sign and date the receipt of the vaccines.
- ✔ Enter new stock in your vaccine register (an example can be found at www.immune.org.nz).
- ✔ Immediately store vaccines in the refrigerator.
- ✔ Place new vaccines behind current stock to ensure rotation with batch numbers and expiry dates within easy view (where possible).

Storing

- **All immunisation providers must use a pharmaceutical refrigerator for vaccine storage.**
- All National Immunisation Schedule and privately purchased vaccines must be stored between +2°C to +8°C.
- Your refrigerator should have an externally visible maximum and minimum temperature display.
- All clinic vaccine refrigerators must have a digital temperature recording device (eg, data logger) to record and download data from the previous month.
- Leave the vaccines in their original packaging, as this acts as insulation.
- Keep any National Cold Chain Audit TagAlert monitors and record cards with the vaccines they arrived with.
- The vaccine stock kept in the refrigerator does not exceed the manufacturer's recommendations for maximum storage capacity.
- Air should be able to circulate in the refrigerator. There should be 25 to 30mm between vaccines at the back of the refrigerator and shelf above.
- The refrigerator should have grill-like shelving to allow for air circulation.
- Do not store any non-medical material in refrigerator, for example, food.
- Minimise opening and closing the refrigerator door.
- Keep the top of the refrigerator clear.

The efficiency of refrigerators can decline with excessive ambient (surrounding) temperatures.

Position your refrigerator:

- in a well-ventilated room
- away from direct sunlight or a heat source (ie, autoclave, heater)
- at least 10 cm away from surrounding surfaces, to allow air to circulate around the condenser of the refrigerator
- against an internal rather than external wall, and levelled in a way that allows the door to close automatically if left ajar.

The refrigerator must be left on at all times and have an independent power point and a plug-in surge protection unit. The plug should be taped over, with a written warning against unplugging the refrigerator.

Do not move the refrigerator before contacting the refrigerator manufacturer.

Domestic refrigerator

Domestic refrigerators are not recommended by the Ministry of Health for vaccine storage. Domestic refrigerators are not designed to maintain the +2°C to +8°C temperature range and they warm up quickly.

All domestic refrigerators should be replaced with a pharmaceutical refrigerator. If your clinic is currently using a domestic refrigerator please follow the checklist below.

Checklist

- ✔ Develop an agreed plan and timeframe with your local immunisation coordinator to work towards the purchase of a pharmaceutical refrigerator.
- ✔ A domestic refrigerator must have a digital temperature monitoring device (eg, data logger) that measures the current temperature and the minimum and maximum temperatures reached since the device was last reset.
- ✔ Vaccine stock should not exceed 50 percent of a domestic refrigerator's total storage capacity.
- ✔ Store vaccines according to temperature sensitivity and the temperature mapping of the refrigerator (eg, live vaccines in the coolest part and freeze sensitive in the warmest part).
- ✔ Vaccines must not be stored near the ice plate or in the door.
- ✔ Fill freezer shelves with ice packs or plastic bottles of plain water.
- ✔ Water buffers (bottles filled with salt water) should be placed in empty spaces (eg, refrigerator floor or door to assist in preventing temperature swings when the door is open).
- ✔ Defrost the domestic refrigerator regularly or once the ice layer is 5–10mm thick.

More information on vaccine storage in a domestic refrigerator can be found in the *National Guidelines for Vaccine Storage and Distribution 2012*.

What to do if you have a cold chain failure

If your vaccine refrigerator temperature is outside the +2°C to +8°C temperature range at any time:

- refer to the Temperature Control Chart on page 9 and the *Immunisation Handbook 2011*
- label the vaccines 'not for use' and leave in the refrigerator
- download the data logger and check for inconsistencies or temperature fluctuations
- contact your local immunisation coordinator for advice
- if you cannot contact your local immunisation coordinator, contact your IMAC regional advisor for advice
- document the steps and actions you have taken in your cold chain record.

National Cold Chain Audit

The National Cold Chain Audit monitors the cold chain of the National Immunisation Schedule vaccines from their New Zealand point of origin at the National Vaccine Store until the last dose in the vaccine box has been administered.

TagAlert monitors and record cards are attached to randomly selected National Immunisation Schedule vaccine packs (except those for influenza). They start the journey in the vaccine pack at the National Vaccine Store at ESR; travel through the ProPharma regional stores and onto the provider. In some cases, they continue on to outreach or school programmes. The TagAlert monitor, record card and vaccines travel together until the last dose of vaccine from the pack is administered.

The TagAlert monitor will detect temperature problems associated with storage or transport of vaccines. However, the effectiveness of the programme depends on how well the record cards are completed at each step.

When a TagAlert monitor and record card arrives at your clinic

There is a bright yellow sticker on the vaccine pack when a TagAlert monitor and record card are attached.

When the TagAlert monitor and record card arrives at your clinic the first two lines on the record card should have been completed with an ‘OK.

Record the vaccine’s date of arrival, the cold and warm status from the TagAlert display, your clinic’s name and town in the space provided on the record card.

Keep the TagAlert monitor and record card with the vaccine box they arrived with. Secure the card around the pack with either tape or a rubber band.

The TagAlert displays an ‘OK’ symbol if the temperature the vaccines have been stored in is between+2°C to +8°C.

The digital monitor has four visible ‘alert numbers’:

- 1 = for temperatures 0°C and below
- 2 = for temperatures above 10°C
- 3 = for temperatures above 25°C
- 4 = for temperatures above 34°C

Each time you use a vaccine with a TagAlert monitor attached, check the monitor for any visible alarms.

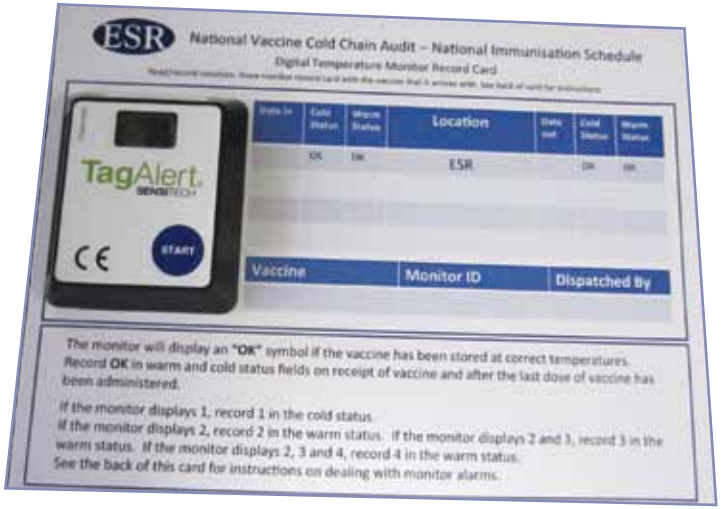
If the vaccine travels onward (eg, to a school or outreach programme) ensure that the TagAlert monitor reads 'OK', then record the date out and complete the cold and warm status section on the record card. Send the vaccines, the TagAlert and record card together.

When the last dose of the vaccine is prepared or administered, record the date out and complete the cold and warm status sections on the record card for the final time.

If one of the TagAlert visible alarms is shown do not remove the vaccines from the refrigerator or dispose of the vaccines without seeking advice from your local immunisation coordinator.

It is likely all the vaccines have experienced a cold chain failure, not just the vaccine box with the TagAlert attached. Label all the vaccines 'Not for use', document the number from the TagAlert display on the record card and contact your local immunisation coordinator to discuss further action.

For more information on the National Cold Chain Audit including frequently asked questions see the *National Guidelines for Vaccine Storage and Distribution 2012*.



Return the TagAlert monitor and the record card to ESR in the envelope provided to:

ESR – National Vaccine Store
34 Kenepuru Drive
PO Box 50-348
Porirua 5240

Self-audit for safe vaccine handling and storage

Completing this self-audit in the recommended timeframes below and using it as a tool with new staff can help improve your clinic's vaccine management.

Daily

- Record the vaccine refrigerator's maximum and minimum temperatures at the same time every day.
- Check and view any National Cold Chain Audit TagAlert monitors currently in your vaccine refrigerator and, if required, take necesary action.
- Document your clinic's cold chain history as required (eg, failure, actions taken, purchase of new cold chain equipment).

Monthly

Jan ❑ Feb ❑ Mar ❑ Apr ❑ May ❑ Jun ❑

Jul ❑ Aug ❑ Sep ❑ Oct ❑ Nov ❑ Dec ❑

Yes	No	
❑	❑	All National Immunisation Schedule vaccines are stored between +2°C to +8°C.
❑	❑	The refrigerator temperature is monitored and documented at the same time each working day.
❑	❑	Temperature charts are reviewed monthly to determine if there are any cyclical changes.
❑	❑	Vaccines are left in their original packaging with ventilation around boxes.
❑	❑	All vaccine batch numbers and their expiry dates are entered into a vaccine register.
❑	❑	Vaccines are stored with the batch number and expiry label showing.
❑	❑	The volume of vaccines kept in the refrigerator does not exceed the manufacturer's recommendations for maximum storage capacity.
❑	❑	Non medical materials are not stored in refrigerator eg, food.
❑	❑	The top of the refrigerator remains clear except for the temperature record. No ice is visible on the back plate inside the refrigerator.
❑	❑	Contact your local immunisation coordinator when temperatures are outside +2°C to +8°C.
❑	❑	Download your electronic temperature monitoring device (eg, data logger) each month to check for inconsistencies or temperature changes. Review this information with your immunisation coordinator.
❑	❑	Retain a copy of your monthly downloads from your electronic temperature monitoring device, either electronically or as a hard copy or both.

Six-monthly

Apr ❑ Oct ❑

Yes	No	
❑	❑	The door seal is checked and in good condition. A paper check is done – see *Immunisation Handbook 2011*.
❑	❑	Refrigerator interior cleaned – see the *Immunisation Handbook 2011*.

Annually

_____ (month) ❑

Yes	No	
❑	❑	Refrigerator is situated in a well-ventilated room and not in direct sunlight or against a heat source.
❑	❑	The refrigerator has an independent power point, which is taped over or permanently wired into the outlet to overcome the risk of deliberate, or accidental disconnection. Ensure a power surge protector is in place.
❑	❑	The refrigerator must be a minimum of 10 cm away from surrounding surfaces to allow air to circulate around the condenser.
❑	❑	The refrigerator has been serviced annually according to manufacturer's recommendations.
❑	❑	The refrigerator has been externally monitored by either your local immunisation coordinator or refrigerator manufacturer.
❑	❑	The clinic has an appropriately sized chilly bin for the alternative storage of vaccines eg, during a power failure.
❑	❑	The battery for the digital min/max thermometer is replaced as per the manufacturer's recommendations.
❑	❑	Electronic temperature logging devices should be independently calibrated annually.
❑	❑	Provider cold chain policy is reviewed and updated.
❑	❑	Review the temperature gradients in your refrigerator – discuss with your local immunisation coordinator.
❑	❑	Review your methods to safely return vaccines for destruction.

Name: _____ Signature: _____ Date: _____

Review the results in your practice meetings to continuously improve vaccine management.

Temperature Control Flow Chart

ALL VACCINES MUST BE STORED BETWEEN +2°C to +8°C
(including National Immunisation Schedule, influenza and privately purchased vaccines)
Record refrigerator temperatures at the same time daily

BELOW 0°C – Too LATE!!

1. **DO NOT USE any vaccines.**
2. Do not discard any vaccines. Isolate all vaccines in the refrigerator at this stage and label them with do not use until advised otherwise. Keep the refrigerator door closed.
3. Download your data logger and check for inconsistencies or temperature fluctuations.
4. Contact your local immunisation coordinator to report and discuss the cold chain failure.
5. Your local immunisation coordinator will indicate what changes are required,
   eg, contacting refrigerator manufacturers to adjust thermostat.
6. Make a list of all damaged vaccines for your records on the Clinic Cold Chain History section of this guide.
7. If advised, then return damaged vaccines to ProPharma (see 'Returning Vaccines for Destruction' section).
8. Do not re-order vaccines until the refrigerator temperature is within +2°C to +8°C.

0°C TO +2°C
ALERT– ACT QUICKLY!!

1. Download your data logger to check for inconsistencies or temperature fluctuations.
2. Discussion with your local immunisation coordinator will indicate what changes are required.
3. Monitor refrigerator closely checking temperature twice daily (am and pm) until within range.

+8°C to +25°C

1. Check the obvious, eg, door open, refrigerator unplugged.
2. Download your data logger to check for inconsistencies or temperature fluctuations.
3. Contact your local immunisation coordinator if the refrigerator temperature has been above +8°C for more than 24 hours.
4. Make a list of all damaged vaccines for your records on the Clinic Cold Chain History section of this guide.
5. If advised, then return damaged vaccines to ProPharma (see Returning Vaccines for Destruction section).
6. The refrigerator should be checked by the manufacturer or maintenance technician before ordering more vaccines. Consult with your local immunisation coordinator.

Contact Healthcare Logistics for advice on the influenza vaccines or privately funded vaccines.

Returning vaccines for destruction

Contact your local immunisation coordinator before returning any vaccines for destruction.

Unwanted, discontinued, expired or damaged National Immunisation Schedule vaccines need to be disposed of safely by returning them to your ProPharma regional store for controlled destruction.

Vaccines should never be disposed of in a sharps bin or down the sink.

Vaccines can be damaged in many ways:

- in transit
- vaccines delivered to a provider outside the recommended temperature range
- vaccines are not refrigerated on arrival at the clinic
- expired vaccines
- clinic vaccine refrigerator malfunction.

Temperatures below O°C can destroy the effectiveness of many vaccines. In contrast, the potency of MMR is particularly affected by extended exposure to heat. Physical changes to vaccines are not always apparent after exposure to freezing or very high temperatures, so close attention must be paid to temperature controls to ensure ineffective vaccines are not given.

Returning vaccines for destruction

1. Before returning any vaccines for destruction contact your local immunisation coordinator for advice and support.

2. Separate damaged or expired vaccines from normal stock and clearly mark them with a 'vaccines for destruction' label. The label for your ProPharma regional store can be downloaded from the ProPharma website at www.fundedvaccines.co.nz

Sample sticker – Auckland branch.

3. Vaccines for destruction should be clearly marked and packed using the standard health and safety precautions that apply to medical sharps waste.

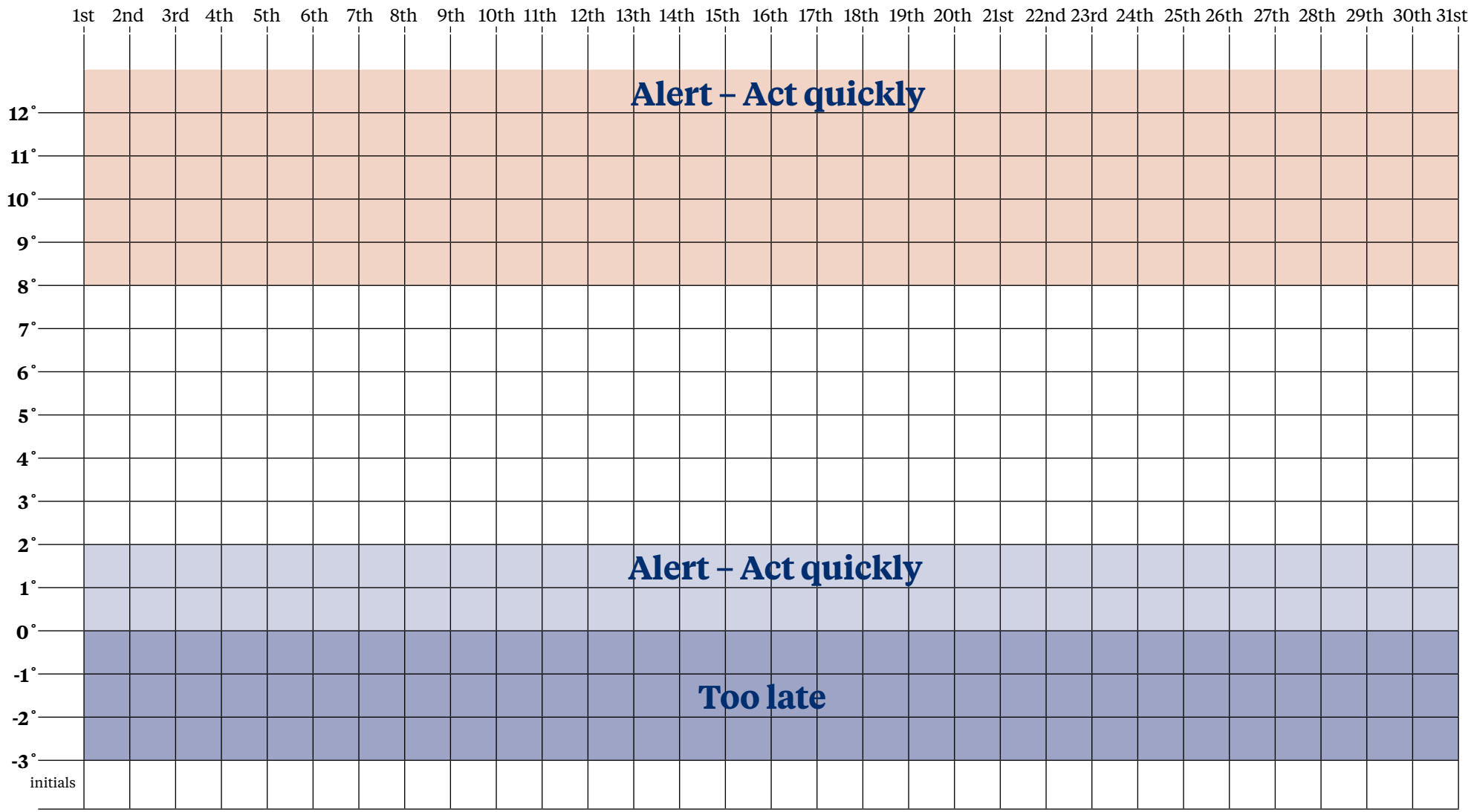
4. Pack the returning vaccines in a cardboard box for the courier with a completed 'Vaccines for Destruction' label. Needles should never be included in the returning vaccine package.

5. Please ring ProPharma to arrange for vaccines to be picked up.

For advice on returning influenza, private and travel vaccines contact Healthcare Logistics directly.

Daily vaccine fridge min/max temperature recordings

Month: _____



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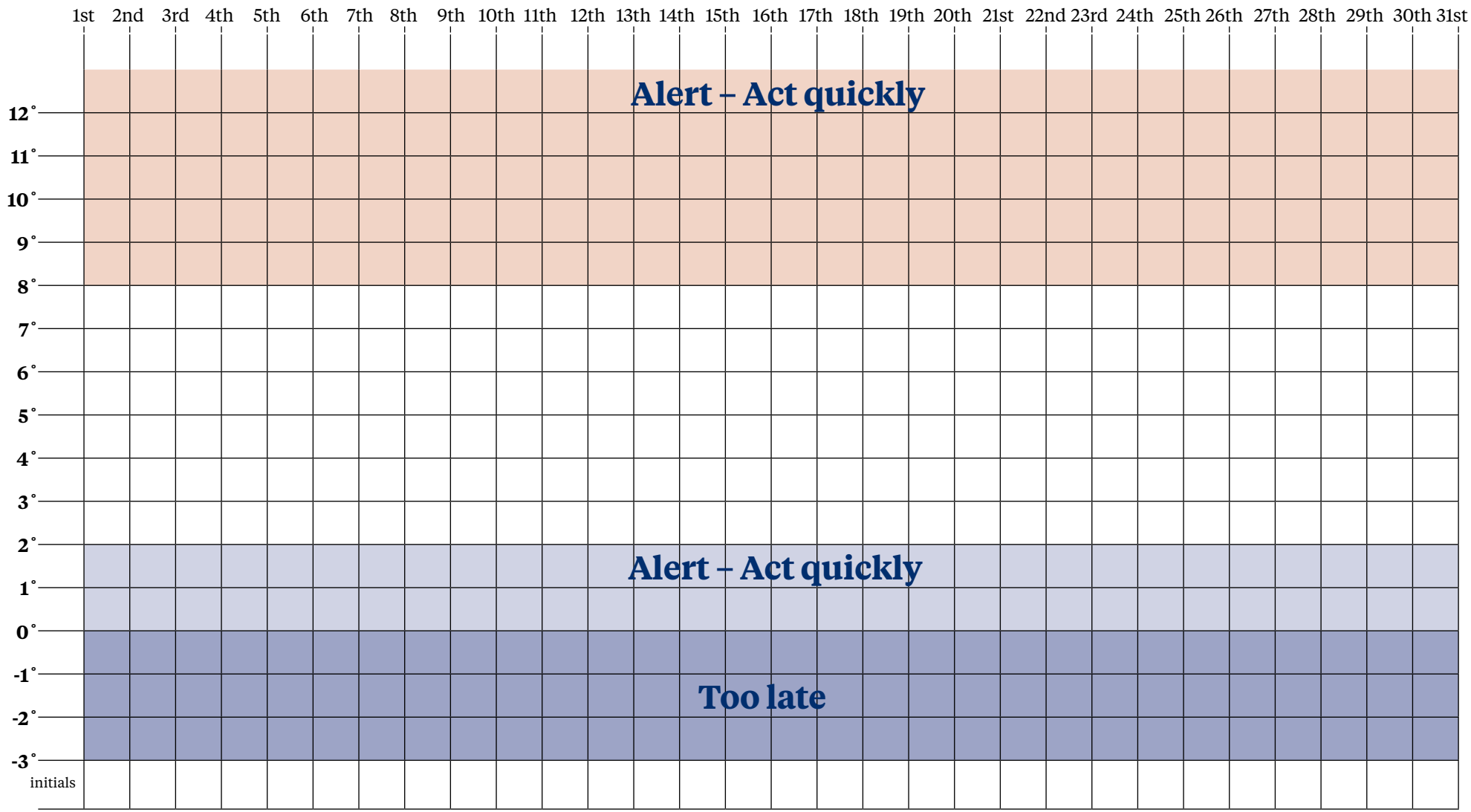

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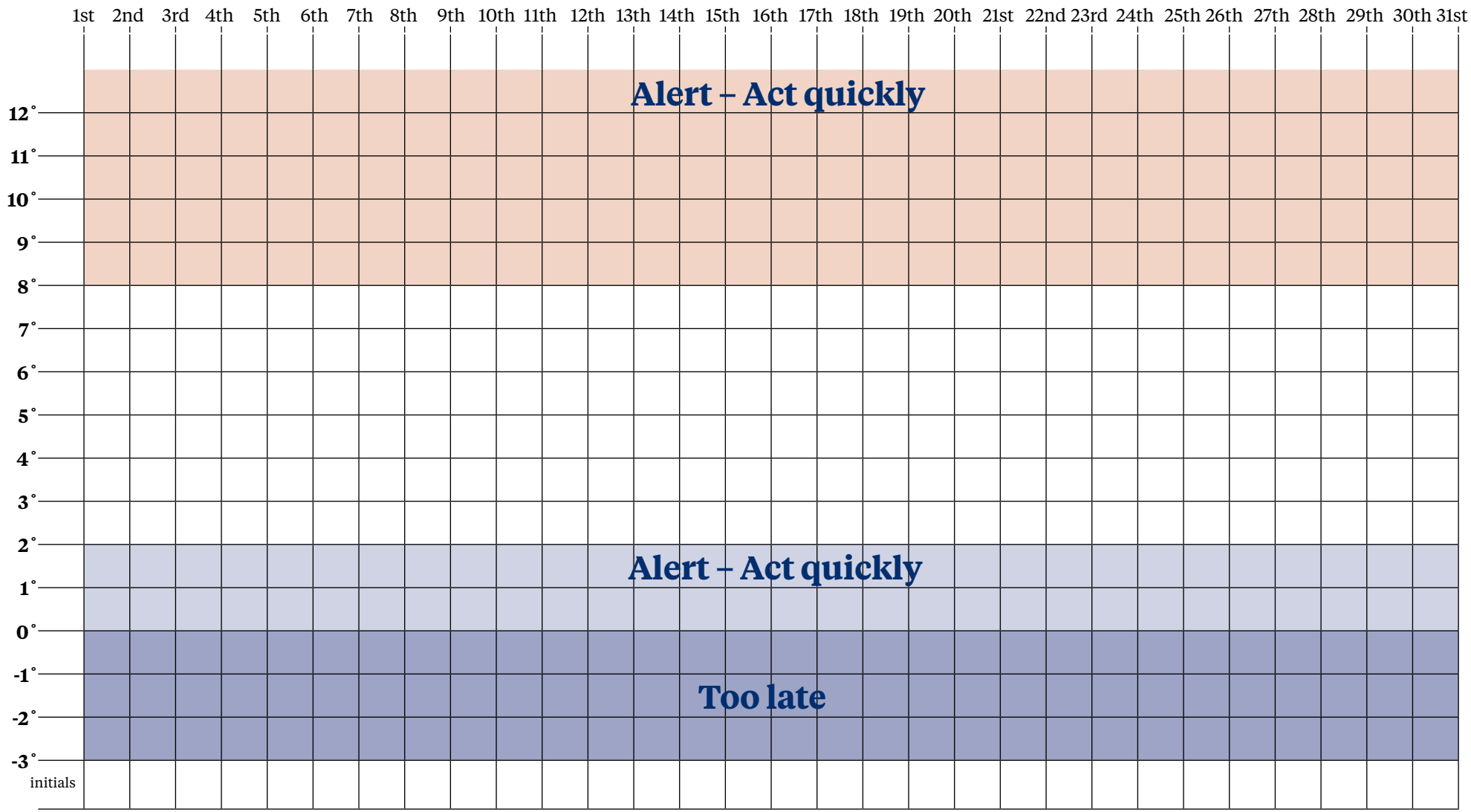

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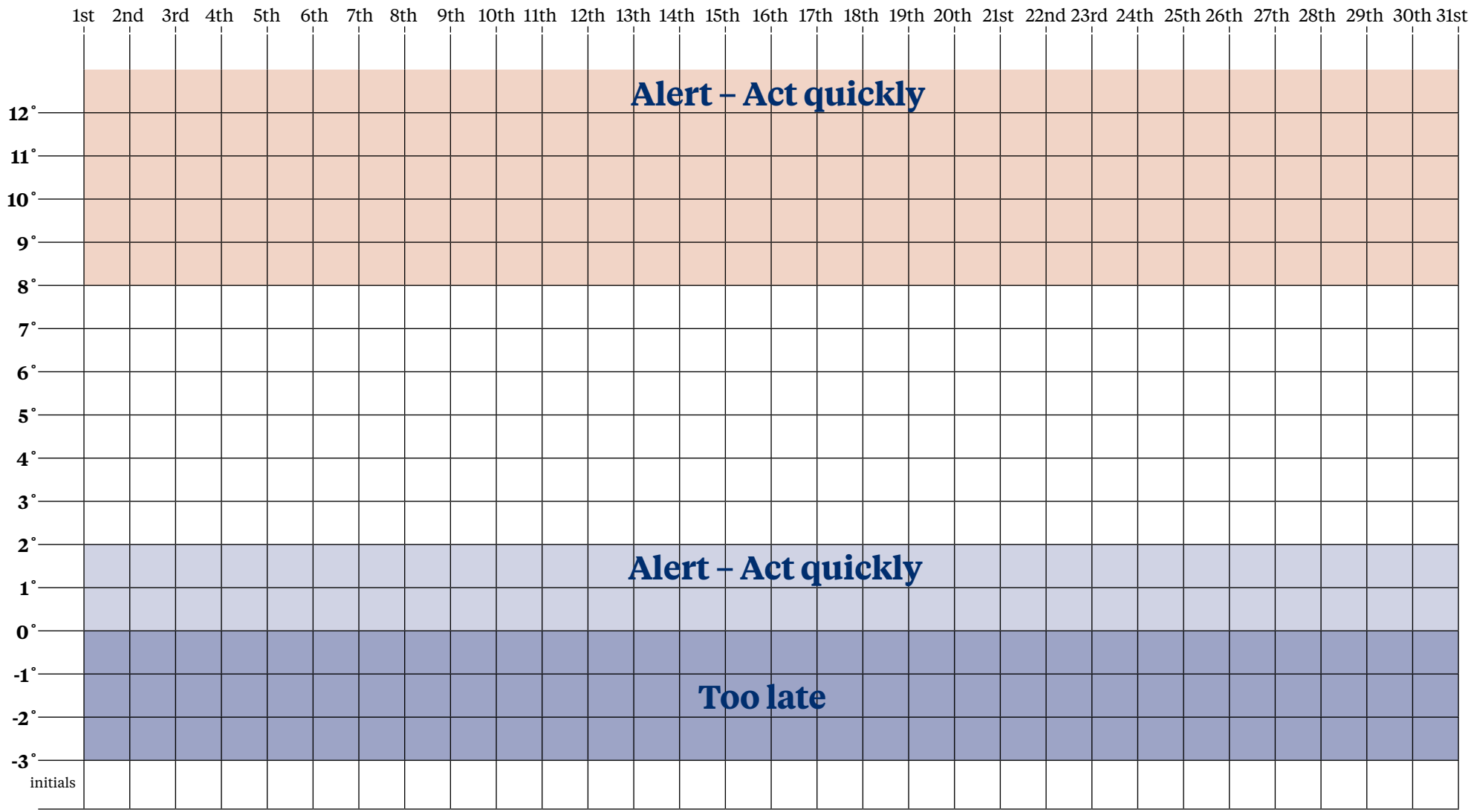

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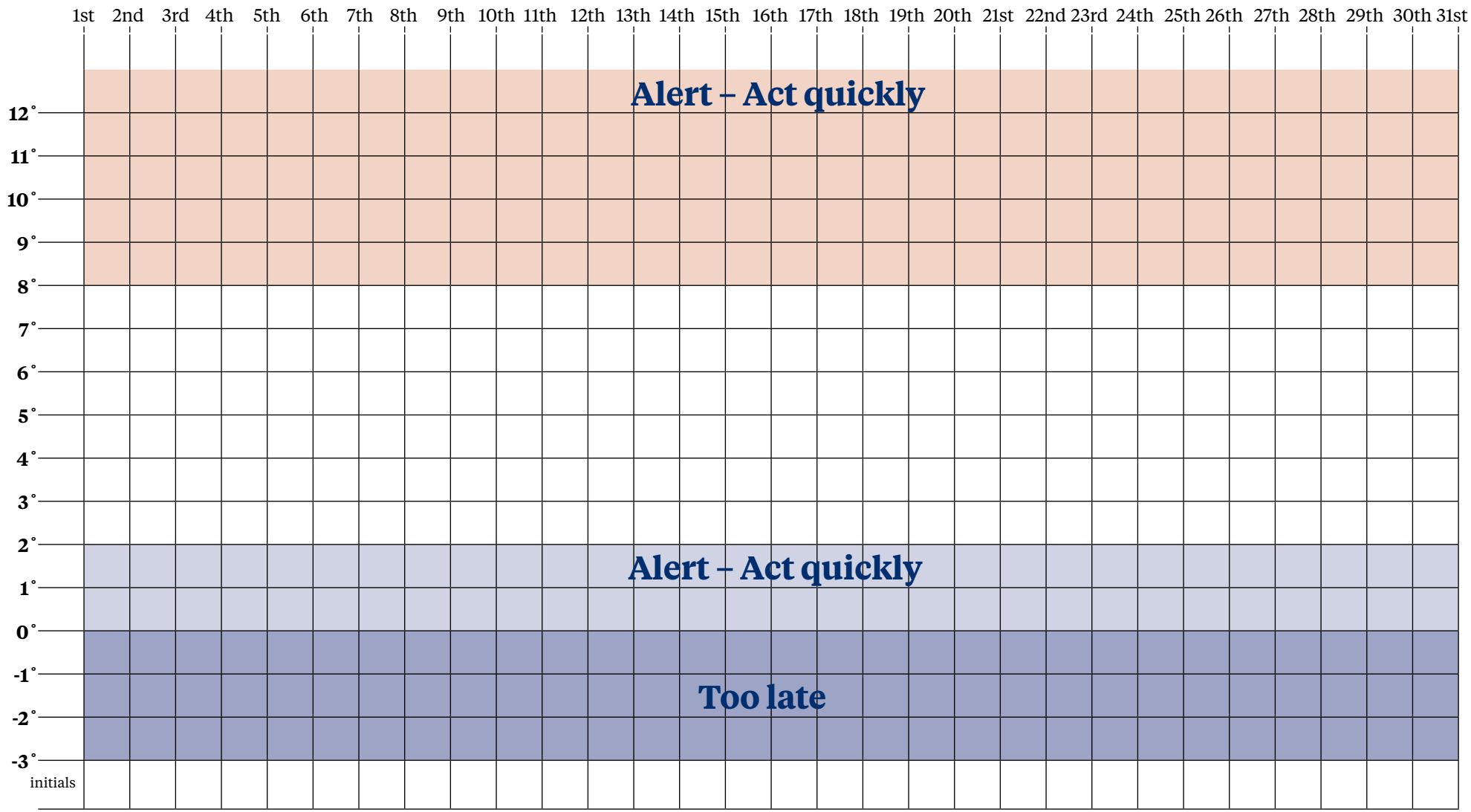

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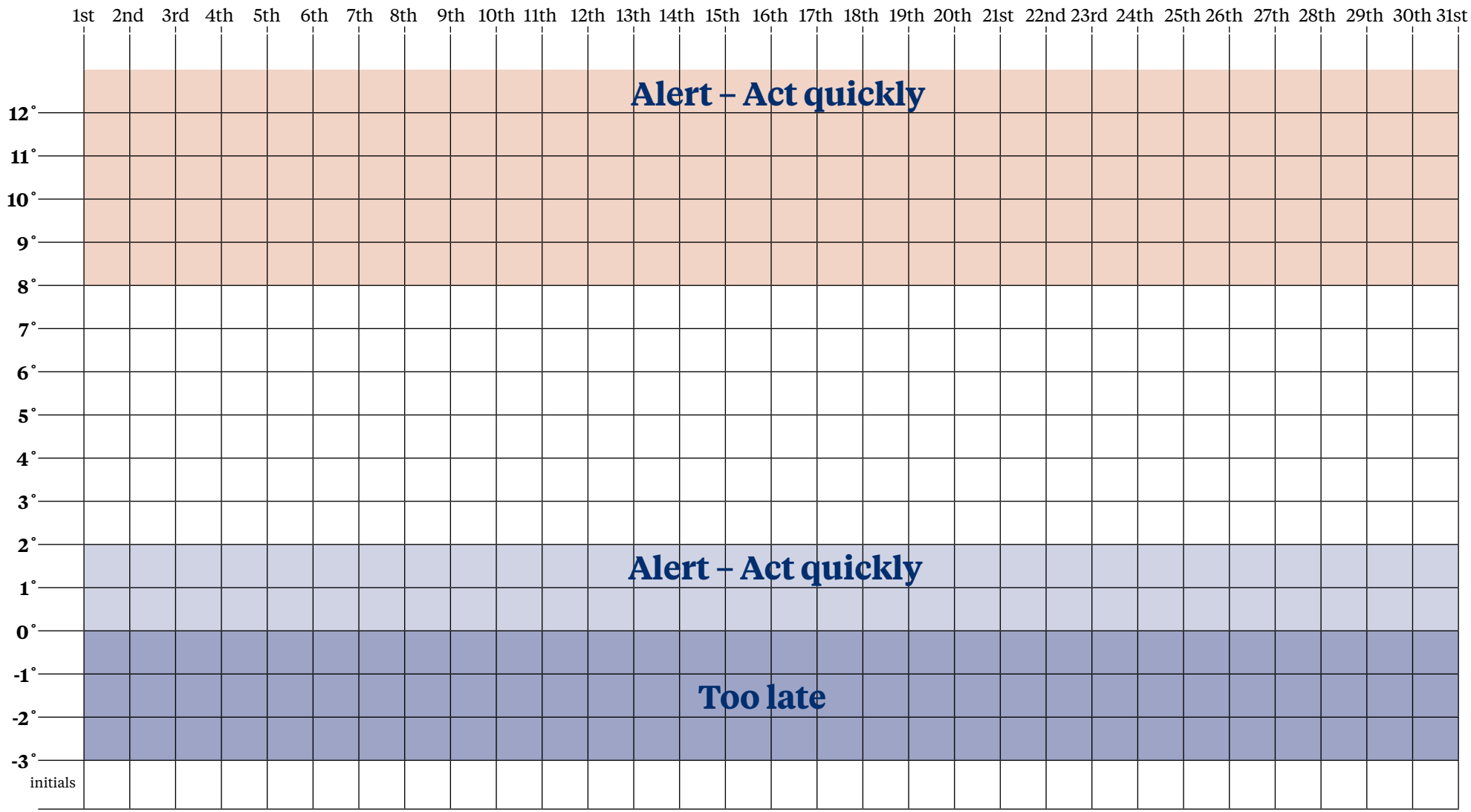

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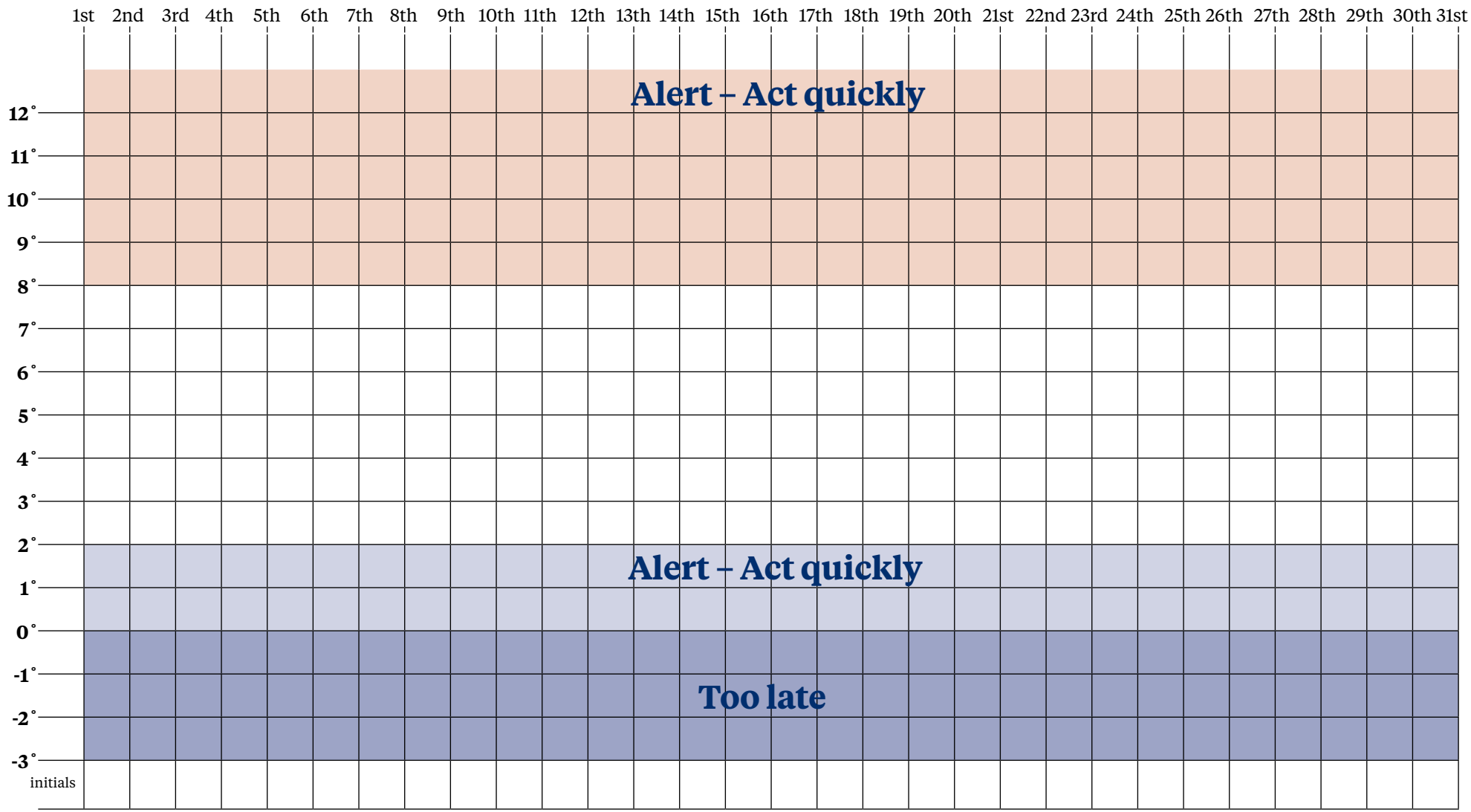

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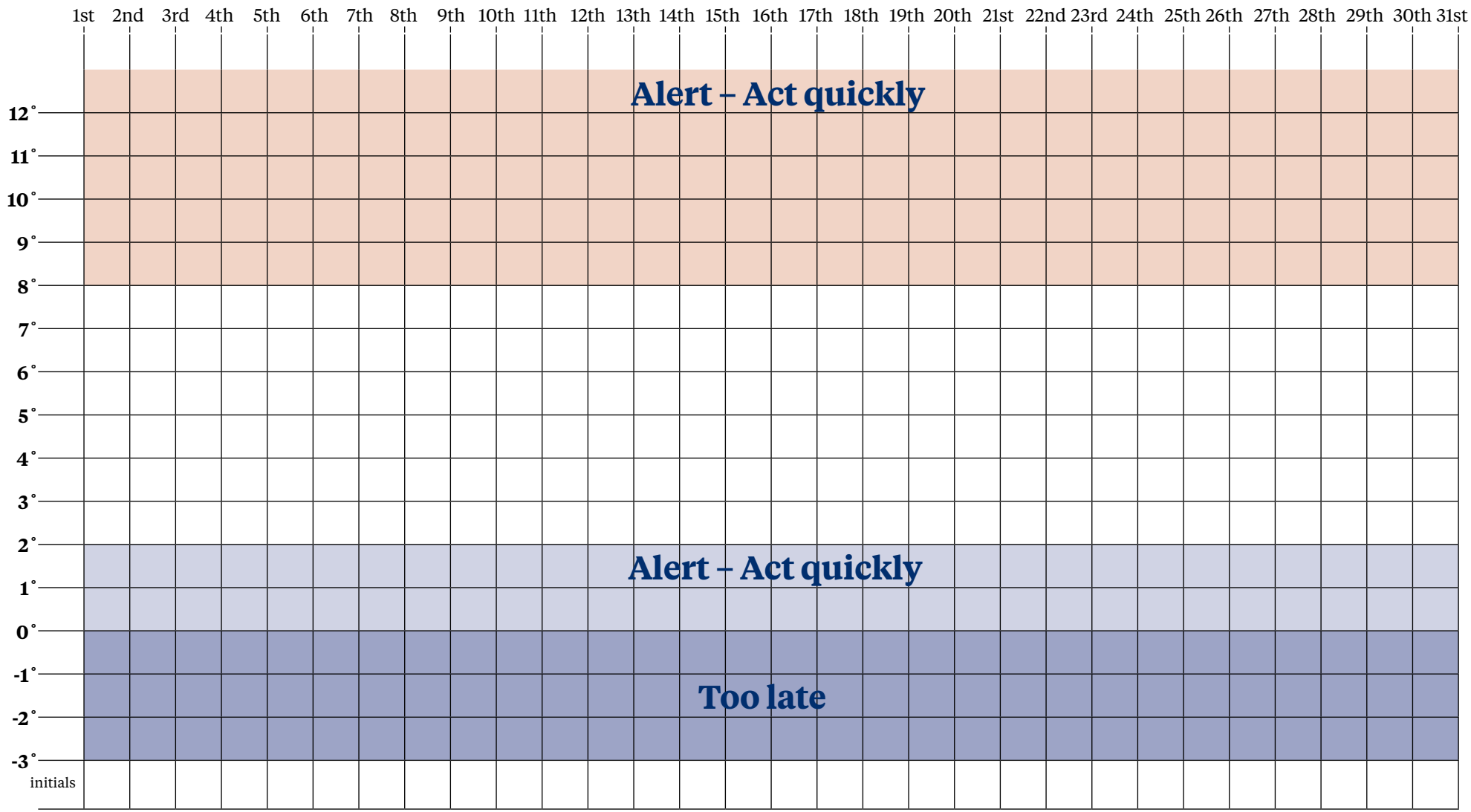

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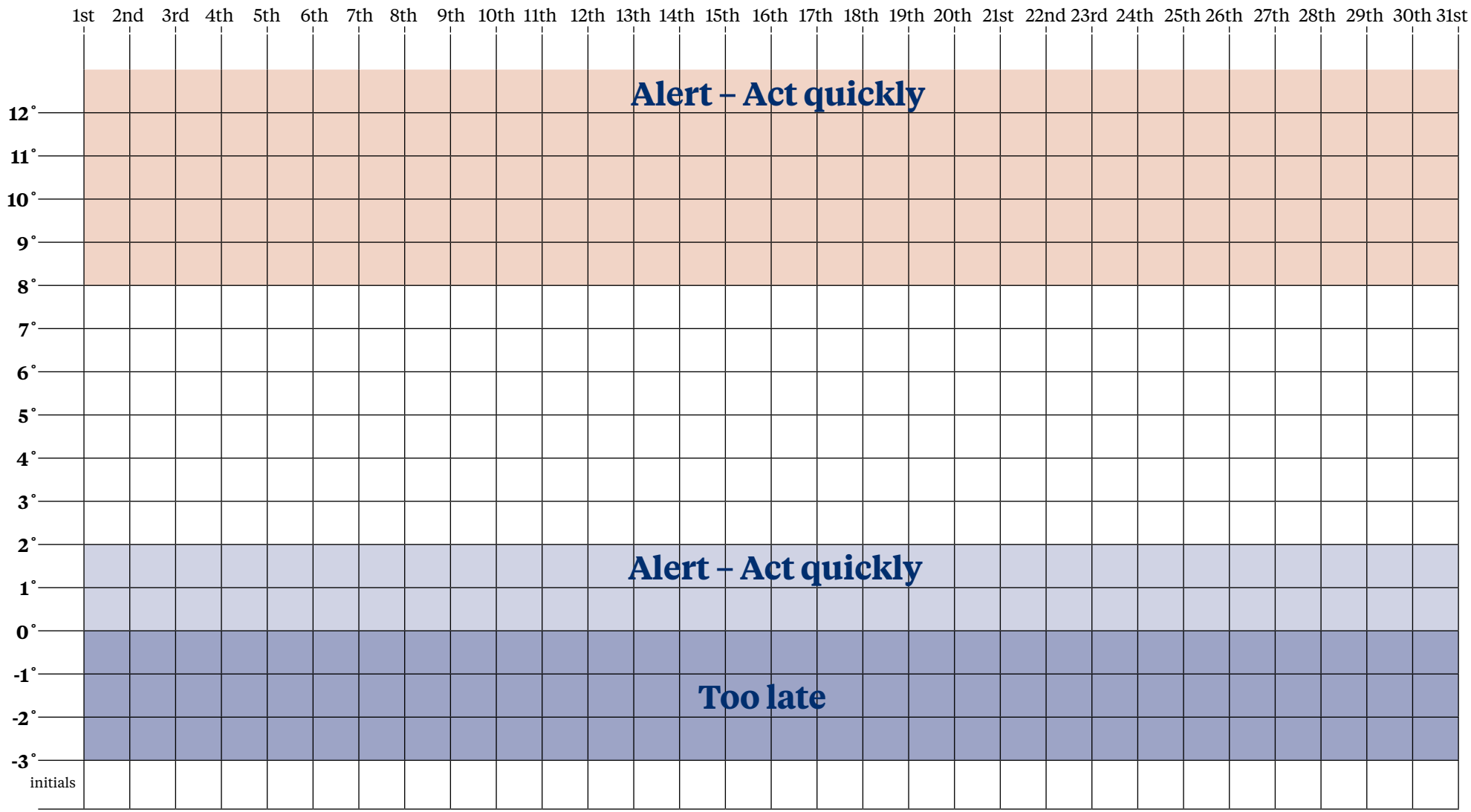

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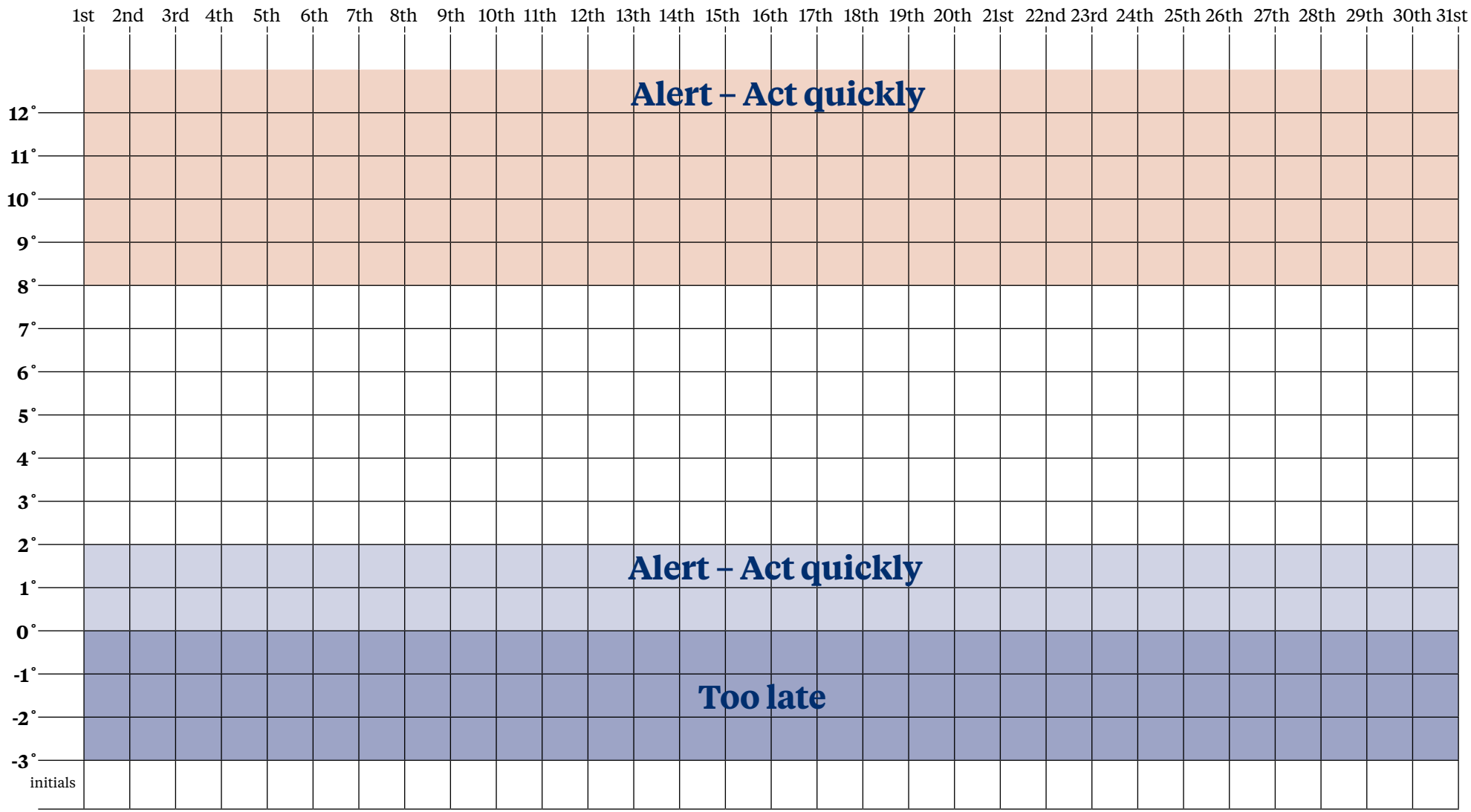

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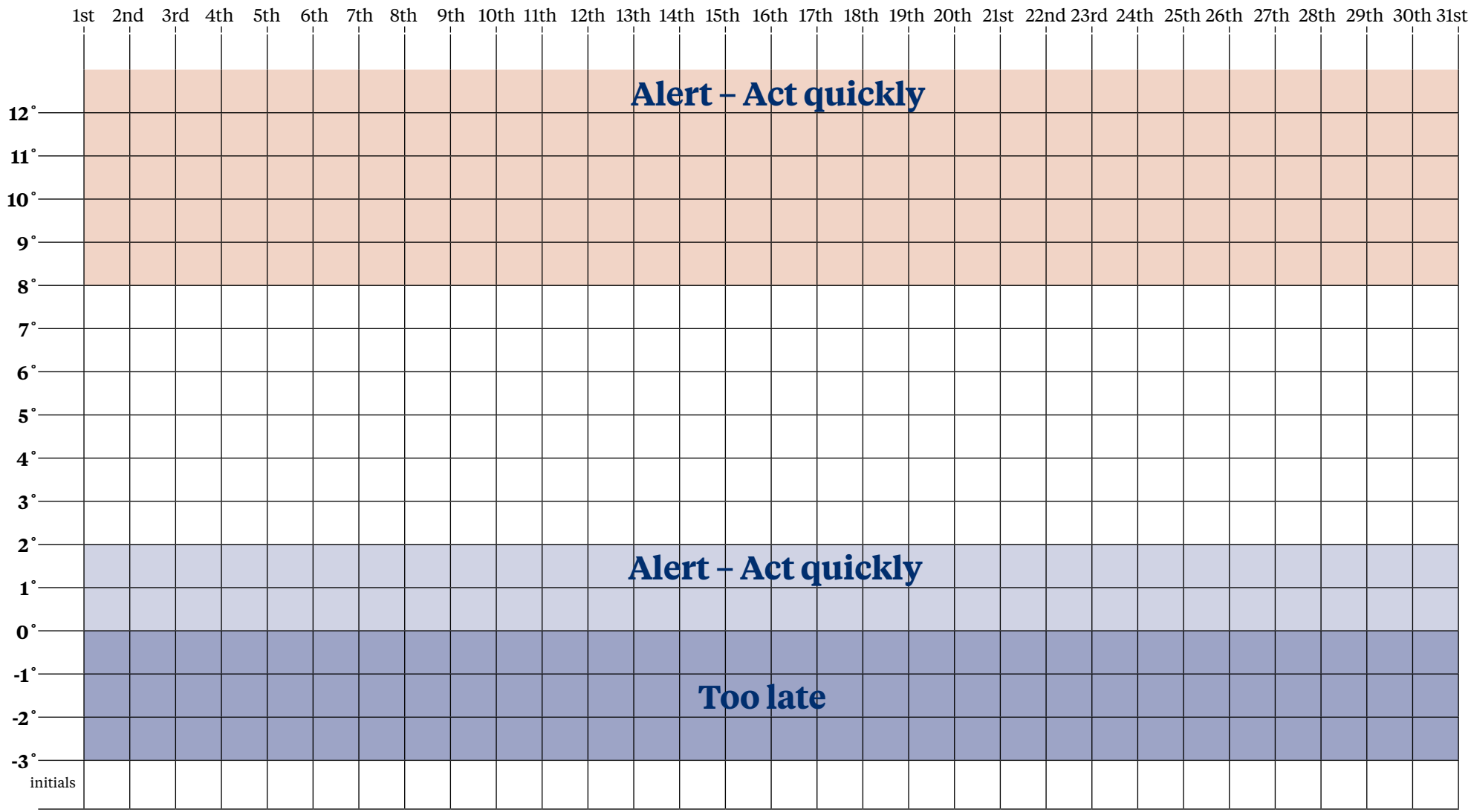

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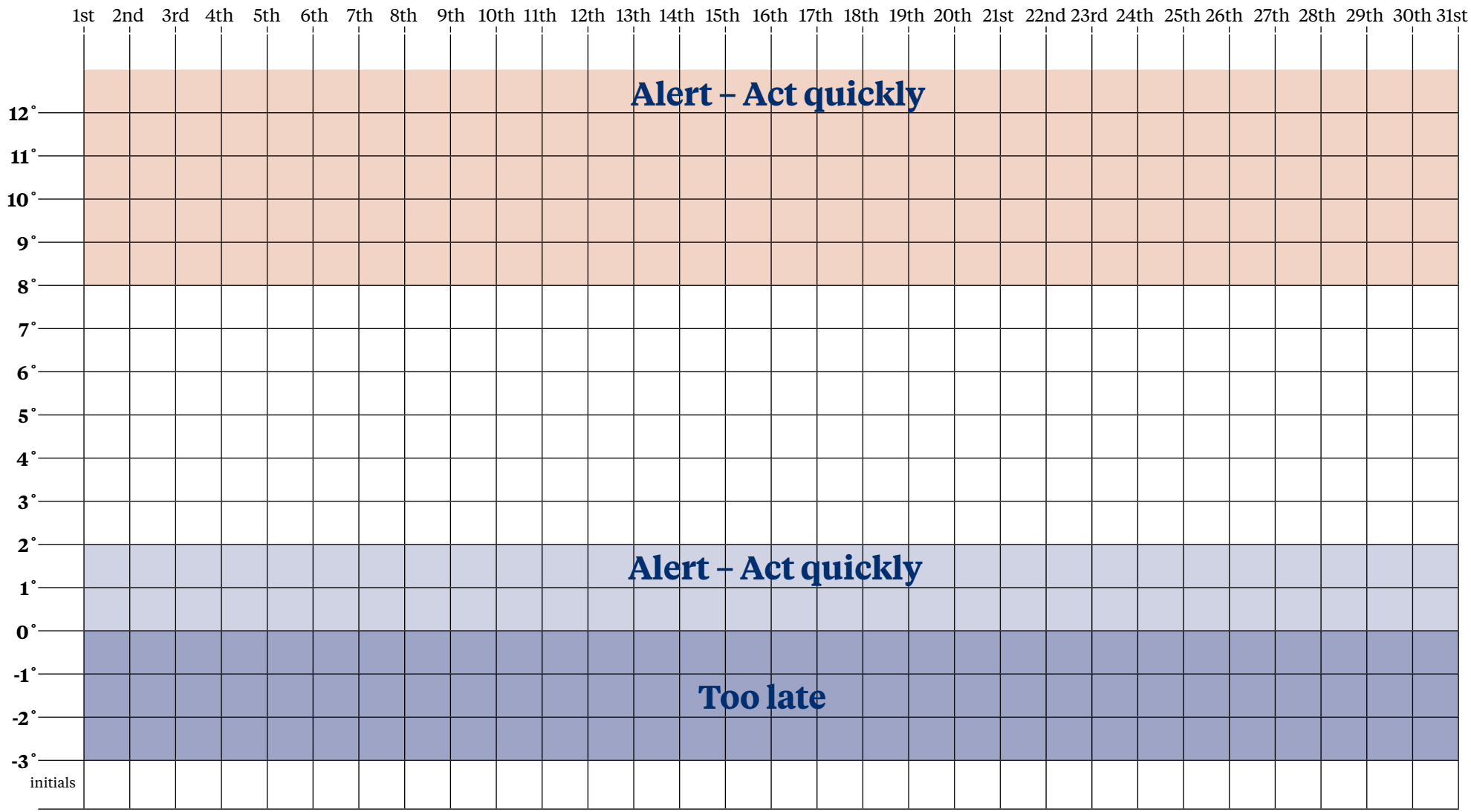

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Clinic cold chain history

Record of clinic cold chain events for the year, for example:

- change in the individual responsible for the clinic's cold chain management
- cold chain accreditation review
- staff training
- annual logging
- purchase of a new vaccine refrigerator
- cold chain failure(s) and actions taken
- review of clinic's cold chain policy
- annual calibration of the clinic's digital temperature monitoring device (eg, data logger)
- annual vaccine refrigerator maintenance.

Date	Comments – Action taken	Name	Sign

Date	Comments – Action taken	Name	Sign

Key contacts

Regional immunisation advisors (IMAC)

Northern:	Phone: 027 497 6971 Email: imacnth@ihug.co.nz
Central:	Phone: 027 232 4567 Email: imaccent@ihug.co.nz
South Island:	Phone: 027 242 2451 Email: imacsth@ihug.co.nz

For immunisation coordinator contact details, contact the regional immunisation advisor for your region or the Immunisation Advisory Centre.

Immunisation Advisory Centre (IMAC)

Phone: (0800) IMMUNE (0800 466863) or (09) 373 7599

Institute of Environmental Science and Research (ESR) – National Vaccine Store

PO Box 50-348, Porirua 5240

Phone: 0800 4ESR EH (0800 437 734) Option 2 or (04) 914 0792

ProPharma regional stores

ProPharma provides a vaccine distribution service only, not a technical inquiry/assistance service. All technical inquiries should be directed to the local immunisation coordinator or regional immunisation advisor in the first instance.

ProPharma Whangarei	(09) 438 9681
ProPharma Auckland	(09) 570 1081
ProPharma Hamilton	(07) 957 3850
ProPharma Wellington	(04) 576 1811
ProPharma Christchurch	(03) 389 5459
ProPharma Dunedin	(03) 474 5061

Healthcare Logistics

Healthcare Logistics stores and distributes influenza vaccines, private and travel vaccines.

Healthcare Logistics customer service number is (09) 969 0736.

References

Health (Retention of Health Information) Regulations 1996.

Ministry of Health. 2011. *Immunisation Handbook 2011*. Wellington: Ministry of Health.

Ministry of Health. 2012. *National Guidelines for Vaccine Storage and Distribution 2012*. Wellington: Ministry of Health.

Resource Management Act 1991.


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