

Adverse events prevention and management guideline

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1. Purpose

This guideline provides detailed guidance for myotherapists who perform dry needling on how to:

- minimise the risk of adverse events during treatment, and
- manage adverse events that do arise.

Myotherapy Association Australia (MA) expects myotherapists who practise dry needling to follow this guideline and ensure that other staff in their practice involved in dry needling also follow it. Departures from practice recommended by this guideline, which place patients at greater risk, may lead to disciplinary action under MA's Rules of Association.

MA may update this guideline from time to time to reflect current practice. The version of this guideline on MA's website at any given time is the current version.

Myotherapists who perform dry needling are also expected to be familiar with, and follow, the current federal and relevant state or territory and/or local council standards, regulations and guidelines for skin penetration treatments. If this guideline should contradict those federal and state/territory texts, the federal and state/territory/local council texts overrule this guideline, and myotherapists should follow them on the point in conflict.

Where a myotherapist is also qualified as an acupuncturist or physiotherapist, they should read this guideline alongside the guidelines on safe dry needling practice and adverse events management provided by their acupuncturists' professional association.

2. Definitions

See the Definitions section of Myotherapy Australia's Code of Practice for the definitions of 'adverse event' and 'dry needling'.

3. Severity levels of adverse events

See the Definitions section of Myotherapy Australia's Code of Practice for the definitions of 'adverse event' and 'dry needling'.

This guideline refers to three different severity levels of adverse events. The following summary of these levels is closely based on that of Physiotherapy Alberta in their Dry Needling Adverse Events FAQs (2021):

Mild (minor)

- bruising
- bleeding
- pain during treatment
- pain after treatment
- aggravation of symptoms followed by improvement
- feeling relaxed/ energised
- feeling tired/ drowsy
- feeling faint
- dizziness
- nausea
- sweating

Significant

- prolonged pain at site
- extensive bruising
- profuse sweating
- severe nausea
- vomiting
- fainting
- headache
- extreme fatigue

- severe emotional reaction
- gastrointestinal disturbance
- skin irritation
- slurred speech
- forgotten needle/patient
- seizure

Serious

- pneumothorax
- puncture of other vital tissue
- systemic infection
- broken needle
- needle stick injury

4. Risks of adverse events

Myotherapists who perform dry needling are expected to

- keep abreast of literature on risks of dry needling, and
- update their informed consent process information on these risks in line with the current literature.

Risks will vary depending on the technique used, the patient's health, the area of the body treated and the myotherapist's competence.

4.1. Patients' conditions that pose extra risks

- A person with diabetes
 - o is more likely to faint if their blood sugars aren't managed before the needling, and
 - o may have poor peripheral circulation, so the myotherapist needs to assess the risk of needling in peripheral areas.
 - o Dry needling, because it affects the patient's autonomic nervous system, may cause a reaction that will affect the patient's medications and cause an over-correction of their condition. The myotherapist should discuss this possibility with the patient when seeking their informed consent.
- Where a patient has a bleeding disorder such as haemophilia:
 - o Smaller gauge needles should be used to minimise bleeding.
 - o The risk of needling over an artery must be carefully assessed.
- Where a patient is using a high dosage of a blood-thinning medication such as Plavix or Warfrin:
 - o Use smaller gauge needles.
 - o Apply pressure to the insertion site after withdrawing the needle.
 - o Avoid needling into joints to avoid causing haemarthrosis.
- A myotherapist mustn't needle the scalp area of an infant before the fontanelle has closed: the risk is too great.
- Patients with the following conditions present a greater risk of infection:
 - o a cancer patient who is on immunosuppressants
 - o a patient with an acute immunological disorder (such as acute states of rheumatoid arthritis, psoriatic arthritis or systemic lupus erythema), and
 - o a patient with an incompetent heart valve or valve replacement. (In this case, seek advice/consent and/or an antibiotic prescription from the patient's GP or cardiac specialist.)
 - o A patient taking oral corticosteroids may pose an increased infection risk.
- Don't needle into an artificial joint because of the risk of infection. Needling around an internal fixation device is inadvisable for the same reason.
- Avoid needling near a recent surgical implant that's been implanted within the past six months, although there's little risk of dry needling causing a post-surgical infection, there is the risk that if a post-surgical infection occurs, the dry needling may be blamed for causing it. It's recommended that the myotherapist seek clearance from the surgeon in these circumstances.
- A patient with an allergy to metals may have a reaction to the needles.
- Where a patient has epilepsy, particularly unstable epilepsy:
 - o Use a limited number of needles.

- o Needle with care.
- o Be cautious in using strong stimulation of needles.
- o Consider how to position the patient: it may be preferable to have them lie on their side.
- Where a patient is frail, for example after prolonged illness, consider using fewer, smaller-gauge needles, with minimal stimulation of the needles, over a shorter treatment time.
- Where a patient is on medications, particularly for blood pressure or diabetes, the myotherapist should discuss the following risk with them when seeking their informed consent to dry needling. Dry needling, because it affects the patient's autonomic nervous system, may cause a reaction that will affect the patient's medications and cause an over-correction of their condition.
- Use caution when needling very thin or fragile skin.
- Don't administer electroacupuncture to a patient with a pacemaker, unless you've consulted the patient's cardiologist and the cardiologist has agreed to the treatment.

4.2. High risk areas of the body

The Australian Society of Acupuncture Physiotherapists guidelines (2013) list the following areas of the body that are high risk for acupuncture/dry needling. A myotherapist should have specific training for needling in these areas and use extra caution in doing so. They need to be thoroughly confident in their anatomical knowledge, palpation and needle technique.

- Any point in the thorax (risk of pneumothorax): needling should be shallow and/or away from lung tissue and/or over bone/cartilage. Use pincer-gripping where possible.
 - o The lung field extends two to three centimetres above the clavicular line; anterio-laterally it extends to rib six mid-clavicular line and to rib eight mid-axillary line.
 - o The pleura extends two ribs below the lung: to the eighth rib at the mid-clavicular line and to rib 10-12 laterally (mid-axillary line).
 - o Posteriorly the lung extends to the 10th rib and the pleura to the 12th rib, at the lateral border of the erector spinae.
 - o Slimmer patients present a greater risk of pneumothorax.

o Kyphotic and scoliotic patients may present a greater risk of pneumothorax.

- Eye orbits: don't needle here are all; only non-insertion techniques can be used here.
- Don't needle neck points over the major vessels, carotid, baroreceptors, spinal cord and brain stem.
- Over the gall bladder: needling here should be superficial or oblique.
- All abdominal organs (including kidney, liver, spleen, intestines and urinary bladder) are at risk from needling directly over them. The risk increases further with anatomical variance and/or where the organ is enlarged.
- Over the sternum and infrascapular fossa: needling here should be superficial/oblique in case the patient has a congenital foreamen here.
- Between the spinous processes of vertebrae or over the nerve roots.
 - o The distance from the skin to the spinal cord or the roots of the spinal nerves varies from 25 to 45 millimetres in different individuals.
 - o The spinal cord terminates around the L1 to L2 level of the vertebral column. Don't puncture deeply in this region, to avoid infection or creating perioneural cycsts.
- In general, avoid needling:
 - o tender points close to vulnerable structures
 - o breast tissue
 - o vulnerable pathological sites including varicose veins, acutely inflamed areas and areas of unhealthy or infected tissue
 - o limbs affected by lymphoedema.
- Myotherapists should use dry needling cautiously on pregnant patients, particularly in the first trimester, as there is a risk of miscarriage.
 - o Research indicates that normal correct acupuncture in the second and third trimesters has not led to miscarriage. This research finding can also guide dry needling during these trimesters.
 - o For such patients, however, the myotherapists should take particular care to ensure the patient understands the risks before giving their informed consent.
 - o The myotherapist should also have checked with their insurer that their liability cover includes treatment of pregnant women.
 - o Only needle the lumbar spine and sacral areas with caution.

4.3. Research on risk of adverse events

Physiotherapy Alberta as of July 2021 summarised the literature on adverse events as follows (Physiotherapy Alberta (2021)):

- `8.6 per cent of patients receiving acupuncture and 19 per cent of patients receiving trigger point dry needling experience an adverse event'.
- 'Most adverse events associated with dry needling are mild (e.g., bleeding, bruising, pain during and after needling).'
- `39.4% of adverse events in a study occurred during treatment.
- '60.6% of adverse events in a study occurred after treatment.'
- 'Only a small proportion of dry needling adverse events require medical intervention to manage the event.
- 'Systemic reactions vary in presentation and severity and can affect level of alertness and ability to function or render one unconscious.
- 'Pneumothorax is the most frequent serious adverse event and is caused by needling for pain in the shoulder, neck, thorax and back, as well as needling for asthma and breathing problem. Practitioners may misinterpret a patient's pneumothorax symptoms as related to musculoskeletal pain.
- 'Serious adverse events are preventable and can be attributed to faults in practitioner technique or judgement.'

1.1. Keep within scope of practice

You should only perform dry needling within your scope of practice. That is:

- Obviously, don't perform dry needling if you haven't been trained to do so see the Code of Practice on training requirements for dry needling.
- Ensure you meet the dry needling continuing professional development requirements stated in the Myotherapy Australia Code of Practice and Professional Development Policy.

5. Informed consent

Myotherapy Australia advises myotherapists to have a written or online form for clients to consent to likely treatment at the start of a course of assessment and treatment.

If dry needling is part of your scope of practice:

- Include a section in your consent form that explains that dry needling may be used in their treatment and summarises the risks of adverse reactions.
- Before performing dry needling on a patient, explain the risk of adverse reactions/events, seek their verbal consent to dry needling, and note their verbal consent in your clinical notes. Don't rush this give the patient time to consider the information and formulate questions, so you can be sure they understand the risks and alternatives, so you have their informed consent.

Your verbal explanation of the risks of dry needling should include:

- common adverse outcomes (e.g., pain, bruising, bleeding, drowsiness, post-treatment pain), which a reasonable person would want to know when deciding to receive treatment, and
- adverse outcomes that are highly unlikely but have severe consequences or particular relevance to the patient: e.g., pneumothorax when needling in thorax or lower cervical region or pain in hand or wrists that may prevent the patient from doing something they urgently need to do the next day.
- a summary of the probability of the various adverse outcomes based on the current literature.
- alternatives to the proposed dry needling treatment (which may include no treatment), and
- an opportunity for the patient to ask questions to ensure they understand what they're consenting to (or declining to consent to).

Where the patient is pregnant, you should explain current research on the risk of pregnancy complications from dry needling compared to the risk of pregnancy complications in general.

6. Minimising risk of adverse events

6.1. Identifying unusual risks to the patient in dry needling

Before dry needling, ask the patient whether:

- they have a bleeding disorder or are on anti-coagulant medication
- pain or the sight of blood has caused them to faint in the past.

If you 'll be needling in the thorax, find out whether the patient intends after the treatment to do anything that involves changes in air pressure (such as flying or scuba diving).

If that's the case, as well as being alert for symptoms of pneumothorax and seeking medical treatment if they have those symptoms, they mustn't undertake those planned activities if they have the symptoms.

6.2. Hygiene

You must keep the room where dry needling takes place very clean.

The myotherapist will:

- Perform dry needling in a room with walls and floors of a non-permeable, easily cleaned material.
- Have easy access to a handbasin that is used only for handwashing, before and during the treatment.
- Wash their hands thoroughly before each needling session and again during the session if anything occurs that may compromise their hands' cleanness, and dry them thoroughly with a single-use paper towel before touching anything.
- Not touch the shaft of needles during treatment.
- Not re-insert a needle already inserted during treatment.
- Dispose of any needles, swabs or wipes and sterile guide tubes used, after each use.
- Dispose of any other needles that have been exposed to the air, after the patient session.
- Dispose of cotton swabs/balls that have been in contact with blood in a plastic-lined clinical bin, and
- Ensure that linens contaminated with blood or other body fluids are washed in bleach before re-use.

Local councils may have requirements for premises in which dry needling is performed: you're advised to familiarise yourself with these.

6.3. Swabbing the skin with antiseptic

The Australian Immunisation Handbook 2018 doesn't require wiping the skin with an antiseptic such as an alcohol wipe, unless the skin is visibly not clean.

Where, however, the patient is immune compromised, seek their informed consent to wipe the skin with a single-use antiseptic swab or wipe before inserting needles.

6.4. Use of gloves

You must wear gloves when performing dry needling if the current commonwealth or relevant state/territory guidelines require this.

If gloves aren't required by those guidelines, consider the following points in deciding whether to wear gloves.

- Gloves may reduce your sensitivity/dexterity, and even increase the risk of needle-stick injury.
- You must wear gloves if you have non-intact skin.
- You may need to wear single-use gloves if you anticipate excessive bleeding.
- Contact with blood or body fluids is unlikely when inserting an acupuncture needle into intact skin.
- However, contact with blood or body fluids is more likely when removing a needle, so you may need to wear gloves then.
- An option is to wear a glove just on the palpating hand.

6.5. Needle safety

Dispose of needles by placing them in a sharps container that complies with Australian Standard AS4031 or AS/NZ4261, and dispose of full sharps containers in accordance with the requirements for disposal of such containers in the relevant state or territory.

6.6. Avoiding tattooing

If you need to mark the patient's skin before inserting needles (e.g., for training purposes), use only betadine and not ink for marking, to avoid tattooing the patient. In these cases, test for an allergic reaction to iodine by applying the betadine on a small area of the patient's skin before using it more extensively.

7. Managing adverse events

7.1. Preparing for adverse events

Consider your practice and ask yourself:

- What adverse events are possible within my dry needling scope of practice?
- What first aid supplies and other equipment (including personal protective equipment) do I need to manage the range of possible adverse events?
- Are these supplies/equipment handy to treatment areas?
- If there are others involved in your practice
 - o Who is responsible for checking and replenishing the first aid supplies/equipment?
 - o Who else will need to help manage adverse events and what do you want them to do?
 - o Where will you keep your adverse event management plan so these people will have access to it?
 - o How will you ensure people who join the practice read the adverse event management plan?
 - o Do you have a process to ensure that clients or their support people who contact the practice, concerned about an adverse event, are promptly put in touch with the treating myotherapist?
 - o Do you have a system to record serious adverse events and your investigation of them?

7.2. Adverse event management plans

If you're not a solo practitioner, and others may be involved in monitoring your patients for an adverse event or helping manage an adverse event, you must provide those others with a written adverse event management plan.

If you're a solo practitioner and will monitor your patients and manage an adverse event yourself, we strongly recommend that you have a written adverse events management plan. This will help you think out how you will handle various adverse events so you're well prepared to manage them if they arise. It will also be evidence of your preparedness for adverse events if one does arise and your care of the patient is later scrutinised.

An adverse event management plan will naturally focus mainly on significant/serious adverse events. It needs to cover:

- how a patient will be monitored for adverse events
- information and periodic refresher training for people working in the practice on:
 - o possible adverse events
 - o how to monitor patients for adverse events
 - o what they need to do to manage a significant/serious adverse event or a close call
 - o where to find first aid supplies and other equipment relevant to managing a serious adverse event
 - o the process and time frame for reporting a significant/serious adverse event or close call afterwards
- criteria for advising the patient that their adverse reaction poses a risk to their safety after they leave the practice
 - o For example, if the patient is tired or drowsy after the treatment, and they have driven to the session, the practice should have a process for arranging alternative transport for them.
- how to inform the patient about continued management of an adverse event after they leave the practice and when to seek treatment if it continues
- timely communication of details of the adverse event to any health professional who referred the patient, including a request that the health professional respond quickly to the patient if they express concerns
- a process to investigate a significant/serious adverse event or close call afterwards, to understand the factors that caused it and introduce changes to reduce the chance of it happening again.

7.3. Managing minor adverse events

• If excessive pain persists after the needle is inserted, remove the needle. If the pain continues after treatment, advise the patient to apply heat or ice.

• Take care to avoid injuring blood vessels, but if bleeding does occur, after withdrawing the needle apply pressure with a cotton swab to the insertion site. Apply ice locally to minimise bruising. Wear gloves to avoid contact with the blood.

- If a needle becomes stuck:
 - o If this was caused by over-rotation of the needle, rotate it in the opposite direction and remove.
 - o If this is being caused by muscle tension, leave the needle in for a short time, relax the tissue around the needle with massage, ice massage or by inserting one or two needles around the needle; then remove the stuck needle.
 - o You can reduce the risk of stuck needles by placing the patient in a relaxed position initially, avoiding excessive twisting of the needle and not needling tendinous muscle tissue.
- If a needle becomes bent:
 - o Calmly tell the patient not to move, relax the local muscle and remove the needle slowly following the course of the line of the bend.
 - o To avoid bent needles, insert the needle cautiously (in case you strike hard tissue), and with the patient in a comfortable position (so they won't cause the needle to bend by moving or contracting the muscle).
- If a needle breaks:
 - o Calmly tell the patient to keep still and calm so the needle doesn't go deeper.
 - o If the end of the embedded section of needle is exposed, remove it with tweezers.
 - o If the end of the embedded section of needle isn't exposed, press the tissue around the insertion site until the embedded section of needle is exposed, and remove it with tweezers.
 - o If you can't remove the needle, draw a circle around the insertion site, make a note of the time of the incident, and seek medical attention to remove the needle surgically.

7.4. Arrangements in preparation for significant/serious adverse events

In case a significant/serious adverse event arises (such as fainting, pneumothorax):

- Stay with the patient as much as possible.
- In case it isn't possible to stay with the patient, have a warning bell or call system in the treatment area that the patient can use to call for assistance if left temporarily unattended.
- Advise the patient, before needling in areas where pneumothorax is a risk, of the symptoms of pneumothorax and that they should alert staff if these arise; also that they shouldn't fly or go scuba-diving until the symptoms have been assessed by a doctor.
- Keep a blanket and stethoscope in designated places in the treatment area.
- Have a sharps container in the treatment area in case the needles have to be removed.

7.5. Fainting/vasovagal syncope

If a patient has a history of fainting, use fewer needles and minimal stimulation.

If the patient loses consciousness during dry needling:

- Remove the needles.
- Lie the patient down if they're not already lying down; consider elevating their feet.
- Consider applying resuscitation techniques you've learned.
- Keep the patient warm and monitor their vital signs.
- If the patient sustained injuries in falling when they fainted, assess these and give first aid as appropriate.
- If the patient is alert or recovers alertness, consider giving them liquid to restore blood glucose and stimulate their sympathetic nervous system.
- Once the patient recovers consciousness, monitor them for other signs of physiological dysfunction: nausea, dizziness, fatigue, confusion.
- Don't let the patient leave until they've recovered alertness and full function.
- If they drove to the practice, and aren't fully alert and awake to drive, arrange other transport for them.
- Consider referring them to another health professional such as a GP if the patient is anxious about the severity of their response.

7.6. Pneumothorax

The symptoms of pneumothorax may arise during dry needling or after the patient has left the clinic. They include:

- shortness of breath, difficulty breathing, wheezing; dry, hacking cough
- pain, whether mild or intense, that may indicate a lung injury
- feeling unwell, cyanosis, changes in vital signs.
- decreased breath sounds on auscultation.

If these symptoms occur during treatment, remove the needles, monitor the patient's vital signs, and arrange transport to take them to hospital for medical assessment.

If the patient experiences these symptoms after leaving the practice (which is the case in about two- thirds of incidents of pneumothorax), and contacts the practice about them:

- The patient should immediately be put in touch with the treating myotherapist.
- If the treating myotherapist considers from the symptoms the patient reports, that it may be a case of pneumothorax, they will advise the patient to arrange transport to take them to an emergency department or their GP for medical assessment.
- If the treating myotherapist is unavailable, other practice staff will advise the patient to arrange transport to take them to an emergency department or their GP for medical assessment.

Follow up with the patient to check that they've had medical assessment and find out what diagnosis/action resulted. Record this in the clinical record.

7.7. Needle stick injury

If the myotherapist or another staff member is stuck by a needle already used on the patient:

- Wash well around the puncture and encourage bleeding.
- Have blood tests for hepatitis B and C and for HIV.
- Ask the patient to have these tests as well.
- If the patient is HIV positive, urgently seek medical advice.

To mitigate the risks of needle stick injuries:

- Consider having myotherapists and others who may assist in dry needling sessions vaccinated for hepatitis B and C, diphtheria, measles, mumps, pertussis (whooping cough), rubella, tetanus, varicella (chicken pox) and ensure that they have annual influenza vaccinations.
- Only allow staff trained in dry needling to remove needles from a patient.

8. After an adverse event

8.1. Monitoring for adverse events in follow-up sessions

In follow-up sessions, ask the patient about any adverse reactions to the dry needling they've had.

In particular, if a patient has persistent pain following needling in the check, neck, low back or shoulder and/or feels unwell, consider whether they have pneumothorax. (Research shows that practitioners may misinterpret pneumothorax as musculoskeletal pain.)

Where a serious adverse event has occurred, the myotherapist will promptly inform their professional indemnity insurer.

8.2. Learning from adverse events

Any significant/serious adverse event, or near-miss from such an event, should be:

- recorded in the clinical notes on the patient
- discussed in the practice as an opportunity for learning, and
- investigated to consider what caused them and what changes may avoid their recurrence. Changes decided as an outcome of investigation of a significant/serious adverse event, or near-miss, should be:
- made, and
- later, evaluated to consider whether they're achieving the desired improvement in safety.

9. References

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