safety IN PRACTICE

Community Pharmacy SSRIs 2020-21

Every patient, every time

AUCKLAND DISTRICT HEALTH BOARD
Te Toka Tumai

Waitematā District Health Board
Best Care for Everyone

Contents

Why choose SSRIs for Safety in Practice?

A key aim of the Safety in Practice programme is to reduce preventable harm to patients. Non-adherence of antidepressants is associated with harm relating to increased risk of relapse and recurrence.[1] Effective interactions with patients have been shown to be important in their acceptance of antidepressants and continuation of therapy. Quality patient relationships and communications have a positive effect upon adherence behaviours, and the partnership is central in exploring adherence concerns.[2] Community pharmacist have a role in supporting adherence to antidepressant medication throughout treatment, particularly around exploring patient concerns relating to adherence and efficacy.[1]

Addressing adherence will also impact other chronic conditions the patient may have. Patients with comorbid depression and chronic disease have a 3 times higher likelihood of non-adherence to prescribed medications for their chronic conditions.[3]

Clinical guidelines recommend antidepressants are continued for at least 6 months after symptom remission, but one third of patients discontinue within the first month, and 44% by the third month of treatment. Contributing factors to discontinuation may include the stigma associated with depression, comorbidities, adverse effects which precede the delayed antidepressant effect, and patient belief about antidepressant medication.[1]

Patients starting antidepressant treatment often report having difficulties recalling information received at time of diagnosis, so pharmacists are well placed to reiterate key educational messages at every follow-up opportunity as treatment progresses. When asked, patients specifically want to know what to expect (in terms of time to onset and functionality), side effects and ways to manage them, and when to notify their doctor. Community pharmacists are in a unique position to reinforce this patient education, to support them and communicate concerns or recommendations to the prescriber if needed.

The Safety in Practice Programme works with community pharmacy to provide them with tools to encourage effective patient interactions, enhance their knowledge about their medicines and what to do if they experience side effects. Mental Health is coming into the spotlight here in New Zealand following the Mental Health Enquiry from the Ministry of Health. Further afield, there has been a recent call to action from the NHS (National Health Service) to involve community pharmacy more in the management of patients with mental health issues. Findings from interventions and quality improvement initiatives provide a window to what is possible and might be worth exploring.[2]

This change package focuses on the use of SSRI (Selective Serotonin Reuptake Inhibitor) antidepressants. These medicines are the most commonly prescribed class of antidepressant medication in New Zealand. SSRIs available in New Zealand include citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and sertraline.

Pharmacist Scope of Practice

According to The Pharmacy Council of New Zealand, “Pharmacists ensure safe and quality use of medicines and optimise health outcomes by contributing to patient assessment and to the selection, prescribing, monitoring and evaluation of medicine therapy”.[4]

Optimal medicines management and patient education are core responsibilities of pharmacy practice. It is best practice to document all interventions and recommendations made to evidence work done. This is one way pharmacists can demonstrate the work that they do, in line with Pharmacy Council of New Zealand Competence Standard O1.4.7. The process measures are evidence that best practice activities have been performed.

Competence Standard O1.4.7: 'Supports and provides continuity of care with accurate and timely documentation of clinical and professional interventions and recommendations, using agreed handover protocols.'

Equity

We all have a role to play in reducing inequity in health in New Zealand. Particular groups are consistently disadvantaged in regard to health, and these inequities affect us all.[4] Health inequities are avoidable, unnecessary and unjust differences in the health of groups of people.[4] This may be between socioeconomic groups, ethnic groups, different geographical regions, levels of ability or disability, and between males and females. Research indicates the poorer you are, the worse your health will be.[5] Inequalities experienced in early life influence people in later life, and inequalities take a cumulative toll on an individual's health over their lifetime.[4]

To promote equity in health, we need to understand the inequity, design interventions to reduce them, review and refine the intervention and evaluate their impact. It is important to minimise the impact of disability and illness on socioeconomic position and access to the determinants of health.[5]

In particular as health providers, we need to emphasise the power of joint decision making and trust with patients, it is important to prioritise time to listen to their health issues in their words, ideally with protected time in consultation room, involving their whānau if preferred by them. It is important they have an understanding of the treatment options, the risks involved and where to go for help.

The most effective conversations are based on a mutual trust and understanding, giving patient's confidence they are in control and empowered to make informed decisions. There are significantly increased risks of avoidable medicine related harm in Māori and Pasifika, it is important we understand this and take special care to ensure optimal health outcomes for all.

Previous teams' experiences

Benefits	Challenges
•Confidence within the team that patient education is taking place •Good conversations with patients by all staff members •Improved concordance and understanding of medication •Have a better relationship with the GPs and practice nurses in the area	•Time commitment required •Frequent reinforcement needed to effect change •Took time to effect change •It is dificult to talk to everyone in detail during busy times •Contacting patients afterwards and thinking about how to best approach the conversation.

1.1 Getting your team ready for Safety in Practice

- Identify responsible leads to drive the programme in your pharmacy
- Organise a staff meeting to introduce the programme; it is critical to have the whole team engaged. Safety in Practice works when all team members take part and make their processes safer for all of your patients.
- Develop a Standard Operating Procedure (SOP) document for locums and new staff. Think about how you can all ensure new team members are up to speed on what you do and why. This way your results continue to show improvement when regular staff are not there.
- Decide on preferred patient resources with your team; make them readily available.
- Decide how to document interventions, discussions and education; agree on this as a team.
- Decide who will be responsible for completing the data collection sheet and submitting data. Share this task so skills are developed across team members.
- Engage with your GPs, discuss the programme and the resources you will be using. If they have any questions you can refer them to the Safety in Practice website.
- Display posters in the pharmacy so patients are aware that you are a 'Safety in Practice' pharmacy. Posters will be available at the learning sessions, or you can request one from info@safetyinpractice.co.nz

1.2 Aim

All patients receiving SSRIs will receive education about the medicine at the time of medicine collection by June 2021.

1.3 Measures & rationale

This module comprises process and outcome measures. The **process measures** are evidence the activity has taken place. This information needs to be recorded in the patient file (Toniq or RxOne).
The **patient outcome measures** assess whether the patient has understood and can recall correctly the information provided.
To assess your processes, we require data from a random sample of 10 patients each month. We do not require NHI or patient identifiable data so please ensure it is anonymous.

- Please see Table 1 for further guidance regarding these measures
- The questions relate to the patient or carer as appropriate
- The target population for data collection is patients aged 18 years and over
- For prescriptions with repeats, data collection will focus on initial dispensing encounter
- Medicine refers to the SSRI.

Table 1: Measures and rationale

	Process measure	Rationale
1.	**Is there documented evidence there was a discussion about how to use the medicine (including the importance of not stopping suddenly)?** Yes ☐ No ☐	Generally SSRIs are taken once daily in the morning because they can cause insomnia. Some people prefer evening dosing because they can also cause drowsiness. SSRIs are not affected by food. It is important to take SSRIs daily and not to stop taking abruptly because this can cause withdrawal symptoms. Let them know when they can expect to notice any changes in their health. Advise people to try not to miss doses, help them to find ways to remember to take their medicines regularly. Do not take double doses to make up for missed doses. If they do miss a dose, the general advice is to take the medicine as soon as they remember, but if it is nearly time for the next dose, take that at the right time.
2.	**Is there documented evidence there was a discussion about side effects?** Yes ☐ No ☐	Side effects include sweating, diahhroea, nausea, sleep changes, suicidal behaviour, aggression, hyponatraemia, bleeding, sexual dysfunction, serotonin syndrome. See individual data sheets for a comprehensive list www.nzf.org.nz Suggested management strategies are available on www.healthnavigator.org.nz and listed in section 8 (Additional Resources) **Patients, family and friends should watch for and report any worsening depression, suicidal ideation or other unusual changes in behaviour to the doctor. There is an increased risk of suicidality in adolescents and young adults under 25 years, particularly those under 18 years)** Rather than saying 'suicidal behaviour' you may find it easier to say 'self-harm' or 'hurting yourself'. **Note:** Talking about self-harm will not increase the risk of it occurring.
3.	**Is there documented evidence there was a discussion about interactions with other medicines and supplements?** Yes ☐ No ☐	Interactions include: • serotonin toxicity with other serotonergic medicines such as tramadol, ondansetron • medicines that increase the risk of bleeding, such as anticoagulants and NSAIDs. • medicines metabolized via cytochrome p450 (this varies between SSRIs.) • medicines that prolong the QT interval such as amiodarone • medicines that cause hyponatraemia such as diuretics • medicines that lower the seizure threshold such as tricyclic antidepressants and tramadol. Check individual medicines using the www.nzf.org.nz interactions checker. If there are interactions identified,

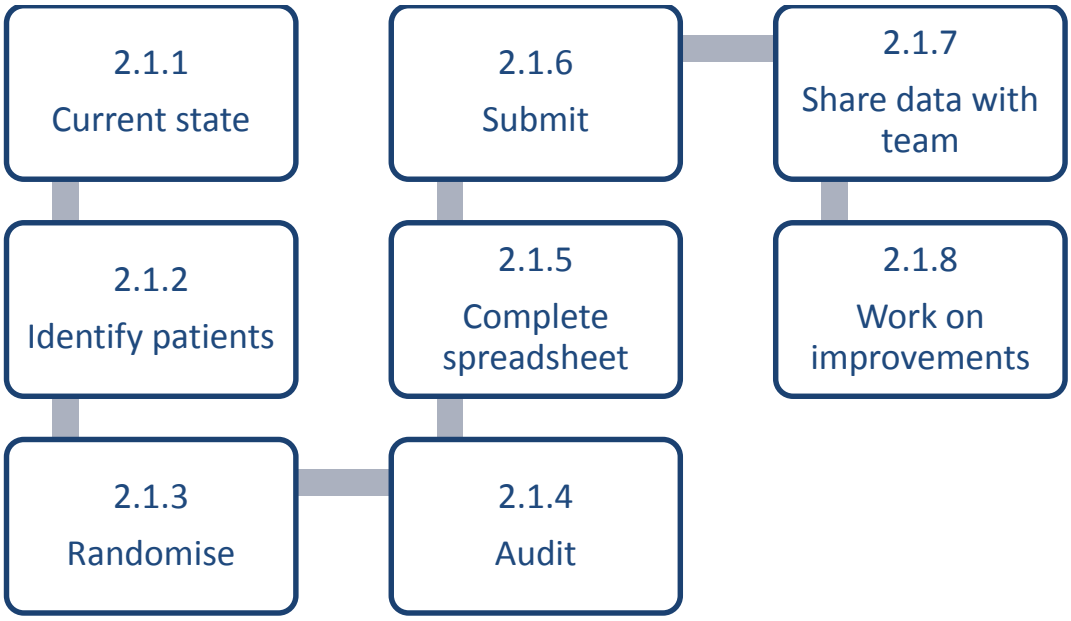
		contact the prescriber to discuss. It may be helpful to contact local GPs in advance to let them know you are working on this module and may be contacting them about SSRIs. Ask the patient to let you/their doctor know about any OTC medicines or supplements they are taking because SSRIs interact with St Johns wort, 5HTP and other OTC medicines.
4.	**Is there documented evidence the patient was offered written information about the medicine?** Yes ☐ No ☐	To offer is to specifically ask if they would like to receive some written patient information. This could include resources on: • Choice and Medication for Waitematā DHB region www.choiceandmedication.org/waitemata • Health Navigator www.healthnavigator.org.nz patient information • Medsafe www.medsafe.govt.nz consumer medicines information leaflets

Outcome Measures		
From the 10 random patients selected, ask the following questions either during a follow up phone call or when they return for a repeat. Use open questions and listen carefully to their answers. If you are unable to locate them after 2 attempts, document as NA in the spreadsheet and note this in the comments column.		
5.	Was the patient able to correctly describe (dose and frequency) how to use their medicine? Yes ☐ No ☐ N/A ☐	***'Tell me, how do you usually take your medicine?'*** • Yes - if they could tell you how to correctly take their medicine • No - if they didn't know how correctly to take their medicine • N/A – if you could not get hold of the patient
6.	Was the patient able to identify a possible side effect of their medicines? Yes ☐ No ☐ N/A ☐	***'Do you know any side effects that might happen?'*** This question is to assess whether the education provided was effective. Relying on spoken, and non-verbal cues such as the person saying *'yes'* or nodding is not accurate.[6] Answer guidance: • Yes - if they could identify a possible side effect • No - if they couldn't name any side effects • N/A – if you could not get hold of the patient

2.0 Instructions

When you receive a script for an SSRI, go through the Process Measures for "Every patient, every time".
Document the information in the patient file e.g. in Toniq as an intervention or in RxOne as an event audit, so it can be found easily. To upload a checklist onto Toniq, there is a guide in the resources section of your clinical module on the website here. If you are using RxOne, the checklists have been incorporated for you.

2.1 Monthly data collection and submission



2.1.1 Current state

To assess your processes you will collect data from 10 *random* patients every month. As a team, you will then reflect on your results, look for opportunities for improvement and use PDSA cycles (Plan, Do, Study, Act)
Your first set of data (baseline data) is relating to the month of August and is due on September 10th.
Note: we expect low scores for the baseline, or 'Current State' August data.

2.1.2 Identify patients

Run a report on Toniq or RxOne for all of the relevant medicines dispensed during the month.
(Refer to www.safetyinpractice.co.nz for detailed instructions on how to generate a report)

2.1.3 Randomise

From the report select a **random sample of 10 patients** using an online random number generator.
Note the SiP programme does not endorse any advertising that comes with these online tools.

2.1.4 Audit

For the 10 **randomised** patients, find **documented** evidence that the Process Measures occurred and record responses into the spreadsheet.

Contact the 10 patients and go through the Outcome Measures with them. Record their responses into the spreadsheet. If you are unable to locate a patient after 2 attempts, select NA and note this in the comments column on the spreadsheet.

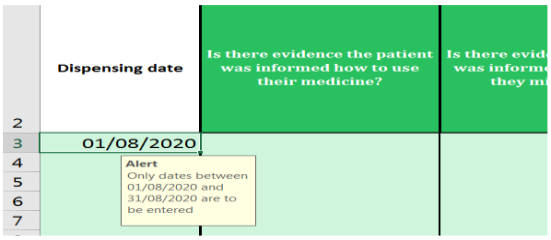
Advise patients you may contact them to ask two questions because you are taking part in Safety in Practice. Let them know this is to check how you and the team are working; it is not to test them.

Having this information scripted may help e.g. *"We are now providing a follow-up service for people who use some anti-inflammatory medicines. We select 10 patients each month and give them a quick phone call about their medicine. This is to check how we as a pharmacy team are working; it is not to test you"*

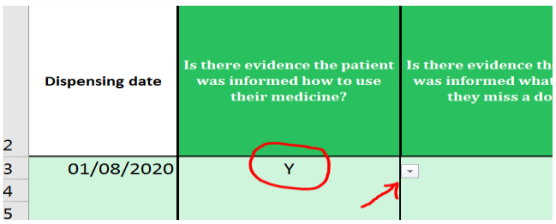
2.1.5 Complete the spreadsheet

Tip: Your first set of data (baseline data) is relating to the month of August so this is due on September 10th.
Please note: we expect low scores for the baseline August 2020 data, prior to the Safety in Practice programme beginning

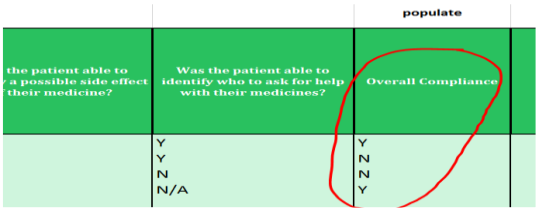
Download the spread sheet for your module in the Resources section of www.safetyinpractice.co.nz



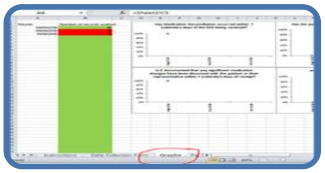
Record the date of dispensing in a DD/MM/YY format in the left column. (Alert boxes in yellow will guide you). For your first data from dispensings in August (reported in September) this is 1/8/20



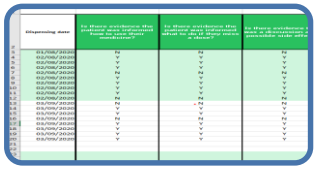
Mark Y, N or N/A by clicking on the dropdown menu, against for each measure and each patient according to your findings in the previous section.



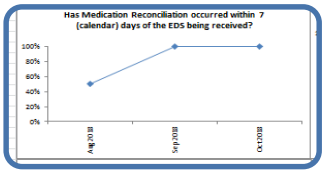
The final measure "Overall compliance" will auto-populate.



Graphs will be automatically generated in the next tab in the spread sheet.



Next month, add your data to the same spread sheet.



This means you can track your progress over time.

2.1.6 Submit

Submit your data on the 10th of each month to audit@safetyinpractice.co.nz

> Tip: Please ensure all data sent to Safety in Practice in anonymised

2.1.7 Share data with your team

Safety in Practice works when all team members take part. Make the data available for everyone to see. Print the graphs and put them up in the tea room so the whole team can see the progress being made and have the opportunity to make suggestions on how to improve.

2.1.8 Work on improvements

As a team, look for opportunities for improvement and use PDSA cycles (Plan, Do, Study, Act). Refer to the Quality Improvement Workbook for other quality improvement tools.

2.2 Change idea examples

The following ideas have been tested and implemented by previous teams:

General	• Discuss results of baseline data collection together and include SiP as a regular agenda item at team meetings • Arrange education session for pharmacy team to include SSRI counselling and how to identify patients more at risk of harm • Discuss how could your counselling of SSRIs be made safer • Think about whether you will use a checklist, or alerts for interactions • Get to know your GP teams and let them know you are part of the Safety in Practice programme, focusing on SSRIs.
Clinical processes	• As a team, identify barriers that will prevent you from providing education to patients and look for ways of addressing them • Embed systems to include routine counselling of SSRIs • The aim is to reduce the risk of harm from SSRIs and improve adherence and discussion with patients.
Documentation	• Use Toniq and RxOne templates
Discussion with patient	• Create prompt card for education points • Optimise use of Self Care Cards • Provide information to patients about SSRIs and what to do if they experience side effects eg See www.healthnavigator.org.nz for resources

3.1 Contacts

- Questions, feedback or general enquiries: info@safetyinpractice.co.nz
- Submitting data: audit@safetyinpractice.co.nz
- Website: www.safetyinpractice.co.nz

3.2 Resources

Patient leaflets

- Choice and Medication for Waitematā DHB region www.choiceandmedication.org/waitemata
- Health Navigator www.healthnavigator.org.nz patient information
- Medsafe www.medsafe.govt.nz consumer medicines information leaflets

Patient support

- www.depression.org.nz Support for people with depression and anxiety
- www.clearhead.org.nz An online tool to guide people to support services
- www.heartsandminds.org.nz Promoting wellbeing for people, families and communities
- www.framework.org.nz/awhi-ora-service Awhi Ora service, supporting wellbeing by connecting with community services.
- www.mentalhealth.org.nz Mental Health Foundation.
- Healthline call: 0800 611 116
- Text or call: 1737 To connect with trained counsellors if stressed, anxious or depressed

3.3 References

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Appendix 1: Key discussion points

Take time to explain that many people are taking SSRIs, and the benefits of taking them. Discuss goals of treatment, which are ultimately full remission of symptoms and a return of psychosocial functioning.

Ask them what they already know from the GP, so you have a starting point and don't duplicate what they already know. It is important they know what to expect, when they will start to feel better, expected side effects and how to manage them, the length of treatment, and who they can contact for advice. This is a gradual process.

NOTE: SSRIs are also used for other conditions, both on and off label. These conditions include obsessive compulsive disorder, bulima nervosa, premenstrual dysphoric disorder, social phobia, post-traumatic stress disorder, pruritus or cholestasis in palliative care (unapproved).

- It will take some time until they notice an improvement. They will start to see an improvement in 1-2 weeks, with the maximum effect in 6 to 8 weeks.
    - Within one week, decreased agitation and anxiety, improved sleep and appetite.
    - Within 1-3 weeks, increased activity, sex drive, self-care, concentration and memory. Thinking and movement normalise, but there is a potential increased risk for suicide during this time.
    - 2-4 weeks or more, relief of depressed mood, less hopelessness and subsiding of suicidal ideation.
- Some people may have side effects. These will most likely experience side effects in the first few weeks, often before any improvement is noticed, but these will gradually improve. If they don't improve, or if they are worried, it is best that they see their doctor.
- It is important to keep taking the medicine every day, even after they feel better. Stopping suddenly can bring on symptoms of withdrawal. If they do want to stop taking it, this should be discussed with their doctor, so they can gradually reduce the dose before they stop. Even after their mood has improved, it is crucial that they continue their antidepressant for the required time (at least 6 to 9 months) to prevent recurrence.
- Some patients may require indefinite treatment, but in general, these medicines will need to be taken for 1-3 years to prevent relapse.
- It is important they see their doctor if they have thoughts of hopelessness, suicide or self-harm. Explain that this does happen sometimes, it is a known side effect of the medicine, and if it does happen, they should see their doctor straight away so it can be managed.

Appendix 2: Side effects

Information from Health Navigator www.healthnavigator.org.nz

Like all medicines, SSRIs can cause side effects, although not everyone gets them. Often side effects improve as your body gets used to the new medicine.

Suicidal behaviour

The use of antidepressants has been linked with an increase in suicidal thoughts and behaviour. Children, teenagers, young adults and people with a history of suicidal behaviour are particularly at risk. This is most likely during the first few weeks of starting an antidepressant or if the dose is changed. It is important to look for signs of suicidal behaviour such as agitation or aggression and ask about suicidal thoughts, self-harm, worsening of low mood, If you notice any of these signs, contact your doctor immediately.

It is ok and important to ask about suicidal thoughts and this will not increase risk. Note: citalopram is not recommended for people under 18 years of age.

Risk of bleeding

SSRIs can increase your risk of bleeding especially if taken with NSAIDs (non-steroidal anti-inflammatory drugs) such as diclofenac and ibuprofen. Check with your doctor or pharmacist before you take pain relief. Any abnormal bleeding should be reported to the prescribing doctor.

Sexual side effects

SSRIs in both men and women can cause reduced sexual drive, lack of libido and problems keeping an erection, and reduce the intensity of orgasm. It's important to talk to your healthcare provider if you get these effects, as they can be difficult to deal with and may not go away. Your healthcare provider may be able to suggest treatment or may reduce the dose of the SSRI or change to a different one.

Table 2: Other side effects

Side effects	What should I do?
Nausea (feeling sick)	This is quite common when you first start an SSRI. Try taking your dose with food.
Headache	Stay well hydrated Try paracetamol to ease headache
Difficulty falling asleep	Try taking the SSRI in the morning Avoid caffeine, alcohol, nicotine
Feeling sleepy, drowsy, dizzy or tired	Try taking the SSRI at night time Be careful when driving or using tools until you know how this medicine affects you Tell your doctor if troublesome
Dry mouth Increased sweating Tremor	These are quite common when you first start taking an SSRI and may go away with time Tell your doctor if troublesome, a lower starting dose might help
Changes in appetite Changes in weight	Tell your doctor It may be helpful to make changes to your diet and usual exercise.
Loss of sex drive or libido	Tell your doctor
Suicidal thoughts, thoughts of harming yourself, or worsening depression	Tell your doctor immediately or ring HealthLine 0800 611 116 or text 1737
Changes in heart beat such as fast heart rate or irregular heart beat	Tell your doctor immediately or ring HealthLine 0800 611 116
Signs of serotonin syndrome such as feeling agitated and restless, heavy sweating, shivering, fast heart rate or irregular heartbeat, headache, diarrhoea and rigid or twitching muscles	You are at increased risk of serotonin syndrome if you just started taking an SSRI or increased the dose or started other medicines that can cause serotonin syndrome Tell your doctor immediately or ring HealthLine 0800 611 116

Appendix 3: SSRI checklist

Process measures

1. Is there documented evidence there was a discussion about how to use the medicine (including the importance of not stopping suddenly)?

   Yes ☐ No ☐

2. There is documented evidence there was a discussion about side effects?

   Yes ☐ No ☐

3. There is documented evidence there was a discussion about interactions with other medicines and supplements?

   Yes ☐ No ☐

4. There is documented evidence the patient was offered written information about the medicine?

   Yes ☐ No ☐

Patient outcome measures

5. Was the patient able to correctly describe (dose and frequency) how to use their medicine?

   Yes ☐ No ☐ N/A ☐

6. Was the patient able to identify a possible side effect of their medicine?

   Yes ☐ No ☐ N/A ☐