ANDREA-LD

GP Support Package

Version 2.0

05/02/2014

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

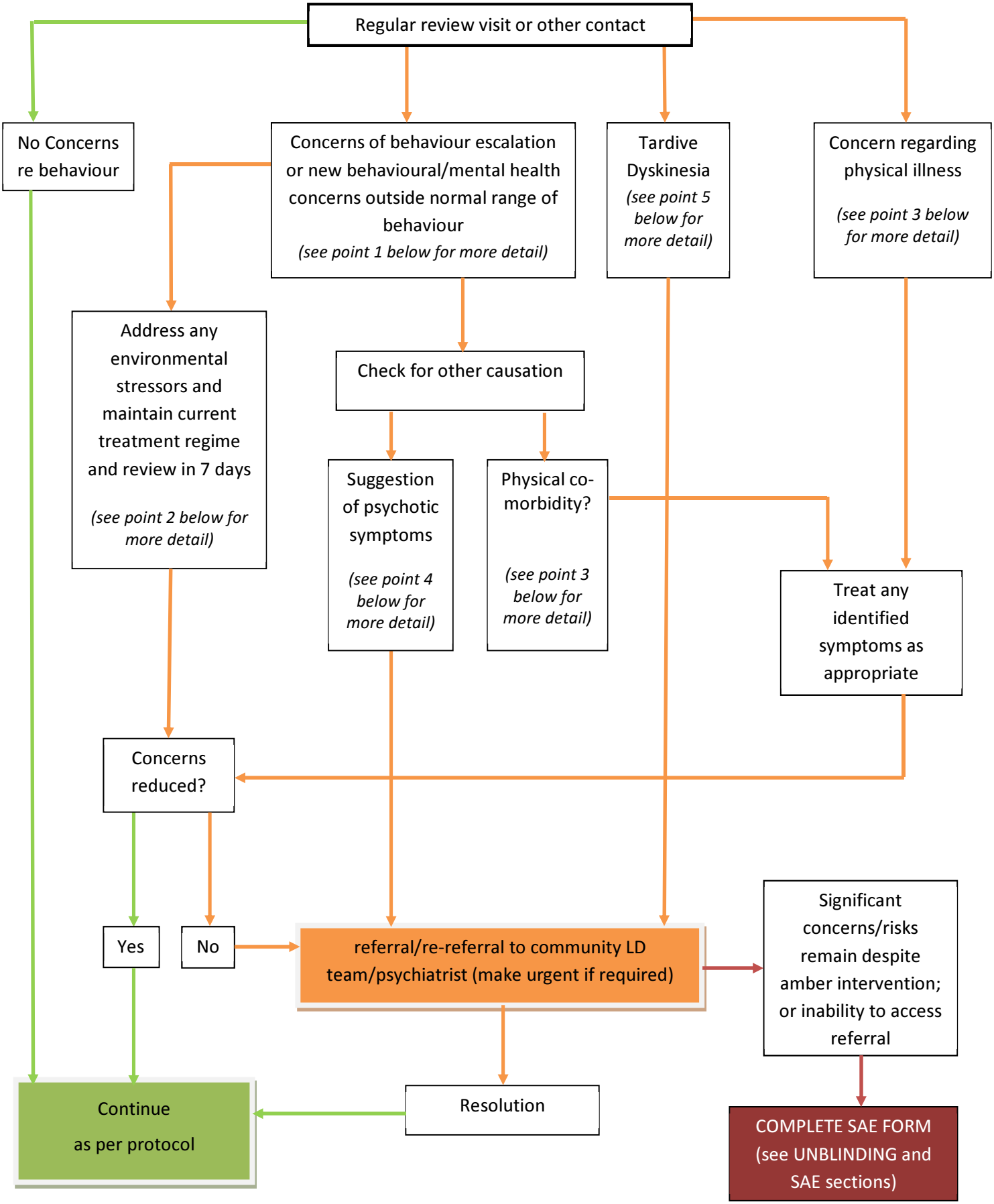
sewtu
South East Wales Trials Unit
Uned Ymchwil De-ddwyrain Cymru

NHS
National Institute for Health Research

Table of Contents

ANDREA-LD GP Management Flow Chart

PART 1



PART 2

1. Concerns of behaviour escalation or new behavioural/mental health concerns outside normal range of behaviour

It is quite likely that carers or families will raise concerns relating to the individual for whom they care in relation to alteration of behaviour. In this first stage of assessment you can ask a few simple questions to signpost the next step in the flow chart:

Does this seem to be a new condition rather than worsening of usual behaviour?

If it is not worsening of usual behaviour, it is worth deciding if there is an underlying physical or psychiatric condition. Completely new patterns of behaviour are unusual so detailed questioning will ensure it is definitely a new behaviour. If it does seem a new behaviour, then it is best to follow the advice on physical illness (likely to be common) or psychotic symptoms (likely to be more rare) in the flow chart. You may be directed to which step by the nature of the behaviour and other symptomatology.

If it is the usual pattern of behaviour then the next step is to assess its severity.

If this is worsening of usual behaviour -has the individual displayed behaviour as concerning as this before starting in the study?

If the answer is yes then it is likely that this is simply a fluctuation in normal patterns as people with challenging behaviour tend to have ups and downs in the normal course of their condition.

In such situations it is unlikely to be a direct result of the study. Such fluctuations are best approached by watchful waiting.

Where the behaviour is at a greater degree or the current degree causes great concern then the most likely short term reason for deterioration is environmental stressors-so please follow the advice in the environmental stressor box. If there is no such stressor then checking for a physical condition or new psychiatric symptoms would be worthwhile

2. Environmental stressors

If carers do report a change in the level of a person's challenging behaviour, it's important to try and identify what the reasons for this might be. More often than not, these will be linked with some kind of change in the person's environment rather than any change in the person themselves. Some good questions to put to carers include:

- Has there been any change in the person's routine (e.g., have they been provided with their normal pattern of day activity, been able to go out as often as they normally do, been able to see people that they normally see)?
- Has there been any change in the people working with the person (e.g., Have there been a lot of relief staff on duty who don't know the person well and not fully briefed regarding key aspects of their care?; Has a particular carer of whom the person is particularly found been away from for some reason?; Have the person's parents been away on holiday and unable to visit? Has the service manager been off on leave?)

- Are all carers currently implementing agreed support plans (particularly behavioural support plans)? How do carers check that this is the case?
- Have there been any reductions in levels of support to the person that impact on the ability to implement these plans?
- Are the reported increases well-known ones that happen at a particular time of year (Christmas and birthdays are often difficult times for people)
- Has the person been exposed to any recent triggers (for example, having to go to particular places that they don't like or asked to do things that they're not keen on; have they been left alone for lengthy periods?)

This is not an exhaustive list-but it gives you an idea of things to probe for. Carers will often not be aware that these sorts of issues may in themselves explain why the person may have been a little more difficult lately. The solution here is clearly to prompt the carers to address the environmental issues identified rather than to treat the person. Allowing some time for this to occur and the behaviour to settle is the best strategy here therefore.

Escalation of challenging behaviour and non-psychotic psychiatric symptoms

Escalation of challenging behaviour is especially linked to anxiety symptoms and may particularly be associated with environmental stressors. Addressing these stressors, as outlined above, may resolve the problem. If this does not resolve the issue please refer to the "What to do if Challenging Behaviour Escalates" section below.

3. Physical illnesses

Individuals with a learning disability are especially prone to developing physical illness but given communication difficulties, behavioural difficulties may be the presenting feature. Sources of pain (such as ear infections, headaches, abdominal pain (because of urinary tract infection, constipation)) may be especially difficult to pick up and should be actively sought out.

4. Suggestion of psychotic symptoms

The Participants in this study will have been screened for the presence of serious mental illness so, in theory, few if any should experience a relapse of psychosis or evolution of a new illness. However, the presence of mental illness in people with learning disability can be masked by a variety of factors including intellectual function and communication barriers. Therefore, some people whose medication was thought to have been originally prescribed for "Challenging Behaviours" may have in fact had an undiagnosed psychotic illness, such as Schizophrenia or a Bipolar Disorder.

If a patient in the study starts to develop an unusual pattern of speech or behaviour, it is important to remain vigilant for potential psychosis. In people with mild learning disability the presentation would usually be similar to that seen in the general population i.e. abnormal beliefs out of keeping with their social situation which are not amenable to reason or abnormal perceptions, which are not explained by obvious environmental stimuli. However, when the person lacks a level of intellectual function or emotional development commensurate with a chronological age, their ability to express their symptoms coherently may be severely diminished. Here a carer's account of unusual behaviours or communication which is out of keeping with their pre-morbid presentation may be critical in highlighting the evolution of serious mental illness.

In these circumstances it is appropriate to contact your local community Learning Disability Team to ask for an urgent psychiatric assessment. They may be able to reassure you, or could, if necessary, ask for the medication code to be broken to identify the current prescription and withdrawal of the patient from the study.

5. Tardive Dyskinesia

Tardive Dyskinesia is characterised by chewing or sucking movements, grimacing and choreoathetoid movements particularly affecting the face, but also potentially the limbs and most importantly muscles responsible for swallowing and respiration. While this syndrome can occasionally be seen in drug naive patients, it is more common in those who have taken anti psychotic medication for many years. However, neither dose nor duration of treatment is the sole determinant, and it is also more common in women, the elderly and patients with diffuse brain pathology. Almost half of the cases arise when drugs are being reduced or discontinued.

The cause is uncertain but could be super sensitivity to dopamine, resulting from prolonged dopaminergic blockade, and arises with many anti psychotic agents. Many treatments have been tried, but none is universally effective, hence the need to avoid prolonged unnecessary prescription of anti psychotic medication, especially at higher doses.

Should any patient develop symptoms suggestive of Tardive Dyskinesia during the study, it is recommended that you contact your local Learning Disability Team for further psychiatric evaluation, including, if necessary a breaking of the code to identify the current prescription and withdrawal of the patient from the study. This advice does not preclude you from seeking other expert opinion, such as a consultant neurologist if you feel this to be a more appropriate course of action.

CONTACT DETAILS FOR LD TEAMS

WALES

ABERTAWE BRO MORGANNWG UNIVERSITY and CARDIFF & VALE HEALTH BOARDs

Service	Community Learning Disabilities Team (CLDT)	Contact Numbers and Admin Staff	LD Psychiatrist	Psychiatrist's Secretarial Support
Cardiff (West)	Vanessa Townsend - Team Manager	Steven Olden 02920 383555	Dr Zed Ahmed	Kim Brunt 02920 564457 kim.brunt@wales.nhs.uk
Cardiff (East)	Joanne John - Team Manager	Lynne O'Connor 02920 674040	Dr Glyn Jones	Sandra Jones 02920 564457 sandra.jones@wales.nhs.uk
The Vale	Bridget McCormick - Team Manager	Sarah Smith 01446 725100	Dr Basil Cardoza	Janet Pickford 02920 564457 janet.pickford@wales.nhs.uk
Merthyr	Michele Hanson - Team Manager	Christine Richards 01685 351285		
RCT East	Madeleine Collins - Team Manager	Sue Graham/Christine Richards 01685 887811	Dr Ray Jacques	Lynn Wodecki 01443 220411 lynn.wodecki@wales.nhs.uk
RCT West	Elizabeth Pritchard - Acting Team Manager	Christine Richards 01443 436937	Dr Elin Owen	Carey Powell 01443 220402 carey.powell@wales.nhs.uk
Swansea	Maria Anderton - Temporary Team Manager	Sam Ayres 01792 614100 (145)	Dr Saravanamuthu Ganeshanantham	Sarah Punnett 01792 784021 sarah.punnett@wales.nhs.uk
Neath	Rachel Sommerville - Team Manager	Julie Hopkins 01639 685512 (526)	Dr Mohammed El-Tahir	Lynn Anderson 01792 784019 lynn.andersen@wales.nhs.uk
Bridgend	Sian Jones - Team Manager	Vanessa Warren 01656 815353 (498)	Dr Andrew Bhasker Issac	Annette Bell 01443 220403 annette.bell@wales.nhs.uk

ANEURIN BEVAN HEALTH BOARD

Service	Community Learning Disabilities Team (CLDT)	Contact Numbers and Admin Staff	LD Psychiatrist	Psychiatrist's Secretarial Support
Blaenau Gwent	Alexis Clayden – Team Leader (01495 322657)	Louise Lewis – Administrator 01495 322658	Dr Mollie Thomas (Associate Specialist)	Nicola Jones 01495 322 655

Caerphilly	Heather Thomas – Team Leader (01443 864577)	Karen Dunn – Administrator 01443 864703	Dr Catherine Bright – Consultant	Jane Blair 01443864578
Monmouthshire (North)	Linda Marshall – Team Leader (01873 735411)	Jane Lewis – Administrator 01873 735412	Dr Mollie Thomas (Associate Specialist)	Nicola Jones 01495 322 655
Monmouthshire (South)			Dr Ceri Richings – Consultant	no one in post but Nicola Jones (above) will help
Newport	Chris Edmunds – Team Leader (01633 210504)	Samantha Collard – Administrator 01633 210183	Dr Sundari - Consultant	Roxanne Green 01633 210122
Torfaen	Steve Harris – Team Leader (01633 624100)	Teresa Caddick – Administrator 01633 624101	Dr Ceri Richings – Consultant	no one in post but Nicola Jones (above) will help

ENGLAND

Service	Address	Contact Numbers
North Bristol Community Learning Difficulties Team	New Friends Hall Heath House Lane Stapleton Bristol, BS16 1EQ	Phone: 0117 908 5000 Fax: 0117 958 6048
Central Bristol Community Learning Difficulties Team	New Friends Hall Heath House Lane Stapleton Bristol, BS16 1EQ	Phone: 0117 958 5666 Fax: 0117 958 6048
South Bristol Community Learning Difficulties Team	The Withywood Centre Queens Road Withywood Bristol, BS13 8QB	Phone: 0117 987 8383 Fax: 0117 987 8442
South Gloucestershire - Kingswood - Community Learning Difficulties Team	Hanham Road Kingswood South Gloucestershire, BS15 8PQ	Phone: 01454 862480
South Gloucestershire - Thornbury - Community Learning Difficulties Team	Unit 5 Midland Way Thornbury South Gloucestershire, BS35 2BS	Phone: 01454 862450
North Somerset Community Learning Disabilities Team	Partnership House, Worle, Weston Super Mare, BS22 6WA	Phone: 01934 427600
Bath and North East Somerset	St Martins Hospital Clara Cross Lane Bath BA2 5RP	Phone: 01225 831566

WHAT TO DO IF CHALLENGING BEHAVIOUR ESCALATES

If a patient's challenging behaviour escalates during the study there are a number of options. Firstly, it is important to rule out any treatable physical or remediable environmental causes. It is unlikely, but not impossible, that an escalation in challenging behaviour may be related to some previously unrecognised psychosis in which case referral to your local Psychiatric or Learning Disability Service is warranted.

By far the most likely scenario is that this is a simple fluctuation in the patient's normal pattern of challenging behaviour which should be addressed through the usual range of support strategies. However, if you feel that adjustment in medication is necessary you may wish to prescribe a short course of Benzodiazepine (agent and dose will be dependent upon individual patient characteristics) or, if appropriate, an "as required" option to be administered as necessary when alternative calming strategies have proved unsuccessful.

You may, if simple interventions prove unsuccessful, contact the Study Team with a view to delaying the next incremental reduction in medication or in an extreme situation withdraw from the study.

At all times advice on acute behavioural management will be available from your local Community Learning Disability Team or, out of hours, through the on-call Psychiatric Service.

ADVERSE EVENTS
Definitions and reporting procedures.

It is the responsibility of the PI (GP) to report <u>all</u> adverse events to SEWTU within 24 hours of becoming aware of it. Any queries concerning adverse event reporting should be directed to the Trial Manager in the first instance.

HOW TO REPORT

Complete an ANDREA-LD SAE form as follows and fax to SEWTU on 02920 687612

1. The first report should be marked as 'Initial'. Any other types of report ('follow up' or 'final' will be prompted by the study team.
2. Complete the 'report date' and 'Details of subject affected by Event'
3. Complete 'Details of Event'. Note, an adverse event is considered serious if it**:**
    - Results in death
    - Is life-threatening (Note: The term "life-threatening" in the definition of serious refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.)
    - Required hospitalisation or prolongation of existing hospitalisation (Note: Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure, for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened or elective procedures does not constitute an adverse event.)
    - Results in persistent or significant disability or incapacity
    - Consists of a congenital anomaly or birth defect
    - Other medically important condition (Note: other events that may not result in death are not life-threatening, or do not require hospitalisation may be considered as a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.)
4. Complete 'Details of Investigational Medicinal Product(s)' section with as much detail as possible. Note, for the question 'Is the SAE related to the IMP?', consider the following:

Most adverse events and drug reactions that occur in this trial, whether they are serious or not, may be due to drug reduction. They will not be toxicity related effects. The assignment of the causality should be made using the definitions in the table below.

Relationship	Description
Unrelated	no evidence of any causal relationship with the trial/intervention
Unlikely	little evidence to suggest a casual relationship with the trial/intervention (e.g. the event did not occur within a reasonable time after administration of the trial medication). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatment).
Possible	some evidence to suggest a causal relationship with the trial/intervention (e.g. because the event occurs within a reasonable time after administration of the trial medication). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant treatments).
Probable	evidence to suggest a causal relationship. The influence of other factors is unlikely.
Definite	clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.
Not assessable	insufficient or incomplete evidence to make a clinical judgement of the causal relationship.

5. Complete ‘Details of other treatment’ and ‘Further information relevant to assessment’ sections with as much detail as possible.
6. Sign the form and send a copy as described at the end of the form. Place the original in the Trial Site File and add a copy to the patient’s medical notes.

UNBLINDING

EMERGENCY

If, having worked through the management flow chart above, you still have significant concerns or feel that risks remain despite amber intervention or there was an inability to access referral, you may feel it appropriate to request emergency unblinding of treatment allocation.

In such a situation, you must report an adverse event as described above by completing a Serious Adverse Event (SAE) Form (this can be found in your Site File) and submitting it to the Trial Manager. The Chief Investigator or Clinical Reviewer will then contact you to discuss the issues surrounding the situation and, if necessary, confirm that the participants treatment allocation needs to be unblinded

ROUTINE
Breaking the code (blind) at the 9 month visit.

When each patient reaches their 9 month visit, it will be time for the blind to be broken thus revealing whether they were in the reduction arm or were receiving treatment as normal.

The ANDREA-LD team will reveal the allocation to you along with details of the dose of medication the patient is currently taking. It will be your responsibility to have a discussion with the patient and their carer (or representative) in order to relay this information.

For those still receiving medication, any on-going treatment and dosage could be based on the dose the patient finished on depending on the clinical judgment of the GP and the patient's needs at the time.

Once the blind has been broken and the patient’s treatment allocation and drug dosage is known, we would like you to share this information with any secondary services involved in their care. Knowledge of how the patient progressed in the trial could be of importance in future decision making regarding treatment.