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New Court Surgery
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Royal Wootton Bassett
Swindon
Wiltshire
SN4 7AX

Dr Claire Balysz
Assistant Coroner
Wiltshire & Swindon Coroner's Office
26 Endless Street
Salisbury
Wiltshire
SP1 1DP

Date: 22th December 2015

Dear Dr Balysz

Inquest touching on the death of Tania Hristova (Date of Death – 17.11.14)
Regulation 28 Report request addressed to New Court Surgery

We write following receipt of the Regulation 28 report issued by the Coroner, the contents of which have been noted.

It is noted that Dr Bailes attended the inquest on 6th May 2015 on behalf of the partners at the surgery to give evidence as a factual witness. He was not declared an Interested Person. The Record of Inquest recorded a conclusion of suicide. The partners wish to pass on their condolences to the family of Mrs Hristova.

Thank you for granting an extension in respect of the response making it due by 31st December 2015.

In response to the two points as set out in section 5 of the Regulation 28 Report, we provide a response with supporting evidence.

The partners at the surgery have had detailed discussions and taken a number of steps to address the concerns raised and improved the care and service provided to patients taking SSRI antidepressants. The partners have taken a number of steps to ensure that regular medication reviews are undertaken and patients are actively made aware of the mental health support services available to them.

A significant event meeting was held on 11th May 2015 and 12th May 2015 to discuss learning points and actions to be taken. A number of steps were implemented and these will be set out in the course of this response.

Medication Reviews and repeat prescriptions

At the significant event meeting, awareness was raised about the use of medication review codes. It was agreed that a written summary of the medication review was required to be recorded in the patient's notes with the medication review "*read code*". The use of medication review codes allows reliable audits to be performed and to identify patients that require a medication review.

An audit was undertaken to help identify patients on SSRI antidepressants that were due to have a medication review and arrangements were made to contact those patients to make a review appointment either by telephone or to take place in person at the surgery.

There is currently a system in place whereby patients on repeat medications are notified that they ought to make an appointment for a medication review on their reorder form when they request a prescription. There is a "*counting down*" procedure each time they request a repeat prescription. Patients that repeatedly ignore this are being contacted by telephone or letter asking them to make a medication review appointment or a message asking them to make an appointment is added to their electronic prescription. As part of our investigations, we have contacted local pharmacists and asked them to ensure that the messages are duly passed on to patients.

As part of improving our management of patients on SSRI antidepressants, partners agreed that we would write to all such patients to invite them to attend for a medication review and provide additional information about coming off antidepressants and about SSRI antidepressants generally. A copy of the letter is **enclosed** for information.

As an additional measure, patients are also being advised to have an annual medication review in the month of their birthday.

A repeat audit of patients on SSRI antidepressants was performed in October 2015. This consisted of a computer database search of such patients who are due to have a medication review. These patients are being considered on a case by case basis over the next 6 months as resources permit.

The practice has reviewed its repeat prescribing system and has now upgraded to electronic prescribing. This allows messages to be added electronically to prescriptions which the patient can read themselves or the pharmacist can then pass on, (if their prescription is sent to the pharmacist). The surgery has also moved over to an online ordering facility through our clinical computer system. Patients register securely to obtain password and log in details, which then allows them to request repeat medications that still have issues remaining. Once the medication has reached its last issue it would then require a medication review.

Offer of counselling/other mental health support services

During the significant event review meeting, it was agreed that when a patient is started on SSRI antidepressants, they would be warned of the possible development of suicidal feelings and what to do should this occur. It was discussed that patients should also be requested to discuss their condition and treatment with family/friends who may be able to then spot negative mood changes and/or suicidal thoughts. Awareness has been raised with the doctors to document this clearly in the patient records.

It was also agreed that when starting antidepressants, clear follow up arrangements should be documented. It should also be documented that counselling/CBT has been offered and it should also be clearly documented as to whether the offer was accepted or declined. If accepted, the relevant arrangements should be clearly documented.

The letter sent to relevant patients as included with this response also contained a link with information about the local mental health support services available through the NHS. There were also two information leaflets from patient.co.uk **enclosed** with the letter which provide general background information about SSRI antidepressants and coming off them.

We have also made available information on how to access counselling in the waiting room in order that such information is readily accessible to patients.

The partners have taken substantial additional steps to address the points raised and are confident that there is a robust system in place at the surgery to ensure appropriate medication reviews and the offer of counselling to all patients taking SSRI antidepressants.

If we can assist further, please do not hesitate to contact us.

Yours sincerely

Partners at New Court Surgery
Enc.

1. *Copy letter sent to patients on SSRI antidepressants*
2. *X2 leaflets from Patient.co.uk*

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4 Feb 2015

Coming off Antidepressants

This leaflet is provided by the Royal College of Psychiatrists, the professional body responsible for education, training, setting and raising standards in psychiatry. They also provide readable, user-friendly and evidence-based information on various mental health problems.

The aim of this leaflet is to help you decide about when and how to come off antidepressants.
Some people find coming off antidepressants is quite easy. But others may get withdrawal or a return of the depression.
We asked people to tell us what it was like for them to come off antidepressants. This leaflet brings together the views of the 817 people who completed our survey and shared their experiences.

Survey findings

In our survey, the most common drug stopped was citalopram. This was taken by 235 people. Fluoxetine was next, taken by 173 people, followed by venlafaxine (109), sertraline (89), escitalopram (51), mirtazapine (38), paroxetine (29) and duloxetine (26).
36% stopped their antidepressant suddenly. Males were more likely to do this (m=44%, f=34%). Younger people were also more likely to stop suddenly (59% of 18-24 year-olds compared with just 20% of the over-65s).
512 (63%) people in our survey experienced withdrawal when stopping their antidepressants.
Some drugs were more likely to cause withdrawal than others. In the table below we have split the drugs into 3 groups (high, medium and low withdrawal).

High		Medium		Low	
	% with withdrawal		% with withdrawal		% with withdrawal
Venlafaxine	82%	Sertraline	62%	Fluoxetine	44%
Escitalopram	75%	Citalopram	60%	Mirtazapine	21%
Paroxetine	69%				
Duloxetine	69%				

A further 43 people were on tricyclic antidepressants. 63% of them had withdrawal. 23 people were on other types of antidepressant, but the individual numbers on these drugs were too small to be able to draw conclusions.

Common withdrawal symptoms

Overall, the most common symptoms were:

- anxiety (70%)
- dizziness (61%)
- vivid dreams (51%)
- electric shocks / head zaps (48%)
- stomach upsets (33%)
- flu-like symptoms (32%)
- depression (7%)
- headaches (3%)
- suicidal thoughts (2%)
- insomnia (2%)

Anxiety was the most common symptom for every antidepressant except duloxetine, for which 'dizziness' was the most common. The least common symptoms across all types were stomach upsets and flu-like symptoms. These patterns were the same for men and women.

Why do people stop?

The people in our survey decided to stop for a number of reasons:

Reason for stopping	Number of people

Felt better	219
Side-effects	213
Didn't help	175
Wanted to try without	46
Pregnant	39
On advice of doctor	21

When to stop?

Deciding when to stop is really important.
If you have had one episode of depression, you are usually advised to stay on antidepressants for 6 months to 1 year after you feel better. If you stop too soon, your depression may come back.
If your problems have been going on for some time, your doctor may advise you to stay on antidepressants much longer.
It is important to be aware of two things if you do stop:

- You may get withdrawal.
- The condition for which you were taking your antidepressants may come back.

Seeking advice

We strongly advise that your decision to stop is made with your doctor.
In our survey:

- 372 people got advice from a professional
- 95 from the internet
- 75 from the information leaflet provided with their pills
- 35 from someone who had stopped antidepressants
- 289 did not seek advice

A quarter of people in our survey were not aware that there could be problems linked with stopping.

What is withdrawal like?

People in our survey reported that the symptoms generally lasted for up to 6 weeks. A small percentage of symptoms lasted longer than this. A quarter of our group reported anxiety lasting more than 12 weeks.
Of the common symptoms reported, the one rated severe by most people was anxiety. The symptoms that were rated moderate by most people were stomach upsets, flu-like symptoms, dizziness, vivid dreams and electric shocks/brain zaps.
The less common symptoms were reported as severe: returning depression, headache, suicidal thoughts, insomnia, fatigue and nausea.

I want to stop - how should I go about it?

We would suggest the following:

BEFORE

- **Make an informed decision:**
  - discuss the options with your doctor
  - be aware of possible withdrawal or return of depression
- **Make a plan:**
  - choose a good time
  - decide the speed of reduction
  - who will you contact if there are problems?
- **Seek support:**
  - from friends and family
  - work - will you need some time off?

DURING

- Reduce slowly.
- Research suggests:
  - if treatment has lasted less than 8 weeks, stopping over 1-2 weeks should be OK
  - after 6-8 months of treatment, taper off over 6-8 weeks
  - if you have been on maintenance treatment, taper more gradually: eg, reduce the dose by not more than ¼ every 4-6 weeks
- Stay in touch with your doctor.
- Be prepared to stop the reduction or increase your dose again if needed.
- Keep a diary of your symptoms and drug doses.

AFTER

- Keep an eye on your mood.
- It may take some time before you fully stabilise.
- It is important you look after yourself and keep active.
- Keep practising cognitive behavioural therapy (CBT)/relaxation techniques if you have been taught these.
- Go back to see your doctor is you are worried about how you feel.

Advice from others who have stopped

People who responded to our survey also made the following suggestions (we don't necessarily endorse these suggestions - we leave them to you to consider):

Before deciding to stop

- Be prepared.
- Seek advice first.
- Research, but don't let online stories scare you.
- Listen to doctors and your own body and mind.
- Don't feel societal pressure to come off. If you have a medical condition (diabetes/asthma etc) you shouldn't be made to feel bad for taking medications.
- Stop for the right reason. Not to please others.
- Weigh up pros of taking drugs against the side-effects from continued use.
- If you don't get on with the GP you've previously seen, ask to see one with an interest in mental health
- It takes time/patience/perseverance.
- Think/write down with someone why you want to stop.

Once you have decided to stop

- Be sure you're ready; avoid stopping during any disruptive periods in your life - the timing needs to be right.
- Talk to someone else who's been there.
- Let others know. Have support around you.
- Understand the possible withdrawal symptoms you might experience
- Have plans in place to manage your mood. Have something else to focus on.
- Get details of who to contact if you have a problem.
- Advice for family/partners would be useful.
- View it like recovery from an operation. Be good, focused and approach it in a lifestyle change sort of way.
- If possible plan time off in advance.

During withdrawal

- Be prepared; sometimes withdrawal can take longer than expected.
- Rest, drink water, eat healthily, and be kind to yourself.
- Take time off work if you need to

Dose adjustment

- Go slowly - reduce by small amounts.
- Ask if you can reduce very slowly at the end with liquid instead of pills.
- Keep some tablets in reserve so you can stop extra slowly.
- Increase your dose temporarily to control symptoms if needed.
- Be aware that your symptoms may come back, at any time, if the dose is reduced further .
- Don't be ashamed to go back on antidepressants if needed.
- Don't feel bad if you can't come off at 1st or 2nd attempt.

Setting

- Avoid people/situations that may cause stress whilst coming off.

Activity and monitoring

- Keep a diary to reflect on your thoughts/feelings.
- Exercise.
- Avoid unnecessary responsibilities.
- Ask a friend or someone close to you to monitor your mood in case you go down again - they might notice this

before you do.

Symptoms of withdrawal

- Just as side-effects are a sign that medications are getting into your body, withdrawal effects are a sign they are leaving.
- If you get side-effects, don't allow other people to minimise their importance.
- It's tough, but persevere; it will get better eventually.
- Side-effects will pass - they are time-limited.
- Be alert to feelings. If your mood gets worse or your anxiety increases, it's not failure, it just might not be the right time to stop.
- Withdrawal symptoms may feel like a return of depression.

After withdrawal

- Expect to feel a little lower or flat for a while afterwards.
- Seek talking therapy to get to the root of the problem/consider talking treatments as an alternative.
- Keeping busy is the key to staving off the depression coming back, as your focus is outside yourself.
- You are not a failure if you can't come off them.
- Recognise why you don't need them and be proud of other ways you've helped yourself.
- Try cognitive behavioural therapy (CBT).
- Do some exercise.

Sources of information suggested by our responders

- http://antidepressantsteps.com/self-help/antidepressants/whenToStop.php
- http://www.mind.org.uk/help/medical_and_alternative_care/making_sense_of_coming_off_psychiatric_drugs
- http://antidepressantsteps.com/_uploads/booklet_full/2.pdf

Final comments

63% of people in our survey said they had experienced withdrawal or a return of depression. This is a higher figure than other research suggests (about 30%). It is possible that the research has underestimated the problem, but it is also possible that people were more likely to respond to our survey if they had problems stopping.
Either way, we hope that you find the advice given in this leaflet useful.
We would also like to reassure readers that despite some people having symptoms of withdrawal when stopping antidepressants, antidepressants are not addictive.
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Leaflet

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5 Feb 2014

SSRI Antidepressants

SSRI antidepressants are used to treat depression and some other conditions. They can take 2-4 weeks to build up their effect to work fully. A normal course of antidepressants lasts at least six months after symptoms have eased. Side-effects may occur, but are often minor. At the end of a course of treatment, you should gradually reduce the dose as directed by your doctor before stopping completely.

SSRI antidepressants are not just for depression

SSRI stands for selective serotonin reuptake inhibitor. They are a group of antidepressant medicines that are used to treat depression. They are also used to treat some other conditions such as bulimia nervosa, panic disorder, and obsessive-compulsive disorder.

How do SSRI antidepressants work?

Antidepressants alter the balance of some of the chemicals in the brain (neurotransmitters). SSRI antidepressants mainly affect a neurotransmitter called serotonin.

How effective are SSRI antidepressants?

About 5-7 in 10 people with moderate or severe depression have an improvement in symptoms within a few weeks of starting treatment with an antidepressant. However, up to 3 in 10 people improve with dummy tablets (placebos), as some people would have improved in this time naturally. So, if you have depression, you are roughly twice as likely to improve with an antidepressant compared with taking no treatment. But, they do not work in everybody. As a rule, the more severe the depression, the greater the chance that an antidepressant will work well.
Note: antidepressants do not necessarily make sad people happy. The word 'depressed' is often used when people really mean sad, fed-up, or unhappy. True depression is different to unhappiness and has persistent symptoms (which often include persistent sadness). See separate leaflet called Depression for more information about this condition.
The success rate of SSRI antidepressants can vary when used to treat the other conditions listed above (bulimia, panic disorder and obsessive-compulsive disorder).

How quickly do SSRI antidepressants work?

Some people notice an improvement within a few days of starting treatment. However, an antidepressant often takes 2-4 weeks to build up its effect and work fully. Some people stop treatment after a week or so thinking it is not helping. It is best to wait for 3-4 weeks before deciding if treatment with an SSRI is helping or not.
If you find that the treatment is helpful after 3-4 weeks, it is usual to continue. A normal course of antidepressants lasts at least six months after symptoms have eased. If you stop the medicine too soon, your symptoms may rapidly return. Some people with recurrent depression are advised to take longer courses of treatment (up to two years or longer).

When you are taking SSRI antidepressants

It is important to take the medication each day at the dose prescribed. Do not stop taking an SSRI medicine abruptly. This is because you may develop some withdrawal symptoms. The dose is usually gradually reduced before stopping completely at the end of a course of treatment. But don't do this yourself - your doctor will advise on dosage reduction when the time comes. It is best not to stop treatment or change the dose without consulting a doctor.

Are there different types of SSRI antidepressants?

There are several different types. They include citalopram, escitalopram, fluoxetine, paroxetine and sertraline. Each of these comes in different brand names. There is no best type that suits everyone. If the one chosen does not suit, it is sometimes necessary to change the dose, or change the preparation. Your doctor will advise. Also, if SSRI antidepressants do not help then another type of antidepressant may be advised.

What about side-effects and risks?

Most people have either minor, or no, side-effects. Possible side-effects vary between different preparations. The leaflet that comes in the medicine packet gives a full list of possible side-effects. You should read this before you start taking the medicine. It is beyond the scope of this leaflet to list all side-effects, but the following highlights some of the more common or serious ones.
As a rule, tell your doctor if a side-effect persists or is troublesome. Your doctor can advise on the best course of action -

for example, to stop the medication, a switch to a different medicine, etc.

The most common side-effects
These include diarrhoea, feeling sick (nauseated), vomiting (being sick), and headaches. It is worth keeping on with treatment if these side-effects are mild at first as they may wear off after a week or so.

A possible sedating effect
SSRIs can cause drowsiness (a sedating effect) in some people. This side-effect is not common, and is not as much of a problem as with some other types of antidepressants. However, you must be aware of the possiblity, especially if you are a driver, as it may impair your ability to drive safely. Any sedative effect is likely to be greatest in the first month of starting treatment, or on increasing the dose. The Driver and Vehicle Licensing Agency (DVLA) advises that you should not drive during this time if you feel that you are drowsy or sedated at all.

Bleeding into the gut
Some research has suggested that SSRIs may be associated with a small increased risk of bleeding into the gut, but the evidence is inconclusive. This is especially in older people and in people taking other medicines that have the potential to damage the lining of the gut or interfere with clotting. Therefore, ideally, SSRIs should be avoided if you take aspirin, warfarin, novel anticoagulants (such as dabigatran, apixaban and rivoraxaban) or non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen. If no suitable alternative to an SSRI can be found and you have an increased risk of bleeding, your doctor may advise that you take an additional medicine. This will help to protect the lining of the gut.

Small increased risk of fractures
Research studies suggest that there is a small increased risk of fractures in people taking an SSRI. However, the reason for this increased risk is not clear.

Nervous system side-effects
Dizziness, agitation, anxiety, difficulty sleeping, and tremor have all been reported as possible side-effects.

Sexual problems
Problems with sexual function are a common symptom of depression. However, in addition to this, all antidepressants may cause some problems with sexual function. For example, problems getting an erection, vaginal dryness and decreased sex drive have been reported as side-effects in some people.

Antidepressants and suicidal behaviour
In recent years there have been some case reports which claim a link between taking antidepressants and feeling suicidal, particularly in teenagers and young adults. This may be more a risk in the first few weeks of starting medication or after a dose increase. It is debatable whether this possible risk is due to the medicine or to the depression. If it is due to the medication then the risk remains very small. And, overall, the most effective way to prevent suicidal thoughts and acts is to treat depression. However, because of this possible link, see your doctor promptly if you become increasingly restless, anxious or agitated, or if you have any suicidal thoughts. In particular, you should speak with your doctor if these develop in the early stages of treatment or following an increase in dose.

Are SSRI antidepressants addictive?
SSRIs are not tranquillisers, and are not thought to be addict ve. Most people can stop an SSRI without any problem. At the end of a course of treatment you should reduce the dose gradually over about four weeks before finally stopping. This is because some people develop withdrawal symptoms if the medication is stopped abruptly. If you have withdrawal symptoms it does not mean that you are addicted to the the medicine, as other features of addiction such as cravings for the medicine do not occur.
Withdrawal symptoms that may occur include:

- Dizziness
- Anxiety and agitation
- Sleep disturbance
- Flu-like symptoms
- Diarrhoea
- Tummy (abdominal) cramps
- Pins and needles
- Mood swings
- Feeling sick (nauseated)
- Low mood

These symptoms are unlikely to occur if you reduce the dose gradually. If withdrawal symptoms do occur, they will usually last less than two weeks. An option if they do occur is to restart the drug and reduce the dose even more slowly.

How to use the Yellow Card Scheme
If you think you have had a side-effect to one of your medicines you can report this on the Yellow Card Scheme. You can do this online at the following web address: www.mhra.gov.uk/yellowcard.

The Yellow Card Scheme is used to make pharmacists, doctors and nurses aware of any new side-effects that medicines may have caused. If you wish to report a side-effect, you will need to provide basic information about:

- The side-effect.
- The name of the medicine which you think caused it.
- Information about the person who had the side-effect.
- Your contact details as the reporter of the side-effect.

It is helpful if you have your medication - and/or the leaflet that came with it - with you while you fill out the report.

Further help & information

Mind
15-19 Broadway, London, E15 4BQ
Tel: (Infoline) 0300 123 3393, (General) 020 8519 2122
Web: www.mind.org.uk

Further reading & references

- Depression in adults; NICE Clinical Guideline (October 2009)
- British National Formulary
- Depression; NICE CKS, August 2013

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Dr M VALENTINE, Dr J BAILES, Dr R GONSALVES
Dr D MARSHALL, Dr J MADDISON

«SYSTEM_Date»

«PATIENT_Title» «PATIENT_Forename1» «PATIENT_Surname»
«PATIENT_House»
«PATIENT_Road»
«PATIENT_Locality»
«PATIENT_Town»
«PATIENT_County»
«PATIENT_Postcode»

Dear «PATIENT_Title» «PATIENT_Surname»

As part of improving our Practice, we are currently reviewing all our patients on antidepressant medication. We notice that you have had a prescription for a medication that is used for depression in the last 3 months and that we do not have a medication review documented over the past 6 months. The medication you are on can also be used for other conditions as well. If you have seen a doctor about this medication recently, please contact the surgery and inform the receptionist, who will inform your GP.

If you are feeling better and have stopped your medication, please let us know so that we can update your medication list.

If you have stopped the medication and feel depressed or much worse, please contact the surgery for a review before re-starting. It is important to treat depression and if you are interested in any other methods of managing your depression or mood problems, you may find the following link helpful:

www.lift.awp.nhs.uk

We also enclose some standard leaflets about your medication.

If you have not seen a GP recently, please ensure you contact the surgery to book an appointment for a review (this could be done over the telephone).

Yours sincerely

On behalf of New Court Surgery