# Committee for Examinations
# Objective Structured Clinical Examination

## Station 10
## Gold Coast April 2019

The Royal Australian & New Zealand College of Psychiatrists

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**1.0 Descriptive summary of station:**

The candidate is to take a focussed history from Jennifer Manning, a 29-year-old woman with a history of bipolar disorder who is currently stable on sodium valproate. She wants advice about family planning, and the candidate must explain management recommendations including referring to the latest suggested changes to practice guidance regarding sodium valproate, its associated risks, and more robust consent processes.

**1.1 The main assessment aims are to:**

- Take a focussed history from a patient with bipolar affective disorder, identifying the key issues to enable recommendations around pregnancy to be made to the patient.
- Explain the risks and benefits of management strategies to a patient wanting to get pregnant for a second time.
- Specifically refer to medications usually prescribed for bipolar disorder, and their role in pregnancy in a careful and considered manner.

**1.2 The candidate MUST demonstrate the following to achieve the required standard:**

- Elicit that Jennifer's bipolar disorder stability has been dependent on maintenance valproate.
- Outline at least one significant effect on the offspring caused by valproate.
- Provide a risk benefit analysis for at least one pharmacological option to replace valproate.
- Explain the need for effective contraception, without interruption, throughout treatment with valproate.

## 1.3 Station covers the:

- **RANZCP OSCE Curriculum Blueprint Primary Descriptor Category**: Mood Disorders
- **Area of Practice**: Adult Psychiatry
- **CanMEDS Domains**: Medical Expert, Communicator, Scholar
- **RANZCP 2012 Fellowship Program Learning Outcomes**: Medical Expert (Management - Therapy); Communicator (Patient Communication - To Patient; Synthesis); Scholar (Application of Knowledge)

***References:***

1. Galbally M, Snellen M, Walker S, Permezel M. Management of antipsychotic and mood stabilizer medication in pregnancy: recommendations for antenatal care. Aust N Z J Psychiatry. 2010;44(2):99-108.
2 Koren G, Nava-Ocampo AA, Moretti ME, Sussman R, Nulman I. Major malformations with valproic acid. Can Fam Physician. 2006;52:441-2, 4, 7.
3 Jentink J, Loane MA, Dolk H, Barisic I, Garne E, Morris JK, et al. Valproic acid monotherapy in pregnancy and major congenital malformations. N Engl J Med. 2010;362(23):2185-93.
4 Mawer G, Briggs M, Baker GA, Bromley R, Coyle H, Eatock J, et al. Pregnancy with epilepsy: obstetric and neonatal outcome of a controlled study. Seizure. 2010;19(2):112-9.
5 Diav-Citrin O, Shechtman S, Bar-Oz B, Cantrell D, Arnon J, Ornoy A. Pregnancy outcome after in utero exposure to valproate : evidence of dose relationship in teratogenic effect. CNS Drugs. 2008;22(4):325-34.
6 Gerald Briggs RF, Sumner Yaffe. Drugs in pregnancy and lactation. 9th Edition ed: Lippincott Williams & Wilkins; 2011.
7 Diav-Citrin O, Shechtman S, Bar-Oz B, Cantrell D, Arnon J, Ornoy A. Pregnancy outcome after in utero exposure to valproate. CNS Drugs. 2008;22(4):325-34.
8 Pennell PB, Klein AM, Browning N, Baker GA, Clayton-Smith J, Kalayjian LA, et al. Differential effects of antiepileptic drugs on neonatal outcomes. Epilepsy Behav. 2012;24(4):449-56.
9 Veiby G, Daltveit AK, Engelsen BA, Gilhus NE. Pregnancy, delivery, and outcome for the child in maternal epilepsy. Epilepsia. 2009;50(9):2130-9.
10 Tomson T, Landmark CJ, Battino D. Antiepileptic drug treatment in pregnancy: changes in drug disposition and their clinical implications. Epilepsia. 2013;54(3):405-14.

11 Thisted E, Ebbesen F. Malformations, withdrawal manifestations, and hypoglycaemia after exposure to valproate in utero. Arch Dis Child. 1993;69(3 Spec No):288-91.

12 DiLiberti JH, Farndon PA, Dennis NR, Curry CJ. The foetal valproate syndrome. Am J Med Genet. 1984;19(3):473-81.

13 Meador KJ, Baker GA, Browning N, Clayton-Smith J, Combs-Cantrell DT, Cohen M, et al. Cognitive function at 3 years of age after foetal exposure to antiepileptic drugs. N Engl J Med. 2009;360(16):1597-605.

14 Viinikainen K, Eriksson K, Monkkonen A, Aikia M, Nieminen P, Heinonen S, et al. The effects of valproate exposure in utero on behavior and the need for educational support in school-aged children. Epilepsy Behav. 2006;9(4):636-40.

15 Christensen J, Gronborg TK, Sorensen MJ, Schendel D, Parner ET, Pedersen LH, et al. Prenatal valproate exposure and risk of autism spectrum disorders and childhood autism. JAMA. 2013;309(16):1696-703.

16 Bromley RL, Mawer G, Clayton-Smith J, Baker GA. Autism spectrum disorders following in utero exposure to antiepileptic drugs. Neurology. 2008;71(23):1923-4.

17 Hale TW. Medications and mothers' milk. 14th ed ed. Texas: Hale Publishing; 2010.

18 Stahl MM, Neiderud J, Vinge E. Thrombocytopenic purpura and anaemia in a breast-fed infant whose mother was treated with valproic acid. J Pediatr. 1997;130(6):1001-3.

19 Meador KJ, Baker GA, Browning N, Clayton-Smith J, Combs-Cantrell DT, Cohen M, et al. Effects of breastfeeding in children of women taking antiepileptic drugs. Neurology. 2010;75(22):1954-60.

20 Veiby G, Engelsen BA, Gilhus NE. Early child development and exposure to antiepileptic drugs prenatally and through breastfeeding a prospective cohort study on children of women with epilepsy. JAMA Neurol. 2013.

21 Guidance: Valproate use by women and girls. Information about the risks of taking valproate medicines during pregnancy: Medicines and Healthcare products Regulatory Agency. *23 March 2018.* Last updated 18 May 2018. https://www.gov.uk/guidance/valproate-use-by-women-and-girls.

22 Mawhinney E, Campbell J, Craig J, Russell A, Smithson W, Parsons L, et al. Valproate and the risk for congenital malformations: Is formulation and dosage regime important? Seizure. 2012;21(3):215-8.

### 1.4 Station requirements:

- Standard consulting room.
- Four chairs (examiner x 1, role player x 1, candidate x 1, observer x 1).
- Laminated copy of ‘Instructions to Candidate’.
- Role player: female in late 20s, not overweight.
- Pen for candidate.
- Timer and batteries for examiner.

## 2.0 Instructions to Candidate

You have **eight (8) minutes** to complete this station after **two (2) minutes** of reading time.

You are working as a junior consultant psychiatrist in a private consulting room.

You are about to see Jennifer Manning, a 29-year-old married woman, who has been referred by her GP for advice about her psychotropic medication. She has a history of bipolar disorder (type 1), and is currently being treated for this condition with valproate. She has a daughter who is nearly 5 years old, and now Jennifer and her husband would like a second child.

Your tasks are to:

- Assess the risks and benefits of Jennifer's current treatment in the context of her history.
- Make recommendations about treatment options to Jennifer.

**You will not receive any time prompts.**

**Station 10 - Operation Summary**

**Prior to examination:**

- Check the arrangement of the room, including seating and other specifics to your scenario.
- On the desk, in clear view of the candidate, place:
  - A copy of 'Instructions to Candidate' and any other candidate material specific to the station
  - Pens.
  - Water and tissues (available for candidate use).
- Do a final rehearsal with your role player.

**During examination:**

- Please ensure mark sheets and other station information, are out of candidate's view.
- At the **first bell**, take your places.
- At the **second bell**, start your timer, check candidate ID number on entry.
- TAKE NOTE there are no cues / scripted prompts for you to give.
- DO NOT redirect or prompt the candidate unless scripted – the role player has prompts to use to keep to the aims.
- If the candidate asks you for information or clarification say:

  ***'Your information is in front of you – you are to do the best you can'.***
- At **eight (8) minutes**, as indicated by the timer, the final bell will ring. Finish the examination immediately.

**At conclusion of examination:**

- Retrieve all station material from the candidate.
- Complete marking and place your mark sheet in an envelope by / under the door for collection (**do not seal envelope**).
- Ensure room is set up again for next candidate. (See 'Prior to examination' above.)

**If a candidate elects to finish early after the <u>final task</u>:**

- You are to state the following:

  ***'Are you satisfied you have completed the task(s)?***

  ***If so, you <u>must</u> remain in the room and <u>NOT</u> proceed to the next station until the bell rings'.***

- If the candidate asks if you think they should finish or have done enough etc., refer them back to their instructions and ask them to decide whether they believe they have completed the task(s).

## 3.0 Instructions to Examiner

### 3.1 In this station, your role is to:

Observe the activity undertaken in the station, and judge it according to the station assessment aims and defined tasks as outlined in 1.1 and 1.2.

When the candidate enters the room, briefly check ID number.

The role player opens with the following statement:

***'Mark and I are planning for a second child, and were told to consult you before I become pregnant.'***

### 3.2 Background information for examiners

In this station, the candidate is to take a history to establish the information required to conduct a risk benefit analysis and discussion with the patient. This involves confirming the current presentation and previous management strategies tried. A screen for co-morbidities, strengths and risk factors are also important, as well as a review of supports.

Given this is a difficult choice facing the patient, the candidate is expected to sensitively engage Jennifer, demonstrating empathy and utilising reflective listening skills. There is a significant risk of relapse in this case even with effective management strategies, and this would need to be discussed with the patient. While the candidate may not give a precise figure of the risk of relapse, it must be acknowledged as high and the importance of a good management plan emphasised.

The discussion should involve risks and benefits of continuing treatment which must be weighed up with risks and benefits of changing treatments. The risk of exposure to a teratogen must be acknowledged, and options including termination if she falls pregnant while on this medication can be raised. The key is to present the risks of treatment with the current agent, an alternative agent or no pharmacological treatment at all. The candidate should also consider the preferred option of ceasing the valproate, and outline how this should be replaced; including which choice of alternative, the timing of the medication change, the speed of tapering off the valproate, and the value of adding folic acid.

The key is to present the risks of treatment with current agent, an alternative agent or no pharmacological treatment. Consultation is essential, and the idea is to support the patient to make an informed decision.

The candidate is not expected to focus non-pharmacological interventions in the treatment recommendations.

In keeping with the latest UK guidance[21] candidates should demonstrate some awareness of the recommended changes to consent that have been endorsed by the National Health Service (NHS) and Europe.

In order to 'Achieve' this station the candidate **MUST**:

- Elicit that Jennifer's bipolar disorder stability has been dependent on maintenance valproate.
- Outline at least one significant effect on the offspring caused by valproate.
- Provide a risk benefit analysis for at least one pharmacological option to replace valproate.
- Explain the need for effective contraception, without interruption, throughout treatment with valproate.

A surpassing candidate will skilfully guide the patient through their choices, encourage the involvement of family; emphasise integrated perinatal care planning, working in liaison with the obstetrician and GP; and consider the option of a second opinion. The candidate may also incorporate non-pharmacological interventions alongside the pharmacological ones, including how the aspects of a comprehensive birthing plan will mitigate risk of relapse.

It is both effective and cost-effective to integrate perinatal mental health care into obstetric and primary care settings. Providing adequate perinatal care and parenting support, as well as monitoring for both perinatal depression and anxiety alongside any emergence of manic symptoms will reduce risks.

Whether to prescribe medication or not is based on a growing body of literature that suggests that untreated maternal mental illness can have serious adverse outcomes on foetal wellbeing that may be equal to, or worse, any potential adverse effects of psychotropic medications. For instance, untreated ante-natal depression and / or anxiety has been associated with reduced maternal nutrition, poor antenatal attendance, increased smoking and substance use. Increased risks of obstetric complications (e.g. spontaneous abortion, pre-eclampsia, increased uterine artery resistance, intra-uterine growth retardation, pre-term delivery, and low birth-weight babies) have also been noted. Neonates born to depressed and / or anxious mothers tend to have smaller head circumferences, lower Apgar scores, higher cortisol levels at birth (which could lead to psychopathology later in life), and an increased need for special care nursery due to some medical complication.

Since valproate was introduced in 1974, product information has included a warning about the possible risk of birth defects. As the risks to unborn children have been increasingly understood, the warnings have been strengthened. Recent review and recommendations were carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines. The PRAC recommendations were adopted by the Co-ordination Group for Mutual Recognition and Decentralised Procedures– Human (CMDh) that endorsed a strengthened regulatory position on valproate medicines in March 2018. [*The CMDh represents European Union Member States as well as Iceland, Liechtenstein and Norway and is responsible for ensuring safety standards for medicines authorised via national procedures across the EU. Its recommendations are sent to the European Commission, which make EU-wide legally binding decisions*.]

The recommendation is that valproate must no longer be used in any woman or girl able to have children unless she has a 'pregnancy prevention programme' in place. This recommendation is intended to ensure that patients are fully aware of the risks, and the need to avoid becoming pregnant.

The European Medicines Agency statement (EMA/145600/2018) recommends that a pregnancy prevention programme should include:

- an assessment of each patient's potential for becoming pregnant,
- pregnancy tests before starting and during treatment as needed,
- counselling about the risks of valproate treatment and the need for effective contraception throughout treatment,
- a review of ongoing treatment by a specialist at least annually,
- introduction of a new *risk acknowledgement form* that patients and prescribers will go through at each such annual review to confirm that appropriate advice has been given and understood.

Valproate is approximately 90% protein bound and cleared through hepatic metabolism. Pregnancy may affect the disposition of valproate, especially in late pregnancy[11].

Maternal use of valproate, both as monotherapy and as part of a polytherapy regimen, has been associated with an increased risk of congenital malformations[2-6]. Birth defects associated with valproate use during pregnancy include:

- spina bifida
- facial and skull malformations (including cleft lip and palate)
- malformations of the limbs, heart, kidney, urinary tract and sexual organs.

'Foetal valproate syndrome' refers to a consistent craniofacial phenotype, often with major malformations, growth deficiency or neurodevelopmental dysfunction[6]. Several studies have suggested that the risk for major congenital malformations is dose dependent, with greater risks associated with doses equal to or greater than 1000mg daily[2, 3, 6].

Infants exposed to valproate in utero may develop neurological manifestations, including irritability, jitteriness, hypotonia, hypertonia (or variable tone) and feeding problems. These signs and symptoms usually occur within 12 to 48 hours after birth[12]. Other possible neonatal complications include hepatic toxicity and hypoglycaemia[1, 12, 13].

In women who take valproate while pregnant, approximately 3–4:10 children may have developmental problems, and several studies suggest that children exposed to valproate in utero show poorer cognitive outcomes compared to infants exposed to other antiepileptic medicines[14, 15]. The long-term effects are not well known but the effects on development can include:

- developmental delay: infants of women taking antiepileptic medicines may have an increased risk of growth restriction, small for gestational age, transiently reduced Apgar score and low birth weight[9, 10]
- lower intelligence
- poor speech and language skills
- memory problems.

Maternal use of valproate has also been associated with an increased risk of autism spectrum disorder and childhood autistic spectrum disorders[16, 17]. There is also some evidence children may be more likely to be at risk of developing symptoms of attention deficit hyperactivity disorder (ADHD).

The decision to treat should be made on an individual case basis by considering the risks and benefits to both mother and foetus. Most research to date on valproate use during pregnancy has been in women with epilepsy. Seizure activity and genetic predisposition in epileptic women may have independent effects on congenital malformation rates[1].

Women taking valproate should consider changing to an alternative mood stabiliser in the pre-conception period to minimise teratogenic risk. Discontinuation of a maintenance treatment for bipolar disorder, however, is associated with high rates of relapse, especially if discontinuation occurs abruptly. A trial of a slow dose reduction should be considered. Untreated or inadequately treated bipolar disorder during pregnancy increases the risk of pregnancy complications.

Women on valproate should be counselled and encouraged to plan their pregnancies. If a woman decides to take the risk of remaining on valproate, folic acid should be commenced as soon as effective contraception has ceased, as valproate is known to interfere with folate metabolism[1]. Alternatively, folic acid supplementation (5mg daily) is recommended to commence at least one month prior to conception and during pregnancy to reduce teratogenic risk[1].

When valproate is the treatment of choice during pregnancy, valproate levels should be monitored and titrated to the lowest effective dose[1]. When valproate treatment during pregnancy cannot be avoided, use the lowest effective dose (preferably as monotherapy) to minimise teratogenic risk[8]. Appropriate ultrasonographic and other examinations (such as measuring maternal serum levels of alpha-fetoprotein and foetal cardiography) should be offered to women using valproate during pregnancy[1, 3].

It is recommended that if pregnancy does occur on valproate that high resolution USS is critical, with closer and more frequent monitoring. Other factors that need to be considered: planning of the delivery, close monitoring post-partum; proactive consultation with experts (obstetrician, perinatal psychiatrist and paediatrician); possible admission to a specialist mother and baby unit.

### 3.3 The Standard Required

**Surpasses the Standard** – the candidate demonstrates competence above the level of a junior consultant psychiatrist in several of the domains described below.

**Achieves the Standard** – the candidate demonstrates competence expected of a junior consultant psychiatrist. That is the candidate is able to demonstrate, *taking their performance in the examination overall*, that

i. they have competence as a ***medical expert*** who can apply psychiatric knowledge including medicolegal expertise, clinical skills and professional attitudes in the care of patients (such attitudes may include an ability to tolerate uncertainty, balance, open-mindedness, curiosity, 'common sense' and a scientific approach).

ii. they can act as a ***communicator*** who effectively facilitates the doctor patient relationship.

iii. they can ***collaborate*** effectively within a healthcare team to optimise patient care.

iv. they can act as ***managers*** in healthcare organisations who contribute to the effectiveness of the healthcare system, organise sustainable practices and make decisions about allocating resources.

v. they can act as ***health advocates*** to advance the health and wellbeing of individual patients, communities and populations.

vi. they can act as ***scholars*** who demonstrate a life-long commitment to learning as well as the creation, dissemination, application and translation of medical knowledge.

vii. they can act as ***professionals*** who are committed to ethical practice and high personal standards of behaviour.

**Below the Standard** – the candidate demonstrates significant defects in several of the domains listed above.

**Domain Not Addressed** – the candidate demonstrates significant defects in all of the domains listed above or the candidate demonstrates significant defects in the first domain of being a medical expert.

## 4.0 Instructions to the Role Player

### 4.1 This is the information you need to memorise for your role:

You are Jennifer Manning, a 29-year-old female who has been married to Mark for six years. You have a daughter, Emma, who will turn 5 years old in May, and started preschool (or kindergarten) this year. You have returned to work, and are currently employed as a primary school teacher.

**Why you need to talk to a psychiatrist:**

You and Mark are happily married, and have been discussing having a second child. Currently you 'always use condoms' for contraception. Mark is 28 years old, fit and well, and employed in information technology.

You have a history of bipolar disorder, which is a chronic mental illness that presents with episodes of depression or elevated mood (which is called mania). Your illness has been very stable for three years, and you are currently well - your mood is stable. You have been taking a medication called valproate for nearly five years. You remember being told that the medication you are on may be a problem in pregnancy.

You would like to know what your options are, especially as you are very worried about stopping valproate – based on the history below you would be very reluctant to stop it, as you can't afford to get unwell again – it was too traumatic and disruptive the last time. That is why you asked your GP to refer you to a psychiatrist for a specialist opinion.

If asked, you are sleeping well, you have a good appetite and can concentrate well. You have no thoughts of harming yourself or others. You are not troubled by excessive anxiety. You do not have any unusual experiences / symptoms. You understand that you have bipolar disorder, what the symptoms are, and agree that your illness needs treatment.

Mark does not have any relevant past medical or psychiatric history.

**History of your bipolar disorder:**

You have had three severe episodes of illness related to your bipolar disorder plus a couple of more minor relapses.

You first became unwell at age 21 (in 2011) when you experienced an episode of elevated mood, like feeling over the moon; increased energy, really busy tidying the apartment and organising all sorts of things - that irritated your flatmates; decreased need for sleep, being up for many nights in a row; racing thoughts and increased activity; making lots of plans for study and work, but actually difficulty concentrating while studying teaching at college. You can also recall spending excessive amounts of money like buying about 10 pairs of shoes in one go.

After about a week of these symptoms you became convinced that one of your flatmates was trying to poison you. You told your mother about your concerns, and she took you to hospital – she was worried you were on drugs. You were admitted to the acute psychiatric unit for three weeks as an involuntary patient. You were diagnosed with bipolar disorder, and started on two medications called quetiapine and lithium. Unfortunately, you didn't manage to get used to the 'terrible' side effects of headache, tremor of your hands, and nausea and diarrhoea – which you were told was due to the lithium – so the lithium was stopped. Your symptoms settled enough for you to go home, and you remained well for about 18 months on the quetiapine and continued your studies.

However, you started getting unwell again near mid-year exams. Your private psychiatrist, Dr Hatcher, added a medication called valproate five days after you were admitted to hospital for the second time as your acute symptoms only partially responded to increased doses of quetiapine (you can't remember what the higher dose was). You responded well to the combination of medications, and made a full recovery by the time of discharge four weeks later. You were followed up by your private psychiatrist who decided to stop the quetiapine after six months (in early 2013), and the valproate after seven months (end of 2013), and discharged you back to your GP.

Around that time, you also found out you were pregnant, and Emma was delivered in May 2014. It is likely that you had been taking valproate in the first few weeks after Emma was conceived, but you are unsure as it was a long time ago.

You managed with some minor mood instability during the pregnancy but unfortunately, you had to be admitted with a manic relapse three weeks after delivery. You experienced similar symptoms to those described above, as well as getting into arguments with Mark in particular, because of your concerns about the general wellbeing of your baby. The valproate and quetiapine were restarted in the ward. You admit that you actually knew that you had started to get progressively unwell near the end of the pregnancy but didn't seek help – looking back you realise that was a really frightening decision to make.

Dr Hatcher agreed to stop the quetiapine after about a year due to weight gain (7 kilograms), and you have remained on valproate since that time. On occasion, if you feel a bit unwell, your illness is managed by the crisis and assessment team of the public mental health service, who insist on recommencing the quetiapine for short periods.

You currently take a dose of 1000 milligrams twice a day of valproate. You had stopped seeing your private psychiatrist two years ago due to the expense, and have been managed by your GP, Dr Berry, since that time. You have had no further episodes and have been very good with taking your treatment, and have attended your appointments regularly. Your GP has been regularly checking blood tests for your liver function and full blood count, but you cannot remember having a valproate blood level.

**Other symptoms you may be asked about:**

You have never had an episode of depression where you have felt sad, cried a lot, feel socially withdrawn, or had poor sleep.

You have never felt suicidal, and never harmed yourself or others in any way.

Your baby has never been at any risk from you – you have not ever had thoughts to harm her – even when unwell.

You have never been in trouble with the police – even when unwell.

You do not have any other medical history, specifically including thyroid gland problems.

You are on no other regular medications.

You have one to two glasses of wine a week (you prefer white wine), and have never tried illegal drugs.

**About your personal life if asked:**

You were born and raised in the rural town of Roma where your parent still live; they are a six-hour drive from Gold Coast. Your father is 60 and he is a retired truck driver. Your mother is 55 and works part time at a nursing home. Your parents have a happy marriage and they have been together for 35 years. You are an only child.

You have been told that your mother had an episode of 'psychosis' after your birth. Your parents were always reluctant to talk about this, and so you do not know what that really means or have any details except that she was in hospital and took a while to recover. You suspect it may be something similar to what you have been through. She never had any further episodes.

Your childhood was happy and there was no history of trauma or abuse. You were an average student at school, you were able to make and keep friends, and you had no history of behavioural problems. After finishing secondary school, you went to College to study teaching, and have remained in teaching ever since – except when you took time off with Emma. There are no issues at your work.

You had a couple of relationships, before meeting your husband, that were not serious. You met Mark through a friend while at College. You have a group of close friends who all have children. You enjoy reading, going to the movies and gardening. You are usually a quiet and introverted person. Emma appears to be doing well and there are no concerns about her health.

**4.2 How to play the role:**

You will be neatly dressed, but casual. You will be cooperative and openly answer the questions asked of you, but you will not volunteer information unless asked. You will be very worried about what may happen to your illness if the candidate suggests you stop the valproate, and will not readily agree to any advice to do so or to change medication to lithium or quetiapine. You have been well for so long on valproate, and are afraid to risk that by medication changes, or stopping medication.

**4.3 Opening statement:**

***'Mark and I are planning for a second child, and were told to consult you before I get pregnant.'***

**4.4 What to expect from the candidate:**

Most candidates will start by taking your history, and then move on to asking more specific questions about how you have been recently. The candidate should be sensitive to your situation; recommendations should be checked carefully with you, about you and your husband's feelings.

**4.5 Responses you MUST make:**

***'Can I just stay on the valproate?'***

***'Nothing happened to Emma; what could go wrong this time?'***

***'Is there any new information for women of my age on valproate?'***

**4.6 Responses you MIGHT make:**

If asked about your thoughts on termination of pregnancy should there be a problem with the baby.

Scripted response: ***'I don't think Mark and I would ever consider termination.'***

**4.7 Medication and dosage that you need to remember**

Valproate at a dose of 1000 milligrams twice a day.

Previously:

Lithium – you cannot remember the dose as it was so long ago.

Quetiapine (KWET-I-APEEN) when more unwell, up to 800 milligrams a day divided in two doses.

**STATION 10 – MARKING DOMAINS**

**The main assessment aims are:**

- Take a focussed history from a patient with bipolar affective disorder, identifying the key issues to enable recommendations around pregnancy to be made to the patient.
- Explain the risks and benefits of management strategies to a patient wanting to get pregnant for a second time.
- Specifically refer to medications usually prescribed for bipolar disorder, and their role in pregnancy in a careful and considered manner.

**Level of Observed Competence:**

**2.0 COMMUNICATOR**

**2.1 Did the candidate demonstrate an appropriate professional approach to gathering information from the patient? (Proportionate value - 25%)**

***Surpasses the Standard (scores 5) if:***
elicits and integrates information in a manner that can effectively be utilised to come to a conclusion; able to generate a complete and sophisticated understanding of complexity and the conflictual situation; effectively tailors interactions to maintain rapport within the therapeutic environment.

***Achieves the Standard by:***
demonstrating empathy and ability to establish rapport; forming a therapeutic partnership using language tailored to the functional capacity of the patient; communicating in a non-judgemental manner; utilising clinical expertise to elicit key factors in the history of the presenting complaint; sensitively identifying issues, risks and concerns related to the presentation; accommodating communication style and history taking techniques in response to the patient interaction.

To achieve the standard ***(scores 3)*** the candidate **MUST:**
a. Elicit that Jennifer's bipolar disorder stability has been dependent on maintenance valproate.

***A score of 4*** may be awarded depending on the depth and breadth of additional factors covered; if the candidate includes most or all correct elements.

***Below the Standard (scores 2):***
scores 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response.

***Below the Standard (scores 1):***
scores 1 if there are significant omissions affecting quality; errors or omissions significantly adversely impact on alliance and information obtained; unable to maintain rapport.

***Does Not Address the Task of This Domain (scores 0).***

| **2.1. Category: PATIENT COMMUNICATION - To Patient** | **Surpasses Standard** | **Achieves Standard** | | **Below the Standard** | | **Domain Not Addressed** |
|---|---|---|---|---|---|---|
| **ENTER GRADE (X) IN ONE BOX ONLY** | **5** ☐ | **4** ☐ | **3** ☐ | **2** ☐ | **1** ☐ | **0** ☐ |

**2.5 Did the candidate demonstrate effective communication skills appropriate to sensitively delivering information in this situation? (Proportionate value - 25%)**

***Surpasses the Standard (scores 5) if:***
integrates information in a manner that can effectively be utilised by the audience; provides succinct and professional information; takes care to deliver the message while carefully responding to and managing levels of distress.

***Achieves the Standard by:***
providing accurate and structured verbal feedback on the risks to the foetus / child; prioritising and synthesising evidence to aid in decision making; weighing up the general risks and benefits of treatment and pregnancy; adapting communication style to the setting; using language so as to enhance patient understanding; demonstrating discernment in selection of content to mitigate levels of distress.

To achieve the standard ***(scores 3)*** the candidate **MUST:**
a. Outline at least one significant effect on the offspring caused by valproate.

***A score of 4*** may be awarded depending on the depth and breadth of additional factors covered; if the candidate includes most or all correct elements.

***Below the Standard (scores 2):***
scores 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response.

***Below the Standard (scores 1):***
scores 1 if there are significant omissions affecting quality; errors or omissions significantly impact on the accuracy of information provided.

***Does Not Address the Task of This Domain (scores 0).***

| **2.5. Category: SYNTHESIS** | **Surpasses Standard** | **Achieves Standard** | | **Below the Standard** | | **Domain Not Addressed** |
|---|---|---|---|---|---|---|
| **ENTER GRADE (X) IN ONE BOX ONLY** | **5** ☐ | **4** ☐ | **3** ☐ | **2** ☐ | **1** ☐ | **0** ☐ |

**1.0 MEDICAL EXPERT**

**1.14 Did the candidate demonstrate an adequate knowledge and application of relevant biological therapies? (Proportionate value - 40%)**

***Surpasses the Standard (scores 5) if:***
includes a clear understanding of levels of evidence to support treatment options; refers to available guidance; considers value of second opinions.

***Achieves the Standard by:***
demonstrating the understanding of preferred medications during pregnancy; identifying specific treatment outcomes; outlining appropriate selection, benefits / risks relevant to the patient; recommending involvement of her partner and family in decision making; clearly specifying medication(s) choice, dosing and monitoring; selecting information sources to explain benefits / risks in pregnancy versus risk of relapse, application of psychoeducation regarding medications; sensitively considering barriers to implementation; identifying the roles of other health professionals and recommending close liaison with MDT.

To achieve the standard ***(scores 3)*** the candidate **MUST:**

a. Provide a risk benefit analysis for at least one pharmacological option to replace valproate.

***A score of 4*** may be awarded depending on the depth and breadth of additional factors covered; if the candidate includes most or all correct elements.

***Below the Standard (scores 2):***
scores 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response.

***Below the Standard (scores 1):***
scores 1 if there are significant omissions affecting quality; errors or omissions significantly impact adversely on patient care.

***Does Not Address the Task of This Domain (scores 0).***

| 1.14. Category: MANAGEMENT - Therapy | Surpasses Standard | Achieves Standard | | Below the Standard | | Domain Not Addressed |
|---|---|---|---|---|---|---|
| ENTER GRADE (X) IN ONE BOX ONLY | 5 ☐ | 4 ☐ | 3 ☐ | 2 ☐ | 1 ☐ | 0 ☐ |

**6.0 SCHOLAR**

**6.4 Did the candidate prioritise and apply appropriate and accurate knowledge based on available literature and guidance? (Proportionate value - 10%)**

***Surpasses the Standard (scores 5) if:***
candidate acknowledges that scientific information is continuously being updated; that evidence is in a state of known versus unknown and is subject to debate; recognises the delay between evidence and application into clinical practice; acknowledges their own gaps in knowledge; explains the latest European guidance recommending a pregnancy prevention programme.

***Achieves the Standard by:***
identifying key aspects of the available literature and guidance; commenting on the voracity of the available evidence; specifying the key proponents of current knowledge base; discussing major strengths and limitations of available evidence; describing the relevant applicability of theory to the scenario; recognising how research has led to a greater understanding of how to develop core clinical skills.

To achieve the standard ***(scores 3)*** the candidate **MUST:**

a. Explain the need for effective contraception, without interruption, throughout treatment with valproate.

***A score of 4*** may be awarded depending on the depth and breadth of additional factors covered; if the candidate includes most or all correct elements.

***Below the Standard (scores 2):***
scores 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response.

***Below the Standard (scores 1):***
scores 1 if there are significant omissions affecting quality; unable to demonstrate adequate knowledge of the literature / evidence relevant to the scenario.

***Does Not Address the Task of This Domain (scores 0).***

| 6.4. Category: APPLICATION OF KNOWLEDGE | Surpasses Standard | Achieves Standard | | Below the Standard | | Domain Not Addressed |
|---|---|---|---|---|---|---|
| ENTER GRADE (X) IN ONE BOX ONLY | 5 ☐ | 4 ☐ | 3 ☐ | 2 ☐ | 1 ☐ | 0 ☐ |

## GLOBAL PROFICIENCY RATING

Did the candidate demonstrate adequate overall knowledge and performance at the level of a junior consultant?

| Circle One Grade to Score | Definite Pass | Marginal Performance | Definite Fail |
|---|---|---|---|