1.0 Descriptive summary of station:
In this station the candidate is expected to demonstrate an awareness of lithium pharmacokinetics and of the problematic interactions between lithium and angiotensin converting enzyme (ACE) inhibitors including an angiotensin II receptor antagonist candesartan, and then incorporate this into the management of Mrs Harris, a 74-year old woman with bipolar affective disorder and hypertension.

1.1 The main assessment aims are to:
- Demonstrate understanding of the pharmacokinetics of lithium in terms of absorption, excretion and effects on organ systems, leading to safe prescribing practices.
- Discuss the areas to address when making a decision to change medications.
- Provide education to a general practitioner whose decision-making may place a patient at risk due to limited knowledge regarding the use of lithium.

1.2 The candidate MUST demonstrate the following to achieve the required standard:
- Explain that lithium is excreted essentially unchanged through the kidneys.
- Explain the impact of angiotensin II receptor antagonist on lithium levels.
- Identify the importance of a risk-benefit evaluation of continuation or cessation of lithium.
- Contact the GP to explain that the co-prescription of lithium and candesartan can cause serious problems and should be avoided.

1.3 Station covers the:
- **RANZCP OSCE Curriculum Blueprint Primary Descriptor Category**: Mood Disorders
- **Area of Practice**: Old Age Psychiatry
- **CanMEDS Domains**: Scholar, Medical Expert, Collaborator
- **RANZCP 2012 Fellowship Program Learning Outcomes**: Scholar (Application of Knowledge), Medical Expert (Management – Therapy; Management – Initial Plan), Collaborator (Teamwork)

References:

1.4 Station requirements:
- Standard consulting room; no physical examination facilities required.
- Three chairs (examiner x 1, candidate x 1, observer x 1).
- Laminated copy of ‘Instructions to Candidate’.
- Pen for candidate.
- Timer and batteries for examiners.
2.0 Instructions to Candidate

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

This is a VIVA station. There is no role player in this station.

You are working as a junior consultant psychiatrist in an outpatient Mental Health Clinic for Older Persons.

You are preparing to review Mrs Harris, 74-year-old woman with long-standing bipolar affective disorder in remission. Her recent serum lithium level is 0.7mmol/l and renal function within normal limits.

She has been taking lithium for the last five years and she has tolerated this well, with all regular monitored blood results being within normal limits. She complies with all aspects of lithium treatment. Prior to this, her bipolar affective disorder was not well managed with multiple hospital admissions usually under the Mental Health Act.

Mrs Harris has a new General Practitioner, Dr Green, who wrote to you last week to ask that you stop her lithium as he is concerned that she will develop hypothyroidism or go into renal failure if lithium is continued for longer than five years.

He has also informed you that Mrs Harris has recently been diagnosed with hypertension, and he has just started her on the angiotensin II receptor antagonist candesartan cilexetil.

Your tasks are to explain to the examiner:

- the pharmacokinetic profile of lithium including its absorption, distribution, metabolism and excretion.
- clinically important drug interactions and potential complications of lithium with reference to this scenario.
- important factors that may influence your decision regarding whether to change medications for Mrs Harris.
- the key issues to communicate to Dr Green.

You will not receive any time prompts.
Station 9 - 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:
  o A copy of ‘Instructions to Candidate’ and any other candidate material specific to the station.
  o Pens.
  o Water and tissues are available for candidate use.

During examination:
- Please ensure mark sheets and other station information, are out of candidate’s view.
- At the first bell, take your place.
- At the second bell, start your timer, check candidate ID number on entry.
- TAKE NOTE there are no cues for scripted prompts in this station.
- DO NOT redirect or prompt the candidate.
- 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 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 final task:
- You are to state the following:
  ‘Are you satisfied you have completed the task(s)?
   If so, you **must** remain in the room and **NOT** 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.

There is no opening statement or any prompts.

This is a VIVA station. The candidate is to explain to the examiner:
- the pharmacokinetic profile of lithium including its absorption, distribution, metabolism and excretion.
- clinically important drug interactions in this scenario.
- important factors that may influence your decision regarding whether to change medications for Mrs Harris.
- the key issues to communicate to Dr Green.

3.2 Background information for examiners

In this station the candidates are to demonstrate knowledge of safe prescribing practices by applying the pharmacokinetics of lithium, in particular the renal effects, to this scenario. The candidate is expected to be able to demonstrate an awareness of the toxic interactions between lithium and ACE inhibitors, and to incorporate this into the management of an elderly woman with bipolar affective disorder and hypertension.

In order to ‘Achieve’ this station the candidate must:
- Explain that lithium is excreted essentially unchanged through the kidneys.
- Explain the impact of angiotensin II receptor antagonist on lithium levels.
- Identify the importance of a risk-benefit evaluation of continuation or cessation of lithium.
- Contact the GP to explain that the co-prescription of lithium and candesartan can cause serious problems and should be avoided.

Management of the long-term side effects of lithium

The first step is to look at the possibility of reducing / stopping the lithium as sometimes renal or thyroid function can spontaneously improve. If this does not occur or reduction and stoppage is not possible, increased monitoring is indicated. In the case of renal impairment, liaison with a nephrologist is indicated to identify any other factors that may be promoting renal impairment. In the case of hypothyroidism, thyroid replacement is indicated. Such factors should be minimised and increased renal monitoring undertaken.

Deciding whether to stop lithium

The candidate needs to explain any decisions regarding changing medication.

A risk-benefit assessment would indicate that Mrs Harris’s bipolar disorder may deteriorate if she were to stop lithium particularly because many of her admissions have been under the Mental Health Act, so there is a degree of risk when she becomes unwell.

Whilst there is no right or wrong answer to this part of the question, good candidates will be able to explain how they have arrived at their decision as to whether to stop Mrs Harris’ lithium (including risk, efficacy of previous treatments) and if they are to continue lithium, how they will educate the GP or if they are to stop lithium, how they will manage this.

The co-prescription of the angiotensin II receptor antagonist candesartan cilexetil

The candidate should identify that they need to communicate with the GP about ceasing candesartan while Mrs Harris is still taking lithium; preferably before they meet with Mrs Harris so a cohesive plan can be presented to her without causing alarm.

Options are to temporarily stop or reduce the dose of lithium, or consider an alternative antihypertensive. If the angiotensin II receptor antagonist candesartan cilexetil is prescribed, it will be necessary to monitor the lithium levels more often.

They are expected to outline what they would say to the GP, including explaining the clinical risks of stopping lithium, and why the prescription of the angiotensin II receptor antagonist candesartan is unsafe for this patient.
Background to this station

Lithium is commonly used for the treatment of unipolar and bipolar affective disorder. According to the RANZCP guidelines for mood disorders, there is evidence from randomised controlled trials for the effectiveness of lithium as an augmenting agent in depression. Lithium is widely supported for use, and is found to be more effective than placebo in augmentation of TCAs, SSRIs and other antidepressants. For bipolar disorders, lithium is shown to be the most effective mood stabiliser, which may also reduce suicide risk but has important side effects with long-term use.

Lithium’s low therapeutic index and significant toxicity raise serious considerations in its use. Elderly patients are at a particularly high risk of lithium toxicity because of altered pharmacokinetics, polypharmacy, renal impairment, and proneness to medication induced confusion.

Polypharmacy is also a common occurrence in patients with co-morbidities and increased age. Several doctors may be independently caring for the same patient, and communication among them is imperative to ensure safe polypharmacy. There are a number of conditions that can lead to polypharmacy where lithium is one of the medications: insomnia, agitation, psychotic symptoms, physical co-morbidities, use of contraceptive pills and self-medication. Studies showed that more than 50% of patients taking lithium are prescribed additional medications at some point, and reports of pharmacokinetic interactions between lithium and other medications are uncommon.

Three major drug classes have been identified as potential precipitants of lithium toxicity:

- Diuretics that promote renal sodium excretion;
- The antihypertensive class of angiotensin II receptor antagonist, which reduce glomerular perfusion pressure and can enhance the tubular reabsorption of lithium;
- Nonsteroidal anti-inflammatory drugs (NSAIDs) that inhibit renal prostaglandin synthesis.

Pharmacokinetics:

Pharmacokinetics refers to the movement of drug into, through and out of the body; including the time course of its absorption, bioavailability, distribution, metabolism, and excretion (how the person affects the drug). It differs from pharmacodynamics which is the study of the biochemical and physiologic effects of a drug (how a drug affects a person). Both together influence dosing, benefit, and adverse effects.

Lithium ions are almost completely absorbed from the gastrointestinal tract, complete absorption occurring after about 8 hours. Peak plasma concentrations occur after about 2-4 hours of ingestion. Lithium initially distributes into extracellular fluid and then to most other tissues. The final volume of distribution equals that of total body water. Lithium slowly enters cerebrospinal fluid achieving a steady state 40% of the plasma concentration. Elimination occurs via the kidneys but lithium can also be detected in sweat and saliva. Lithium is able to cross the placenta and is excreted in breast milk.

The elimination half-life of lithium is 18-24 hours, but can be longer in elderly patients. Except for a very small fraction that is excreted through sweat and other body fluids, the excretion of lithium is through kidneys. Unlike many other psychotropic drugs, lithium is neither metabolised nor protein bound in the body. Excretion of lithium is linked with sodium excretion. Lithium is known to inhibit its own excretion and clearance of lithium dramatically declines with increasing serum levels of lithium.

Lithium and renal function:

Lithium is completely filtered at the glomerulus and the majority of the filtered load is reabsorbed by the proximal tubule. Significant quantities are also absorbed in the loop of Henle and the early distal nephron. Up to 90% of the filtered load is reabsorbed by the nephron, 60% in the proximal tubule, and the remainder in the thick ascending limb of the loop of Henle, the connecting tubule, and the cortical collecting duct. Lithium can substitute for sodium in several sodium channels, particularly the sodium-hydrogen exchanger in the proximal tubule, the exchanger in the thick ascending limb of the loop of Henle, and the epithelial channel of the cortical collecting tubule.

Acute lithium nephrotoxicity is evidenced by volume depletion, reduced alertness and the potential for cardiovascular collapse. The most common chronic complication is nephrogenic diabetes insipidus where the kidneys cannot respond to anti-diuretic hormone (ADH), the chemical messenger that controls fluid balance. This results in polyuria secondary to a deficit in urine concentrating ability, excessive thirst and polydipsia.

After 10–20 years of treatment, some patients develop lithium-induced interstitial nephropathy which, in small proportion of patients may lead to end-stage renal disease. Lithium-induced hypercalcaemia and nephrotic syndrome are rare complications of lithium therapy. In patients on long-term lithium therapy periodic monitoring of kidney function by measuring serum creatinine concentration and glomerular filtration rate is necessary.
Interactions:

As an alkali metal and monovalent cation, lithium is not biotransformed or highly protein-bound but is excreted unchanged by the kidneys. Therefore, any drug that has the potential to reduce renal function may lead to accumulation of lithium. Drugs with nephrotoxic potential should generally be avoided in patients who are receiving lithium.

Drug-drug interactions may contribute to altered lithium serum concentrations and decreased efficacy or increased toxicity. In particular, drugs that affect sodium or water balance may result in interactions with lithium.

In one study 10,615 elderly patients treated continuously with lithium for a total of 26,666 patient years of therapy were identified. The mean age of the cohort was 72, 62% were women. During the 10-year study period, 413 patients were admitted to the hospital with lithium toxicity. These patients were, on average, about 2 years older than the rest of the cohort and were marginally more likely to be women (66%). Patients admitted with lithium toxicity spent a total of 7,885 days (median 11; interquartile range 6–23 days) in the hospital. Sixty-one (15%) were treated in a critical care unit, 13 (3%) underwent dialysis, and 19 (5%) died before discharge. Of the 413 elderly patients admitted with lithium toxicity, many had received prescriptions for a potential interacting medication during the preceding month. After adjustment for potential confounders, the use of diuretics (particularly loop diuretics) and angiotensin II receptor antagonist in the preceding month was associated with a modest increase in the risk of admission for lithium toxicity. In new users of these agents, the risk of toxicity was considerably higher. Patients newly treated with diuretics were nearly six times more likely to be hospitalised, and those started on angiotensin II receptor antagonist were four times more likely to be hospitalised.

In no analysis was the use of thiazide diuretics or NSAIDs associated with a significantly greater risk of hospitalisation for lithium toxicity, even in new users of these agents. As expected, no association was found between topical corticosteroid use and lithium toxicity. Sensitivity analyses employing various definitions of the discontinuation date, individual observation period, and covariate exposure interval yielded uniformly consistent results. Approximately 2.4% of all hospitalisations for lithium toxicity in this cohort could be ascribed to new use of a loop diuretic in the preceding 28 days, and about 3.0% of such admissions could be ascribed to new use of an angiotensin II receptor antagonist.

Candesartan is prescribed in patients treated for hypertension where an agent acting on the renin-angiotensin system (RAS) is considered to be clinically indicated. The active ingredient is candesartan cilexetil. Candesartan is an angiotensin II receptor blocker / antagonist (ARB / AIIRA) used to treat hypertension as monotherapy or in combination with other medications. It is also indicated in congestive cardiac failure in addition to angiotensin II receptor antagonist or when angiotensin II receptor antagonist cannot be used.

Candesartan is contraindicated in people with allergy to the drug; in pregnancy; in severe liver disease or biliary obstruction; diabetes or kidney problems, and including in people taking direct renin inhibitors (e.g. irbesartan); angioedema, including that caused by other angiotensin II receptor antagonist (e.g. losartan).

In some patients, such as those with liver problems, kidney problems, dehydration, or those who recently have lost body fluids, e.g. through vomiting or diarrhoea or by using water tablets, a lower starting dose should be prescribed. Electrolyte problems (e.g. high blood potassium levels, low blood sodium levels) or a low-salt (sodium) diet also place people at risk when taking candesartan.

Medications that interact with candesartan therefore include:

- Lithium because the risk of its side effects may be increased by candesartan
- Diuretics (e.g. frusemide, hydrochlorothiazide) because the risk of hypotension may be increased
- Potassium-sparing diuretics (e.g. spironolactone, triamterene) or potassium supplements because the increased risk of hyperkalaemia
- Other angiotensin II receptor antagonist (e.g. losartan) or aliskiren because the risk of certain side effects (e.g. kidney problems, high blood potassium levels, low blood pressure) may be increased
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g. celecoxib, ibuprofen, indomethacin) because they may decrease candesartan's effectiveness and the risk of serious kidney problems may be increased.

Lithium and candesartan may interact and cause serious side effects because candesartan can slow down the elimination of lithium. This can lead to increased lithium blood levels. If taken in combination, patients may experience typical signs of toxicity: new or worsened tremors, fatigue, muscle weakness, confusion, slurred speech, vomiting, diarrhea, loss of appetite, blurred vision, trouble walking, ringing in the ears, seizures, dizziness, or heart palpitations.

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Incidence of long term side effects of lithium and their management:

In a paper published in the Lancet in 2015, the authors completed a retrospective analysis of laboratory data from Oxford University Hospitals National Health Service Trust (Oxfordshire, UK) investigating the incidence of renal, thyroid, and parathyroid dysfunction in patients (aged ≥ 18 years) who had at least two creatinine, thyrotropin, calcium, glycated haemoglobin, or lithium measurements between Oct 1, 1982, and March 31, 2014, compared with controls who had not had lithium measurements taken. They used survival analysis and Cox regression to estimate the hazard ratio (HR) for each event with lithium use, age, sex, and diabetes as covariates.

Adjusting for age, sex, and diabetes, presence of lithium in serum was associated with an increased risk of stage three chronic kidney disease (HR 1·93, 95% CI 1·76–2·12; p<0·0001), hypothyroidism (2·31, 2·05–2·60; p<0·0001), and raised total serum calcium concentration (1·43, 1·21–1·69; p<0·0001), but not with hyperthyroidism (1·22, 0·96–1·55; p=0·1010) or raised adjusted calcium concentration (1·08, 0·88–1·34; p=0·4602). Women were at greater risk of development of renal and thyroid disorders than were men, with younger women at higher risk than older women. The adverse effects occurred early in treatment (HR <1 for length of treatment with lithium). Higher than median lithium concentrations were associated with increased risk of all adverse outcomes.

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 well-being 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.

Does Not Achieve the Standard – the candidate demonstrates significant defects in most of the domains listed above or the candidate demonstrates significant defects in the first domain of being a medical expert.
STATION 9 – MARKING DOMAINS

The main assessment aims are to:

- Demonstrate understanding of the pharmacokinetics of lithium in terms of absorption, excretion and effects on organ systems leading to safe prescribing practices.
- Discuss the areas to address when making a decision to change medications.
- Provide education to a general practitioner whose decision-making may place a patient at risk due to limited knowledge regarding the use of lithium.

6.0 SCHOLAR

6.4 Did the candidate prioritise and apply appropriate and accurate knowledge about pharmacokinetic profile of lithium based on available literature / research / clinical experience? (Proportionate value - 30%)

**Surpasses the Standard (scores 5) if:**
da discuss major strengths and limitations of available evidence; recognises the impact of specific presentations, people and new knowledge on current understanding; acknowledges their own gaps in knowledge.

**Achieves the Standard by:**
identifying key aspects of the available literature; providing a detailed and comprehensive description of the absorption, distribution, metabolism and excretion profile of lithium; describing the relevant applicability of theory to the scenario; mentioning that it is not protein bound nor metabolised (distributed in water containing tissues).

To achieve the standard (scores 3) the candidate MUST:
a. Explain that lithium is excreted essentially unchanged through the kidneys.

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 or 1):**
scoring 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response; significant omissions affecting quality scores 1.

**Does Not Achieve the Standard (scores 0) if:**
unable to demonstrate adequate knowledge of the literature / evidence relevant to the scenario; inaccurately identifies or applies literature / evidence; provides a basic explanation of lithium’s indications and side effects but little regarding absorption or excretion.

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1.0 MEDICAL EXPERT

1.14 Did the candidate demonstrate an adequate knowledge and application of clinically important complications and drug interactions of lithium? (Proportionate value - 30%)

**Surpasses the Standard (scores 5) if:**
includes a clear understanding of levels of evidence to support known treatment interactions.

**Achieves the Standard by:**
explaining the renal and thyroid complications of lithium; identifying specific treatment outcomes and prognosis; demonstrating an understanding of lithium’s major drug interactions, for instance NSAIDs or diuretics; medication choice, dosing and monitoring.

To achieve the standard (scores 3) the candidate MUST:
a. Explain impact of angiotensin II receptor antagonist on lithium levels.

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 or 1):**
scoring 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response; significant omissions affecting quality scores 1.

**Does Not Achieve the Standard (scores 0) if:**
errors or omissions impact adversely on patient care; unable to identify major drug interactions; neglects to explain renal or thyroid complications; does not tailor responses to the patient’s circumstances.

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1.13 Did the candidate formulate and describe a relevant initial management plan in relation to the request to stop lithium? (Proportionate value - 30%)

**Surpasses the Standard (scores 5) if:**
provides a sophisticated link between the plan and key issues identified; clearly addresses difficulties in the application of the plan.

**Achieves the Standard by:**
demonstrating the ability to prioritise and implement evidence based acute care; identifying medication options; linking relevant investigations with assessment of physical condition, considering patient preference; recognising of their role in effective treatment; discussing the importance of ascertaining prior response to medications; identification of potential timeframes for communications and managing barriers.

To achieve the standard **(scores 3)** the candidate **MUST:**
a. Identify the importance of a risk-benefit evaluation of continuation or cessation of lithium.

**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 or 1):**
scores 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response; significant omissions affecting quality scores 1.

**Does Not Achieve the Standard (scores 0) if:**
errors or omissions will impact adversely on patient care; plan lacks structure or is inaccurate; plan not tailored to patient’s immediate needs or circumstances.

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3.0 COLLABORATOR

3.2 Did the candidate appropriately involve the GP in developing a management plan? (Proportionate value - 10%)

**Surpasses the Standard (scores 5) if:**
takes a leadership role in treatment planning; effectively negotiates complex aspects of care; provides a clear explanation of why the requested medication is contraindicated; recognises the risk of causing patient alarm.

**Achieves the Standard by:**
suitably engaging the general practitioner; communicating proposed recommendations clearly and with good judgment; expressing views and expectations candidly and respectfully; taking appropriate and effective leadership to ensure positive patient outcomes; dealing effectively with potential disagreement.

To achieve the standard **(scores 3)** the candidate **MUST:**
a. Contact the GP to explain that the co-prescription of lithium and candesartan can cause serious problems and should be avoided.

**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 or 1):**
scores 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response; significant omissions affecting quality scores 1.

**Does Not Achieve the Standard (scores 0) if:**
candidate allows the request for medication; errors impact adversely on the finalised plan.

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**GLOBAL PROFICIENCY RATING**

Did the candidate demonstrate adequate overall knowledge and performance at the defined tasks?

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