

EXEMPLAR

EPA- 2 Compounding Pharmaceutical Products

Key themes Compounding workflow, ambiguous formula, extemporaneous dispensing, quality assurance

Scenario in prose

John Williams (64 years old) presents a prescription for salicylic acid & sulfur aqueous cream for scalp lesions, prescribed by his GP. The intern and supervising pharmacist agree this is an opportunity to perform a Short Practice Observation for Compounding.

History of presentation

John frequently experiences episodes of 'flaky scalp' which John himself has not found troublesome. His doctor noticed these symptoms today, particularly around the hair margins, and offered to prescribe him something for the scale. Mr Williams agreed to try a cream, but very little information was provided to him about it.

John handed the script to a pharmacy assistant who was unaware the prescribed product needed to be compounded, and advised Mr Williams his medication should be ready to collect in about 15 minutes.

Medications

- Perindopril arginine 5mg mane for hypertension
- Paracetamol/codeine 500/30mg 2 prn for back pain (rarely required)
- Paracetamol SR 665mg tablets 2 prn for back pain (typically 2 at night)

Patient information

- John Williams
- 64 year old male, balding
- Health Care Concession card

Medical history, including allergies and adverse drug reactions

- Hypertension
- Chronic lower back pain
- History of adverse drug reaction (ADR): oxycodone – nausea and vomiting

Prescription order received

Dr Geoff Almanson (Medical Practitioner) Suite 111 The Boulevard Pharmville NSW 2300 Prescriber no. 444XXX	Dr Geoff Almanson (Medical Practitioner) Suite 111 The Boulevard Pharmville NSW 2300 Prescriber no. 444XXX
Patient's Medicare no. 2323123456 Pharmaceutical benefits entitlement no. <input type="checkbox"/> PBS Safety Net entitlement cardholder (cross relevant box) <input type="checkbox"/> Concessional or dependant RPBS beneficiary or PBS Safety Net concession cardholder	Patient's Medicare no. <input type="checkbox"/> PBS Safety Net entitlement cardholder (cross relevant box) <input type="checkbox"/> Concessional or dependant RPBS beneficiary or PBS Safety Net concession cardholder
Patient's name John Williams Address 14 Rosewood Ave Fassifern NSW 2283	Patient's name John Williams Address 14 Rosewood Ave Fassifern NSW 2283
Date PBS <input checked="" type="checkbox"/> RPBS <input type="checkbox"/> Brand substitution not permitted <input type="checkbox"/>	Date PBS <input checked="" type="checkbox"/> RPBS <input type="checkbox"/> Brand substitution not permitted <input type="checkbox"/>
Pharmacist patient COPY Salicylic acid and sulfur 2% cream Apply after showering prn  If not a Medical Practitioner, tick your prescriber type: Dentist <input type="checkbox"/> Nurse Practitioner <input type="checkbox"/> Midwife <input type="checkbox"/> Optometrist <input type="checkbox"/> Prescriber to sign original and duplicate Turn over for privacy notice	Medicare / DVA Salicylic acid and sulfur 2% cream Apply after showering prn  I declare that I have received this medicine(s) and the information relating to any entitlement to a pharmaceutical benefit is correct. Turn over for privacy notice Patient's or agent's signature _____ Date of supply ____/____/____ Agent's address _____ PK023.1711

Performance Outcomes (PO)¹ to be demonstrated

Performance outcome(s)	Description
3.15	Preparing and supplying extemporaneously compounded medications safely and accurately in accordance with current legislation, scope of practice, PharmBA Guidelines and other relevant jurisdictional requirements.
4.2	Identifying and acknowledging professional limitations and seeking appropriate support where necessary, including additional professional education and/or referral of patients to other health care professionals.
5.3	Recognising and responding to the inherent complexity, ambiguity and uncertainty of contemporary and future professional practice.

The activity may also provide evidence relating to other performance outcomes and this should be recorded in the 'Intern assessment and feedback form'

Key activities undertaken during short practice observation

<p>Decision making phase</p> <p><i>Intern discusses their thought process as they determine the safety/appropriateness of the prescription with the preceptor.</i></p>	<p>The intern:</p> <ul style="list-style-type: none"> • Checks the prescription for legality, validity and completeness – unclear whether the 2% applies to both the salicylic acid and sulfur, or if the salicylic acid strength is missing? • Checks that no suitable proprietary product is available – identifies <i>Coco-Scalp Ointment</i>[®] is similar but also contains coal tar and is not PBS-subsidised. Patient has a concession card, so a compounded product is also more cost effective for this patient. • Speaks with the patient to collect relevant background and intended use to inform safety and suitability – doctor hasn't named the condition, but suggests it is likely seborrheic dermatitis. Also advises the time to prepare the product will be closer to half an hour. • Consults APF and finds the formula for 2% salicylic acid and 2% sulfur in Aqueous Cream for seborrheic dermatitis – checks with supervisor whether this is correct formula. The supervisor confirms experience with prescriber where this was the intended formula when this same prescription order was written for a different patient. • Consults PBS website to ensure each ingredient is covered by PBS.
<p>Technical dispensing process phase</p> <p><i>Intern performs procedural aspects of preparing medicine for supply</i></p>	<p>The intern:</p> <ul style="list-style-type: none"> • Dispenses prescription and prepares dispensing label. • Checks compounding area: ingredients are available and in date. Sets up weighing scales, amber glass jar, etc. • Cleans compounding area (including slab and spatula) with 90% ethanol. • Considers wearing rubber gloves but determines this is not necessary. • Completes the APF's extemporaneous dispensing form, including working formula. • Shows the supervisor the prescription, label, compounding area and worksheet for approval. • Incorporates the ingredients into the cream on a slab using plastic spatulas and method of doubling, under direct supervision by the pharmacist supervisor. • Adds the cream into 100g brown glass jar with screw-top lid. The supervisor suggests and demonstrates a simpler technique for transfer of product to final container. • Labels the final container with the dispensing label, and CALs "For external use only", Label 7a with 28-day expiry, and Label 23. Adds additional product label with the typed words: "Store below 25 degrees C. Do not apply to broken skin or sensitive areas. Wash hands after use". • Takes the jar to the supervisor for the final product check for quality and completeness, who then signs off on the prescription and extemporaneous dispensing form. • Cleans compounding area and equipment (wipes with paper towel, then washes with detergent and water) under supervision.

	<ul style="list-style-type: none"> Supplies product to patient, while counselling on directions, expectations and storage.
<p>Entrustment discussion</p>	<p>The supervising pharmacist later chats with the supervisor pharmacist about the SPO to inform an Entrustment assessment. The two pharmacists then meet with the intern for an Entrustment discussion.</p> <p>Key elements of discussion</p> <ul style="list-style-type: none"> The intern's decision-making process was methodical and competent. The intern's technical skills were also adequate, and strategies to improve transfer of product to the final container were reinforced during the discussion. Considering the need to re-order any used ingredients for next time. Making suggestions around managing the time taken and the patient's expectation of waiting times. <p>Some 'What-if' questions were asked during the entrustment discussion including:</p> <ul style="list-style-type: none"> What if this were a new prescriber, how would you determine whether the doctor intended for both ingredients to be prescribed at 2% strength? In what circumstances would wearing gloves be appropriate for extemporaneous compounding? What potential risks do these ingredients pose to other team members in the pharmacy, e.g. if there is residue in the sink? Where can you find this information? What if the doctor asked about the maximum strength of salicylic acid and/or sulfur that the intern would be comfortable compounding for this condition? What resource(s) would you use to support your recommendations? What if the patient was unwilling to come back to collect the medicine, and you were too busy to make it straight away?
<p>Feedback and assessment of EPA</p>	<p>The intern's performance was to a standard that both the supervising pharmacist and the preceptor would feel confident the intern could complete this without close supervision in the future.</p> <p>For any future compounding cream or ointment that can be prepared on a slab, the supervising pharmacist/preceptor would like to check the label and extemporaneous dispensing form/worksheet BEFORE the product is made, and again check the final product, but the intern can otherwise proceed without direct supervision. However, the intern MUST raise anything that is remotely unclear for discussion with a pharmacist at any stage of the process.</p> <p>The intern is now Entrustment Level 3 for simple compounding of creams or ointments.</p>

Performance outcome(s)	Preceptor feedback and expectations of Intern**
3.15	See above: "Entrustment discussion" & "Feedback and assessment of EPA"
4.2, 5.3	Intern to review Martindale and Safety Data Sheets to be familiar with the information it contains, and to ask supervising pharmacists for assistance with anything unclear or unsure in the future.

***Note that the feedback and expectations of the Intern should consider and be tailored to the stage of training of the Intern.*