Shared Decision Making and Consent: Phase 1 Final Report

Appendix D

Structured Role Play Materials

June 2021

Contents

1 Instructions for Role Play

Background

PRSB (Professional Record Standards Body) works with the public and professionals to define the standards needed for good care records. An information standard defines what needs to be recorded in the electronic health record about a person for safe and effective care. PRSB is developing a standard for the information that should be recorded about shared decision making (SDM) and consent.

SDM is a process where patients and healthcare professionals consider various options related to a healthcare intervention, such as an investigation, procedure, or lifestyle change, together as equal partners. The overall aim of is to understand what matters most to the person to support them to decide. Shared decisions are enabled where both parties have a clear understanding of the person's diagnosis as well as wishes, goals, and aspirations. Consideration of the options should be informed by up-to-date evidence of the benefits and risks of any action (including the option to take no action) as well as the person's ideas, concerns and expectations about the intervention being considered.

PRSB has developed a draft standard in consultation with multidisciplinary healthcare professionals, patients, and the public and informed by a review of the SDM evidence including best practice guidance from NICE (National Institute for Health and Care Excellence) and the GMC (General Medical Council). As part of this phase of work we are starting to test how the standard might work in practice with a series of roleplays conducted online.

Purpose

The purpose of this exercise is to simulate various shared decision-making discussions across different scenarios in healthcare to establish components of the standard that support recording of the SDM process and areas where it could be improved. This is intended to test if the standard is practical to complete (respecting patient and clinician time) and if it has the relevant sections and elements to record the information that the clinician and patient would like to be recorded for the scenario. The output will be used to refine the draft standard.

Scenarios:

You will have been allocated a role (as clinician, patient, or observer) for one of the following scenarios:

- Colorectal Cancer
- Multimorbidity
- Mental Health
- Children's dental case

- Genetic condition
- Polypharmacy
- Elective surgery (Abdominal Aortic Aneurysm)
- Gynaecology

Preparation

- **Video conference software:** To participate you will need to use a device capable of running Microsoft Teams (preferably a laptop or desktop with a webcam). You can open teams in your computer browser but you may wish to download and install the Teams App, here. You can do this in advance and if you experience any issues, please contact Alannah at alannah.mcgovern@theprsb.org
- **Materials:** You will be sent pre-reading materials outlining what you will be asked to do on the day. This will include instructions (this document), as well as information required for you to play your role (script). Please familiarise yourself with the contents in advance (you do not need to learn this off by heart). You may wish to print these off in advance of the session so that you have them to hand to refer to during the role play. If you have any comments or queries about your allocated scenario, please send them to James at james.critchlow@theprsb.org.
- **Session allocation:** You will have been allocated a two-hour session. Please check that it is the date and time you were expecting.

On the day

Date: [enter date here]

Time: [enter time here]

Agenda:

- Introductions (5 mins) - Introductions and familiarisation with the purpose and use case scenario and characterisations.
- Briefing and setup (10 mins).
- Role play (1 hour est.) - Allow for pauses to discuss or alter the scenario or the recording form if needed to allow the role play to work effectively. There may also be immediate reflection and feedback from participants and observers.
- Discussion and debrief (45 mins est.) - Later feedback from all those involved after time for further consideration.

Participants and roles:

- Clinician: Role to conduct the shared decision-making discussion with reference to materials provided and to record in the discussion in the electronic form provided.
- Patient: Role to participate the shared decision-making discussion with reference to materials provided.

- Observer: To assist the clinician to record the discussion in the electronic form created to simulate the record (if required).
- Analyst: To observe and support as appropriate.

Logging on:

- Please click the link in your email to join your allocated session in Microsoft Teams.

Introductions:

- Participants will briefly be asked to introduce themselves.
- If you are acting as patient or clinician, please turn on your camera.
- Please note that after introductions the session will be recorded to help with later analysis.

Briefing and setup:

- A brief overview of the session will be given.
- Participant's readiness will be checked.
- Setup of electronic form (for completion by clinician).

Role play:

- Clinician and patients will work through the scenario as if it were a real consultation.
- Some scenarios will simulate more than one consecutive consultation relating to the same decision.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a realistic consultation to test if the standard supports effective and manageable recording of the discussion and any decisions.
- Please have your scenario and character notes to hand during the role play.
- Clinician to record the discussion on the electronic form where possible, or alternatively to complete afterwards.
- As a patient you do not need to make notes.
- There will be the option to pause if something is not working so it can be addressed, and the role play restarted.
- Some role plays might involve more than one consultation and possibly with different clinicians for example with a GP initially and a specialist later.

Discussion and debrief:

- At the end, the participants and observers will be asked for their feedback on both the role play process and the standard, so we can make improvements for the next session.

After the event

- After time for reflection further feedback will be sought and welcomed.

2 Vascular Surgery

Scenario Background

Abdominal Aortic Aneurysms (AAA) are a common condition affecting mainly older men. It is a condition which has different treatment options, and the patients almost always have co-morbidities.

An AAA occurs when there is weakening of the arterial wall and as a result the artery enlarges and eventually can burst. The risk of rupture increases exponentially with size. Rupture is usually fatal and accounts for about 5,000 deaths per year in the UK.

Treating an AAA before it has burst carries risk and therefore a risk benefit analysis has to be performed with the patient to decide on which treatment modality is appropriate. Not all treatment modalities are suitable for every patient.

The different treatment modalities are:

1. Conservative (will never have a procedure).
2. Deferred (may have a procedure in the future).
3. Open surgery.
4. Endovascular (minimally invasive).

Patient Scenario

John is a 70-year-old man has been found to have an incidental AAA as part of another routine scan. John has no symptoms from his aneurysm.

He has is worried as stories about AAAs as his father died of a ruptured aneurysm.

He is referred to see the consultant vascular surgeon.

The outline of sequence of events with decisions made are shown below:

1. Initial Appointment
    a. Initial clinical assessment.
    b. Information given to the patient. The nature of aneurysmal disease. Why it is important, potential treatment options but with context. (ie relative risks of dying with or without treatment).
    c. It is possible that after this initial consultation that the patient will never be suitable for intervention and after discussion with the patient he is discharged.
    d. Initial management:
        i. Smoking cessation.
        ii. Medications e.g., Aspirin and cholesterol lowering.
        iii. General health advice- keep exercising.
        iv. Driving – if the AAA is larger than 6cm, the patient must inform DVLA and stop driving. This can be a factor for the patient to increase their desire to have intervention.
    e. Investigations and assessments arranged:
        i. CT imaging.
        ii. CPX testing.
        iii. Anaesthetic review discussion of anaesthetic options including risks.
2. Patient returns for investigations and assessments.

3. *Patient is discussed at MDT as to best treatment option clinically. Note this is a clinical decision.*
4. Review appointment:
    a. Treatment options review in light of the results of the investigations and anaesthetic opinion.
    b. Decision made as to treatment option, or discharge.
5. Treatment if indicated.
6. Admission for treatment.
7. Review post treatment, is discharged or follow up programme as needed.

Patient Background

Patient is “John” a 70 year old man.

John is quite active and enjoys a reasonable amount of walking and gardening

He drives and regularly takes his wife out to nice places to walk with lunch or afternoon snack.

He has several grandchildren through his 2 children he and his wife visit them quite frequently to see them all and do some child minding.

He had a routine scan for ?? and this showed the enlarged artery. He doesn’t smoke, but enjoys a beer or glass of wine in the evenings (approx. 6 units a week).

No preparational research is needed by the patient.

3 Polypharmacy

3.1 Clinician briefing

Background to scenario

Polypharmacy - the use of multiple medications – is common in older patients with multimorbidity and is associated with poor outcomes.[1] Several factors including adverse drug-drug and drug-disease interactions are responsible and may contribute to and be compounded by decreased renal and hepatic clearance of drugs in older people.[2] Criteria for polypharmacy are mixed but it generally occurs where a significant number of prescribed medications are taken over an extended period of time, although not all polypharmacy is clinically inappropriate.[3] Interventions are commonly targeted at those on 10 or more medications. Recognition of polypharmacy related harms have informed the drive for deprescribing:

"Deprescribing is a collaborative process, with the patient and/or their carer, to ensure the safe and effective withdrawal of medicines that are no longer appropriate, beneficial or wanted, guided by a person-centred approach and shared decision-making."

English Deprescribing Network[4]

For some medications and in certain circumstances, temporary deprescribing (as a 'drug holiday' may be indicated. For example, drug holidays of 1 – 2 years are routinely considered for patients after 3 – 5 years of oral bisphosphonate therapy for osteoporosis, primarily due to the risk of atypical femoral fractures (AFF).[5,6] Gastrointestinal side effects (heartburn, acid reflux, or other) are the most given reason for bisphosphonate non-adherence (mostly in osteoporotic women).[7] Rarer complications include AFF, osteonecrosis of the jaw or external auditory canal, and oesophageal reactions.[8] As these agents accumulate in bone there is some anti-fracture efficacy after a treatment is stopped.

Appointment

Peter is a 70-year-old retired plasterer , who attends her GP for an annual medication review. He lives alone in a one-bedroom high-rise council flat in London. He has multiple cardiovascular risk factors including a 45 pack-year smoking history, hypertension,

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[1] Masnoon, N., Shakib, S., Fortin, M., Kalisch-Ellett, L., Caughey, G. (2017). What is polypharmacy? A systematic review of definitions. BMC Geriatric, 17(1), 230.

[2] *Ibid.*

[3] NICE (2017). Multimorbidity and polypharmacy. Key therapeutic topic.

[4] EDeN (2019). English Deprescribing Network [website]

[5] GPnotebook. Drug holiday from bisphosphonates [website].

[6] Reid, I. (2021). Bisphosphonate holidays. Drug and Therapeutics Bulletin. 59. 35 - 36

[7] Goldshtein, I., Rouach, V., Shamir-Stein, N., Yu, J., Chodick, G. (2016). Role of side effects, physician involvement, and patient perception in non-adherence in oral bisphosphonates. Advanced Therapeutics. 33(8). 1374 – 84.

[8] BNF (2021): Alendronic acid. British National Formulary [online].

hyperlipidaemia, and type 2 diabetes. He is a healthy weight and a light drinker (2 -3 glasses of wine a week). He has mild heart failure following a myocardial infarction five years ago. He has had an endoscopy which confirmed gastro-oesophageal reflux disease (GORD) in the past but until recently his symptoms of acid-heartburn (dyspepsia) were controlled using omeprazole (a PPI which reduced stomach acid). A bone density (DEXA)[9] scan 6 months ago showed no significant deterioration in his osteoporosis. Peter's symptoms of dyspepsia have been getting worse recently. He has no ALARM[10] symptoms and his recent blood results showed normal haemoglobin and platelets.

Peter takes multiple prescribed medications, shown in the table below:

Medication	**Dose**	**Route**	**Freq.**	**Indication**
Ramipril	2.5mg	PO[11]	OD[12]	Heart Failure
Bisoprolol fumarate	2.5mg	PO	OD	Heart Failure
Clopidogrel	75mg	PO	OD	Secondary prevention
Simvastatin	60mg	PO	OD	Secondary prevention
Amlodipine	5mg	PO	OD	Hypertension
Metformin hydrochloride (modified release)	1g	PO	OD	Type 2 Diabetes
Omeprazole	20mg	PO	OD	GORD
Diclofenac potassium	75mg	PO	PRN	Osteoarthritis
Alendronic acid	10mg	PO	OD	Osteoporosis
Colecalciferol (10µg) with calcium carbonate (1.25g) (Calcichew-D3® Forte)	1 tablet	PO	OD	Osteoporosis

Role Play

Instructions

You are a pharmacist conducting a medications review. Using the information provided above, please support the patient to come to a decision about his prescribed medications:

- Please record the aspects that you feel are relevant into the record provided. You can do this during or after the role play.

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[9] DXA = dual-energy x-ray absorptiometry – a gold standard measurement of bone mineral density

[10] ALARM symptoms include: Anaemia, dysphagia (difficulty swallowing), haematemesis (vomiting blood), melaena (passage of black tarry stools), persistent vomiting, involuntary weight loss.

[11] PO = *'per os'* (by mouth)

[12] OD = Once a day; BD = Twice a day ; TDS = Three times a day ; QDS = Four times a day ; *nocte* = at night.

- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the standard.
- There is an option to pause if something is not working so it can be addressed, and the role play restarted.
- You may wish to use the STOPP START Medication Review Tool (provided) during the role play. Alternatively, you can use any tools or materials you would ordinarily use in your day-to-day practice.
- You can access directly the BNF website by clicking here or, for medications the patient is currently taking, by clicking the name of the drug in the table above.

The framework of **options for treatment** below are suggestions for the role play scenario but you may wish to discuss other options based on your clinical judgement. You only need to discuss options that you judge as clinically appropriate. If appropriate you may wish to present a combination of options.

Option 1: 'Do nothing' e.g., Keep taking the drug and provision of lifestyle advice (such as smoking cessation, reducing alcohol intake, healthy eating & exercise strategies).
Option 2: Delay decision and agree to review later.

Option 3: Stop the drug.

Option 4: Switch to another drug.

Option 5: Increase/reduce the dose of another drug the patient is taking.

Option 6: Combination of the above if appropriate.

In the table below are suggested actions for four of the drugs the patient is taking.

Medication	Suggested Action	Reason
Omeprazole	Switch to lansoprazole (30mg PO OD)	MHRA[13] discourages concomitant use of clopidogrel and omeprazole
Simvastatin	Switch to atorvastatin (20mg PO nocte)	MHRA recommends maximum dose of 20mg simvastatin with concomitant amlodipine use
Diclofenac potassium	Stop. Could consider a trial of low dose topical NSAID for patient's knee pain.	Diclofenac is contraindicated in cardiovascular disease Regular use can exacerbate GORD and

[13] MHRA = Medicines and Healthcare Products Regulatory Agency

		causing GI ulcers (may be causing patient's GI symptoms)
Alendronic acid	Alendronate holiday – temporarily stop taking the drug (for up to 2 years). Could explain that: • After 5 years a bisphosphonate holiday is due as alendronate therapy over time increases the risk of complications such as atypical femoral fractures. • Randomised trials have shown that for many patients the risk of most types of fracture does not increase after discontinuation of alendronate therapy. • in one study, compared to current users, discontinuation of oral bisphosphonate reduces the risk of atypical femoral fractures AFF by 60% after 3 - 15 months and by 87% > 15 months, but that the absolute risk was low.[14]	MHRA has warned of the risk of atypical femoral fractures with bisphosphonates. Patient has taken bisphosphonates for > five years and regular use can exacerbate GORD and causing GI ulcers (may be causing patient's GI symptoms)

[14] Black *et al.* (2020). Atypical femur fracture risk versus fragility fracture prevention with bisphosphonates. New England Journal of Medicine. 383. 743 – 753.

3.2 Simulated patient briefing

Please refer to the following information during the role play.

Appointment 1:

Name: Peter Jackson

Age: 70-year-old

Job: Plasterer (retired)

Background:

You are a 70-year-old retired plasterer who has attended your local GP practice for an annual medication review with the pharmacist. You live alone in a one-bedroom high-rise council flat in London. You have smoked a pack of cigarettes a day for 45 years. You have high blood pressure, high cholesterol, and type 2 diabetes. However, you are a healthy weight and a light drinker (2 - 3 glasses of wine a week). You have been diagnosed with mild heart failure following a heart attack five years ago. In the past you had a camera test (endoscopy) that looked at your stomach and confirmed gastro-oesophageal reflux disease (GORD). Until recently your symptoms of acid-heartburn (dyspepsia) were controlled by taking omeprazole (a 'PPI' medicine which reduces stomach acid). You had a bone density (DEXA)[15] scan 6 months ago that showed no significant deterioration in your osteoporosis.

Past medical history:

- High blood pressure
- High cholesterol
- Mild heart failure
- Type II diabetes
- GORD
- Osteoporosis
- Osteoarthritis
- You are healthy weight.
- You have never had any previous surgeries.

Drug history:

- See medications list in Appendix A. If asked, say that you do not have any allergies to any medications.

Social history:

- You have smoked 20 cigarettes a day for 45 years and would like to quit smoking.
- You only occasionally drink alcohol (2 - 3 glasses of wine a week).
- You live alone in a one-bedroom high-rise council flat.

[15] DXA = dual-energy x-ray absorptiometry – a gold standard measurement of bone mineral density

Ideas/concerns/expectations

- The most important thing to you now is getting rid of symptoms that are preventing you from having quality time with your daughter and grandchildren. These include your heartburn symptoms and your knee pain from osteoarthritis.
- You are concerned about the number of medications you have been taking and you worry that because you have so many you may be forgetting to take something important.
- You have had a couple of 'near misses' where you have nearly fallen. You are worried about falling and getting a bone fracture.
- Occasionally you find yourself worrying about having another heart attack.

Instructions:

- When you are asked to make a decision, please make a decision using your own judgement based on what has been discussed and what you feel you as the patient would choose.

Appendix A – Your current medications

You take multiple prescribed medications, shown in the table below:

Medication	Dose	Route	How often	Reason
Ramipril	2.5mg	Mouth	Once a day	Heart Failure
Bisoprolol fumarate	2.5mg	Mouth	Once a day	Heart Failure
Clopidogrel	75mg	Mouth	Once a day	To help prevent another heart attack
Simvastatin	60mg	Mouth	Once a day	To help prevent another heart attack
Amlodipine	5mg	Mouth	Once a day	High blood pressure
Metformin hydrochloride (modified release)	1g	Mouth	Once a day	Type 2 Diabetes
Omeprazole	20mg	Mouth	Once a day	GORD
Diclofenac potassium	75mg	Mouth	As needed	Osteoarthritis
Alendronic acid	10mg	Mouth	Once a day	Osteoporosis (taken for > five years)
Colecalciferol (10µg) with calcium carbonate (1.25g) (Calcichew-D3® Forte)	1 tablet	Mouth	Once a day	Osteoporosis

4 Gynaecology

4.1 Clinician briefing

Background to scenario:

Pelvic organ prolapse (POP) is where a woman's pelvic organs are no longer supported by her pelvic floor and can therefore bulge (prolapse) into the vagina.[16] This may involve organs including her uterus (uterine prolapse), bladder (cystocele), rectum or large bowel (rectocele), vaginal vault or small bowel (enterocele).[17] Treatment options include a variety of surgical and non-surgical measures. Until recently, the former included the use of surgical meshes and tapes implanted into the vaginal wall to replace weakened pelvic tissue.

In December 2017, the National Institute for Health and Care Excellent (NICE) recommended that transvaginal mesh repair should only be used in the context of research due to inadequate evidence of efficacy and serious safety concerns.[18] In July 2018 the government announced a high vigilance restriction period that 'paused' indefinitely vaginal mesh and tape procedures to treat urinary stress incontinence in England.[19]

Appointment 1:

Jan is a 60-year-old multiparous (gravida 3, para 2)[20] Caucasian woman who has attended her local GP surgery for a routine cervical screening test. Her two sons were born via normal vaginal delivery without complications. She continues to work part-time as a barrister. She has never had surgery. She rarely drinks alcohol but has smoked 5 - 10 cigarettes a day for 50 years. Her BMI (body mass index) is high at 31.1. During the examination the practice nurse notices a bulge to the entrance of her vagina (introitus) when she is straining and alerts you as the GP. Jan tells you that she had noticed a sensation of pressure, but it had not bothered her until now. She has regular bowel motions. She discloses that she has very occasionally leaked urine when she coughs, laughs, or sneezes, but denies having to rush to 'spend a penny' and says she does not need to go any more than usual (about five times a day). Her bladder is not palpable, and no masses are found during bimanual examination.

You explain to the patient her diagnosis of uterine prolapse and invite her back for an appointment to discuss her options.

Instructions:

You are a GP working in primary care. Using the information provided, please support the patient to come to a decision about her treatment:

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[16] RCOG (2020). Pelvic organ prolapse.

[17] BMJ Best Practice (2020). Uterine prolapse.

[18] NICE (2017). Interventional procedures guidance [IPG599]. Transvaginal mesh repair of anterior or posterior vaginal wall prolapse.

[19] NHS Improvement and NHS England (2018). VAGINAL MESH: HIGH VIGILANCE RESTRICTION PERIOD: Immediate action required, all cases should be postponed if it is clinically safe to do so [letter].

[20] Gravidity = the number of times a woman has been pregnant; Parity = the number of times a woman has given birth to a foetus of 24+ weeks gestational age

- Please record the aspects that you feel are relevant into the record provided. You can do this during or after the role play.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the standard.
- There is an option to pause if something is not working so it can be addressed, and the role play restarted.

The **options for treatment** below are suggestions for the role play scenario but you may wish to discuss other options based on your clinical judgement.

- Option 1: 'Do nothing' – take no further action.
- Option 2: Delay the decision (observation/watchful waiting)
- Option 3: Conservative management including observation/watchful waiting, provision of lifestyle advice or goal setting (including smoking cessation, diet and exercise with the goal of weight loss) + pelvic floor exercises.
- Option 4: Referral for gynaecological review

Appointment 2:

Four years later Jan has managed to quit smoking and has achieved a healthy weight. However, her prolapse related symptoms have significantly worsened (these now include urinary urgency, frequency, and voiding problems) and following unsuccessful attempts to insert a pessary she has been returned to you, her gynaecologist for a shared decision regarding prolapse surgery.

Instructions

You are a gynaecologist running an outpatient clinic in secondary care. Using the information provided, please support the patient to come to a decision about her treatment:

- Please record the aspects that you feel are relevant into the record provided. You can do this during or after the role play.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the standard.
- There is an option to pause if something is not working so it can be addressed, and the role play restarted.
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The **options for treatment** below are suggestions for the role play scenario but you may wish to discuss other options based on your clinical judgement. You may also wish to use the NICE patient decision aid surgery for uterine prolapse, which has been provided and provides information on the benefits and risks.

- Option 1: Continue conservative management ('do nothing')
- Option 2: Not sure – schedule review.
- Option 3: Vaginal hysterectomy
- Option 4: Vaginal sacrospinous hysteropexy with sutures

- Option 5: Manchester repair
- Option 6: Sacro-hysteropexy with mesh.

4.2 Simulated patient briefing

Please refer to the following information during the role play.

Appointment 1:

Name: Jan Ellis

Age: 60-years-old

Job: Barrister (part-time)

Background:

You originally attended your local GP surgery for a routine cervical screening test. During the examination the practice nurse noticed a bulge to the entrance of your vagina (introitus) upon straining and alerted your GP. You told the doctor that you had noticed a sensation of pressure, but it had not bothered you before. You had regular bowel motions. You disclosed that you had very occasionally leaked urine when coughing, laughing, or sneezing. You never had to rush to 'spend a penny' and you did not need to go any more than usual (about five times a day). The GP performed an examination of your vagina (bimanual examination). The GP explained to you your diagnosis of uterine prolapse, which is where a woman's pelvic organs are no longer supported by her pelvic floor and can therefore bulge (prolapse) into the vagina. The GP has invited you back for an appointment to discuss your options.

Obstetric and gynaecological history:

- You have two adult sons who were born by normal vaginal delivery with no complications.

Past medical history:

- You are obese (BMI = 31.1) and would like to achieve a healthier weight.
- You have never had any previous surgeries.

Drug history:

- You do not have any allergies to any medications.

Social history:

- You have smoked 5 – 10 cigarettes a day for 50 years and would like to quit smoking.
- You only occasionally drink alcohol.

Ideas/concerns/expectations

- The most important thing to you is to continue to be able to work as a lawyer, which you love.
- If asked what you know already about any of the investigation/treatment options presented, please deny existing knowledge.

Appointment 2:

Name: Jan Ellis

Age: 64-years-old

Job: Barrister (part-time)

Background

Four years later you have managed to quit smoking and have achieved a healthy weight. However, your prolapse related symptoms have significantly worsened (these now include urinary urgency (sudden urge to urinate), frequency (the need to urinate many times during the day/night), and voiding problems (difficulty emptying the bladder). Following unsuccessful attempts to insert a pessary (a plastic/silicone device inserted into the vagina to hold a prolapsed womb or vaginal wall in place) you have returned to your gynaecologist for a shared decision regarding prolapse surgery.

Obstetric and gynaecological history:

- You have two adult sons who were born by normal vaginal delivery with no complications.

Past medical history:

- You are a healthy weight (BMI = 24.5) but are worried that your symptoms are interfering with you regular exercise.
- You have had three unsuccessful attempts to insert a pessary and do not wish to try again.

Drug history:

- You do not have any allergies to any medications.

Social history:

- You managed to quit smoking and although you get occasional cravings, are very satisfied.
- You only occasionally drink alcohol.

Ideas/concerns/expectations

- You are concerned that your sister had previously had an operation for the same condition several years ago ‘that later went wrong’. You have also heard ‘a lot of worrying things’ in the media about the use of meshes and tapes. You are worried about the outcome of a class action lawsuit in Australia where a court ruled that a medical devices company had failed to warn doctors and patients about the risks of vaginal mesh implants.
- You have recently become a grandmother to a baby girl. You want to be able to see her as much as possible and help out with childcare.

Instructions:

- If asked what you know already about any of the investigation/treatment options presented, please deny existing knowledge.
- When you are asked to make a decision, please make a decision using your own judgement based on what has been discussed and what you feel you as the patient would choose.

5 Children's Dental Case

5.1 Simulated patient briefing

Please refer to the following information during the role play.

Instructions:

- You are the parent of a child with visual impairment and cerebral palsy.
- The child is a non-speaking part in the role play (but the clinician may attempt to engage and include them).
- If asked what you know already about any of the investigation/treatment options presented, please deny existing knowledge.
- The clinician (dentist) will conduct the consultation as they normally would. When you are asked to decide, please use your own judgement based on what has been discussed and what you feel you as the parent would choose.

Role 1:

Name: Amy Baxter

Age: 29-years-old

Job: Parent and carer for your son Ben and classroom teaching assistant.

Role 2:

Name: Ben Baxter

Age: 10-years-old

Background

You have brought your son Ben for a routine appointment at the dentist. Ben is visually impaired and non-verbal due to his cerebral palsy.

Cerebral palsy (CP) is a non-progressive it (does not get worse over time) condition that can affect a baby's brain. When this happens, it tends to occur either when the baby is growing in the womb or in the period shortly after birth. It is not always known what had led to the child's CP; up to 60% are due to an abnormally formed brain before birth but other causes include cases where the brain doesn't get enough oxygen, where there is infection, or trauma around the time of birth.

Ben has a non-identical twin sister who is fit and well. Both children were born underweight at 31 weeks (six weeks premature) by caesarean section and therefore they were placed in an incubator together in the hospital's Neonatal Intensive Care Unit (NICU). You feel strongly that an incident that occurred during Ben's stay at NICU has caused his CP. At the time a nurse had taken you aside and told you that when

Ben was receiving milk through a feeding tube he had started choking and turned blue. The incident lasted for about 6 minutes. After this had happened you noticed that Ben was struggling more than before to latch on to the breast and his sucking ability seemed to have gotten worse, but he otherwise appeared to be well, and you were reassured by the neonatal staff at discharge that they could find nothing abnormal.

A baby check at the GP found nothing abnormal and Ben was breastfeeding much better (but not as well as his sister). As time went on you became concerned that Ben was not meeting his developmental milestones in the same was as his sister. At 3 months he was unable to support his head well, would smile at the sound of your voice but not in response to your or other people's smiles, and he was unable to grasp or hold objects. At 6 month of age Ben was diagnosed with cerebral palsy. [You do not need to disclose this background to the dentist during the appointment (unless you feel it appropriate) but it is provided for context].

Ben has the following problems and issues due to his CP:

- He is quadriplegic: Ben is affected by spastic paralysis in all four limbs and therefore uses a wheelchair.
- He is visually impaired: Ben suffers from the following:
    - Strabismus: A severely turned-out eye so both eyes cannot work together.
    - Cataracts: Cloudy areas of the lens within his eye.
    - Refractive issues: Giving him blurry vision. (despite glasses to correct his near-sightedness).
- He has communication issues: Ben can produce sounds but is unable to produce speech that is clear and understood by others. He uses a touchpad to communicate.
- He is intellectually impaired: Ben finds it difficult to understand new concepts.
- He has problems with saliva control (drooling).

Ben has recently suffered from severe dental pain from a 'baby tooth' which has now subsided.

Appointment

- Ben has recently suffered from severe dental pain from a 'baby tooth' which has now subsided, but you are anxious to make sure that his pain does not return.
- You have also noticed that recently Ben has been off-colour, miserable and is drooling & dribbling more than usual. Ben keeps putting his fingers in his mouth, particularly at mealtimes, which is unusual for him.
- The dentist has seen Ben several times over the years for regular check-ups and you have always been happy with his service.

Consent for treatment:

- As Ben's mother you are legally able to consent on his behalf for any medical treatment.

- As Ben is aged under 16 and is not Gillick competent he has no legal right to consent to or refuse treatment.

Past dental history:

- Ben has recently suffered from severe dental pain from a ‘baby tooth’ which has now gone away.
- He has never had any dental procedures before.
- Ben has a sweet tooth (He eats chocolate and sweets most days) and he loves fizzy drinks.
- You assist him with brushing his teeth twice a day.

Drug history:

- Ben is not taking any medicines and does not have any allergies to any medications or anaesthetic.

Social history:

- Ben attends a local school for children with physical disabilities and learning difficulties.

Ideas/concerns/expectations:

- You are worried and anxious as you can tell from Ben’s behaviour that he is sometimes still in pain and agitated.
- You sometimes feel guilty as you know he consumes ‘too much sugar’, but you do not want to deprive him of the things that he loves.
- As a mother of a child with CP you are very used to dealing with health care professionals. However, your belief that Ben’s CP is the result of a mistake by the NICU team has meant that you are extremely cautious when presented with any medical procedure for your son. You are particularly keen to understand the benefits, risks, and alternatives of any treatment for Ben.

6 Colorectal Cancer

6.1 Clinician briefing

Background to scenario:

Appointment 1:

Jenny is an 83-year-old woman who presented to her GP three weeks ago following a change in bowel habit where she noticed bright red blood mixed in with loose stools. She was eating and drinking normally and had not noticed any involuntary weight loss. She had no additional ALARM[21] symptoms. Nothing abnormal was detected during abdominal examination and the patient denied any pain. She had no family history of colorectal cancer and there was no history suggestive of familial adenomatous polyposis or Lynch syndrome. The GP ordered blood tests (FBC, LFTs U&Es)[22] and made an urgent 'Two Week Wait' referral for suspected lower GI cancer.

Appointment 2:

You are a colorectal surgeon who Jenny came to see in your outpatient clinic. During the appointment you took a full history, performed a full abdominal and digital rectal examination (you felt an irregular mass and there was fresh red blood on your finger after withdrawal); and discussed with the patient her blood results (these showed a mild microcytic anaemia but were otherwise normal). You referred the patient for optical colonoscopy. This found a 2.5 cm mass (ulcerated and bleeding) within 8 cm of the anal verge. Biopsy showed a moderately differentiated malignant adenocarcinoma. A CT scan of the chest, abdomen, pelvis, and MRI scan of the liver found no evidence of nodal involvement or metastasis (Likely stage 1 cT1-T2 cN0 M0 / Dukes' A – see Appendix A). Jenny's case was discussed at the MDT review meeting.

Role Play - Part A

Appointment 3:

Jenny has come to see you in clinic to discuss her options for treatment (see role play instructions below).

Instructions

You are a colorectal surgeon running an outpatient clinic in secondary care. Using the information provided, please support the patient to come to a decision about her treatment:

- Please record the aspects that you feel are relevant into the record provided. You can do this during or after the role play.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the standard.

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[21] ALARM symptoms/signs include: Anaemia, dysphagia (difficulty swallowing), haematemesis (vomiting blood), melaena (passage of black tarry stools), persistent vomiting, involuntary weight loss.

[22] FBC = Full Blood Count, LFTs = Liver Function Tests, U&Es = Urea & Electrolytes

- There is an option to pause if something is not working so it can be addressed, and the role play restarted.

The **options for treatment** below are suggestions for the role play scenario but you may wish to discuss other/alternative options based on your clinical judgement. You may also wish to use the NICE guideline [NG151] on Colorectal Cancer, which has been provided and provides information on the benefits and risks (e.g., 1.3.1, 1.3.2, 1.3.6 – 1.3.9) and recommendations for information sharing (e.g., 1.2.1, 1,2,2, 1.2.3, 1.2.5, 1.2.7).

- Option 1: Continue conservative management ('do nothing')
- Option 2: Not sure – schedule review.
- Option 3: Transanal excision (TAE) via transanal minimally invasive surgery (TAMIS)
- Option 4: Transanal excision (TAE) via transanal endoscopic microsurgery (TEMS)
- Option 5: Endoscopic submucosal dissection (ESD)
- Option 6: Total mesorectal excision (TME) (See NICE guideline 1.3.9 if offering this option)

Role Play - Part B

Appointment 4:

- Part B of the role play assumes that the patient opted for a surgical procedure and that this was completed without complications.

Three weeks after her procedure Jenny comes to see you in clinic to discuss the outcome.

- The pathology results reveal a pT1 grade tumour with unfavourable histological features.

Instructions

You are a colorectal surgeon running an outpatient clinic in secondary care. Using the information provided, please support the patient to come to a decision about the possible next stage of her treatment:

- Please record the aspects that you feel are relevant into the record provided. You can do this during or after the role play.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the standard.
- There is an option to pause if something is not working so it can be addressed, and the role play restarted.
- If the patient opted out of the procedure in role play part A please ask the actor to select an appropriate intervention to setup part B.

The **options for treatment** below are suggestions for the role play scenario but you may wish to discuss other/alternative options based on your clinical judgement. You may also wish to use the NICE guideline [NG151] on Colorectal Cancer, which has been provided and provides information on the benefits and risks (e.g., 1.3.1, 1.3.2, 1.3.6 – 1.3.9)

and recommendations for information sharing (e.g., 1.2.1, 1,2,2, 1.2.3, 1.2.5, 1.2.7). See Appendix also B for excerpt of NCCN guidelines for pathway post transanal local excision for T1 N0.

- Option 1: Continue conservative management ('do nothing')
- Option 2: Not sure – schedule review.
- Option 3: Low anterior resection (LAR)
- Option 4: Abdominoperineal resection (APR)
- Option 5: Chemotherapy + Radiotherapy
- Option 6: Short-course radiotherapy

Appendix A: Tumour Staging in Colorectal Cancer[23]

Tumour staging describes cancer spread. The UK uses two main staging systems for colorectal cancers: i) TNM (Tumour, Nodes, Metastasis) ii) Dukes' system

TNM Stage	Dukes' Stage	5-year survival
Stage 0: Tis N0 M0 (carcinoma *in situ)*	**n/a**	> 99%[24]
Stage 1:	**Dukes' A**	
T1 N0 M0		> 90%
T2 N0 M0		> 90%
Stage 2:	**Dukes' B**	
T3 N0 M0		70 – 85%
T4 N0 M0		55 – 65%
Stage 3:	**Dukes' C**	
Any T N1 M0	C1 if apical node	45 – 55%
Any T N2 M0	C2 if apical node	20 – 30%
Stage 4: Any T Any N M1	**Duke's D**	< 5%

Local spread (T1 = invasion into submucosa ; T2 = invasion into muscularis propria ; T3 = invasion through muscularis propria ; T4 invasion through the serosa or into adjacent organs). Lymph node spread (N1 = metastasis to three or less nodes ; N2 = metastasis to more than 3 nodes). Distant metastasis (M1 = metastasis to any distant site). *NB*: cTNM

[23] Adapted from: Young A., Hobbs, R., Kerr, D. ABC of Colorectal Cancer 2011. Second Edition. BMJ Books. Wiley-Blackwell and GPNotebook 2021.

[24] Hsieh, M and Others. Recurrence, death risk, and related factors in patients with stage 0 colorectal cancer: A nationwide population-based study. Medicine 2020. Volume 99(36). Pages e21688

refers to a pre-treatment clinical classification (based on e.g., imaging, physical exam, and endoscopy) whereas pTNM is a pathological classification (based on histopathology).[25]

Appendix B: Pathologic Findings after transanal local excision (TAE) for T1 N0[26]

If pT1, NX without high-risk features → Observe → Surveillance.

If pT1, NX with high-risk features **or** pT2, NX → Transabdominal resection (preferred) or Chemo/Radiotherapy (Capecitabine + radiotherapy or 5-Fluorouracil infusion + radiotherapy or Short-course radiotherapy)

6.2 Simulated patient briefing

Please refer to the following information during the role play.

Appointment 1:

Name: Jenny Smith

Age: 83-years-old

Job: Retired care home worker

Background:

- *NB*: The first two appointments provide background information only and are not part of the role play.

Appointment 1:

You are an 83-year-old woman who presented, with your daughter, to your GP three weeks ago following a change in bowel habit where she noticed bright red blood mixed in with loose stools. You were eating and drinking normally and had not noticed any involuntary weight loss. You did NOT have any of the following concerning[27] symptoms:

- Breathlessness
- Difficulty swallowing
- Vomiting blood
- Blacky tarry / smelly stools
- Persistent vomiting
- Involuntary weight loss

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[25] NICE guideline [NG151] on Colorectal Cancer (2020).

[26] Adapted from NCCN Guidelines for Rectal Cancer. National Comprehensive Cancer Network 2021. [Accessed April 2021]

[27] ALARM symptoms/signs include: Anaemia, dysphagia (difficulty swallowing), haematemesis (vomiting blood), melaena (passage of black tarry stools), persistent vomiting, involuntary weight loss.

Nothing abnormal was detected during abdominal examination and you were not in any pain or discomfort. You have no family history of cancer and you have no other medical conditions The GP ordered blood tests and made an urgent 'Two Week Wait' referral for suspected lower GI cancer (in the lower digestive tract).

Appointment 2:

You have come to see a colorectal surgeon in the outpatient clinic. During the appointment, the doctor took a full medical history, performed a full physical examination of your belly and back passage. She told you that she felt a 'mass' and there was fresh red blood on her finger after withdrawal), which was concerning and needed further investigation. The doctor discussed your blood results (these showed a mild anaemia but were otherwise normal). You were referred for optical colonoscopy (a camera test via the back passage), as well as a CT scan of your chest, abdomen, pelvis (Computed tomography) and MRI (Magnetic Resonance Imaging) scan of your liver to look for signs of cancer elsewhere in the body.

Play - Part A

Appointment 3:

You have returned to the outpatient clinic with the colorectal surgeon to hear your results and discuss options for treatment (see role play instructions below and further background below).

Role Play - Part B

Appointment 4:

- Part B of the role play assumes that the patient opted for a surgical procedure and that this was completed without complications.

Three weeks after your surgical procedure you have a follow-up appointment with the colorectal surgeon in clinic to discuss the outcome. (see role play instructions and further background below).

Instructions

- When you are asked to decide, please make a decision using your own judgement based on what has been discussed and what you feel you as the patient would choose.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the standard.
- There is an option to pause if something is not working so it can be addressed, and the role play restarted.

Past medical history:

- You are a healthy weight.
- You have never had any previous surgeries.

Drug history:

- You do not have any allergies to any medications that you know of.

Social history:

- Ex-smoker: You have previously smoked 5 – 10 cigarettes a day for most of your adult life but you managed to quit, aged 60.
- You only occasionally drink alcohol.
- Aside from your recent symptoms you have previously considered yourself to be ‘as fit as a fiddle’.
- You live with your husband in a bungalow and have one daughter and a grandson.

Ideas/concerns/expectations

- The most important thing to you is to continue to be able to spend time with your grandson.
- If asked what you know already about any of the investigation/treatment options presented, please deny existing knowledge.

7 Mental Health

7.1 Clinician briefing

Please refer to the following information during the role play.

Instructions:

You are a GP conducting a 6-week postnatal check. Using the information provided, please support the patient to come to a decision about his testing options:

- Please record the aspects that you feel are relevant into the record provided. You can do this during or after the role play.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the standard.
- There is an option to pause if something is not working so it can be addressed, and the role play restarted.

Individuals present :

- Louise Baxter – Patient (D.O.B 14/05/1995 – 26 years old)
- Baby Emily – **NB: This is a non-participatory role, but you may wish to engage/interact with the child as you normally would.**
- Alex Baxter – Husband

Appointment:

- Louise is a 26-year-old new mother (gravida 2, para 1)[28] who has attended your afternoon clinic for her 6-week postnatal check.
- Just prior you conducted a 6-week baby check on her baby daughter Emily. Emily was born at term via normal vaginal delivery (birthweight 7 lb 2oz). There were no complications, and the check is normal.
- The baby's father Alex is also in attendance. Please engage with him as you normally would.
- For the purposed of the role play the simulation of the 6-week postnatal check only needs to include a discussion of the mother's mental health and well-being. Please initiate and conduct the conversation to elicit the patient's problems as you normally would. You may wish to use the following screening questions:
    - **How are you finding being a mum?**
    - **Tell me about the birth.**

[28] Gravidity = the number of times a woman has been pregnant; Parity = the number of times a woman has given birth to a foetus of 24+ weeks gestational age

- For the purposes of the role play a copy of the Edinburgh Postnatal Depression Scale has been provided in appendix A, filled out as if completed by the patient at the time. NB: A score > 12 has PPV 57%, & NPV 99% for postnatal depression.[29]

The **options for treatment** below are suggestions for discussion in the role play scenario but you may wish to discuss other options based on your clinical judgement.

- Option 1: 'Do nothing' – GP safety netting and signposting to mental health resources and organisations.
- Option 2: Facilitated self-help strategies (e.g., guided self-help, computerised cognitive behavioural therapy (CBT), exercise, sleep hygiene measures etc.) +/- referral for counselling +/- referral for CBT.
- Option 3: Sertraline (antidepressant SSRI), 25 mg OD (once a day). This drug has been shown to be undetectable in the serum of breast-fed infants.[30]

Appendix A: Edinburgh Postnatal Depression Scale (completed by patient)

(See section 7.3)

7.2 Simulated patient briefing

Background

Postnatal depression is the development of a depressive illness following childbirth that is characterised by the core symptoms of major depressive disorder (as opposed to the emotional lability associated with the 'baby blues.'[31]

There are four individuals present in the role play:

- The doctor (GP).
- Louise Baxter – Patient (D.O.B 14/05/1995 – 26 years old).
- Baby Emily – **NB: This is a non-participatory role.**
- Alex Baxter – Husband (See Appendix B for additional briefing notes).

Patient briefing

Name: Louise Baxter.

Age: 26-years-old.

Job: Bank Cashier (part-time). Currently on maternity leave.

Appointment:

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[29] *Op.cit.* PPV = Positive predictive value, NPV = negative predictive value.

[30] SSRI = Selective serotonin reuptake inhibitor.

[31] BMJ Best Practice. Postnatal depression (2020). Postnatal depression - Symptoms, diagnosis and treatment | BMJ Best Practice

- You are Louise, a 26-year-old new mother who as attended your GP for your 6-week postnatal check.
- This followed a successful normal vaginal delivery where your baby, Emily, was born weighing 7 lb 2oz at term. You have been pregnant once before but had a miscarriage at 6 weeks.
- The GP also performed your daughter Emily's 6-week baby check as part of the appointment. Emily is fit and well. She was pleased to see you interacting well with your daughter.
- For the purposed of the role play the simulation of the 6-week postnatal check will likely only include a discussion of your mental health and well-being. It is assumed that all other checks have been completed and are normal, however the clinician may choose to conduct a full postnatal check (See Appendix C relevant background).
- Ideas/concerns/expectations: Your greatest fear is that if you are diagnosed with a mental illness, you will have your baby taken away. This may make you hesitant, at least at first, to discuss any negative feelings you have had with the doctor.
- As part of the postnatal check the GP asked you the following routine screening questions:

How are you finding being a mum?

This should prompt you to disclose the following:

- Having a baby, particularly a little girl, is what you have always wanted. When your daughter was born, you felt elated. However, since the first week after birth you have had several 'highs and lows.' You have sometimes found yourself getting tearful and crying for no reason. You did not expect this and do not understand why it happens.

If asked directly you can disclose the following:

- **Sleep Changes:** Since the first week after birth, you have felt tired all the time. You cannot remember the last time you have been able to get a good night's sleep. You put this down to needing to feed the baby.
- **Loss of interest:** You no longer feel the motivation to do the things you would normally enjoy. When friends or family call you would normally chat for hours but now you prefer not to pick up the phone.
- **Feelings of guilt/worthlessness:** You feel very guilty about your negative feelings. You feel that you are somehow ungrateful for what you have as this should be the happiest time of your life.
- **Lack of energy:** You feel constantly drained. You have partly put this down to the aftereffects of the pregnancy.
- **Difficulty concentrating:** You have been learning French in evening classes during your pregnancy. But in the last few weeks you have been unable to concentrate or complete the home learning tasks.

- **Loss of appetite:** You have always been a foodie and continue to cook meals for the home, but recently you have not wanted to eat.
- **Psychotic symptoms:** Any symptoms suggestive of psychosis such as delusions (Fixed false beliefs e.g., believing that the government is spying on you and intends to harm you or your baby) or hallucinations (e.g., hearing voices, smells, or seeing things that are not real).
- **Suicidal ideation:** This must be emphatically denied. Explain that even if the thought had crossed your mind, you would never kill yourself as you must be there for your daughter and husband.
- **Harm to baby:** This must be emphatically denied. This is unthinkable to you.

Tell me about the birth.

This should prompt you to disclose the following:

- The birth went better than you could have hoped. You were delighted that your baby was born in April as you had wanted her to be a Taurus star sign like her mother. You had a 'natural' birth without an epidural or other medication, which was what you wanted. You had the birth in hospital as you agreed with your husband it was safer if things went wrong.

The clinician may ask you to fill out a questionnaire to assess for depression. This has been completed and can be found in Appendix A.

Past medical history:

- Aside from during your pregnancies, you have never had any previous medical investigations or surgeries.

Medication history:

- You are not taking any medications and do not have any allergies.

Social history:

- You have never smoked. There are no smokers in your household.
- You drank alcohol occasionally in the past but stopped before trying for a baby and have not resumed.
- You have never tried recreational drugs.

Ideas/concerns/expectations

- Your greatest fear is that if you are diagnosed with a mental illness, you will have your baby taken away.
- You are worried about how any prescription medications may affect the baby if you do start to breastfeed again.
- You are worried that you are becoming a burden to your husband, who often must spend time away at sea.

Appendices

Appendix A: Edinburgh Postnatal Depression Scale (completed by patient)

(See section 7.3)

Appendix B: Husband briefing

Name: Alex Baxter

Age: 31-years-old

Job: Officer in the Royal Navy (Lieutenant)

- During the appointment you may be asked to 'leave the room' at a certain point. This can be simulated by switching off your screen and waiting until you are asked to return by the clinician.
- Your interventions/responses during the role play should generally support what your wife is saying but with a bias towards suggesting things are slightly worse than she has disclosed.

At appropriate points during the role play you may wish to raise the following points:

- Louise was previously passionate about doing things 'naturally'. It was particularly important to her to have a natural birth and to **breast feed** and not rely on formula milk. You are concerned that her having stopped breast feeding is very out of character and may be a sign of something serious.
- You feel that her **mood** has been extremely low. You have only every seen her like this once before when she had a miscarriage.
- You are worried about how she will cope when you are redeployed overseas with the Royal Navy. Especially as she does not seem to be having much contact with her friends, who were her support network throughout the pregnancy.
- You have no concerns that Louise will harm herself or the baby.

Appendix C: Six-week postnatal check guide to responses

During the post-natal check, you may be asked certain questions that require reference to the following information:

Obstetric history:

- Your baby was born via normal vaginal delivery on the maternity ward. She was delivered head-first by the midwife. She weighs 7 lb 2oz. She is a term baby (38 weeks).
- There were no significant complications during the birth, but you did have a vaginal tear that required some stitches. The pain stopped after two-weeks and this is healing well.

- Your lochia (vaginal discharge after birth) stopped a week ago. Your periods have not yet resumed.
- Your lochia (vaginal discharge after birth) stopped a week ago. Your periods have not yet resumed.
- You have not resumed having sexual intercourse.
- Your bladder and bowel are functioning normally.
- You were breast feeding and this was especially important to you. However, in recent weeks you have lost your enthusiasm and have stopped. Your husband has been preparing formula milk on your behalf. You have never had any breast discomfort and prior to stopping the baby was taking the breast well.

Social history:

- You have never smoked. There are no smokers in your household.
- You drank alcohol occasionally in the past but stopped before trying for a baby and have not resumed.
- You have never tried recreational drugs.
- **Sleep Changes:** Since the first week after birth, you have felt tired all the time. You cannot remember the last time you have been able to get a good night's sleep. You put this down to needing to feed the baby.
- You may be provided the opportunity to speak to the clinician without your partner present:
    - **Domestic violence:** This should be emphatically denied. Your partner is a loving and supportive husband and concerned for your welfare. Although you did have an argument 2 weeks ago that you regret.

7.3 Edinburgh Postnatal Depression Scale (completed by patient)

Edinburgh Postnatal Depression Scale[1] (EPDS)

Name: Louise Baxter Address: 42 West Register Street

Your Date of Birth: 14/05/1995

Baby's Date of Birth: 02/05/2021 Phone: 07123432123

As you are pregnant or have recently had a baby, we would like to know how you are feeling. Please check the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

Here is an example, already completed.

I have felt happy:
- ☐ Yes, all the time
- ☒ Yes, most of the time — This would mean: "I have felt happy most of the time" during the past week.
- ☐ No, not very often — Please complete the other questions in the same way.
- ☐ No, not at all

In the past 7 days:

1. I have been able to laugh and see the funny side of things
   - ☐ As much as I always could
   - ☐ Not quite so much now
   - ☒ Definitely not so much now — 2
   - ☐ Not at all

2. I have looked forward with enjoyment to things
   - ☐ As much as I ever did
   - ☐ Rather less than I used to
   - ☒ Definitely less than I used to — 2
   - ☐ Hardly at all

*3. I have blamed myself unnecessarily when things went wrong
   - ☐ Yes, most of the time
   - ☒ Yes, some of the time — 2
   - ☐ Not very often
   - ☐ No, never

4. I have been anxious or worried for no good reason
   - ☐ No, not at all
   - ☐ Hardly ever
   - ☒ Yes, sometimes — 2
   - ☐ Yes, very often

*5 I have felt scared or panicky for no very good reason
   - ☐ Yes, quite a lot
   - ☒ Yes, sometimes — 2
   - ☐ No, not much
   - ☐ No, not at all

*6. Things have been getting on top of me
   - ☐ Yes, most of the time I haven't been able to cope at all
   - ☒ Yes, sometimes I haven't been coping as well as usual — 2
   - ☐ No, most of the time I have coped quite well
   - ☐ No, I have been coping as well as ever

*7 I have been so unhappy that I have had difficulty sleeping
   - ☒ Yes, most of the time
   - ☐ Yes, sometimes — 3
   - ☐ Not very often
   - ☐ No, not at all

*8 I have felt sad or miserable
   - ☐ Yes, most of the time
   - ☒ Yes, quite often — 2
   - ☐ Not very often
   - ☐ No, not at all

*9 I have been so unhappy that I have been crying
   - ☐ Yes, most of the time
   - ☒ Yes, quite often — 2
   - ☐ Only occasionally
   - ☐ No, never

*10 The thought of harming myself has occurred to me
   - ☐ Yes, quite often
   - ☐ Sometimes
   - ☐ Hardly ever — 0
   - ☒ Never

Score = 19/30

Administered/Reviewed by Doctor Date 14/05/2021

[1]Source: Cox, J.L., Holden, J.M., and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. *British Journal of Psychiatry* 150:782-786 .

[2]Source: K. L. Wisner, B. L. Parry, C. M. Piontek, Postpartum Depression N Engl J Med vol. 347, No 3, July 18, 2002, 194-199

Edinburgh Postnatal Depression Scale[1] (EPDS)

Postpartum depression is the most common complication of childbearing.[2] The 10-question Edinburgh Postnatal Depression Scale (EPDS) is a valuable and efficient way of identifying patients at risk for "perinatal" depression. The EPDS is easy to administer and has proven to be an effective screening tool.

Mothers who score above 13 are likely to be suffering from a depressive illness of varying severity. The EPDS score should not override clinical judgment. A careful clinical assessment should be carried out to confirm the diagnosis. The scale indicates how the mother has felt ***during the previous week***. In doubtful cases it may be useful to repeat the tool after 2 weeks. The scale will not detect mothers with anxiety neuroses, phobias or personality disorders.

Women with postpartum depression need not feel alone. They may find useful information on the web sites of the National Women's Health Information Center <www.4women.gov> and from groups such as Postpartum Support International <www.chss.iup.edu/postpartum> and Depression after Delivery <www.depressionafterdelivery.com>.

SCORING

QUESTIONS 1, 2, & 4 (without an *)
Are scored 0, 1, 2 or 3 with top box scored as 0 and the bottom box scored as 3.

QUESTIONS 3, 5-10 (marked with an *)
Are reverse scored, with the top box scored as a 3 and the bottom box scored as 0.

Maximum score: 30
Possible Depression: 10 or greater
Always look at item 10 (suicidal thoughts)

Instructions for using the Edinburgh Postnatal Depression Scale:

1. The mother is asked to check the response that comes closest to how she has been feeling in the previous 7 days.
2. All the items must be completed.
3. Care should be taken to avoid the possibility of the mother discussing her answers with others. (Answers come from the mother or pregnant woman.)
4. The mother should complete the scale herself, unless she has limited English or has difficulty with reading.

[1]Source: Cox, J.L., Holden, J.M., and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. *British Journal of Psychiatry* 150:782-786.

[2]Source: K. L. Wisner, B. L. Parry, C. M. Piontek, Postpartum Depression N Engl J Med vol. 347, No 3, July 18, 2002, 194-199

8 Multimorbidity

8.1 Clinician briefing

Andrei, a retired construction worker, is a 75-year-old man with multimorbidity and poor mobility. You know him and his family well. Following the death of his wife he has lived alone for three years in a second floor flat, where he has domiciliary care check-in visits three times a week.

He remains a heavy drinker and lifelong smoker with a 53 pack-year history. His other cardiovascular risk factors include hypertension, hypercholesterolaemia, and type 2 diabetes. Five years ago, he had a 'mild' heart attack (NSTEMI[32]) and has since had several percutaneous coronary intervention (PCI) procedures since then. Andrei has atrial fibrillation and 9 months ago had a stroke, which has left him with a mild right sided hemiparesis[33] and expressive dysphasia[34]. He has a history of recurrent falls. His symptoms of dyspepsia are controlled by PPI therapy. His CHA_2DS_2-VASc score for atrial fibrillation stroke risk is 6 (9.6% risk per year). 10 years ago, he was diagnosed with chronic obstructive pulmonary disease (COPD) and has been admitted several times over the years for acute exacerbations, but he is not on home oxygen.

Andrei presented to you one month ago with his carer, after she noticed he had passed offensive smelling black tarry stools in the commode that morning.[35] You contacted the local medical registrar on call and arranged urgent transfer to hospital, where he was admitted by the acute medical team. Andrei had no additional ALARM[36] symptoms and was haemodynamically stable. An endoscopy was performed, which was unable to identify a source of bleeding. The melaena subsequently resolved and the patient was discharged with no scheduled follow-up.

You have since received a clinic letter from the stroke physician requesting the prescription of a direct oral anticoagulant (DOAC) therapy due to atrial fibrillation.

Role Play

Please refer to the following information during the role play.

Appointment 1:

Instructions:

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[32] NSTEMI = Non-ST-Segment elevation myocardial infarction

[33] Hemiparesis = weakness or paralysis of one side of the body

[34] Expressive dysphasia = Difficulty putting words together to make meaning

[35] GPnotebook: Melaena

[36] ALARM symptoms include: Anaemia, dysphagia (difficulty swallowing), haematemesis (vomiting blood), melaena (passage of black tarry stools), persistent vomiting, involuntary weight loss.

You are a GP working running your morning clinic. Using the information provided, please support the patient to come to a decision about his treatment options:

- Please record the aspects that you feel are relevant into the record provided. You can do this during or after the role play.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the standard.
- There is an option to pause if something is not working so it can be addressed, and the role play restarted.

The **options for treatment** below are suggestions for discussion in the role play scenario but you may wish to discuss other options based on your clinical judgement.

- Option 1: 'Do nothing' – take no further action.
- Option 2: Delay the decision
- Option 3: Prescribe DOAC

During the scenario you may also wish to refer to the further information provided in the appendices below:

Appendices

Appendix A: Options for Direct Oral Anticoagulant (DOAC) therapy for prophylaxis of stroke and systemic embolism in non-valvular atrial fibrillation:

Medication	Dose	Route	Freq.	Major side effects
Dabigatran extexilate	110 – 150mg	PO	BD	Bleeding, Stomach upset.[37]
Rivaroxaban	20mg	PO (with food)	OD	Bleeding
Apixaban	5mg*	PO	BD	Bleeding
Edoxaban	60mg*	PO	OD	Bleeding

*Patient weighs 75kg and normal kidney function.

[37] Vazquez and others. Direct oral anticoagulants (DOACs). Vascular Medicine 2015. [Accessed May 2021].

Appendix B: Past medical History / Problem List (Quick reference)

- Suspected upper GI bleed (1/12 ago).
- Hypertension (8 years ago).
- Hypercholesterolaemia (5 years ago).
- Diabetes (13 years ago).
- NSTEMI (5 years ago). X 3 percutaneous coronary interventions since.
- Atrial fibrillation - CHA_2DS_2-VASc score for atrial fibrillation stroke risk is 6 (9.6% risk per year).
- Ischaemic stroke (9/12 ago). Mild right-sided hemiparesis and a mild expressive dysphasia.
- Recurrent falls
- GORD.
- COPD 10 years ago. X 4 admissions for acute exacerbations. Not on home oxygen.
- Smoker (53 pack years)

Appendix C: Current Medications

Medication	Dose	Route	Freq.	Indication
Ramipril	2.5mg	PO	OD	Secondary prevention
Bisoprolol fumarate	2.5mg	PO	OD	Secondary prevention
Aspirin	75mg	PO	OD	Secondary prevention[38][39]
Atorvastatin	80mg	PO	OD	Secondary prevention
Metformin hydrochloride	1g	PO	BD	Type 2 Diabetes
Omeprazole	20mg	PO	OD	GORD
Tiotropium/Olodaterol (2.5µg/2.5µg per dose inhaler)	2 puffs	INH	OD	COPD
Salbutamol (100µg per dose inhaler)	1 – 2 puffs	INH	PRN	COPD
Colecalciferol (10µg) with calcium carbonate (1.25g) (Calcichew-D3® Forte)	1 tablet	PO	OD	History of recurrent falls[40].

[38] Isted, A. and others. Secondary prevention following myocardial infarction: a clinical update. British Journal of General Practice 2018. [Accessed May 2021].

[39] NICE. Stroke and TIA: Scenario: Secondary prevention following stroke and TIA. NICE Clinical Knowledge Summaries 2020. [Accessed May 2021].

[40] GPnotebook: Vitamin D and calcium supplementation in the elderly

8.2 Simulated patient briefing

Background:

Name: Andrei Peters

Age: 75-years-old

Job: Retired construction worker

You live with multiple long term medical conditions and poor mobility. Following the death of your wife you have lived alone for three years in a second floor flat. You have visits from homecare workers three times a week. You use a walking frame to get around at home. You are a heavy drinker and lifelong smoker (having smoked a pack a day for 53 years). You have several issues relating to your heart and circulation, including high blood pressure, high cholesterol, and diabetes. You had a 'mild' heart attack (NSTEMI[41]) five years ago and have since had several procedures to unblock the blood vessels in your heart (known as percutaneous coronary intervention (PCI)). You also have atrial fibrillation (a type of irregular heartbeat). Nine months ago, you had a stroke that left you with a mild weakness/paralysis on your right-hand side (hemiparesis[42]) and a mild difficulty with finding your words (expressive dysphasia[43]). Since you had the stoke, you have fallen over several times – fortunately, you have not suffered further injuries or been admitted to hospital as a result, but the last time your daughter found you on the kitchen floor unable to get up. You also have chronic obstructive pulmonary disease (COPD) and as a result, you have been admitted several times over the years for related bacterial lung infections (acute exacerbations). You are being treated with prescription medication for gastro-oesophageal reflux disease (GORD), which is currently gives you no symptoms.

Appointment 1:

- **This appointment is for background only and is not part of the role play.**

About one month ago you saw your GP with your carer, after she had noticed you had passed offensive smelling black tarry stools in the commode that morning.[44] The GP was worried that this was a sign of an internal bleed of your digestive system and so arranged to transfer you urgently to hospital where you were admitted and assessed by the medical team. During your hospital stay you had an endoscopy (camera test). The doctors could not find a source of the bleeding and your subsequent bowel habit returned to normal. You were therefore discharged without any follow-up appointments.

Please refer to the following information during the role play.

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[41] NSTEMI = Non-ST-Segment elevation myocardial infarction

[42] Hemiparesis = weakness or paralysis of one side of the body

[43] Expressive dysphasia = Difficulty putting words together to make meaning

[44] GPnotebook: Melaena

Role Play

Appointment 2:

Name: Andrei Peters

Age: 75-years-old

Job: Retired construction worker

Background:

You live with multiple long term medical conditions and poor mobility. Following the death of your wife you have lived alone for three years in a second floor flat. You have visits from homecare workers three times a week. You are a heavy drinker and lifelong smoker (having smoked a pack a day for 53 years). You have several issues relating to your heart and circulation, including:

- High blood pressure (diagnosed 8 years ago).
- High cholesterol (diagnosed 5 years ago).
- Diabetes (diagnosed 13 years ago).
- You had a 'mild' heart attack (NSTEMI[45]) five years ago. You have and has since had several procedures to unblock the blood vessels in your heart (known as percutaneous coronary intervention (PCI)).
- You have atrial fibrillation (a type of irregular heartbeat).
- You had a stroke 9 months ago. As a result, you have a mild weakness/paralysis on your right-hand side (hemiparesis[46]) and a mild difficulty with finding your words (expressive dysphasia[47]).
- Since you had the stoke, you have fallen over several times – fortunately, you have not suffered further injuries or been admitted to hospital as a result, but the last time your daughter found you on the kitchen floor unable to get up.
- You were diagnosed with chronic obstructive pulmonary disease (COPD) 10 years ago. As a result, you have been admitted several times over the years for related bacterial lung infections (acute exacerbations). If asked, you are not on home oxygen.
- You are being treated with prescription medications for GORD[48] (acid reflux) but do not have any symptoms currently (e.g., heartburn).

Medication history:

You are taking multiple prescribed medicines and have brought the following list with you to the appointment, which you can refer to during the role play if needed.

- You do not need to understand in detail how these medications work.

[45] NSTEMI = Non-ST-Segment elevation myocardial infarction

[46] Hemiparesis = weakness or paralysis of one side of the body

[47] Expressive dysphasia = Difficulty putting words together to make meaning

[48] GORD = Gastro-oesophageal reflux disease

- If you are asked if you know why you are taking a particular medication, please respond as per the last column in the table below.
- If asked, you DO NOT have any allergies to any medications.

Medication	**Dose**	**Route**	**Freq.**	**Your understanding of what it is for.**
Ramipril	2.5mg	Tablet by mouth	Once a day	To prevent another heart attack.
Bisoprolol fumarate	2.5mg	Tablet by mouth	Once a day	To prevent another heart attack.
Aspirin	75mg	Tablet by mouth	Once a day	To prevent another heart attack.
Atorvastatin	80mg	Tablet by mouth	Once a day	To prevent another heart attack.
Metformin hydrochloride	1g	Tablet by mouth	Twice a day	For your type 2 Diabetes
Omeprazole	20mg	Tablet by mouth	Once a day	For your acid reflux (GORD)
Tiotropium/Olodaterol (2.5µg/2.5µg per dose inhaler)	2 puffs	Inhaler	Once a day	For your COPD
Salbutamol (100µg per dose inhaler)	1 – 2 puffs	Inhaler	As needed	For your COPD
Colecalciferol (10µg) with calcium carbonate (1.25g) (Calcichew-D3® Forte)	1 tablet	Tablet by mouth	Once a day	To prevent bone fractures as you have had several falls[49].

Presenting complaint:

- You have been invited by your GP to discuss a potential change to the medication(s) you are taking.

Social history:

- You have smoked a pack of 20 cigarettes a day for 53 years. You like smoking and do not want to give up, despite knowing the consequences.
- You drink a bottle the equivalent of a bottle of red wine most evenings.

[49] GPnotebook: Vitamin D and calcium supplementation in the elderly

- You are a talented painter and despite your stroke episode you have continued to produce sketches and watercolours.

Ideas/concerns/expectations

- Your greatest fear is having another heart attack. When this first happened, you were woken in the middle of the night with ‘crushing chest pain like somebody had put an anvil on my chest’ and your wife was able to phone the ambulance. Since she has died your fears of having a similar episode have increased.
- The most important thing to you is being well enough to receive visits from your daughter and granddaughter (who is 3 years old).

9 Genetic Condition

9.1 Clinician briefing

Huntington's disease is a degenerative illness of the brain and nervous system that is caused by a faulty and autosomal dominant gene (HTT gene on chromosome 4).[50] The central dogma of molecular biology holds that a gene is DNA coding for RNA that codes for a protein.[51] Huntington's is a trinucleotide repeat disorder displaying genetic anticipation, therefore successive generations generally have earlier ages of onset and increased severity of disease. A child born where one of the parents is heterozygous for the abnormal Huntington's gene has a 50% chance of inheriting it and therefore will develop the malady.[52] Most people with Huntington's develop the disease between the ages of 30 to 50 and death occurs approximately 15 – 20 years after symptoms first start.[53] There is no known cure for the illness itself. A juvenile form of the illness affects children and young adults under the age of 21. The condition causes disturbances in a person's movement, thinking, and behaviours.[54] These begin subtly, worsen over time, and may include:

Movement:

- Chorea: Involuntary 'dance-like' body movements, inability to hold a posture and unusual facial expressions (See video).[55]
- Impaired voluntary movements: This can result in poor coordination/clumsiness, slurred speech, difficulty swallowing, and poor balance/falls. Later, symptoms progress to muscle rigidity, spasticity, and dystonia (a condition of muscle spasms causing twisting/contortions of the body – see video).[56]

Thinking (cognition):

- This may include: Difficulty concentrating, memory & learning problems, and impaired judgement/decision making.

Behaviours and mental health:

- Personality changes: Some people may develop irritability/temper outbursts, lack of enthusiasm (for previously enjoyable activities), and impulsivity (e.g., snap decisions, gambling, changes in sex drive).

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[50] BMJ Best Practice. Huntington's disease. [Accessed April 2021].

[51] Crick, F. Central dogma of molecular biology. Nature (1970). [Accessed April 2021]

[52] Huntington's Disease Association. Huntington's disease: A genetic testing guide. [Accessed April 2021].

[53] Huntington's Disease Association. Huntington's disease: A guide for GPs and primary care teams. [Accessed April 2021].

[54] GPnotebook. Huntington's disease: clinical features and course. [Accessed April 2021].

[55] YouTube. Neurology – Topic 17 Huntington's disease patient. UCD Medicine. [Accessed April 2021].

[56] YouTube. What is dystonia? UFHealth. [Accessed April 2021].

- Mental health: Clinical depression is common in people with Huntington's.

Most people who are ultimately diagnosed with Huntington's (> 92%) have a known family history of the disease.[57] Individuals with family history may be faced with decisions about whether to have the following:[58]

- Predictive testing: A blood test offered to a person (who usually must be > 18 years old) at risk of the disease but who DOES NOT have Huntington's symptoms.
- Diagnostic testing: A blood test offered to a person (of any age) who DOES have Huntington's symptoms.
- Prenatal diagnosis (PND) testing: A test performed following a successful natural conception to see if the developing foetus has the Huntington's gene.
- Preimplantation genetic diagnosis (PGD) testing: This involves testing the DNA and chromosomes to identify an unaffected embryo before transfer to the woman's womb using IVF.[59]

Role Play - Part A

Please refer to the following information during the role play.

Appointment 1:

Instructions:

You are a genetic counsellor working at a Regional Genetics Clinic. Using the information provided, please support the patient to come to a decision about his testing options:

- Please record the aspects that you feel are relevant into the record provided. You can do this during or after the role play.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the standard.
- There is an option to pause if something is not working so it can be addressed, and the role play restarted.
- It is recognised that in reality the counselling process may take place over several successive appointments, with time to digest and ponder the information shared in between, but for practical purposes for each part of the role play we are simulating one appointment.

Patient background:

Matthew Ryan (18 years) has been referred to you from his GP. You know his family well. His grandfather died with Huntington's disease agreed 70. His father was diagnosed with the illness at 30 and died aged 45 when Mathew was 5. His mother does not carry the HTT

[57] BMJ Best Practice. Huntington's disease: History and exam. [Accessed April 2021].

[58] Huntington's Disease Association. Huntington's disease: A genetic testing guide. [Accessed April 2021].

[59] IVF = *in vitro* fertilisation

gene. His sister underwent predictive testing aged 21, which was unequivocally normal (< 27 repeats).

The **options for treatment** below are suggestions for discussion in the role play scenario but you may wish to discuss other options based on your clinical judgement.

- Option 1: 'Do nothing' – take no further action.
- Option 2: Delay the decision
- Option 3: Consent for predictive genetic testing.[60]
- Option 4: Do not consent for predictive genetic testing.

During the scenario you may also wish to refer to the following further relevant background for this appointment:

- Risk of Huntington's in asymptomatic individuals with one affected parent (Appendix A).
- Professional guidance:
    - You may wish to refer to the HDA leaflet providing guidance for GPs and primary care teams on Huntington's disease.[61]
- Predictive testing for Huntington's disease:
    - When discussing the risks and benefits you may wish to refer to the HDA leaflet on predictive testing for Huntington's disease.[62]
- Driving:
    - In the UK there is a legal duty for driving license holders to inform the DVLA (Driver and Vehicle Licensing agency) where there is a 'relevant' or 'prospective' disability that could affect their ability to drive.[63]
    - People who are at risk of Huntington's disease OR have had a positive test result are NOT obliged to inform the DVLA of the risk status until they develop symptoms.
    - You may wish to signpost the person to the HDA leaflet on Huntington's disease and driving.
- Occupational restrictions (armed forces):[64]
    - The MOD policy is that candidates who are known carriers of the Huntington's gene OR with a 'proven, immediate family history of this condition' (unless known not to carry the gene) are NORMALLY graded UNFIT.

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[60] NHS (website). Tests: Huntington's disease. [Accessed April 2021]

[61] Huntington's Disease Association. Huntington's disease: A guide for GPs and primary care teams. [Accessed April 2021].

[62] Huntington's Disease Association. Huntington's disease: Predictive testing for Huntington's disease. [Accessed April 2021].

[63] Huntington's Disease Association. Huntington's disease: Huntington's disease and driving. [Accessed April 2021].

[64] Ministry of Defence. JSP 950 Medical Policy Leaflet 6-7-7: Joint Service Manual of Medical Fitness. [Accessed April 2021].

    - The policy states that '[g]enetic testing should not be initiated solely for the purposes of recruitment.'
    - You may wish to signpost the person to the MOD policy leaflet that contains information on Huntington's disease and recruitment into the armed forces (Section 10. Footnote 7 states that 'If there is clear evidence that a candidate is unlikely to develop Huntington's disease during a Service career, then they may, on a case by case basis be considered FIT.').
- Life insurance:
    - According to the HDA, 'it is probable that a positive test result would make it more difficult to get life insurance.'[65]

Role Play - Part B

Please refer to the following information during the role play.

Appointment 2:

- *NB*: This follow-up scenario assumes that Matthew has a known positive status for the Huntington's gene, irrespective of the decision you made in the first appointment.
- The scenario occurs approximately 8 years after appointment 1.

Patient background:

Matthew Ryan (26 years) has come to see you with his wife for a routine appointment in your afternoon clinic. Matthew has predictive test results in his electronic health record showing 42 trinucleotide repeats (unequivocally abnormal – see Appendix B).

Instructions:

You are a genetic counsellor working at a Regional Genetics Clinic. Using the information provided, please support the patient (couple) to come to a decision about next steps.

- Please record the aspects that you feel are relevant into the record provided. You can do this during or after the role play.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the standard.
- There is an option to pause if something is not working so it can be addressed, and the role play restarted.
- It is recognised that in reality the counselling process may take place over several successive appointments, with time to digest and ponder the information shared in between, but for practical purposes for each part of the role play we are simulating one appointment.

[65] Huntington's Disease Association. Huntington's disease: Predictive testing for Huntington's disease. [Accessed April 2021].

- **The patient's wife is a non-speaking part in the role play (but you may attempt to engage and include her). She is medically fit and well and does not carry the Huntington's gene.**

The **options for treatment** below are suggestions for the role play scenario but you may wish to discuss other options based on your clinical judgement.

- Option 1: 'Do nothing' – take no further action. Leaves couple to decide whether to:
  - Conceive naturally and accept the risk of a child inheriting the HTT gene.
  - Consider other options including adoption.
- Option 2: Delay the decision
- Option 3: Try to conceive naturally and if successful undergo prenatal diagnosis (PND).
- Option 4: Seek preimplantation genetic diagnosis (PGD)

During the scenario you may also wish to refer to the following further relevant background for this appointment:

Role Play - Part C (optional if time)

Please refer to the following information during the role play.

Appointment 3:

- *NB*: This follow-up scenario assumes that Matthew has a known positive status for the Huntington's gene, irrespective of the decision made in the first appointment.
- The scenario occurs approximately 26 years after appointment 2.

Instructions:

You are a genetic counsellor working at a Regional Genetics Clinic. Using the information provided, please support the patient to come to a decision about his testing options:

- Please record the aspects that you feel are relevant into the record provided. You can do this during or after the role play.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the standard.
- There is an option to pause if something is not working so it can be addressed, and the role play restarted.
- It is recognised that in reality the counselling process may take place over several successive appointments, with time to digest and ponder the information shared in between, but for practical purposes for each part of the role play we are simulating one appointment.

Relevant background on Advanced decision to refuse treatment (ADRT):

- You may wish to refer to the HDA leaflet on ADRT and complete the HDA ADRT form (Appendix C) with the patient.

Appendices

Appendix A: Risk of Huntington's in asymptomatic individual with one affected parent:[66]

Age (years)	Risk (%)
20	49.96
25	49.00
30	47.60
35	45.50
40	42.50
45	37.80
50	31.50
55	24.80
60	18.70
65	12.80
70	6.20
75	4.60

Appendix B: Possible results of Huntington's predictive testing:[67]

Number of trinucleotide repeats	Interpretation
< 27 repeats	Unequivocally normal
27 – 35 repeats	Normal (small chance of repeat expansion in future generations)
36 – 39 repeats	Abnormal (Reduced penetrance - chance the person may be affected late in life or not at all)
> 40 repeats	Unequivocally abnormal (Full penetrance)

[66] Adapted from Predictive testing for Huntington's disease. [Accessed April 2021].

[67] Adapted from Predictive testing for Huntington's disease. [Accessed April 2021].

Appendix C: My Advance Decision to Refuse Treatment (form):[68]

Separate document.

9.2 Simulated patient briefing

Background

Huntington's disease is a degenerative illness of the brain and nervous system that is caused by an abnormal gene (on chromosome 4).[69] A gene is biological information/instructions, inherited from a person's parents, that is present in every cell of the body and is used to produce proteins. A chromosome is a long DNA molecule that contains many genes.[70] Each cell of the body contains 23 pairs of chromosomes. A child born where one of the parents has the abnormal Huntington's gene has a 50% chance of inheriting it and therefore will develop the malady.[71] Most people with Huntington's develop the disease between the ages of 30 to 50 and death occurs approximately 15 – 20 years after symptoms first start.[72] There is no known cure for the illness itself. A juvenile form of the illness affects children and young adults under the age of 21. The condition causes disturbances in a person's movement, thinking, and behaviours.[73] These begin subtly, worsen over time, and may include:

Movement:

- Chorea: Involuntary 'dance-like' body movements, inability to hold a posture and unusual facial expressions (See video).[74]
- Impaired voluntary movements: This can result in poor coordination/clumsiness, slurred speech, difficulty swallowing, and poor balance/falls. Later, symptoms progress to muscle rigidity, spasticity, and dystonia (a condition of muscle spasms causing twisting/contortions of the body – see video).[75]

Thinking (cognition):

- This may include: Difficulty concentrating, memory & learning problems, and impaired judgement/decision making.

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[68] Produced by Huntington's Disease Association. [Accessed April 2021].

[69] BMJ Best Practice. Huntington's disease. [Accessed April 2021].

[70] DNA = Deoxyribonucleic acid

[71] Huntington's Disease Association. Huntington's disease: A genetic testing guide. [Accessed April 2021].

[72] Huntington's Disease Association. Huntington's disease: A guide for GPs and primary care teams. [Accessed April 2021].

[73] GPnotebook. Huntington's disease: clinical features and course. [Accessed April 2021].

[74] YouTube. Neurology – Topic 17 Huntington's disease patient. UCD Medicine. [Accessed April 2021].

[75] YouTube. What is dystonia? UFHealth. [Accessed April 2021].

Behaviours and mental health:

- Personality changes: Some people may develop irritability/temper outbursts, lack of enthusiasm (for previously enjoyable activities), and impulsivity (e.g., snap decisions, gambling, changes in sex drive).
- Mental health: Clinical depression is common in people with Huntington's.

Most people who are ultimately diagnosed with Huntington's (> 92%) have a known family history of the disease.[76] Individuals with family history may be faced with decisions about whether to have the following:[77]

- Predictive testing: A blood test offered to a person (who usually must be > 18 years old) at risk of the disease but who DOES NOT have Huntington's symptoms.
- Diagnostic testing: A blood test offered to a person (of any age) who DOES have Huntington's symptoms.
- Prenatal diagnosis (PND) testing: A test performed following a successful natural conception to see if the developing foetus has the Huntington's gene.
- Preimplantation genetic diagnosis (PGD) testing: This involves testing the DNA and chromosomes to identify an unaffected embryo before transfer to the woman's womb using IVF.[78]

Instructions

- When you are asked to decide, please choose using your own judgement based on what has been discussed and what you feel you would choose the patient. (When deciding in part A, please try to disregard the briefing information found in part B).
- If asked what you know already about any of the investigation/treatment options presented, please deny knowledge of the specifics.
- Remember that the role plays are not intended to be a test for participants' ability to apply SDM, but to create a 'realistic' consultation to test the information standard.
- There is an option to pause if something is not working so it can be addressed, and the role play restarted.

Please refer to the following information during the role play.

Appointment 1:

Name: Matthew Ryan

Age: 18-years-old

[76] BMJ Best Practice. Huntington's disease: History and exam. [Accessed April 2021].

[77] Huntington's Disease Association. Huntington's disease: A genetic testing guide. [Accessed April 2021].

[78] IVF = *in vitro* fertilisation

Job: Unemployed (student)

Background:

You live at home in a three-bedroom council flat with your and sister (who is 21 years old). Neither of them has the Huntington's gene. Your grandfather died with Huntington's disease aged 70. Your father was diagnosed with the Huntington's disease aged 30 and was honourably discharged from the British Army (Royal Engineers) as a result. He died when you were 5 years old after living for 15 years with the illness. You idolise your father and have strong ambitions to follow his army career, as a Royal Engineers mechanic. You have a passion for motorcycles and recently completed your compulsory basic training (CBT) certificate and are studying your Level 2 Diploma in Motorcycle Maintenance and Repair Competence. For your 18th birthday you were delighted to receive a 125cc bike from your family.

Presenting complaint:

- You were referred by your GP to a genetic counsellor working at a Regional Genetics Clinic a few months after your 18th birthday, to request a blood test for the Huntington's gene.
- After you turned 18 your mother disclosed to you that your father died of the disease. Your sister had previously undergone predictive testing and received a negative (all clear) result.
- You had previously resolved not to have the test. For the following reasons:
    - You had convinced yourself that you did not have the faulty gene.
    - You are worried about whether a positive result would prevent your prospective career in the armed forces.
    - You are concerned that a positive result may mean that you will no longer be allowed to legally ride your motorbike.
- However, you are now torn as to whether to have the test after some recent events have made you feel a bit anxious. These happened the other day and were:
    - On a night out you spilt your glass of beer across the bar.
    - When you got home you had an argument with your sister who told you that you were being unusually bad tempered.
    - The next morning you could not remember the names of the people you met at the nightclub.
- You recognise that you had drunk more alcohol than you normally would, but you feel these things were unusual for you. You are worried that these might be the first symptoms or signs of Huntington's disease.
- You have not had any other symptoms and otherwise have felt fit and well.

Past medical history:

- You have never had any previous medical investigations or surgeries.

Drug history:

- You are not taking any medications and do not have any allergies.

Social history:

- You have never smoked.
- You only tend drink alcohol on nights out, which you do once or twice a month with your friends.
- You are a healthy weight and play as a striker on weekends for the local town under-21s football team.

Ideas/concerns/expectations

- The most important thing to you is being able to continue to ride your motorbike and enjoy all the things you do now.
- Your main worry is that you are developing the juvenile form of Huntington's disease.
- You are concerned about how a positive result will affect your career in the armed forces.

Role Play - Part B

Please refer to the following information during the role play.

Appointment 2:

- *NB*: This follow-up scenario assumes that you have a known positive status for the Huntington's gene, irrespective of the decision you made in the first appointment.

Name: Matthew Ryan

Age: 26-years-old

Job: Motorcycle mechanic

Background:

Eight years later you have married the love of your life and wish to have a child. You do not have any Huntington's symptoms, but you have had the predictive test aged 19, which was positive. Consequently, you were deemed unfit for recruitment by into the armed services.[79] Instead, you completed your level 3 diploma in motorcycle maintenance and are now working as a mechanic for an internationally recognised Japanese motorcycle manufacturer. Your wife understands that you have a degenerative & life-limiting condition and is 'incredibly supportive'. You have brought your wife to an appointment with a genetic counsellor working at a Regional Genetics Clinic.

[79] Ministry of Defence. JSP 950 Medical Policy Leaflet 6-7-7: Joint Service Manual of Medical Fitness. [Accessed April 2021].

- **Your wife is a non-speaking part in the role play (but the clinician may attempt to engage and include them). She is medically fit and well and does not carry the Huntington's gene.**

Presenting complaint:

- You have come to a routine appointment at your GP to discuss the fact that you and your wife wish to have a baby.

Past medical history:

- Aside from predictive testing you have never had any previous medical investigations or surgeries.

Drug history:

- You are not taking any medications and do not have any allergies.

Social history:

- You have never smoked.
- You drink alcohol occasionally.
- You feel generally fit and well and continue to play football as part of a five-a-side team.

Ideas/concerns/expectations

- The most important thing to you both is being able to have a biological child of your own that does not have the Huntington's gene.
- You also want to be able to have children as early as possible, so that you can raise them 'like a normal father would' and 'to see them grow up.' You also want them 'to get to know me and remember me as I am now, without the scary personality changes that will come with my illness.'
- If asked, you are both open to the possibility of adoption.
- If asked, you are currently having protected sex and your wife currently has the Mirena coil contraceptive device inserted.

Role Play - Part C (optional if time)

- *NB*: This follow-up scenario assumes that you have a known positive status for the Huntington's gene, irrespective of the decision you made in the first appointment. Following IVF treatment, you are the proud father of identical twin daughters (they are now aged 22 are do not carry the Huntington's gene).

Name: Matthew Ryan

Age: 52-years-old

Job: Retired motorcycle mechanic

Background:

You started to develop Huntington's symptoms 16 years ago. These have gradually worsened to the point where you are now unable to work as a mechanic. Over this period, you have also had several episodes of clinical depression. Your wife is now your full-time carer and has attended this appointment to support you.

- **Your wife is a non-speaking part in the role play (but the clinician may attempt to engage and include them).**

Presenting complaint:

- You have come to an appointment with a genetic counsellor working at a Regional Genetics Clinic, who has invited you to discuss/assist you with making an Advanced decision to refuse treatment (ADRT).[80] An ADRT is a legally binding expression of your future health wishes.

Past medical history:

- Developed symptoms of Huntington's 16 years ago, which have gradually worsened. These include:
    - Movement: You have increasingly frequent involuntary movements (chorea). You have difficulty balancing and, after several falls, prefer to use a wheelchair to get around the house.
    - Personality change/mental health: You are increasingly irritable and have temper outbursts and feel extremely guilty about this. You have lost your enthusiasm for motorcycles and your wife is concerned as you have been losing quite a lot of money recently on football betting sites.
    - Thinking: You find it difficult to concentrate and to remember things.
- You have never had any surgeries.

Drug history:

- If asked, you do not have any allergies and are taking the following medication:
    - Sertraline (150mg) for depression
    - Olanzapine (15mg per day) for the chorea. (This drug has increased your appetite, which you have found particularly distressing along with swallowing difficulties).

Social history:

- You have never smoked.
- You drink alcohol occasionally.

[80] Huntington's Disease Association. Huntington's disease: Advanced decision to refuse treatment.

Insight:

- You understand and fully recognise that your debilitating symptoms are due to Huntington's.

Ideas/concerns/expectations

- You are aware that your illness is getting worse and that you will not have the capacity to refuse treatment in future. You have resolved to refuse any lifesaving medical treatments.

10 Human Readable Form of the Standard

SDM Record		
Element	**Record Entry (Electronic)**	**Recording Guidance**
Encounter details		Assume location, date& time, specialty and performing professional all done automatically by the system
Consultation Method (drop down choice)		Drop down choice for NHS DD codes (face to face, telephone etc)
Person accompanying patient (free text)	[Name] [Relationship] [Role]	Where present record name relationship & role
Professionals present (free text)	[Name] [Relationship] [Role]	Where additional professionals present record name, relationship, job title.
Use of an interpreter (drop down choice)		Use of an interpreter - drop down choice
Recording of the conversation		
i) Patient interview recorded indicator (drop down choice)		
ii) Consent for patient interview recording (drop down choice)		
file)		
Problems being addressed		
Problems being addressed	[problem or diagnosis]	record coded problem or diagnosis
Patient understanding of their diagnosis / condition		What is the patient's understanding of their condition. Record here.
Supporting the shared decision		
Pre-meeting information shared		A record of actions taken to prepare the patient to make a shared decision before the appointment. This should include a summary of any resources the person was offered to prepare them for the decision making process.
Agenda setting		A record of the agenda setting process undertaken to support the shared decision.
Decision dialogue		
Establishing the conversation		A description of what was said to: Establish collaboration, Declare the alternatives, Purpose and reasons for the SDM conversation.
Goals and hopes		The overall goals, hopes, aims or targets that the person has. Including anything that the person wants to achieve that relates to their future health and wellbeing. Each goal may include a description of why it is important to the person. Goals may also be ranked in order of importance or priority to the person.
Patient ideas, concerns, expectations (and priorities)		Description of the patient's major concerns/priorities. What is most important to them?
Patient prior knowledge of intervention?		Record of patient's prior knowledge of options.
Options entry		Record of the options discussed.
Risks communication entry		Record of the risks discussed for each option.
Benefits entry		Record of the benefits discussed for each option.
(Alternatively) Risks & benefits discussed		Record of the risks and benefits discussed.
Documenting level of certainty		A statement about the level of certainty of evidence for the option(s) discussed.
Recording the decision		
Decision made		Record of the decision made.
Persons stated reason(s) for decision made		A record of the person's understanding/justification for why they made the decision agreed.
Actions for person or their carer		Agreed actions for the person or their carer. For each action the following should be identified: outcome expectations, including person's expectations.
Actions for professionals		Agreed actions for the professional including planned investigations, procedures and treatment for a person's identified conditions and priorities.
Planned review date/interval		This is the date/interval when this information will next be reviewed.
Evaluating the decision		A record of the perception of the decision and collaborative process from the perspective of the clinician and the patient, including: Clinician's view of the patient's level of health literacy A record of whether or not the clinician agreed with the decision A record of the patient's satisfaction with the decision made A record of decisional regret if experienced by the patient
Was the decision made the person's preferred option?		Coded yes or no (drop down list)
If NO, what was the reason given to person?		Describe the reason given to the person why their first choice could not be accommodated.
What was the person's preferred option		Code or free text of person's preferred option.
Person's reason given for preferred option		Account of person's reason for preferred option.
Did the clinician agree with the person's decision?		Coded yes or no (drop down list)
IF NO, what was the reason given to the person?		Description of what was said to the person regarding clinician's disagreement with their decision.
Decision support tool item entry		
Decision support tool identifier		Any alphanumeric identifier associated with the decision support tool (if applicable).
Decision support tool name		The name of the decision support tool.
Decision support tool type		The type of the decision support tool.
Decision support tool location or URL		The URL for the decision support tool.
Decision support tool MIME type		MIME type of the document e.g. application, pdf, website.
Post-appointment actions		A record of the actions taken to support the shared decision after the index appointment. For example printouts summarising the options or decisions made, signposting to relevant online or physical information resources.
Performance measures (drop down menu)		A record of any performance measures used for measuring the effectiveness of shared decision making. e.g. CollaboRATE, Observer OPTION 5, Observer OPTION 12, SDM-Q-9 / SDM-Q-Doc etc.
Documenting consent		A record of documents recording consent for an intervention.
date		The date when consent was taken.
Location		The location where consent was taken.
Consent form type		Record of consent form used - possibly drop down choice
Consent form location / URL		The URL for the consent form.
Consent form MIME type		MIME type of the document e.g. application, pdf, website.
Performing professional		The professional who completed the consent form.
Person completing record		Details of the person completing the record.
Consent form used (Y/N)		An indicator of whether a consent form was used.
Type of consent given (verbal, written, implied)		Clinician's interpretation of the type of consent given.