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REGISTRARS

Mastering your Fellowship

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Abstract

The series, "Mastering your Fellowship", provides examples of the question format encountered in the written examination, Part A of the FCFP(SA) examination. The series aims to help Family Medicine registrars prepare for this examination. Model answers are available online.

Keywords: FCFP(SA) examination, Family Medicine registrars

Introduction

This section in the *South African Family Practice Journal* aims to help registrars prepare for the FCFP(SA) Part A examination (Fellowship of the College of Family Physicians), and includes examples of the question formats encountered in the written examination, i.e. multiple choice questions (MCQs), extended matching question (EMQ), the modified essay question (MEQ) and critical reading paper (evidence-based medicine). Each of these question types is presented according to a theme. The MCQs are based on the 10 clinical domains of Family Medicine, the MEQs are aligned with the five national unit standards, and the critical reading section includes evidence-based medicine and primary care research methods. Please visit the Colleges of Medicine website for guidelines on the Fellowship examination: http://www.collegemedsa.ac.za/view_exam.aspx?examid=102

We are interested to hear how this series is assisting registrars and their supervisors in preparing for the FCFP(SA) examination. Please email your feedback and suggestions to us.

1. MCQ (multiple choice question): general adult medicine

A 67-year old male patient was seen at a nearby primary healthcare clinic two days ago with a fever. He returned today. The clinical nurse practitioner asks you to review him at the emergency centre of the district hospital as she is unable to find a clear focus of infection in this patient with persistent fever. Other than well-controlled hypertension, he does not have a noteworthy surgical history, nor a history of heart disease. On further enquiry, he reports a loss of appetite, painful muscles and joints, and intermittent episodes of headaches. On examination, he has a temperature of 38.4 °C, a pulse of 120 beats per minute and blood pressure of 95/55 mmHg. You notice dark, small linear lesions in the fingernail beds and 3+ of blood on urinalysis (negative for leucocytes or nitrite).

After stabilising him in the emergency centre by inserting an intravenous line, commencing normal saline infusion, and monitoring his vital signs, which of the following would be the next most appropriate step in his management plan?

a) Taking one set of blood cultures, and then starting intravenous empirical antibiotics.

b) Taking three sets of blood cultures at least 30 minutes apart before administering an antibiotic.

c) Testing his erythrocyte sedimentation rate and C-reactive protein.

d) Taking three sets of blood cultures timed with the fever spikes.

e) Arranging for urgent echocardiography at the referral hospital.

2. MEQ (modified essay question): the family physician's role as a leader of clinical governance

A 34-year old male was seen in the emergency centre of your hospital over the weekend. He presented with a depressed level of consciousness, neck stiffness and fever. The intern on duty examined the fundi and stated that the patient did not have any papilloedema, and then discussed the case with the medical officer (MO) on duty, who advised that a lumbar puncture should be performed. The intern attempted the procedure a few times, but failed. The MO suggested that the patient should be admitted on empirical treatment for bacterial meningitis. The patient was observed to have following observations and signs 24 hours later in the ward:

- Glasgow Coma Scale of 10/15.
- A temperature of 38 °C.
- Blood pressure of 160/70 mmHg.
- A pulse rate of 56 beats per minute.
- Unequal pupils.

An urgent computed tomography scan was arranged for the patient, and a brain abscess with cerebral oedema and midline shift was found. The patient was referred to neurosurgery after the diagnosis was made.

2.1 What type of patient safety incident does this constitute? Justify your answer (2 marks).

2.2 What is the severity assessment code (SAC) for this incident? Justify your answer (4 marks).

2.3 How would you describe the category of the incident? Provide a brief motivation for your answer (4 marks).

2.4 Provide a framework for the root cause analysis in this patient (4 marks).

2.5 What recommendations would you make to the patient safety committee at the hospital? (4 marks)

2.6 Describe the behaviour identified in this case study according to the Just Culture approach (2 marks).

3. Critical appraisal of research

Please read the following abstract and answer the questions which follow: Ridker PM, Danielson E, Fonseca FA, et al. Rosuvastatin to prevent vascular events in men and women with elevated C-reactive protein. N Engl J Med. 2008;359(21):2195–207. doi: 10.1056/NEJMoa0807646. [Epub 2008 Nov 9.]

Abstract

Background: Increased levels of the inflammatory biomarker, high-sensitivity C-reactive protein, predict cardiovascular events. Since statins lower levels of high-sensitivity C-reactive protein, as well as cholesterol, we hypothesised that people with elevated high-sensitivity C-reactive protein levels, but without hyperlipidaemia, might benefit from statin treatment.

Method: We randomly assigned 17 802 apparently healthy men and women with low-density lipoprotein (LDL) cholesterol levels of less than 130 mg/dl (3.4 mmol/l) and high-sensitivity C-reactive protein levels of 2.0 mg/l or higher to rosuvastatin 20 mg daily or placebo, and followed them for the occurrence of the combined primary end-point of myocardial infarction, stroke, arterial revascularisation, hospitalisation for unstable angina, or death from cardiovascular causes.

Results: The trial was stopped after a median follow-up of 1.9 years (maximum of 5.0). Rosuvastatin reduced LDL cholesterol levels by 50% and high-sensitivity C-reactive protein levels by 37%. The rates of the primary end-point were 0.77 and 1.36 per 100 person-years of follow-up in the rosuvastatin and placebo groups, respectively (hazard ratio for rosuvastatin 0.56, 95% confidence interval [CI]: 0.46–0.69, $p < 0.00001$), with corresponding rates of 0.17 and 0.37 for myocardial infarction (hazard ratio 0.46, 95% CI: 0.30–0.70, $p = 0.0002$), 0.18 and 0.34 for stroke (hazard ratio 0.52, 95% CI: 0.34–0.79, $p = 0.002$), 0.41 and 0.77 for revascularisation or unstable angina (hazard ratio, 0.53, 95% CI: 0.40–0.70, $p < 0.00001$), 0.45 and 0.85 for the combined end-point of myocardial infarction, stroke or death from cardiovascular causes (hazard ratio 0.53, 95% CI: 0.40–0.69, $p < 0.00001$), and 1.00 and 1.25 for death from any cause (hazard ratio 0.80, 95% CI: 0.67–0.97, $p = 0.02$). Consistent effects were observed in all subgroups evaluated. The rosuvastatin group did not have a significant increase in myopathy or cancer, but did have a higher incidence of physician-reported diabetes.

Conclusion: In this trial of apparently healthy persons without hyperlipidemia, but with elevated high-sensitivity C-reactive protein levels, rosuvastatin significantly reduced the incidence of major cardiovascular events (ClinicalTrials.gov number, NCT00239681).

Questions

3.1 What is the essential difference between random sampling and randomisation? (2 marks)

3.2 What were the disadvantages of using a combined primary end-point in this randomised controlled trial? (2 marks)

3.3 Using the composite end-point, how would you express the efficacy of rosuvastatin as primary prevention? (8 marks)

3.4 This trial was terminated after a median follow-up of 1.9 years, as opposed to the planned 5.0 years. Comment on why, and by whom, randomised controlled trials may be terminated early (4 marks).

3.5 What is meant by the term "hazard ratio"? (2 marks)

3.6 Provide an interpretation of the 95% CI: 0.46–0.69, and the p-value of ≤ 0.00001 (2 marks).

3.7 What are the advantages of using the 95% CI over the *p*-value? (2 marks).

3.8 The results were analysed by intention to treat (ITT) in this study. What is the benefit of ITT analysis? (4 marks)

3.9 What are the main components of evidence-based decision-making, and how would you use it in your decision-making with respect to rosuvastatin use as primary prevention in your practice setting? (10 marks)

Model answers to the questions

Question 1

Short answer: b)

Long answer: This scenario describes a patient who presents with a picture of infective endocarditis (IE). IE usually has an acute onset, and it is important to have a high index of suspicion in the primary care context. Enquiries should be made of possible risk factors, such as previous cardiac valvular disease, intravenous drug use, the presence of prosthetic devices, as well as cardiac implantable electronic devices, in a patient with unexplained high fever (≥ 38 °C).

The clinical picture varies from non-specific symptoms, such as a fever, headaches, anorexia, myalgia, night sweats and joint pains, to symptoms suggestive of pre-existing cardiac valvular disease, as well as embolic phenomena. An integration of clinical findings, microbiological analysis and imaging results is required for a diagnosis of IE. The modified Duke clinical diagnostic criteria incorporate these three domains, and weigh the findings as either major or minor criteria. Clinicians should note that the Duke criteria were originally developed to help with scientific research classification, and not as a clinical instrument, and should be used as a diagnostic guide, rather than a replacement, for clinical judgment.

Besides stabilising the patient for transfer to the next level of care for further workup, including cardiac imaging, the primary care

clinician should avoid the administration of antibiotic therapy prior to obtaining the blood cultures, as blood cultures are critical in the diagnosis of IE. It is recommended that three sets of blood cultures are taken at least 30 minutes apart. Peripheral samples are preferred. Taking the blood cultures does need not be timed with the fever spikes as bacteraemia in IE is very constant. A single blood culture should be interpreted with care, as the blood cultures in IE are usually all positive. Positive blood cultures allow for identification of the causative organism, as well as susceptibility testing. The antibiotic therapy should be changed from empirical to specific once the culture results have become available. The blood culture results are negative in one third of cases. This complicates the diagnostic process significantly. The most common cause for this conundrum is prior antibiotic administration without taking appropriate blood cultures. IE remains a serious condition with high mortality. It is difficult to diagnose and treat. This supports the recommendation that all patients with suspected IE are referred for specialist care.

Further reading:

- Hitzeroth J, Beckett N, Ntuli P. An approach to a patient with infective endocarditis. S Afr Med J. 2016;106(2):145–150. DOI:10.7196/SAMJ.2016.v106i2.10327
- Cahill TJ, Prendergast BD. Infective endocarditis. Lancet. 2015;387(10021):882–893. DOI: http://dx.doi.org/10.1016/S0140-6736(15)00067-7

Question 2

Important background information (not part of the model answer)

The family physician is expected to be a leader of clinical governance within the district health services. He or she must also help to strengthen the services through leadership in all of his or her other roles as a clinician, consultant, capacity builder, clinical trainer and champion of community-orientated primary care. The new learning outcomes for leadership, clinical and corporate governance were published recently.

Patient safety has been at the forefront of many international and local discussions ever since the Institute of Medicine published the guideline, *To err is human: building a safer healthcare system,* which focused on medical errors in health care, estimated to account for one million adverse events in the workplace in the USA. The National Department of Health in South Africa recognised that patient safety incidents have severe repercussions, and developed a policy in 2015 to help healthcare workers to investigate patient safety incidents in the workplace. The incident described in the question will be investigated using the framework described according to this policy.

Model answer

2.1 What type of patient safety incident does this constitute? Justify your answer (2 marks).

This constitutes a near-miss event (1 mark). This was an incident which did not affect the patient directly due to the failed lumbar puncture. However, institution of definitive care was delayed because of the incorrect initial diagnosis (1 mark).

2.2 What is the severity assessment code (SAC) for this incident? Justify your answer (4 marks).

This was a SAC 2 event (moderate harm) (2 marks) because the near miss could have resulted in an adverse incident, such as brainstem herniation (2 marks).

2.3 How would you describe the category of the incident? Provide a brief motivation for your answer (4 marks).

This was a problem with the clinical process (1 mark), as follows:

- The wrong procedure, process and treatment was offered to the patient (1 mark)
- A lumbar puncture was contraindicated because of the depressed level of consciousness and focal neurology in the patient (1 mark).
- The patient was not afforded reasonable quality of care (1 mark)

2.4 Provide a framework for the root cause analysis in this patient (4 marks).

The framework for the root cause analysis in this patient included the following:

- *Staff:* The clinical assessment, clinical reasoning and technical skills were poor. The staff failed to communicate appropriately. Junior staff members were not appropriately supervised (2 marks).
- *Patient:* The patient failed to report for treatment timeously (1 mark).
- *Service:* Protocol should have been in place to manage patients with a depressed level of consciousness (1 mark).

2.5 What recommendations would you make to the patient safety committee at the hospital? (4 marks)

Recommendations are as follows:

- It should be ensured that all patients are triaged (1 mark).
- There should be supervision of the junior doctors, especially when they are dealing with critically ill patients (1 mark).
- Clear guidelines are needed with regard to managing patients with a depressed level of consciousness. When unsure of the correct management approach, seniors, such as specialists, should be consulted early on (1 mark).
- Patients and communities should be educated on danger signs that indicate that urgent healthcare intervention is required (1 mark).

2.6 Describe the behaviour identified in this case study according to the Just Culture approach (2 marks).

This type of behaviour is considered to be "at-risk behaviour" (1 mark). Additional coaching is required to prevent such an incident from occurring again (1 mark).

Further reading:

- Mash R, Blitz J, Malan Z, Von Pressentin K. Leadership and governance: learning outcomes and competencies required of the family physician in the district health system. S Afr Fam Pract. 2016. DOI: 10.1080/20786190.2016.1148338. Available from: http://dx.doi.org/10.1080/20786190.2016.1148338

- Kohn LT, Corrigan JM, Donaldson MS. To err is human: building a safer health system. Washington DC: National Academies Press, 2000.
- Leape LL, Berwick DM. Five years after "To Err Is Human": what have we learned? JAMA. 2005;293(19):2384–2390.
- National Department of Health, South Africa. Final draft national policy to manage patient safety incidents in South Africa. Ideal Clinic Monitoring System [homepage on the Internet]. c2016. Available from: https://www.idealclinic.org.za/docs/Final%20Draft%20National%20Policy%20to%20manage%20Patient%20Safety%20Incidents%20in%20South%20Africa%2018%20Dec%202015.pdf
- Bowie P, De Wet C, editors. Safety and improvement in primary care: the essential guide. Radcliffe Publishing, 2014.

Question 3

3.1 What is the essential difference between random sampling and randomisation? (2 marks)

The intention of random sampling is to obtain a representative group of a larger population (1 mark).

Randomisation balances known and unknown confounding variables, and its use reduces the likelihood of systematic differences between the intervention and control groups (1 mark).

3.2 What were the disadvantages of using a combined primary end-point in this randomised controlled trial? (2 marks)

It was used to minimise the sample size and is considered to be controversial. The disadvantage is that this way of reducing the sample size may lead to a lower power to detect true differences and false negative results, i.e. a beta error. This controversy is a disadvantage in itself (1 mark).

It also includes outcomes of markedly different clinical severity, e.g. arterial revascularisation versus mortality (1 mark).

3.3 Using the composite end-point, how would you express the efficacy of rosuvastatin as primary prevention? (8 marks)

Four measures of association are generally used to express efficacy. The primary end-point was 0.77 per 100 person-years in the rosuvastatin group, and 1.36 per 100 person-years in the placebo group. These incidence densities are also expressions of risk. Therefore, they may be used to calculate the parameters as indicated:

- *Relative risk (RR)/hazard ratio:* RR/hazard ratio for rosuvastatin (see abstract): 0.77% divided by 1.36% = 56% (2 marks).
- *Absolute risk reduction (ARR):* ARR = 1.36% − 0.77% = 0.59% (2 marks).
- *Relative risk reduction (RRR):* RRR = 1 − RR = 100% − 56% = 44%. The RRR always remains more impressive than the ARR (2 marks).
- *Number needed to treat (NNT):* NNT = 1/ARR = 1/0.59% = 169, meaning that 169 patients need to be treated with rosuvastatin for 1.9 years for one patient to develop the primary outcome of interest. This is not as impressive as the scenario presented using the RRR. The NNT gives us an indication of the cost implications and the duration of treatment. Caution should be exercised with regard to only using the RRR as it usually appears favourable, and is often used to misguide the casual reader (2 marks).

3.4 This trial was terminated after a median follow-up of 1.9 years, as opposed to at the planned 5.0 years. Comment on why, and by whom, randomised controlled trials may be terminated early (4 marks)

The independent function of the Data Safety Monitoring Board (DSMB) of a randomised controlled trial is to provide interim analysis, and to report early on if there are benefits in a particular group that would make it unethical to continue with the trial (1 mark).

In doing so, it ensures the safety of participants, ensures that the study is conducted according to plan, and that action on any interim analysis is taken where indicated (1 mark).

Interim analysis is undertaken every 3–6 months to ensure the safety of the study participants and to review progress (1 mark).

For example, according to the O'Brien-Fleming rule, a p-value of ≤ 0.010 is required to stop a study, and is used to terminate the placebo arm (1 mark).

Background information (not part of the answer)

The early termination of a randomised controlled trial represents an important issue. This may lead to an ongoing cycle of small trials which are underpowered with large treatment effects. When these trials are included in systematic reviews, further challenges are created as, in turn, these systematic reviews are used to calculate the sample size for new trials. Read the South African good clinical practice guidelines for more information on randomised controlled trials and DSMBs.

3.5 What is meant by the term "hazard ratio"? (2 marks)

The hazard ratio refers to the average relative risk in a survival analysis weighted for the proportion of patients surviving at each time point, e.g. the hazard ratio will be < 1 if the treatment is beneficial (1 mark).

It is one of three ways to depict a survival event. (Others, for example, are Kaplan-Meier statistics and frequency rates) (1 mark).

3.6 Provide an interpretation of the 95% CI: 0.46–0.69, and the *p*-value of ≤ 0.00001 (2 marks).

There is a 95% probability that the true population value of the hazard ratio for rosuvastatin lies between 0.46 (lower limit) and 0.69 (upper limit) of 95% CI (1 mark).

The *p*-value of < 0.00001 is less than 0.050 or 0.010, and thus indicates that there is a statistically significant difference between the rosuvastatin and the placebo groups (1 mark).

3.7 What are the advantages of using 95% CI over the *p*-value? (2 marks)

A 95% CI in estimation is generally more informative than a *p*-value in that it:

- Provides an estimate of the values that may include the real value (1/2 mark)
- Can assist in estimating the sample size (a wider CI means a small sample size, and a narrower CI means a larger sample size (1/2 mark).
- Gives an impression of the clinical significance of an effect, and thus assists with decision-making (1/2 mark).
- The first three points cannot be derived from the *p*-value (1/2 mark).

3.8 The results were analysed by intention to treat (ITT) in this study. What is the benefit of ITT analysis? (4 marks)

It preserves the effects of randomisation (1 mark).

If loss to follow-up occurs, the sample is not similar at the end of the study with regard to confounding factors, and this is a problem (1 mark).

Thus, ITT analysis deals with loss to follow-up (attrition bias) in that participants are analysed in the groups to which they were originally allocated, even if they deviated from the study protocol, i.e. dropped out of the study or changed groups (1 mark).

ITT analysis prevents bias that would arise from excluding the protocol deviants whose prognosis in the study may well have been worse than that of those who adhered to the protocol (1 mark).

3.9 What are the main components of evidence-based decision-making, and how would you use it in your decision-making with respect to rosuvastatin use as primary prevention in your practice setting? (10 marks)

The main components of evidence-based decision-making are as follows:

- *The quality of the appraised clinical research evidence:* The component of evidence refers to whether or not there is sound, valid and current available research evidence to support what is being offered to the patient in the form of this therapeutic intervention for primary prevention (2 marks).
- *The available resources and cost-effectiveness of rosuvastatin in your practice setting:* Resources are dependent on whether the practice is in a developed or developing country, private sector or public sector, or is a tertiary hospital or primary care community health centre. It needs to be determined whether or not the therapeutic intervention (in this case rosuvastatin) can be afforded by patient or the practice, as cost is always an important consideration. Rosuvastatin is very expensive and not readily available to all patients, and even less so as primary prevention (2 marks).
- *Patient preference:* The component of patient preference deals with the unique ideas, expectations and concerns that the patient brings to the consultation, and needs to be factored into the decision-making process if the patient is to be served by them. The side-effect profile of the drug is important to note and cannot be ignored. Therefore, it is important to consider the harm to benefit ratio of rosuvastatin (2 marks).
- *Context:* This component pertains to where the practice is located, e.g. the private and public sectors in South Africa. Resource availability is often remarkably different in these settings (2 marks).

An attempt should be made to integrate these components, as emphasising one over the other detracts from the overall quality of the decision-making process. So evidence-based decision-making involves the application of the best evidence to practise. This means that patient values and circumstances must be taken into account when making clinical decisions in practice, and that care needs to be individualised to the patient (2 marks).

Further reading:

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