

PISA Style Scientific Literacy Question

Statins

Read the text about Statins

Statins are drugs which stop the liver producing too much cholesterol. Doctors say that many heart attacks and strokes are prevented each year by the use of statins.

Currently, statins are given to people who have had a heart attack, and to people who have not had a heart attack but have a greater than 20% risk of having one. There are approximately 7 million adults in the UK taking statins.

NICE, the body that licenses drugs in the UK, recently changed its guidance to doctors. The new guidance says that statins should now be given to people who have a 10% chance of having a heart attack. Millions more people in the UK will be prescribed statins because of this.

Many people, including some doctors, are worried about the side effects of statins. Common side effects which have been reported can include headaches, insomnia and upset stomach. Rarer, but more serious side effects can include inflammation of the liver, kidney failure and increased risk of diabetes. Some people also report severe muscle pains.



Several studies have been undertaken into the side effects of statins. A study published by Imperial College London in March 2014 suggested that statins do not have any significant side effects, and that there was no difference between the number of side effects reported by people actually taking the drug and people taking the placebo during the trials.

However, the media often reports on problems associated with statins, and up to half of people who are prescribed statins stop taking them within a year.

QUESTION 1 : STATINS

Some people taking part in a drug trial are given a placebo.

What is a placebo ?

What is the purpose of a placebo ?

QUESTION 2 : STATINS

A drug company wants to carry out a trial to see if it's statin causes side effects. Which of the following is the best experimental design for this trial?

- A All the people in the trial are given the statin
- B All the people in the trial are given the statin except for one person
- C Only people who have reported side effects from using a statin before are given the drug
- D Half the people in the trial are randomly selected to receive the statin, and half are given a placebo

A trial looking at the side effects of statins involving 100 people is carried out.

The percentage of people in the trial reporting side effects is as follows.

| | Percentage of people who reported side effects. |
|--|--|
| People who were given the statin | 29% |
| People who were given the placebo | 27% |

QUESTION 3 : STATINS

Which statement best describes the results of this experiment?

- A The statin causes side effects
- B The statin does not cause side effects
- C A similar number of people reported side effects when taking the placebo as taking the statin
- D Everyone who takes statins experiences side effects

QUESTION 4 : STATINS

What additional information about the side effects does the drug company need to know before it decides whether the drug is safe?

Rhian says that the statement 'Up to half of people who are prescribed statins stop taking them within a year' proves that statins must have side effects.

QUESTION 5 : STATINS

Give a reason why people might stop taking statins that would oppose Rhian's argument.

Read the text about cholesterol:

Cholesterol

Cholesterol is manufactured in the liver. It is carried around in the blood by chemicals called lipoproteins. There are two types of these lipoproteins – High Density Lipoproteins (HDL) and Low Density Lipoproteins (LDL). HDLs are commonly referred to as 'good' cholesterol because they carry cholesterol back to the liver and so prevent it from building up in the arteries and blocking them. HDL levels can be increased by eating a diet rich in polyunsaturated fats such as sunflower oil. LDLs are often called 'bad' cholesterol, because they carry cholesterol away from the liver to the cells. High levels of LDLs can lead to cholesterol building up on the walls of the blood vessels. Eating high levels of saturated fats such as butter can increase levels of LDLs in the blood. To keep your heart healthy you need a high proportion of HDLs compared to LDLs. Keeping these lipoproteins in the right proportions can help to reduce the overall level of cholesterol in your blood.

QUESTION 6 : STATINS

Why are high levels of LDLs in your blood bad for your health ?

QUESTION 7 : STATINS

Roger has been prescribed a statin to reduce his cholesterol. Every month his doctor monitors Roger's cholesterol level by testing a sample of his blood. After 6 months of taking the statin Roger's cholesterol level has not gone down.

Which of these statements is the most likely reason why Roger's cholesterol has not gone down ?

- A Roger experiences some mild side effects whilst taking the statin
- B Roger has continued to eat a diet that is high in saturated fats
- C Roger's doctor increased the dose of the statin he was prescribing
- D Roger forgot to take his statin tablets when he went away for a weekend

QUESTION 8 : STATINS

Statins can help to reduce the risk of heart attacks and strokes by lowering cholesterol.

Give another way that people can reduce their cholesterol levels apart from taking statins.

SCORING : STATINS

Question 1

Full credit :

A dummy pill / inert pill / a pill that does not contain the drug / a sugar pill / a fake treatment / a dummy treatment

Helps you to compare the effects of the real drug / that acts as a control in a drug trial / stops people being influenced by knowing whether they have been the real drug or not. (link the placebo containing no active ingredient to its use)

Partial credit :

A dummy pill / inert pill/ a pill that does not contain the drug / a sugar pill/ a fake treatment/ a dummy treatment (no reference made to its use)

Used to make a drug trial fair / used to compare effects in a drug trial / makes people think they have been given an actual drug / used as a control in a drug trial (without saying that it doesn't contain any drug / active ingredients).

No Credit :

Other responses

Missing

Narrative:

Placebos are used in drug trials as a 'control' to compare any possible effects (positive or negative) of the drug against. They are also a means by which the participants in the trial can be 'blind' as to whether they have been given the drug or not, therefore eliminating the possibility that the effects which are seen or reported have been influenced by the subconscious of the participant. (Related term – 'placebo effect' – a sense of benefit felt by a patient that arises solely from the knowledge that treatment has been given).

| Framework Categories | 2015 Framework |
|----------------------|---------------------------------------|
| Knowledge type | Knowledge of the content of science |
| Competency | Explain phenomena scientifically |
| Context | Health and disease – local / national |
| Cognitive demand | Low / medium |

Question 2

Full credit :

D Half the people in the trial are randomly selected to receive the statin and half are given a placebo.

No credit :

Other responses

Missing

Narrative:

A is incorrect because if all the participants in the trial are given the drug there is no control group to compare the effects of the drug with. Also, it may prevent the trial from being 'blind' as the participants could know they are all being given the drug. This may affect the results due to the 'placebo effect'.

B is incorrect because the control group is too small. It is not a large enough sample to compare the effects of the drug against. The control group would need to be much larger.

C is also incorrect. People who have previously experienced side effects with another type of statin may be more likely to experience side effects from this drug. This may not give a true picture of how likely the new statin is to cause side effects – it may look as though it causes more side effects than it actually would in the general population.

D is correct as this method will allow you to carry out a 'blind' trial, where participants do not know whether they have been given the drug or a placebo. It also allows you to compare the effects of the drug with a similar number of people who did not receive the drug.

| Framework Categories | 2015 Framework |
|-----------------------------|--|
| Knowledge type | Procedural |
| Competency | Evaluate and design scientific enquiry |
| Context | Health and disease – local / national |
| Cognitive demand | Medium |

Question 3

Full credit :

C A similar number of people reported side effects when taking the placebo as taking the statin

No credit :

Other responses

Missing

Narrative :

A is incorrect. The table shows that a number of people did report side effects, but as this number is similar to the number who reported side effects that did not take the drug (had the placebo) you cannot say that the side effects were caused by the drug.

B is incorrect for a similar reason to A. A similar number of people reported side effects whilst taking the placebo. Also, 29% of people did report side effects so you cannot say that it does not cause side effects.

C is the correct statement. This is the only conclusion from the options given that you can come to using the information from the table. The two percentages are very close together (only 2% apart).

D This statement is incorrect as it does not correspond to the information given in the table. The information says that 29% of people reported side effects. For this statement to be true the figure would need to be 100% or very close to it.

| Framework Categories | 2015 Framework |
|-----------------------------|--|
| Knowledge type | Epistemic |
| Competency | Interpret data and evidence scientifically |
| Context | Health and disease – local / national |
| Cognitive demand | Medium |

Question 4

Full credit :

The severity of the side effects / what types of side effects / how bad the side effects are /if the side effects will make people really ill / if the side effects will make people die

No credit :

Other responses

Missing

Narrative :

The drug company doesn't just need to know how many people are experiencing side effects; it also needs to know the nature of those side effects and how severe they are. A small number of people experiencing severe or life threatening side effects may be more of a concern than a large number of people experiencing only mild side effects.

| Framework Categories | 2015 Framework |
|-----------------------------|--|
| Knowledge type | Procedural |
| Competency | Interpret data and evidence scientifically |
| Context | Health and disease – local / national |
| Cognitive demand | Medium |

Question 5

Full credit :

People don't think they need the statin because they don't actually feel ill

People have heard scare stories about the side effects of statins in the media

People are worried about the side effects even if they aren't actually experiencing them

People are worried about the effect on their body in the long term / if they use them for a long time

People think its ok to stop taking them when their cholesterol goes down

People find it hard to remember / can't be bothered to take the statin pill every day so they stop taking them

Partial credit :

If they don't need them anymore (without giving a further explanation)

If they can't afford them (this might apply in England where many people pay for prescriptions).

No credit :

Other responses

Missing

Narrative:

The fact that a high proportion of people who start taking statins stop within a year does not prove that they cause side effects. For proof that this was the case we would need to know how many people had stopped taking the drug *because* of the side effects. There may be a variety of other reasons why people don't continue to take their statins – they may be scared off from taking it because of stories about side effects reported in the media, people may find it difficult to stick to the routine / regime of taking their statins each day, people may think they no longer need the statin once their cholesterol has gone down because their risk of heart attack / stroke has been reduced, and people who feel well may not take their medicine because they don't think they actually need it. People may weigh up the benefits and risks and decide that the benefits in terms of reduced risk of heart attack / stroke are not outweighed by the risk of experiencing side effects in the long term.

| Framework Categories | 2015 Framework |
|-----------------------------|--|
| Knowledge type | Epistemic |
| Competency | Interpret data and evidence scientifically |
| Context | Health and disease – local / national |
| Cognitive demand | High |

Question 6

Full credit :

They can lead to blocked arteries

Lead to increased amounts of cholesterol in the blood

They can increase blood pressure (as a result of blocked arteries)

They cause heart disease (by blocking the arteries)

Increase the persons chance / risk of a heart attack or stroke

Partial credit :

LDL's are 'bad' cholesterol

No credit :

Other responses

Missing

Narrative:

A higher proportion of LDLs leads to increased levels of cholesterol in a person's blood. The cholesterol can build up on the walls of the blood vessels, which causes narrowing of these vessels or even blockages. Narrowing of blood vessels causes high blood pressure, which can damage organs such as the eyes and kidneys. High blood pressure and narrowing of the arteries means that the heart has to work harder to pump blood around the body – this can lead to heart disease. Blockages in arteries supplying the heart can lead to heart attacks, blockages in arteries in the brain can lead to strokes. Both of these events can have serious complications for the person and can be fatal.

| Framework Categories | 2015 Framework |
|-----------------------------|-------------------------------------|
| Knowledge type | Knowledge of the content of science |
| Competency | Explain phenomena scientifically |
| Context | Health and disease – personal |
| Cognitive demand | Low / medium |

Question 7

Full credit :

B Roger has continued to eat a diet that is high in saturated fats

No credit :

Other responses

Missing

Narrative :

A is incorrect. The incidence of side effects does not necessarily mean that the drug is not working properly. People can experience side effects but the drug will continue to work effectively. Side effects would only prevent an improvement in symptoms if the person chose to stop taking the drugs because of them.

B is correct. Statins work by lowering the amount of cholesterol produced by the liver. If a person continues to consume a diet that is high in saturated fat the LDL levels would remain high in proportion to the HDL levels (assuming that he was not also consuming large amounts of polyunsaturated fats as well). The statin will not be able to produce the effect of lowering cholesterol if the diet is continuing to add large amounts of saturated fat to the body – the effect of the statin would be negated by the high fat diet.

C is not correct. If the doctor increased the dose of the statin we would expect to see a greater reduction in the level of cholesterol in the blood.

D is incorrect. Forgetting to take the statin for 2 or 3 days in a 6 month period is unlikely to have a significant impact on the cholesterol levels overall as long as Roger resumed taking the statin on his return. The question says that his blood was tested each month. If there were to be any effect from not taking the statin for those two or 3 days it is likely to have only shown up in that month's blood test, not caused an effect at the end of the monitoring period.

| Framework Categories | 2015 Framework |
|-----------------------------|-------------------------------------|
| Knowledge type | Knowledge of the content of science |
| Competency | Explain phenomena scientifically |
| Context | Health and disease – personal |
| Cognitive demand | Low / medium |

Question 8

Full credit :

- Eating a diet low in saturated fat
- Eating a diet higher in polyunsaturated fats
- Eating foods which contain plant sterols / plant stanols
- Eating a high fibre diet
- Taking regular exercise that raises the heart rate
- Eating a diet high in omega 3 fatty acids

Partial credit :

- Eating named types of cholesterol lowering margarines/ yoghurts etc (without saying that they contain plant sterols/plant stanols)
- Eating less red meat, cakes, pastries, butter, cream etc (without referring to saturated fat)
- Eating more oily fish (without referring to omega 3 oils)
- Using sunflower or olive oil (without referring to polyunsaturated fats)
- Eating less fat / eating a low fat diet (without referring to different types of fat)
- Stopping smoking
- Eating fruit and vegetables / wholegrains (without referring to fibre)

No credit :

Other responses

Missing

Narrative :

People should not rely on statins only to reduce cholesterol. Doctors will want to prescribe the lowest possible dose of statin to reduce the risk of side effects. People can also make lifestyle changes to reduce their cholesterol so that they do not need a statin, or they do not need such a high dose. Eating a diet low in saturated fat, and high in mono or polyunsaturated fats will help to keep a healthy proportion of HDL to LDL. Exercise, and stopping smoking can also help to lower cholesterol. Chemicals known as plant sterols / plant stanols are known to have a cholesterol lowering effect, and there are a wide variety of foods on the market such as yoghurts and spreads that people can eat to lower their cholesterol.

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| Framework Categories | 2015 Framework |
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| Knowledge type | Knowledge of the content of science |
| Competency | Explain phenomena scientifically |
| Context | Health and disease – personal |
| Cognitive demand | Low |