

Drug companies accused of holding back complete information on clinical trials

MPs voice concern after report into decision to stockpile Tamiflu finds discussions about effectiveness hampered by practice

Rajeev Syal, The Guardian, January 3rd 2014

1. Clinical test results are being routinely withheld from doctors, undermining their ability to make informed decisions about how to treat patients, an influential parliamentary committee has claimed. MPs have expressed "extreme concern" that drug manufacturers appear to only publish around 50% of completed trial results and warned that the practice has "ramifications for the whole of medicine".

2. Their conclusions have emerged in a public accounts committee report, which examined the Department of Health's decision to spend £424m on stockpiling the flu drug Tamiflu, before writing off £74m because of poor record keeping. The MPs found that experts failed to agree on how well Tamiflu works, but discussions were hampered because important information was held back.

3. Richard Bacon, a senior member of the committee, said the practice of holding back results was undermining the ability of doctors, researchers and patients to make informed decisions about treatments. "Regulators and the industry have made proposals to open up access, but these do not cover the issue of access to the results of trials in the past which bear on the efficacy and safety of medicines in use today," he said. "Research suggests that the probability of completed trials being published is roughly 50%. And trials that gave a favourable verdict are about twice as likely to be published as trials giving unfavourable results.

4 "This is of extreme concern to this committee. The department [of health] and Medicines and Healthcare products Regulatory Agency [MHRA] must make sure, prospectively and retrospectively, that clinical trials are registered and the full methods and results of all trials are available for independent wider scrutiny by doctors and researchers."

5 The committee noted that an NHS review in 2010 estimated that the chance of completed trials being published is roughly half. Trials with positive results were about twice as likely to be published as trials with negative results.

Dr Fiona Godlee, editor-in-chief of the British Medical Journal, told the MPs that the pharmaceutical industry published more positive results than negative ones from their trials. She noted that the journal had published very clear summaries of systematic reviews of data on individual medicines or classes of medicines where, "when you add together the published and unpublished evidence, you get a very different picture of the quality and effectiveness of those drugs".

6 A review by the non-profit Cochrane Collaboration into 20 existing studies into Tamiflu found it "did not reduce influenza-related lower respiratory tract complications" but did induce nausea.

7 It is now receiving full clinical study reports from manufacturer Roche, which are being used to complete a further review of the effectiveness of Tamiflu. The results of that study should be used by government [...] to review the drug's use, MPs said.

8 They also called on ministers to take action so that full trial results are available to doctors and researchers for all treatments currently being prescribed and carry out regular audits of how much information is being made available.

9 Bacon added: "There is still a lack of consensus over how well the antiviral medicine Tamiflu, stockpiled for use in an influenza pandemic, actually works. The lack of transparency of clinical trial information on this drug to the wider research community is preventing proper discussion of this issue among professionals. We are disturbed by claims that regulators do not have access to all the available information.

10. "The case for stockpiling antiviral medicines at the current level is based on judgment rather than on evidence of their effectiveness during an influenza pandemic. Before spending money in future to maintain the stockpile, the department needs to review what level of coverage is appropriate. It should look at the level of stockpiling in other countries, bearing in mind that the patent for the medicine runs out in 2016."

11. An MHRA spokesman said the body would work with partners in the UK and in the EU to ensure greater transparency in the dissemination of clinical trials information.

PART 1 COMPREHENSION

A. Find in the text words or expressions that match the words below (verbs and other words may not be in the same form as in the text):

1	restrain (title):	hold back	2	test (title):	trial
3	express (title):	to voice	4	efficacy (title):	effectiveness
5	hinder (title):	to hamper	6	hold back \$1:	to withhold
7	weaken: \$1	undermine	8	entire: \$1	whole
9	accumulate: \$2	stockpile	10	efficiency: \$3	efficacy
11	likelihood: \$3	probability	12	examination: \$4	scrutiny
13	approximately: \$5	roughly	14	an additional: \$7	a further
15	to request: \$8	to call on	16	to perform: \$8	to carry out
17	an absence: \$9	a lack	18	really: \$9	ACTUALLY
19	proof: \$10	EVIDENCE	20	expire: \$10	run out

B. Useful vocabulary linked to 'disease'

to be ill (with)	<i>être malade de</i>	contagious / catching	<i>contagieux</i>
to *catch a disease	<i>attraper une maladie</i>	lethal / deadly	<i>mortel</i>
to be stricken with a disease	<i>être frappé d'une maladie</i>	to *fall ill / to be *taken ill	<i>tomber malade</i>
to be bedridden	<i>être cloué au lit</i>	to worsen	<i>s'aggraver</i>
to be down with	<i>être au lit avec</i>	hazardous	<i>dangereux</i>
benign	<i>bénin</i>	harmful	<i>nocif</i>
malignant	<i>malin</i>	harmless	<i>inoffensif</i>

C. common diseases

bronchitis	<i>la bronchite</i>	chickenpox	<i>la varicelle</i>
hepatitis	<i>l'hépatite</i>	smallpox	<i>la variole</i>
rabies	<i>la rage</i>	the mumps	<i>les oreillons</i>
the measles	<i>la rougeole</i>	German measles	<i>la rubéole</i>
tuberculosis (TB)	<i>la tuberculose</i>	the flu (influenza)	<i>la grippe</i>
cholera	<i>le choléra</i>	scarlet fever	<i>la scarlatine</i>
tetanus	<i>le tétanos</i>	diphtheria	<i>la diphtérie</i>

D. Questions on the text:

1. What does an MP stand for? A _____ of _____
2. What about MPs? _____ of _____
3. Why do you think drug manufacturers publish only 50% of their test results?
4. Why do you think drug companies do not want to open up access to the results of tests made in the past? What do you think they fear?

5. Is a drug company just a money-making business?
6. Translate into French paragraph 9

E. Useful vocabulary for medicine and health:

Complete the following text with words from the box

transplants - heavy smokers - National Health Service - collapses - cardiac - treatment
policy - emergency - patient - medical - bypass - addicts - surgery - consultants - interim

Wythenshawe Hospital in Manchester maintains a ¹ **policy** of refusing to carry out heart ² **bypass** operations on smokers. It is important to be clear about the views of the hospital ³ **consultants**. They are happy to treat any smoker who ⁴ **collapses** and needs

⁵ **emergency** treatment, but they draw the line at carrying out expensive, non-urgent, preventive ⁶ **cardiac** surgery on patients who refuse to stop smoking. There is a high risk of complications for ⁷ **heavy smokers** during and after heart ⁸ **surgery**, so many clinicians prefer to provide ⁹ **interim** medical treatment, while encouraging the ¹⁰ **patient** to give up smoking.

The death of a Manchester 25-cigarettes-a-day man, who died after being refused tests at Wythenshawe, has given rise to furious debate in ¹¹ **medical** circles. If this argument is taken further, drunken drivers could be denied emergency ¹² **treatment**, drug ¹³ **addicts** HIV treatment, and drinkers liver ¹⁴ **transplants**. In other words, should any individual who can be shown to have contributed to his own medical problems be refused help on the ¹⁵ **N.H.S.**?

F. Answer in conversation or in writing, as fully as you can:

1. What are your views on the ethical problems raised in the previous exercise?
2. Do we all have a right to free medical treatment, provided by the state, or should we make our own provisions for health care, using private health insurance?
3. What factors have the greatest influence on our health?

PART 2 GRAMMAR

Many verbs like **give, award, lend, promise** can have two objects. When putting these verbs into the passive, it is more usual to make the 'person object' rather than the 'thing object' the subject of the passive verb: **I was given back my change.** (**NOT** My change was given back to me)

G. Improve the following sentences by putting the 'person object' first. Some sentences may already be correct.

1. I was promised a review of my case in due course. **(correct)**
2. The news was told to the whole community. **The whole community was/were told the news.**
3. The survivors are being lent warm clothing. **(correct)**
4. She will be sent a free gift with her mail order catalogue. **(correct)**
5. A lucky mascot has been given to me, to use in my exams. **I have been given a lucky mascot ...**
6. A postgraduate diploma will be awarded to her as soon as she has completed her practical assignments. **She will be awarded a postgraduate diploma ...**
7. A chance to participate in the Olympic games is being refused him, on the grounds of his unreliability. **He is being refused a chance to participate ...**
8. However, he has been offered a place in the national team for the forthcoming international matches. **(correct)**
9. You will be shown your living quarters for the duration of your stay in the camp. **(correct)**
10. A bribe seems to have been offered to the officials in charge of the institution at the time. **The officials in charge of the institution at the time seem to have been offered a bribe.**

Passive constructions are often used with verbs like **say, believe, and know.**

It + passive + that-clause

- It is said that three people died in the accident.
- It was once believed that the earth was completely flat.

Subject + passive + to + infinitive

- Three people are said to have died in the accident.
- The earth was once believed to be completely flat.

Other verbs which can be used in this way include: **consider, think, understand, report, allege, expect, fear, claim** and **deny**. The verb **be rumoured** only exists in the passive form.

H. Complete the second sentence so that it means the same as the first one using the word in brackets. You must use between three and six words, including the word given (contractions count as two words)

1. It is expected that tax increases will be announced in tomorrow's budget statement. (to)
Tax increases **are expected to be announced** in tomorrow's budget statement.
2. We understand that inner-city crime rates are going up in most areas. (be)
Inner-city crime rates **are understood to be going up** in most areas.
3. They say the rock star's wife has had at least two facelifts. (have)
The rock star's wife **is said to have had** at least two facelifts.
4. We fear that nine crew members were lost overboard in the storm. (are)
Nine crew members **are feared to have been lost** overboard in the storm.
5. It was considered that Ralph's speech was one of the best. (to)
Ralph's speech **was considered (judged, thought) to have been (to be)** one of the best.
6. We can't deny having made mistakes in the early stages. (that)
It **cannot be denied (is true, is undeniable) that mistakes were** made in the early stages.
7. Police reported that a man had been helping them with their inquiries. (was)
A man **was reported to have been helping** police with their inquiries.
8. The accused was alleged to have committed fraud. (had)
It **was alleged that the accused had** committed fraud.

If **phrasal verbs or verbs with prepositions** become part of a passive sentence, they must not lose their particle.: *The child was extremely well looked after.*

I. Complete the sentences, if necessary, by choosing the correct particle from the box:

up	down	in	away	out	off
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1. What a mess! John's toys haven't been put **away**.
2. He wasn't here last night. His bed hasn't been slept **in**.
3. The situation is serious, but it will have to be faced, I'm afraid. **(correct)**
4. This the third time our meeting has been put **off**.
5. All cigarettes must be extinguished before you enter the building. **(correct)**
6. The girls were brought **up** on a farm before the Welsh border.
7. Cheques should be made **out** to Wellingtons plc.
8. I must warn you that if you have anything to say, it will be taken **down** and may be used in evidence against you.

Reminder: When comparing with **as .. as**, the adjective does not change even if it is preceded by a number. Numbered comparatives can include such words or phrases as: *half, twice, three times, four times*, etc. The phrase *as much as* is used for non-countable nouns and *as many as* is used for countable nouns. The phrase *more than* is NOT used with numbered comparatives. **It is incorrect to say *four times more than*, etc.**

- This rock weighs twice as much as that one.
- Ronald has four times as much money as Paul.
- The cat had half as many kittens as before.
- Trials with positive results were about **twice as likely to be published as** trials with negative results.

J. Fill in the blank with the correct form of the adjectives and adverbs in parentheses. Supply any other words that may be necessary. Pay attention to the words *as* and *than* for guidance.

- 1. This bowl of soup is **hotter** (hot) than the last bowl.
- 2. She acts three times **as well** (well) as Sandra Bullock.
- 3. Jerry's pet is **more exotic** (exotic) than Sue's.
- 4. Your graduation gift is **better / less good** (good) than mine.
- 5. My job is twice **as serious** (serious) as yours.
- 6. He was **more determined** (determined) than Joe to win the race.
- 7. Charlie has grown **as tall** (tall) as his brother.
- 8. She was twice **as shocked** (shocked) as I after seeing the test results.
- 9. Johnny was **more truthful** (truthful) than before in telling his story.
- 10. I feel **worse / less bad** (bad) today than yesterday.
- 11. They earn ten times **as much** (much) money as their parents.
- 12. When she had puppies, the bitch ate four times **as** much as before.

K. Fill in the blank with the correct comparative word of *than*, *as*, or *from*.

1. A cat is much quicker **than** a mouse.
2. The dolphins swam twice as fast **as** our boat.
3. Jennifer was much more certain of the answer **than** Julie.
4. My twin cousin is indistinguishable **from** the other.
5. Unmanned rockets can now travel much further **than** the moon.
6. John's speech was much different **from** mine.
7. The ball game continued much longer **than** expected.
8. Our cheerleaders were three times as good **as** theirs.
9. Nathan was stronger **than** Michael, so he won the match.
10. I think crumpets are much tastier **than** crepes.