

Guidance for researchers on media coverage of ongoing research involving patients

1. Aim of guidance

This guidance aims to help researchers, communications teams and research support staff to make use of positive opportunities for media coverage of ongoing research without breaching regulations, jeopardising the study or the reputations of those involved.

Even apparently positive media coverage can have a negative impact. If media coverage is not dealt with carefully, it can jeopardise a study by being unethical, break patient confidentiality or expose researchers and the organisation to complaints.

Researchers are reminded in particular about the issue of Research Ethics approval. Researchers who fail to seek approval from the research ethics committee when it should have been sought could be jeopardising their own work – publication without approval could ultimately lead to the sponsor withdrawing sponsorship and then the trial would have to stop.

2. Issues researchers need to consider

Researchers are advised to consider the following:

- **Does the proposed coverage require Research Ethics approval?** Could the coverage effectively be seen as an advertisement for more volunteers? This may especially be so if a 'case study' is included. This difficult area is best discussed with advisers. See section 3 for more discussion.
- **What are the local requirements for patient consent and confidentiality?** Research participants and patients are often very happy to talk to the media, especially if they have had a positive experience. However, the NHS Trust may require that the patient signs a standard media consent form and may insist that the interview is organised through the communications unit.
- **Does the funder of the study require approval of any media coverage even while it is ongoing?**
- **Does the researcher have a contract with the NHS?** NHS trusts usually require staff to only have contact with the media via the Communications Department.

3. When is ethics approval needed?

All information directed at patients including adverts will need to have been approved by the Research Ethics Committee before a study starts. Media coverage even after a study starts is effectively information that can be seen by patients. Does that mean researchers should seek ethics approval?

There is limited guidance from the National Research Ethics Service (NRES) specifically about the approval of media articles. However, even if the suggestion for media coverage comes after a study has started, the proposed article may need to be submitted as an amendment. Approval of the amendment should be in place prior to use of the article. Bear in mind Research Ethics Committees take approximately 30 days to approve an amendment and this may be problematic with media deadlines.

We recommend a common sense approach. If researchers have any queries, they are advised to discuss these with the approving committee. Researchers are advised that, whether or not ethics approval is sought, they should do everything they can to ensure that any media coverage would be approved ethically. Researchers should be careful that the use of case studies or quotations does not raise false hope, coerce or mislead.

In particular the positive experience of one patient should be handled with extreme care.

Two useful examples

The Daily Mail article on a trial [combining botulism](#) treatment for stroke patients with physiotherapy is a good example of coverage that was submitted for research ethics approval. In this case approval was sought and gained. In this instance, care was taken to stress the ongoing nature of the trial and the fact that it was not known what treatment the patient had had.

The BBC online article about a study looking at the use of artificial hibernation to treat strokes is a good example of positive coverage that manages to create interest without using a case study. An article like this that makes no claims for positive results and only covers the science, ideas and clinical need behind it, may well not require ethics approval.

4. Who to tell about media coverage

Before approaching the media or responding to media enquiries, researchers are advised to contact:

- research support staff overseeing sponsorship of the study
- the NHS trust's communications department – if patients are to be interviewed or featured
- the funder of the research.

The Joint Research Office and UCL communications department can also offer advice.

If there is likely to be negative media coverage, researchers should contact the relevant communications department as soon as possible.

5. Tips on dealing with the media about an ongoing trial

Although researchers cannot control what is published by the media, they can influence it:

- Make sure a journalist understands why care needs to be taken – they may well not realise that coverage of an ongoing trial could break research ethics and actually jeopardise its continuation.
- Explain that you will provide information if the proposed article stresses the trial is ongoing.
- When supplying quotes or copy:
 - avoid making preliminary claims as to positive results or efficacy, and avoid phrases that could, if taken out of context, imply positive results
 - if a 'case study' is to be included, insist that, while one patient may experience benefits, another may not
 - stress that full results will have to be analysed to assess the efficacy and safety of a treatment.

6. Making a story more exciting

It is possible to be positive and interesting without claiming efficacy or results:

- Refer to previous studies. For example 'Results from a preliminary study were promising so we have set up this trial....' or 'Previous studies in mice found that so this trial is looking to see'.
- Express your excitement at taking the next step.
- Talk about the clinical need for this research.
- Mention what is unusual about the research – for instance, 'no other research has looked at' (but you must be certain of this) or aspects such as the size of the trial.
- Highlight quirky ideas behind the research that ordinary people can latch on to. For instance the use of 'hibernation' in stroke research in the attached example.
- Talk about the previous breakthroughs in the science that lie behind the research.

7. Useful numbers

- Joint Research Office communications 020 7679 6166
- UCL press office 020 7679 9041
- UCLH press office 020 3447 9897

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Mel could hardly use her hand after a stroke at just 15, but Botox jabs are unlocking her muscles

By CAROL DAVIS

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Mel Strzebrakowska was just 15 and celebrating her father's birthday at home when she suffered her stroke.

She remembers nothing about that day apart from waking up in intensive care.

'I tried to scramble out of bed, but my legs collapsed, and my right hand wouldn't work either,' says Mel, now 24, a retail assistant from Warlingham in Surrey.



On suffering a stroke at 15: 'I couldn't take it in. I was so young. I couldn't believe it had happened to me,' said Mel Strzebrakowska

'I didn't know what was wrong. Then the doctors told me I'd had a stroke.'

'I couldn't take it in. I was so young. I couldn't believe it had happened to me.'

Every year around 150,000 Britons suffer a stroke, where either a blockage in the blood supply deprives the brain of oxygen, or a bleed in the brain causes damage to nerve cells and function.

Risk factors include high blood pressure, diabetes and heart disease.

In Mel's case the cause was more unusual: her stroke was due to an arteriovenous malformation — an abnormal connection between an artery and a vein in the brain.

Although she'd already been diagnosed with this, unfortunately the malformation was so deep that surgery was too risky.

The stroke left Mel weak down the entire right side of her body.

She was unable to walk, and she also struggled to speak.

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When she left hospital three months later, on Christmas Eve, she still needed a wheelchair and faced months of physiotherapy and occupational therapy as she learned to walk and talk again.

The good news was that in October the following year, she was able to have radiotherapy to seal off and shrink the malformation in her brain.

Yet even then she was still suffering the lasting effects of the stroke: her right side remained weak and she couldn't open her hand, which was clenched into a fist.

So Mel had to learn to write with her left hand. Washing, opening a door, even holding on to a bannister or escalator rail were difficult with her right hand because her grip was so tight.



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Up to 30 per cent of stroke survivors suffer this muscle stiffness, known as post-stroke spasticity, which means they have abnormal tightness in some of their muscles.

While doctors don't fully understand why this happens, it is thought that the nerve pathways from the brain which control and normally reduce this muscle tightening have been damaged.

Drugs that relax the muscles can treat the disorder, but many have side-effects and around 40 per cent of patients cannot tolerate them.

With the help of speech and language therapy and rehabilitation therapy, Mel learned to walk and talk again.

She returned to school and university, then started a job in a supermarket.

The only lasting legacy was her clenched right fist.

So, four years after her stroke, Mel also started having injections of Botulinum toxin, or Botox, which are often used to treat post-stroke spasticity.

The poison blocks the release of acetylcholine — a neuro-transmitter that sends the signal from the brain telling muscles to contract.

'The problem with medication is that the drugs are usually taken orally, so they affect the whole body and brain and can thus cause drowsiness, while Botox targets the stiff muscles directly and does not have these systemic side-effects,' says Dr David Werring, a consultant neurologist and clinical senior lecturer at University College London (UCL).

The Botox treatment helped loosen Mel's right hand, but the effects lasted for only a few months before her fist would tighten again. She had to travel to London every three to six months for the injections.

'It was time consuming, but I tried not to get frustrated because I knew they were trying to help me,' she says.



The Botox treatment helped loosen Mel's right hand

Mel continued the Botox treatment for five years.

Then, in 2010 when she was 22, her doctors at UCL mentioned a new study they were doing, combining Botox with regular, targeted physiotherapy sessions.

It was hoped this would have a longer-term effect on tightened muscles in those with post-stroke spasticity.

Dr Werring, who is leading the study, says: 'We know that Botox has a temporary muscle-weakening effect of up to three months, and by combining it with physiotherapy we hope to create a window of opportunity so that the stroke survivor and their physiotherapist can work on those muscles and create a longer-lasting effect.'

The trial, funded by the Stroke Association, is giving participants with post-stroke stiffness in their hands injections of Botox or a placebo combined with physiotherapy to measure the effect on hand function.

Mel joined the trial, continuing to travel to London for injections every three to six months, and then having two-hour physiotherapy sessions every week.

She was also given lots of exercises to do at home, including muscle stretching and strengthening exercises.

She does not know at the moment if she has had the Botox or the placebo, but she suspects the former because gradually she has regained control of her right hand.

'I can wash much more easily, and as well as gripping things I can just let go,' she says.

'Opening doors and jars is so much easier, and I can even hold and release small things like money when I'm on the till at work.'

The doctors will not know the results of the trial for another 12 to 18 months, but Dr Werring says early reports from patients are encouraging.

'Some participants are already reporting real benefits — this is really exciting,' he says.

'Botox will not help all stroke survivors regain hand function, since many have muscle weakness which it cannot treat.'

'But in some stroke survivors with spasticity in their fingers or wrist, and some preserved muscle strength, this treatment is promising.'

'And unlike muscle relaxant medications, including drugs like baclofen or tizanidine, Botox is very safe because it just targets the site of the muscle problem, and is temporary.'

Dr Peter Coleman, deputy director of research for Stroke Association, says: 'We are very excited about this study.'

Dr Peter Coleman, deputy director of research for Stroke Association, says: 'We are very excited about this study.'

'We are always looking for new ways to help stroke survivors adapt to their life after a stroke and recover as much movement as possible.'

'If the treatment proves to be effective, it could help thousands of stroke survivors recover some movement in their arms and hands, enabling them to regain some of their independence and improve their quality of life.'

Mel agrees.

'The physio sessions make a load of difference,' she says.

'Without the treatment, my hand is stiff and I can't use it properly.'

'Now, at last, I can use my right hand again, and can wash and grip and release small objects.'

'And now that the right side of my body is much more flexible, at last I can enjoy going clubbing with friends.'

The UCL trial is recruiting patients with spasticity of the wrist or fingers for this study.

For more information, contact Luci Crook at l.crook@ucl.ac.uk or call 0203 448 8758.

More information at stroke.org.uk or call the helpline on 0303 3033 100.

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Scientist to put patients into 'hibernation' to treat strokes

By Eleanor Bradford
BBC Scotland Health Correspondent

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Scotland is to play a major role in a trial of artificial hibernation to treat strokes, it has been revealed.

Stroke patients from all over the UK will be offered a chance to take part in the Edinburgh University study.

The treatment involves cooling the body by two degrees to prevent further damage to the brain.

Cooling pads and cold intravenous fluids will be used to bring the body's temperature down from 36.8 degrees to between 34 and 35 degrees.

The technique is already used to reduce brain injury after cardiac arrests and birth injuries. It is hoped it will have the same effect in stroke victims.

'Substantial' effect

Dr Malcolm Macleod, head of experimental neuroscience at the University of Edinburgh, said: "People may have heard stories about people falling through the ice and making an amazing recovery because they've been cold at the time."

"There have been a number of small studies looking at whether cooling the body could improve outcome for stroke. It's not enough to tell us for sure if it works but it suggests there may be substantial beneficial effect."

It is not known exactly how cooling the body reduces injury to the brain.

One theory is that it reduces the amount of oxygen required by the brain, another is that it triggers a defence mechanism in the cells.

Small-scale trials suggest it is most effective when used within six hours of a stroke.

Scientists hope it will reduce the number of deaths and the number of people left disabled, and increase the number of people who make a complete recovery from one-in-13 to one-in-10.

"It looks like we'll be ready to go in September of this year, recruitment to the trial will run for about four years, so by 2016 or 2017 we'll have our answer," added Dr Macleod.

"What this trial is trying to test is whether this treatment will make a difference to everyday patients, suffering everyday strokes, in everyday hospitals."



The treatment involves cooling the body temperature to limit damage to the brain

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European results

The EuroHYP-1 study will involve 1,500 patients in 15 European centres. About 200 will be in the UK, up to 80 of whom will be in Scotland.

Scottish researchers will also be involved in collecting and analysing results from all over Europe.

Upon admission to hospital, patients will be asked if they want to take part in the trial or, if they are not able to give consent because of their stroke, it is possible under certain circumstances that relatives can agree on their behalf.

The study has been met with much excitement since there are few treatment options for strokes.

About 13,000 people in Scotland have a stroke every year. A third die, and another third are left with a significant disability.

Recruitment will begin in September or October and run until 2017. Results are expected in 2018.

The study will also be watched carefully by the European Space Agency.

It is interested in human hibernation as a means for long-haul interplanetary space travel.