

RCP should make an urgent statement against Health and Social Care Bill

We write as concerned Fellows of England's Royal College of Physicians (RCP), many of whom attended the Extraordinary General Meeting (EGM) on Feb 27, 2012, at which an overwhelming majority voted for the RCP to oppose the UK Government publicly on the Health and Social Care Bill.¹

RCP Council is currently surveying all Fellows, including those living abroad, and says that it hopes to announce the results on March 16. The experience of all other colleges opposing the Bill was that EGMs voting overwhelmingly against it were followed by similarly overwhelming votes against in the wider survey.

We are concerned, given the urgency of the situation, that the RCP must issue a definitive public statement on March 16 regarding support or opposition on the basis of this wider ballot. Given that debate on this Bill ends on March 19, we must have assurance that the results will be publicly released before then, otherwise all this effort will have been wasted, with significant reputational damage to our college.

Apart from supporting a survey of Fellows, those attending the EGM voted on four additional non-binding motions. The results were as follows:

The RCP (1) considers that the Health and Social Care Bill, if passed, will damage the NHS [National Health Service] and the health of the public in England (89% in favour); (2) should call publicly for complete withdrawal of the Health and Social Care Bill (79% in favour); (3) should seek an alliance with other willing Royal Colleges and NHS stakeholder organisations to call collectively for the withdrawal of the Health and Social Care Bill (81% in favour); and (4) should hold a joint press conference with the BMA [British

Medical Association] and other willing Royal Colleges and NHS stakeholder organisations to make a joint public statement calling for the Bill to be withdrawn (69% in favour).

However, on March 2, 2012, a senior officer of the RCP sent an email stating that "What we need to do is keep our links with government open" and distancing the RCP from what he called the "overtly political step of demanding withdrawal of the Bill". This does not reflect the voting at the EGM, which stressed that this is no time for the RCP to sit on the fence. Since the EGM, alarming stories have emerged that substantiate the concerns of those calling for withdrawal of the Bill.²

We call on our President and RCP Council to make clear and timely public statements reflecting the views and motions expressed at the EGM and the ongoing ballot before this dangerous Bill becomes law.

The signatories are: Mark Aitken, Ruth Akiyo, Chris Allen, Holger Alroggan, Heather Angus-Leppan, John Ashton, Anne Aukett, Alan Bailey, Guy Baily, Ian Barton, Sushen Bhattacharya, Carol Brayne, Gary Brook, Chris Burns-Cox, Richard Butterworth, Philip Buttery, Chris Carne, Charles Cayley, Krishna Chatterjee, Eddy Chua, David Cohen, Alasdair Coles, Francesca Crawley, Paul Cullinan, Andrew Cummin, George Davey-Smith, Mark Dayer, Patrick Deegan, Edward Dickinson, Shah Ebrahim, Martin Eccles, Noemi Eiser, Sarah Elkin, Pamela Ewan, Nick Finer, Helen Firth, Peter Fisher, Andrea Franks, Jonathan Fuld, Nagui Gendi, Julian Gillmore, Trisha Greenhalgh, Richard Greenhall, Chris Griffiths, Indi Gupta, Tayyab Haider, Roger Hayter, Andrew Herxheimer, Graham Hitman, Walter Holland, Philip Home, Nick Hopkinson, Brian Hurwitz, Steve Iliffe, Robin Illingworth, Philip Ind, Anthony Isaacs, Howard Jacobs, Dean Jenkins, Michael Joffe, Lesley Kay, Harry Keen, Kay-Tee Khaw, Helen Lachmann, Robin Lachmann, Sir Peter Lachmann, Aroon Lal, Dan Lee, Ravi Mahadeva, Alan Maryon-Davis, David Matthews, Raymond McAllister, Martin McKee, Dwight McLeod, John McSorley, Paul Meyer, Jenny Mindell, Siobahn Murphy, Shauaib Nasser, Michael Naughton, David Nicholl, Angus Nicoll, James O'Beirne, Sharon O'Brien, Eoin O'Brien, Kevin O'Kane, Kevin O'Shaughnessy, Amanda Ogilvy-Stuart, Jackie Pace, Philip Pearson, Charlotte Pratt, Neil Pride, Brian Quilty, Anisur Rahman, Salman Rawaf, Helen Reeves, Jim Ritter, James Robertson, Alfa Sa'adu, Peter Sandercock, John Scadding, Mathias Schmid, Alwyn Smith, Tom Solomon, Jeremy Stern,

Sarah Stewart-Brown, Sheldon Stone, Shahrad Taheri, Mike Thomas, Richard Thomson, Nigel Trudgill, Shanti Vijayaraghavan, Andy Wardlaw, Charles Warlow, Peter Whincup, Charles Wiles, Bob Will, Ian Williams, John Yates, John Yudkin, Bernard Yung. We declare that we have no conflicts of interest.

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- 1 The Lancet. The Royal College of Physicians of London roars. *Lancet* 2012; **379**: 778.
- 2 Rose D. NHS fairness tsar urged to quit by doctors over 'conflict of interest' following £799,000 payment for U.S. private health giant. *Daily Mail* March 4, 2012. <http://www.dailymail.co.uk/news/article-2109907/NHS-fairness-tsar-urged-quit-doctors-conflict-following-799-000-payment-U-S-private-health-giant.html#ixzz10Eu4oz7a> (accessed March 5, 2012).

Loss of life after evacuation: lessons learned from the Fukushima accident

This is a report of the tragic events that befell hospital inpatients and elderly people in the emergency evacuation after the Fukushima Daiichi Nuclear Power Plant accident on March 11, 2011.

Before the earthquake and tsunami that preceded the nuclear accident, there were eight hospitals and 17 nursing care facilities located within a 20 km radius of the Fukushima Daiichi Nuclear Power Plant. The estimated numbers of hospital inpatients and elderly people in nursing facilities at that time were about 1240 and 980, respectively. On March 11, the huge earthquake and tsunami severely damaged the number 1, 2, 3, and 4 reactors of the Fukushima Daiichi Nuclear Power Plant. The national government issued a State of Atomic Emergency in the evening of that day and evacuation was ordered for



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Figure: Evacuation continues late into the night

residents who lived within a 2 km radius of the plant. The evacuation area was expanded to a 10 km radius the following morning. After the first explosion of the number 1 reactor in the afternoon of March 12 (later discovered to be a hydrogen explosion), the government ordered evacuation from a 20 km radius around the damaged power plant.

Most residents rushed to leave by car or by buses chartered by the government, and evacuation of hospital inpatients had been arranged and was being put into action. However, the situation at the nuclear plant continued to deteriorate, and in the evening of March 13, it was estimated that 840 patients in hospitals or nursing care facilities remained within a 20 km radius of the plant. Later that evening, the government ordered emergency evacuation for all patients in the area. The dawn of March 14 therefore saw the beginning of a hurried transportation of these patients to a screening site in Minamisoma city, 26 km northwest of the plant. Medical personnel did not accompany the patients during transportation. Bed-ridden patients were laid down on the seats, wrapped in protective gowns. During transportation, some patients suffered

trauma by falling from the seats of the vehicles.

Evacuation continued late into the night (figure). As the situation at the damaged plant became more volatile, the evacuation became more rushed and patients were transported by police vehicles as well. The vehicles were packed full, not only with patients but also with residents who had missed the chance to evacuate on their own. Late at night on March 14, patients were required to leave the buses because admitting hospitals or facilities could not be found and the vehicles were required elsewhere. Eventually, the patients were temporarily housed at a meeting room of the Soso Health Care office in Minamisoma city, with no heaters or medical supplies. Many had to wait for more than 24 h before reaching admitting facilities.

27 patients with severe medical problems such as end-stage renal failure or stroke were transported more than 100 km to Iwaki city. At least 12 of them were confirmed dead at 0300 h on March 15, ten of whom seemed to have died in the vehicles during transportation. Later, it was reported that more than 50 patients died either during or soon after evacuation, probably owing

to hypothermia, dehydration, and deterioration of underlying medical problems.

In the Fukushima Daiichi Nuclear Power Plant accident, there were no deaths related to radiation or the explosion of the reactors. However, the evacuation of these patients was accompanied by loss of life. No medical support was provided during evacuation or at shelters, resulting in the deterioration of the physical condition of many patients. Difficulties in reallocating patients forced them to stay in the confined space of the transporting vehicles for long hours. However, no significant contamination was found in the patients evacuated from the 20 km zone despite the fact that 48 h had passed between the first explosion and their evacuation. These facts suggest the danger of unprepared evacuation and the effectiveness of indoor sheltering for protection from radioactive plumes.

The nuclear disaster plans in Japan recommend emergency evacuation of residents within an 8–10 km radius around nuclear power plants.¹ However, no specific plans for hospital inpatients or elderly people in nursing facilities have been established. By contrast with physical injuries caused by the collapse of buildings or the tsunami, radiation itself does not create any immediate threat to life. Rather, ill-prepared evacuation might increase the health risk of hospital inpatients or elderly people. In the case of nuclear disasters, therefore, evacuation of these vulnerable people should be carefully done with medical arrangements in place before transfer.

In preparation for nuclear disasters, detailed evacuation plans for these populations should be developed. Essentials that need consideration include distribution of hospitals and nursing facilities, number of patients in the area, available vehicles and accompanying medical personnel for transportation, evacuation routes, estimated time for evacuation,

available hospitals and facilities for evacuees, and location of monitoring posts for radiation levels.

Although the Great Eastern Japan Earthquake overwhelmed our disaster response system, the deaths that occurred during the evacuation after the Fukushima Daiichi Nuclear Power Plant accident were preventable. Learning from these experiences in Fukushima, we should be better prepared for future nuclear crises.

This is a report from the radiation emergency team of Hiroshima University. We were involved in the initial medical activities after the Fukushima Nuclear Power Plant accident. We thank Naoko Takeoka and Natsuko Kimoto for their assistance in emergency care, and the radiology technicians of the National Institute of Radiological Sciences for assisting with the radiological survey for the evacuated patients at the Soso Health Care office.

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1 Nuclear Safety Commission. Emergency plan for nuclear disaster. Tokyo: Japanese Government, 1980.

Cardiac stem cells in patients with ischaemic cardiomyopathy

The paper by Roberto Bolli and colleagues (Nov 26, p 1847)¹ on cardiac progenitor cell treatment for ischaemic heart failure is a milestone in the history of cardiac cell therapy. However, we noticed some points that possibly interfere with interpretation of the results.

First, the trial is still ongoing, so why did Bolli and colleagues publish partial results at this time? Why not wait until the trial was completed?

Second, 13 analysed patients were from the non-randomised stage of the trial—only ten had undergone random allocation. Moreover, the ratio of treated to control patients (24:32) was reversed (7:3) by the analysis stage, mainly because of patients'

withdrawal. Why did so many control patients lose interest in the study?

We are cautious because of our own experience. When one of us (CS) started a cell therapy programme using CD133+ cells delivered during coronary artery bypass graft (CABG) surgery, a striking improvement in heart function was noted in the initial pilot trial.² A partly randomised, open-label trial later showed a clear benefit of the concomitant cell therapy over CABG surgery alone.^{3,4} Finally, we did a strictly double-blind, fully randomised, placebo-controlled trial (CARDIO133, NCT00462774) and recently analysed the results. Unfortunately, none of the previous positive effects were confirmed. Essentially, we followed the wrong track for nearly 10 years, because we did not strictly adhere to the guidelines on how to do a randomised, controlled clinical trial. We hope this will not be the fate of the SCIPIO concept.

We declare that we have no conflicts of interest.

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- 1 Bolli R, Chugh AR, D'Amario D, et al. Cardiac stem cells in patients with ischaemic cardiomyopathy (SCIPIO): initial results of a randomised phase 1 trial. *Lancet* 2011; **378**: 1847–57.
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- 4 Yerebakan C, Kaminski A, Westphal B, et al. Impact of preoperative left ventricular function and time from infarction on the long-term benefits after intramyocardial CD133(+) bone marrow stem cell transplant. *J Thorac Cardiovasc Surg* 2011; **142**: 1530–9.e3.

Roberto Bolli and colleagues¹ report that cardiac stem cells potentially improve left ventricular function in patients with ischaemic cardio-

myopathy. The results are very promising; however, I have three concerns about safety and efficacy.

First, regarding safety, because the cardiac stem cells given to patients were expanded *ex vivo*, long-term studies will be needed to assess safety. Fortunately, cardiac stem cells are not prone to transformation, but longer culture will result in chromosomal aberration. Second, regarding efficacy, cardiac stem cells have been shown to contribute to regeneration of cardiomyocytes.² Are there mechanisms other than regeneration, such as paracrine effects of injected cells? Finally, regarding methods, intra-coronary infusion was used. Although this technique is practical, was direct injection into the peri-ischaemic zone³ not considered, given the limited number of injected cells?

I declare that I have no conflicts of interest.

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- 1 Bolli R, Chugh AR, D'Amario D, et al. Cardiac stem cells in patients with ischaemic cardiomyopathy (SCIPIO): initial results of a randomised phase 1 trial. *Lancet* 2011; **378**: 1847–57.
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Authors' reply

Publishing the initial results of SCIPIO was important because the feasibility, safety, and efficacy noted in the first 16 (of the planned 20) patients are so striking that a larger phase 2 trial is clearly warranted to assess cardiac stem cells. Since follow-up (2 years) will end in the autumn of 2013, it will not be possible to publish the complete results of SCIPIO before 2014. Given the time needed to set up a follow-up phase 2 trial, waiting 3 years to divulge