

Responses received by *The BMJ*

The BMJ offered institutions and individuals named in the Essay by John Rasko and Carl Power (*BMJ* 2023;381:p1367, doi:10.1136/bmj.p1367) the chance to respond to the allegations made against them. These are the full, unedited responses.

University College London, on behalf of Martin Birchall, 2 June 2023

Thank you for your email to Professor Martin Birchall below, who has asked me to respond on his behalf.

I have contacted UCL staff, who advise and assist on matters concerning UCL's Research Misconduct Procedure.

Our response on behalf of Professor Birchall is as follows: As part of our research misconduct process, two UCL screening panels (2015, 2018) carefully considered the allegations against Professor Martin Birchall. Both screening panels, on the basis of evidence provided, concluded that there was a lack of intent to mislead by Professor Birchall.

I understand you have also contacted the UCL Media Relations team, who will be providing a fuller statement.

With best wishes

Anders Hamsten, 30 May 2023

Thanks so much for offering me a Right of Reply to a coming commentary about Paolo Macchiarini. I respectfully decline.

Careggi University Hospital, Florence, 4 June 2023

Surgeon Paolo Macchiarini worked at the Careggi University Hospital in Florence from 2009 to 2012. He left the hospital under the accusation of advising some patients to undergo private surgery, which is illegal for doctors working in the Italian National Health Service (SSN). As a result, he faced a criminal proceeding by the Italian judicial authority, which concluded with a final acquittal in 2021.

At Careggi Hospital, he performed five compassionate use trachea transplants on highly complex patients, obtaining approval from the Ethics Committee and informed consent from each patient. These procedures were also approved by the National Transplant Center, the Italian governmental authority responsible for such procedures.

All these surgeries took place before the research protocol was approved in October 2011, which means they were locally and nationally approved as compassionate treatment for potentially life-threatening conditions.

Due to the abrupt termination of Dr. Macchiarini's contract at Careggi Hospital following the decisions of the judicial authority, the follow-up of these patients was short and

incomplete, although Dr. Macchiarini reported satisfactory short-term results to the Hospital Medical Directorate.

After Dr. Macchiarini's contract was terminated, the management of the Careggi University Hospital fully cooperated with other institutional bodies to provide all the requested information regarding clinical and legal matters.

At the time of the events, which took place prior to the objections raised by the scientific community, Careggi Hospital provided assistance to patients for whom compassionate use treatments had been authorized by competent bodies.

The spotlight on Dr. Macchiarini's work is a lesson to be learned on the need for the greatest caution in using initial evidence in innovative surgical techniques.

Text from
Press office of Careggi university hospital in Florence

Hospital Clinic Barcelona, 4 June 2023

Dear Editor,

Thank you for giving us the opportunity to clarify some issues raised by Schneider and colleagues in the letter submitted to BMJ. We honestly consider that it is unfair to state that our hospital avoided denouncing Dr. Macchiarini's paper to protect our reputation.

Since 2018 to present, we have been collaborating with authors of the BMJ letter, as well as all authorities, committees and scientific bodies who have requested to us any information with respect to The Lancet 2008 article and other research activities Dr. Macchiarini carried out in Barcelona. More specifically, we have crossed 42 emails with Leonid Schneider since September 2016, and 11 with Patricia Murray since April 2018, addressing all their questions. In addition, Dr. Molins reported in 2019 the patient long-term follow-up, demonstrating that tissue-engineered airway transplant was unsuccessful. All these facts confirm that our hospital has always acted properly, transparently and without hiding any data.

Our hospital appointed an ad-hoc internal commission in 2016 to review Dr. Macchiarini's research activity performed during his stay in Barcelona. Additional clinical data to those previously reported by Dr. Macchiarini were included in Dr. Molins' letter as well as in correspondence to Leonid Schneider and Patricia Murray. Although we informed The Lancet editor that it was necessary to place a stent because of graft collapse three weeks after transplantation, it is important to point out that this information arose from colleagues who worked with Dr. Macchiarini in 2008 but, unfortunately, we have not been able to find such procedure documented in the patient's medical record. In fact, as it was communicated to the Swedish National Board for the Assessment of Research Misconduct two weeks ago, a bronchoscopy indeed demonstrated stenosis of the left bronchus three weeks after transplant, but the first documented stent was the one placed in the transplanted bronchus in October 2008 (ie. four months after transplantation).

Finally, we would like to clarify that Dr. Macchiarini is not working at our institution since 2009, when the Hospital Clinic of Barcelona decided not to renew his contract.

We hope this information will contribute to clarify this unpleasant situation and help taking

the most suitable decision.

Sincerely yours,

Antoni Castells, MD, PhD
Laureano Molins, MD, PhD

Great Ormond Street Hospital for Children, London, 31 May 2023

A Great Ormond Street Hospital spokesperson said:

“At GOSH, we often care for children with highly complex, rare and life-threatening conditions where no conventional treatments are available. When considering the use of novel therapies and treatments on compassionate grounds we have to carefully weigh up with the family the potential risks against chances of success, always being clear and mindful there is a limited body of evidence on likely impact.

A special Inquiry in 2017 found no concerns about GOSH or its staff and described our processes to consider compassionate or exceptional use of treatments as robust. The Inquiry also considered that the Clinical Ethics Service 24 (CES) team based at GOSH was a highly professional and well-structured team with clear lines of reporting and standards for operating.

We are committed to openness and transparency at GOSH and have published the results of Shauna’s treatment [here](#)”

University College London, 2 June 2023

On the record statement to BMJ

A UCL spokesperson said: “UCL and its staff have been open and transparent regarding issues surrounding regenerative medicine research at UCL. In 2016, UCL commissioned an [independent special inquiry](#) which was published in full in September 2017.

“The panel, chaired by Professor Stephen Wigmore from the University of Edinburgh, carried out a thorough investigation of the involvement of UCL and its personnel in regenerative medicine research but with particular focus on the field of tracheal and large airway tissue engineering. The inquiry made a series of recommendations and UCL has acted upon all of them.

“As a world-leading university, UCL takes the integrity of its research very seriously, and we are always seeking to improve our processes and raise our standards. Any research undertaken at UCL is required to conform to the highest legal, ethical and regulatory standards, and we will not hesitate to take the necessary action, if and when this falls short.

“We are committed to supporting our staff as they continue a wide range of excellent research into regenerative medicine, which has tremendous potential to improve patient outcomes with proper support and governance.

“Many of our scientists are leading ground-breaking projects, helping develop new cancer therapies, using artificial intelligence to better predict diseases and innovating new surgical techniques, all of which is transforming the lives of millions of people around the world.”

Re scope of special investigation

The principal purpose of the Special Inquiry into Regenerative Medicine at UCL was to provide an independent investigation into the role of UCL in this area of research, in the wake of the concerns raised into Professor Paulo Macchiarini. The purpose was to explore the governance framework and authorisation of programmes particularly in relation to the manufacture of medical devices (including cellularised cadaveric grafts) in respect of the UCL airway transplantation programme. Issues that related to clinical care and compassionate use, are matters for NHS Trusts, along with the General Medical Council and other regulatory bodies, and were beyond the scope of the Inquiry. Despite this, as part of our response to the inquiry, we communicated with NHS partners and recommended they check/review their compassionate use procedures.

Karolinska Institute, 25 May 2023

KI has not conducted investigations regarding the operations performed by PM. The operations were performed in PM:s role as a physician employed by Karolinska University Hospital.

KI has conducted investigations regarding PM:s research, as a researcher employed by KI, reported in scientific papers after the operations. KI found PM responsible for scientific misconduct in the published papers.

Lancet Group, 1 June 2023

Please find a statement from The Lancet Group below:

“The Lancet journals take issues relating to scientific misconduct extremely seriously and follow best practice guidelines set by the Committee on Publication Ethics (COPE). In accordance with best practice, authors’ institutions are best placed to lead independent investigations into scientific misconduct, and during the course of this complex case, *The Lancet* has referred all allegations it has received to the authors’ respective institutions including the Hospital Clinic Barcelona and UCL. The outcomes of the independent investigations we have received to date have not concluded that a retraction of the 2008 paper is warranted. Should any new information arise, we will consider it accordingly, and we continue to monitor this case closely.

In 2019, *The Lancet* published [a follow up report](#) of the patient whose procedure was outlined in the 2008 paper, as well as a [Correction](#) to the original paper. In February 2023 following advice from COPE, *The Lancet* published an Expression of Concern on both the original paper and the follow up report:

[Expression of concern: Clinical transplantation of a tissue-engineered airway](#)

[Expression of concern: The first tissue-engineered airway transplantation: 5-year follow-up results](#)

Further information about our policies is available here:
<https://www.thelancet.com/publishing-excellence>.”

Paolo Macchiarini

The BMJ attempted to—but ultimately could not—obtain current contact information for Paolo Macchiarini.