



South Central Ambulance Service **NHS**
NHS Foundation Trust

PRIVATE AND CONFIDENTIAL

Mr D C. Horsley
Her Majesty's Coroner for Portsmouth and
South East Hampshire
The Coroner's Court
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Portsmouth
P012GJ

Northern House,
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25th October 2016

Dear Mr Horsley

Re: Report to prevent future deaths

Thank you for your letter dated 6th September 2016 enclosing your Regulation 28 report detailing your concerns relating to the PARAMEDIC 2 adrenaline trial.

Concerns:

To confirm the concerns that you directed towards the Trust, having heard evidence at the inquest in to the death of SH, you were not assured that there were enough warnings on the packaging of the trial drugs packs to remind staff of the categories of patients that should be excluded from being entered in to the trial.

Actions taken:

Since the inquest hearing, the Trust have been working with the University of Warwick (who are sponsor for the PARAMEDIC 2 trial) to provide you with a collaborative approach to rectify the concerns that you have raised.

The matter was first discussed fully at the Paramedic-2 Trial Management Group (TMG) on 8th September 2016 where all five participating sites were represented. At this meeting an action plan was made to design an appropriate label detailing all of the exclusion categories' which would be placed on further issues of the trial drug packs. Following the meeting, a label was designed for this purpose and I am pleased to enclose a copy of the final design for your information.

To ensure that any modifications to the trial drug packaging were not just made within the area covered by the South Central Ambulance Service (SCAS) the TMG decided to roll out their plans across all of the ambulance trusts taking part in the Paramedic-2 trial. The University of Warwick has therefore committed that by January 2017, all trial drugs in circulation will have the new labels affixed to the trial drugs bag or external bag.

Having reviewed the final label design internally, SCAS have decided to purchase bespoke plastic bags with the label agreed by University of Warwick and the Paramedic 2 team, printed on to the bag. This will ensure that the exclusion criteria are clearly visible to our staff when first selecting the trial drug pack. Staff will also be reminded during training and by an internal memo of the importance of ensuring that they are aware of the exclusion criteria and the importance of checking the packaging to remind themselves immediately before the trial drugs are used. Whilst we have assured ourselves that appropriate training on the trial is already in place, the Trust considers that this additional warning will be a vital reminder to our staff when they are presented with the time critical pressures of a cardiac arrest.

The Trust has instructed Midco Print & Packaging Limited to produce the new bags for us. SCAS has committed that by January 2017 that all trial drugs in circulation will have the new labels affixed to the trial drugs bag or external bag.

We take all complaints and concerns seriously and I thank you for bringing your concerns to our attention. We can only improve our service by receiving this feedback and in this instance learning will have taken place and will also be disseminated to the rest of our staff.

I hope that the actions discussed in this letter have assured you that the Trust has responded to your concerns appropriately, but if there are any issues that you wish to discuss further, please do not hesitate to contact me on the address at the top of this letter.

Yours sincerely

A handwritten signature in blue ink, appearing to read "James Chubb", is written over a black rectangular redaction box. The signature is fluid and cursive.

Deputy Chief Executive