Department of Health

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Chief Operating Officer

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Mr A Walsh
Area Coroner
HM Coroner's Court
Paderborn House
Howell Croft North
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27 April 2015

Dear Mr Walsh

Thank you for your letter following the inquest into the death of Mary Marshall.

As a result of evidence heard at the inquest, you would like to see an increased awareness of the implications of Glutamate Dehydrogenase (GDH) positive results and of the need to prescribe appropriate antibiotics to reduce the risk and the occurrence of Clostridium Difficile infection.

You raise several concerns relating to the understanding and handling of GDH positive results: a lack of awareness generally amongst medical staff of the importance of such results, a lack of hospital procedures to inform the patient's GP of a GDH positive diagnosis and the need for all hospitals to record such diagnosis on patient's hospital records for the attention of treating clinicians.

You request that we review the following issues:

- the awareness amongst all Health Practitioners of the significance of GDH positive results and the training of General Practitioners in relation to the relevance of GDH positive results, particularly in relation to the future prescription of antibiotics.

- the procedures in Hospitals to advise General Practitioners and Primary Care Practitioners of a GDH positive result by use of letters similar to the attached letters prepared by the Bolton NHS Foundation Trust. *(You provide a copy of the letter and GDH awareness sheet that Bolton NHS FT has developed and*

which they send to the GP of the patient who has been diagnosed GDH positive).

- whether hospitals have a log, similar to the Extramed system at the Royal Bolton Hospital, recording GDH positive results in the hospital records and their procedures for such results to be brought to the attention of Clinicians at the beginning of every ward round.

Your letter has been shared with leading Clostridium difficile infection (CDI) experts within Public Health England and antimicrobial specialists within NHS England. Whilst they advise that no changes are currently made to existing guidance in this area, there are measures that are currently being taken and considered to improve information exchange and understanding of CDI.

The management of CDI can be complex as many factors need to be considered to achieve the best treatment for the patient.

Tests to identify Clostridium difficile *(C. diff)* form a fundamental part of CDI management. This is outlined in the Department of Health's, *Updated guidance on the diagnosis and reporting of Clostridium difficile (2012) which outlines* two types of tests, which when used in combination, will deliver the most accurate results for the detection of *C. diff* infection.

This national two test screening protocol comprises a '*GDH enzyme immunoassays EIA (or NAAT/PCR) followed by a sensitive toxin EIA. If the first test (GDH or NAAT) is negative, the second test (sensitive toxin EIA) does NOT need to be performed. A third test (e.g. NAAT or PCR) may be optionally added to the algorithm to further identify samples from potential C. difficile excretors.*'

Whilst a GDH positive result may identify the presence of *C. diff*, it does not identify whether the strain is toxigenic or non-toxigenic and the additional toxin test outlined above is therefore required. In addition, being colonised by *C. diff* can provide some protection against CDI. Therefore, it is not entirely accurate to say that a GDH positive result indicates vulnerability to the development of *C. diff* infection.

In Mrs Marshall's case, the absence of the information from a toxin test and other clinical information, makes it difficult to determine whether or not amoxicillin was the most appropriate treatment. It is a reasonable choice of antibiotic to treat a chest infection in community care and, as outlined by NICE, *Evidence Summary, Clostridium difficile infection: risk with broad-spectrum antibiotics* (2015), it presents a lower risk in relation to *C. diff* compared to other broad spectrum antibiotics.

However, it is also possible that the patient could have developed CDI even without the use of amoxicillin due to the multi-factorial nature of CDI and the presence of other risk factors including; age, hospital admission, high dependency unit admission and likely administration of broad spectrum antibiotics.

Furthermore, the Department of Health's guidance is purposely cautious with regards to the treatment of GDH positive, toxin negative patients due to the lack of robust evidence regarding best practice. For this reason our expert advisers have recommended that changes to the national guidance are not required.

Nevertheless, appropriate information relating to a patient's CDI status is essential for informing the most appropriate care and treatment. Nationally work is already being undertaken to ensure that this is recognised. As part of NHS England's Antimicrobial Resistance (AMR) work programme, work has been undertaken to promote the importance of *C. diff* testing. This has been achieved in part by the delivery of three national AMR workshops and a national clostridium difficile study day. All materials will be made available on the NHS England Patient Safety Domain webpage

http://www.england.nhs.uk/ourwork/patientsafety/associated-infections/.

The national workshops included a session on *Improving Antibiotic Prescribing in Primary Care* and specific content about identifying past *C. diff* infections.

To ensure this work is developed further, and in light of the recommendations made, NHS England will work with partners to continue to explore ways to develop a wider understanding of C. *diff* testing and the implications of the results, including but not limited to GDH testing.

In addition, NHS England's patient safety team will consider the specific circumstances of this case to determine if any further action, over and above that already planned, is merited. However, all future work must take account of the national algorithm for *C. diff* testing and mitigate against the risk of unintended consequences, (which may involve patients being treated inappropriately i.e. as though they have CDI) if the implications of GHD positive results are miscommunicated.

Methods to support local health communities in the reporting and sharing of information in relation to a patient's CDI status will also be explored. More widely, NHS England is already working on ideas for improving the provision of information between hospitals and primary care upon patient discharge. This will be informed by examples of best practice implemented locally and by consulting with relevant partners and subject matter experts to determine how information should be disseminated.

I would like to say how sorry I was to hear of Mrs Marshall's death and wish to extend my sincere condolences to her family. I hope that this response is helpful and I am grateful to you for bringing the circumstances of Mrs Marshall's death to my attention.

Yours sincerely

TAMARA FINKELSTEIN