

8th October 2012

Cluster SHA Medical Directors in England
Primary Care Trusts in England (Chief Executives)
NHS trusts in England (Chief Executives)
Hospitals in the independent sector registered with CQC
Independent treatment centres registered with CQC
NHS Foundation Trusts in England (Chief Executives)
Care Quality Commission (CQC) (Headquarters) for
information
General Practitioners (for information)

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Gateway Reference: 18221

Dear Colleague

I am writing to you following the recent issues highlighted at Kingsmill Hospital in relation to pathology services.

My concerns have been prompted by emerging details of the misclassification of oestrogen receptor status affecting the treatment of women with breast cancer at this trust, so this letter is to ask you to take urgent steps regarding a number of issues relating to pathology laboratory management.

I am therefore asking you urgently to assure yourselves and your Boards:

1. That reagents and techniques that are used within your laboratory are appropriately validated and quality controlled for clinical use. This assurance must cover the full spectrum of activity, not just breast tissue analysis.
2. That the quality assurance information you receive in relation to pathology testing (diagnostic and technical) is adequately discussed and – where there are concerns - acted upon promptly and to lasting effect; and
3. That there are adequate reviews of aggregated results, where available, and trends over time to determine whether their distribution is in line with expectation, and undertake urgent investigation where they are not.

At the Trust in question, the EQA returns suggested that accuracy rates were, technically, inside acceptable limits, but they were persistently in the lower quartile. Even though a decision was ultimately made that the combination of a small number of tests and the EQA results merited the service being outsourced to a neighbour with exemplar performance, it has taken time for the trust to realise and investigate the implications of these factors in terms of outcomes for patients.

I am writing to you because I am concerned on behalf of other NHS patients that no other trust should find itself in a similar position. I will be meeting the expert group convened to advise the trust in question to discuss their findings, and will report any more general conclusions reached as soon as possible.

Yours sincerely

A handwritten signature in black ink that reads "Bruce Keogh." The signature is written in a cursive style and is underlined with a single horizontal stroke.

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