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| | <p>REGULATION 28 REPORT TO PREVENT FUTURE DEATHS</p> <p>THIS REPORT IS BEING SENT TO:</p> <p>1. Mr Simon Stevens, Chief Executive Officer, NHS England, PO Box 16738, Redditch, B97 9PT</p> |
| 1 | <p>CORONER</p> <p>I am Mr D M Salter, HM Senior Coroner for Oxfordshire.</p> |
| 2 | <p>CORONER'S LEGAL POWERS</p> <p>I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.</p> |
| 3 | <p>INVESTIGATION AND INQUEST</p> <p>I conducted an inquest on 6 August 2019 at Oxford Coroners Court into the death of Thelma Joyce at the Churchill Hospital, Oxford on 14 February 2019. I gave a brief Narrative Conclusion as follows: <i>'Thelma Joyce underwent necessary chemotherapy in January 2019 for gall bladder cancer but died due to toxicity and side effects caused by the chemotherapy drug, Capecitabine, and a DPD deficiency making her more vulnerable to severe side effects.'</i></p> <p>Oxford University Hospitals NHS Trust (OUH) were represented at the inquest and [REDACTED] Consultant Medical Oncologist, provided helpful oral evidence. I attach a copy of her witness statement dated 5 June 2019.</p> <p>Mrs Joyce's family also attended the inquest. The main issue which they raised concerned the perceived failure to test Mrs Joyce for DPD deficiency prior to commencing chemotherapy. I received evidence that it was not routine to test patients who are due to receive the chemotherapy drugs Capecitabine and 5FU for DPD deficiency mainly because of the absence of a reliable test. However, I also received evidence that, with new technology and developments, there is now a reliable test. Indeed, OUH Trust now have a two-year pilot to test such patients. I attach a copy of my letter to OUH about this for your information.</p> |
| 4 | <p>CIRCUMSTANCES OF THE DEATH</p> <p>Mrs Joyce commenced chemotherapy on 25 January 2019 but had a very severe reaction which led to her being admitted to the Churchill Hospital on 31 January and dying on 14 February despite treatment.</p> <p>The cause of death following post mortem was as follows:</p> <p>I a Pneumonia I b Chemotherapy Toxicity I c Gall Bladder Cancer</p> |

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| | <p>She was subsequently found to have a DPD deficiency. ██████ said if the results of the DPD test had been known beforehand she would not have commenced Mrs Joyce on the chemotherapy because the risk was too great. It is noted from paragraph 5 of the statement that a person with partial DPD deficiency will have low or very low levels of the enzyme. If patients with DPD deficiency receive the chemotherapy drug Capecitabine, then there is a risk the drug will not be eliminated completely and that the levels of the drug in the blood stream will be higher than normal and this can result in side effects which can be more severe than usual. It is also noted that DPD deficiency can affect between 3-5% of people which is not an insignificant number. (I appreciate that up to 20% of people do have severe side effects from Capecitabine and 5FU and not all are DPD deficient).</p> |
| 5 | <p>CORONER'S CONCERNS</p> <p>During the course of the Inquest the evidence revealed matters giving rise to concerns. In my opinion there is a risk that future deaths will occur unless action is taken.</p> <p>In the circumstances it is my statutory duty to make this report to you.</p> <p>The MATTER OF CONCERN therefore is in relation to the possible need for updated guidance in respect of testing for DPD deficiency for patients due to embark on Capecitabine and 5FU chemotherapy.</p> <p>It is reassuring that OUH NHS Trust have a two-year pilot in place to test for DPD deficiency. As far as I understand it, there are as yet no national guidelines or approved tests in respect of DPD deficiency. If it is the case that new technology and developments mean there is now a reliable test, I enquire if there should be guidelines issued concerning the use of a routine test.</p> |
| 6 | <p>ACTION SHOULD BE TAKEN</p> <p>In my opinion action should be taken to prevent future deaths and I believe you have the power to take such action.</p> |
| 7 | <p>YOUR RESPONSE</p> <p>You are under a duty to respond to this report within 56 days of the date of this report. I may extend the period on request.</p> <p>Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.</p> |
| 8 | <p>COPIES and PUBLICATION</p> <p>I confirm that a copy of this report and your response will be sent to Mrs Joyce's family.</p> |

| | <p>The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.</p> | | | | |
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| 9 | <table><thead><tr><th><u>Signed</u></th><th><u>Date</u></th></tr></thead><tbody><tr><td> Mr D.M. Salter HM Senior Coroner for Oxfordshire</td><td>20/8/19</td></tr></tbody></table> | <u>Signed</u> | <u>Date</u> |  Mr D.M. Salter HM Senior Coroner for Oxfordshire | 20/8/19 |
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