

REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	<p>REGULATION 28 REPORT TO PREVENT FUTURE DEATHS</p> <p>THIS REPORT IS BEING SENT TO:</p> <p>(1) [REDACTED] - President, EMEA & Canada, Medtronic Ltd (Medtronic) (2) [REDACTED] - Central Alerting System Manager - Department of Health (DH) and Medicines and Healthcare products Regulatory Agency (MHRA); (3) [REDACTED] - President of The Royal College of Pathologists;</p>
1	<p>CORONER</p> <p>I am R Brittain, Assistant Coroner for Inner North London</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>The investigation into the death of Shayla Anne Walmsley was opened on 21 May 2013 and concluded at the end of the inquest on 4 July 2014. The cause of death was unascertained and the conclusion of the inquest was narrative [REDACTED]</p>
4	<p>CIRCUMSTANCES OF THE DEATH</p> <p>Miss Walmsley was found deceased at her home residence on 9 May 2013. She had a background medical history of diabetes mellitus. Owing to difficulties with controlling her diabetes she was started on a Medtronic insulin pump in 2009. She found this to be beneficial and I heard evidence at the inquest that she did not report any concerns about its functioning.</p> <p>In December 2012 the MHRA asked all insulin pump manufacturers to provide details of issues that had been raised regarding these devices. Medtronic were unable to provide this detail until May 2013. I heard evidence that this data was held at Medtronic's facilities in the USA and that it could not be made available to non-US regulators in any shorter timescale. For the sake of clarity, there was no evidence that this delay contributed to Miss Walmsley's death.</p> <p>In April 2013 Medtronic issued a Field Safety Notice (FSN) into three issues that had been reported as affecting the function of insulin pumps. I was provided with evidence that Miss Walmsley received this FSN by recorded delivery. Two further FSNs were issued later in 2013, although by that time Miss Walmsley had died.</p> <p>I heard evidence from a representative of the Governance Department of the NHS Trust, which provided Miss Walmsley with the insulin pump, regarding the systems in place for receiving and cascading FSNs. It was clear that FSNs (in generality) were often not</p>

	<p>addressed to the most appropriate department or individual within the Trust and, as such, sometimes did not reach those who could take the necessary action. On occasion patients had raised concerns to the Trust, following their receipt of an FSN, before the appropriate individuals within the trust had themselves been made aware of the issuing of an FSN.</p> <p>I heard from Medtronic and the MHRA that, if insufficient feedback has been received from the recipients of an FSN, this could trigger the MHRA to issue a Medical Device Alert (MDA) through the Central Alerting System (CAS). This is an online reporting tool which links directly to NHS Trusts (amongst others). MDAs were issued through CAS for each of the FSNs which related to Medtronic insulin pumps in 2013.</p> <p>A <i>post mortem</i> examination was undertaken as part of the investigation into Miss Walmsley's death, which did not elucidate a cause of death. The presence of a 'Medical Device', which I concluded was the insulin pump, was noted during the examination but was not further analysed. I heard evidence from the pathologist who undertook the <i>post mortem</i> that he did not know the nature of the device and had received no instruction to analyse the device from the Coroner who requested the <i>post mortem</i>.</p> <p>Medtronic provided evidence that insulin pumps have, on occasion, been returned to them for analysis from police officers and pathologists who are investigating deaths of pump users. Unfortunately this did not occur as part of the investigation into the death of Miss Walmsley. The cause of her death remained unascertained at the conclusion of the inquest.</p>
5	<p><u>CORONER'S CONCERNS</u></p> <p>During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you.</p> <p>The MATTERS OF CONCERN are as follows. –</p> <p>(1) Interval to availability of Medtronic data - I am concerned that the investigatory role of non-US regulators could be hampered by the timescale within which Medtronic can provide data on request. Given the potential consequences of a delay in production of this safety data, I believe that future deaths could result and that this warrants consideration by Medtronic.</p> <p>(2) Inconsistency in issuing FSNs - I am concerned that the apparently <i>ad hoc</i> nature by which FSNs are issued delays appropriate individuals within NHS Trusts being aware of safety concerns and that this could result in future deaths. It is clear the the CAS distributes MDAs to NHS Trust governance departments in a reliable manner. I believe that consideration should be made as to whether CAS could be used also to distribute FSNs.</p> <p>I heard evidence from the governance department representative that this would not lead to 'alert fatigue' (where receipt of numerous alerts results in less attention being paid to them). This is because governance departments should be receiving these FSNs in any case and taking steps to distribute as appropriate. I heard concerns from the MHRA that this view may not be shared by all governance departments but, in my judgement, there should be consideration of the use of CAS for FSN distribution.</p> <p>(3) Non-analysis of medical devices at <i>post mortem</i> - I am concerned that future investigations into the deaths of medical device users could be impaired by the lack of analysis of medical devices at <i>post mortem</i>. It is clear that these devices are increasingly being used by patients and, if death is unexplained in such a patient, appropriate analysis should be considered. As such, I believe that it is necessary to emphasise, to those</p>

	involved in death investigation, the potential importance of device analysis.
6	<p>ACTION SHOULD BE TAKEN</p> <p>In my opinion action should be taken to prevent future deaths and I believe the addressees have the power to take such action regarding:</p> <p>Concern 1 - Medtronic</p> <p>Concern 2 - CAS (Department of Health) and MHRA</p> <p>Concern 3 - Royal College of Pathologists</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, namely by 8 September 2014. I, the coroner, may extend the period.</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 have sent a copy of my report to the Chief Coroner and to the following Interested Persons (a) Miss Walmsley's Family and (b) Barts Health NHS Trust.</p> <p>I am also under a duty to send the Chief Coroner a copy of your response.</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>
9	<p>14 July 2014 Assistant Coroner R Brittain</p>