


	<p style="text-align: center;">REGULATION 28 REPORT TO PREVENT FUTURE DEATHS</p> <p>THIS REPORT IS BEING SENT TO:</p> <p>(1) Dr Ian Hudson, Chief Executive Medicines and Healthcare Products Regulatory Agency (MHRA), 151 Buckingham Palace Road, London SW1W 9SZ</p>
1	<p>CORONER</p> <p>I am Dr Andrew Harris, Senior Coroner, London Inner South</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>INQUEST</p> <p>On 23rd January 2013, I opened an inquest into the death of: Miss Akua Anokye-Boateng, aged 7 years, died 16th January 2013, Case Ref: 00154-13.</p> <p>It was concluded on 26th March 2014. The court found that the medical cause of death was: 1a Acute Peritonitis and Shock 1b Perforated Duodenum 1c Non steroidal anti-inflammatory (NSAID) ingestion and Helicobacter associated chronic ulceration of duodenum in sickle cell disease</p>
4	<p>CIRCUMSTANCES OF THE DEATH</p> <p>The following narrative was recorded: <i>Akua had well managed and well controlled sickle cell disease. She suffered a 3 day illness, consulting her GP but collapsing suddenly, unresponsive to prompt resuscitation and dying at 19.16 at KCH on 16.01.13. She had ingested a non steroidal anti-inflammatory drug in May 2012 and suffered a GI upset in August. Her death was unrelated to sickle disease and was caused by unexpected duodenal perforation, although chronic and multi-factorial.</i></p>
5	<p>CORONER'S CONCERNS</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 MATTER OF CONCERN is as follows. –</p> <p>Expert evidence was heard from an experienced academic pathologist that one dose of NSAID was sufficient to damage the GI mucosa in children, which, coupled with a presumed Helicobacter infection, led in this case to the perforation. The consultant paediatrician with responsibility for haemoglobinopathies was unaware of the risk of a single dose in the past and gave evidence that Ibuprofen was an important drug in the management of sickle cell patients, having less side effects than opiates. He reported that it is not current practice to routinely give gastro-intestinal protection when NSAIDs are used briefly in children with sickle disease. Thus it is unclear what is best practice or whether the scientific evidence suggests that guidance is needed for clinicians about further precautions or prevention such as Proton pump inhibitors being routinely used alongside NSAIDs in children, to minimize the risk of similar deaths.</p>

6	<p>ACTION SHOULD BE TAKEN</p> <p>In my opinion action should be taken to prevent future deaths and I believe that the general practitioner and medical director 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, namely by Friday 4th July 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> <p>If you require any further information or assistance about the case, please contact the case officer, [REDACTED]</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: [REDACTED] (mother), GSTT. I have also sent it to [REDACTED] consultant haematologist and [REDACTED] consultant pathologist, who may find it useful or of interest.</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>[DATE] 9th May 2014</p> <p>[SIGNED BY CORONER] </p>