REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. University Hospitals Birmingham NHS Foundation Trust ('UHB') 2. Birmingham Women's NHS Foundation Trust ('BWH')
1	**CORONER** I am Emma Brown, area coroner, for the coroner area of Birmingham and Solihull.
2	**CORONER'S LEGAL POWERS** 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.
3	**INVESTIGATION and INQUEST** On 25th February 2015 I commenced an investigation into the death of Hireiti Kufletsion. The investigation concluded at the end of the inquest on 13th October 2015. The medical cause of death was Multi Organ Failure due to Acute Thrombosis of mechanical mitral valve in the first trimester of pregnancy due to emergency cardiac surgery for acute decompensation due to rheumatic mitral valve disease after previous pregnancy. The conclusion of the Inquest was that death was a result of complications from the presence of a mechanical mitral valve during pregnancy that was compounded by a series of failures in medical care
4	**CIRCUMSTANCES OF THE DEATH** The deceased passed away at the Queen Elizabeth Hospital Birmingham on the 20th November 2014 as a result of thrombosis of a mechanical mitral valve. The deceased had undergone surgery for the placement of a mechanical mitral valve at the Queen Elizabeth Hospital in January 2012 for rheumatic valve stenosis. She was therefore on warfarin therapy and had been advised to avoid pregnancy. The deceased had found she was pregnant in October 2014 and following detailed consideration and advice at the joint Cardiac/Obstetric Clinic run by ██████ Consultant Cardiologist, and ██████ Consultant Obstetrician, at the Birmingham Women's Hospital on the 11th November 2014 had decided to proceed to termination of her pregnancy at 8 weeks gestation, the timing of the termination being deliberately planned to minimise complications. However, following admission to the Birmingham Heartlands Hospital on the 12th November 2014 in respiratory distress there were failures on the part of the cardiology team to adequately investigate complications of the mechanical valve, namely: (a) an urgent trans thoracic echocardiogram was not performed on the 13th November 2014; (b) when trans thoracic echocardiogram was performed on the 14th November 2014 it did not adequately view the mitral valve and could not be safely interpreted as excluding a problem with the valve; (c) the trans thoracic echocardiogram was misleading reported verbally and in writing as showing right heart failure secondary to a respiratory condition; (d) a consultant review and/or advice from Cardiologists at the University Hospital of Birmingham were not sought.

	It is likely that with full investigation of mitral valve function the diagnosis of thrombosis would have been made on the 13th or 14th November 2014. When the diagnosis was made on the 17th November 2014 the deceased was too ill for surgery. With diagnosis earlier it is likely that the deceased would have been transferred to the Queen Elizabeth Hospital and surgery could have been undertaken and death would have been avoided. Failures of clinicians at the Birmingham Heartlands Hospital to prescribed adequate doses of clexane between the 28th and 11th November and the 12th and 14th November 2014 contributed to the development of the fatal thrombosis.
5	**CORONER'S CONCERNS** 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. The **MATTERS OF CONCERN** are as follows. – (1) In giving evidence [redacted] stated that from time to time she does see at her Obstetric/Cardiac clinic pregnant patients with mechanical valves who have had their warfarin changed to celxane at other hospitals in the region on too low a dose of clexane and that review of their anti-factor Xa may not have been arranged to occur with adequate frequency. Therefore pregnant women with mechanical valves maybe at risk from being prescribed insufficient doses of clexane with insufficient review of their anti-factor Xa. (2) It was apparent from evidence given by clinicians at the Birmingham Heartlands Hospital that they did not understand the extent and gravity of the increased risk of thrombosis to pregnant women with mechanical valves and this affected the course of investigations into the deceased's condition ultimately resulting in a delay in diagnosis until it was too late. Whilst this issue has now been brought to the full attention of all departments within the Birmingham Heartlands Hospital that are at real risk of having a pregnant patient with a mechanical heart valve presenting to them it is reasonable to assume that clinicians without specialist cardio-obstetric knowledge across the region do not appreciate the implications of a mechanical heart valve in for a pregnant patient.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you [AND/OR your organisation] have the power to take such action. A review is required of the current local guidelines, recommendations and procedures for the provision of advice from, and where necessary referral to, the joint Cardiac-Obstetric Clinic operated by UHB and BWH.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by the 18 December 2015. I, the coroner, may extend the period. 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.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons: [redacted] the deceased's husband and the Heart of England NHS Foundation Trust.

	I am also under a duty to send the Chief Coroner a copy of your response. 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.
9	**Date: 23rd October 2015** **Signature:**

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	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. National Institute for Health and Care Excellence 2. Royal College of Physicians 3. Royal College of Obstetricians and Gynaecologists 4. British Cardiovascular Society
1	**CORONER** I am Emma Brown, area coroner, for the coroner area of Birmingham and Solihull.
2	**CORONER'S LEGAL POWERS** 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.
3	**INVESTIGATION and INQUEST** On 25th February 2015 I commenced an investigation into the death of Hireiti Kufletsion. The investigation concluded at the end of the inquest on 13th October 2015. The medical cause of death was multi organ failure due to acute thrombosis of mechanical mitral valve in the first trimester of pregnancy due to emergency cardiac surgery for acute decompensation due to rheumatic mitral valve disease after previous pregnancy. The conclusion of the Inquest was that death was a result of complications from the presence of a mechanical mitral valve during pregnancy that was compounded by a series of failures in medical care
4	**CIRCUMSTANCES OF THE DEATH** The deceased passed away at the Queen Elizabeth Hospital Birmingham on the 20th November 2014 as a result of thrombosis of a mechanical mitral valve. The deceased had undergone surgery for the placement of a mechanical mitral valve at the Queen Elizabeth Hospital in January 2012 for rheumatic valve stenosis. She was therefore on warfarin therapy and had been advised to avoid pregnancy. The deceased had found she was pregnant in October 2014 and following detailed consideration and advice at the joint Cardiac/Obstetric Clinic run by [redacted] Consultant Cardiologist, and [redacted] Consultant Obstetrician, at the Birmingham Women's Hospital on the 11th November 2014 had decided to proceed to termination of her pregnancy at 8 weeks gestation. The timing of the termination being deliberately planned to minimise complications. However, following admission to the Birmingham Heartlands Hospital on the 12th November 2014 in respiratory distress there were failures on the part of the cardiology team to adequately investigate complications of the mechanical valve, namely: (a) an urgent trans thoracic echocardiogram was not performed on the 13th November 2014; (b) when trans thoracic echocardiogram was performed on the 14th November 2014 it did not adequately view the mitral valve and could not be safely

interpreted as excluding a problem with the valve;

(c) the trans thoracic echocardiogram was misleading reported verbally and in writing as showing right heart failure secondary to a respiratory condition;

(d) a consultant review and/or advice from Cardiologists at the Queen Elizabeth Hospital were not sought.

It is likely that with full investigation of mitral valve function the diagnosis of thrombosis would have been made on the 13th or 14th November 2014.

When the diagnosis was made on the 17th November 2014 the deceased was too ill for surgery. With diagnosis earlier it is likely that the deceased would have been transferred to the Queen Elizabeth Hospital and surgery could have been undertaken and death would have been avoided.

Failures of clinicians at the Birmingham Heartlands Hospital to prescribe adequate doses of clexane between the 28th and 11th November and the 12th and 14th November 2014 contributed to the development of the fatal thrombosis.

5 CORONER'S CONCERNS

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.

The **MATTERS OF CONCERN** are as follows. –

(1) In giving evidence [redacted] stated that from time to time she does see at the joint Obstetric/Cardiac clinic pregnant patients with mechanical valves who have had their warfarin changed to clexane at other hospitals in the region on too low a dose of clexane (i.e. not a twice daily 60mg/kg dose).Likewise she is aware that review of anti-factor Xa may not be arranged to occur with adequate frequency (once a week).

(2) It was apparent from evidence given by clinicians of different specialties at the Birmingham Heartlands Hospital that they did not understand the extent and gravity of the increased risk of thrombosis to pregnant women with mechanical heart valves and a twice daily dose of clexane was not being routinely prescribed. Furthermore there was evidence that anti factor Xa would only have been reviewed once a month but for the deceased's death which in the opinion of [redacted] was insufficient.

Whilst these issues has now been brought to the full attention of all relevant departments within the Birmingham Heartlands Hospital, it is reasonable to assume that there are haematologists, cardiologists and obstetricians without specialist cardio-obstetric knowledge across the country that do not appreciate the implications during pregnancies of patients with a mechanical heart valve for anti-coagulation therapy but maybe involved in the management and care of such patients.

6 ACTION SHOULD BE TAKEN

In my opinion action should be taken to prevent future deaths and I believe you [AND/OR your organisation] have the power to take such action. A review is required of the current national guidelines for the management of anti-coagulation in pregnant patients with mechanical heart valves.

7 YOUR RESPONSE

You are under a duty to respond to this report within 56 days of the date of this report, namely by the 18th December 2015. I, the coroner, may extend the period.

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.

8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons: [redacted] the deceased's husband, the Heart of England NHS Foundation Trust, the University Hospitals Birmingham NHS Trust and the Birmingham Women's NHS Foundation Trust. I am also under a duty to send the Chief Coroner a copy of your response. 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.
9	**Date:** **23rd October 2015** **Signature:**