Department of Health & Social Care

*From Maria Caulfield MP*
*Parliamentary Under Secretary of State for Primary Care and Patient Safety*

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Mr Derek Winter DL
HM Senior Coroner, City of Sunderland
HM Coroner's Office
Civic Centre
Burdon Road
Sunderland SR2 7DN

24 September 2021

Dear Mr Winter,

Thank you for your letter of 20 July 2021 to Sajid Javid about the death of Vinnie William Ord Dodds. I am replying as Minister with responsibility for maternity care and patient safety.

I would like to start by saying how very sorry I was to read the circumstances of the death of baby Vinnie. I can appreciate how devastating his loss must be to his parents and all who loved him. It is vitally important that we take the learning from Vinnie's death to prevent future tragedies.

In preparing this response, my officials have taken advice from NHS England and NHS Improvement (NHSEI), the National Institute for Health and Care Excellence (NICE), as well as the Royal College of Obstetricians and Gynaecologists (RCOG).

NHSEI advise that there is currently a lack of evidence on the management of large babies in pregnancy (unless diabetes is present), In particular, it is not clear whether the incidence of shoulder dystocia can be reduced through inducing labour in women with big babies or whether it is better to wait for labour to begin naturally. Progress in this area of maternity care should be more clearly informed when the results of the *Induction of labour for predicted macrosomia – The 'Big Baby Trial'*[1] are published in 2022/23 by the University of Warwick. The purpose of the *Big Baby Trial* is to find out if starting labour earlier than usual, at 38 weeks, makes it less likely that shoulder dystocia will happen in women whose babies appear to be bigger than expected.

[1] Big Baby (warwick.ac.uk)

NHSEI further advise that the General Medical Council (GMC) guidance on informed consent (2020)[2] and the Montgomery Lanarkshire ruling[3], describe using the 'material facts' to facilitate informed decision making. This means that doctors must provide information about all material risks including any to which it would be reasonable for them to think the individual patient would attach significance. In its guidance, the GMC advises that doctors must try to find out what matters to patients so that they can share relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action. The GMC guidance also advises that doctors should tailor the discussion about potential benefits and harms to each individual patient, being guided by what matters to the patient and sharing information in a way they can understand.

Under the NHS Long Term Plan, the Maternity Transformation Programme[4] led by NHSEI, is committed to ensuring that all women have a Personalised Care and Support Plan in place, where the principle of fully informed consent is central. A Personalised Care and Support Plan is a series of facilitated conversations in which the person actively participates to explore the management of their health and well-being within the context of their whole life and family situation, so that all considerations that might impact on safe care are accounted for. The agreed personalised care and support plan is a live document that should reflect the decisions the woman makes about the care and support she wants to receive as she moves through her maternity journey. Those decisions should be informed by the discussions she has with her healthcare professional about the benefits and harms of the evidence-based options available at each step on that journey.

In addition, NHSEI advises that clinicians should use the RCOG patient information leaflet for Shoulder Dystocia[5] during conversations where appropriate, which provides information about the balance of risks associated with shoulder dystocia and its management. You may wish to note that the RCOG has advised my officials that an updated RCOG Shoulder Dystocia patient information leaflet has been commissioned, which will refer to the extremely low risk of death after shoulder dystocia.

Turning to the specific matters of concern in your report, I am able to advise the following.

On the matter of national guidance for the management of large babies in pregnancy, you will wish to note that NICE has made recommendations on large for gestational age babies in its clinical guideline on *Intrapartum care for women with existing medical conditions or obstetric complications and their babies* [NG121[6]].

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[2] Decision making and consent - GMC (gmc-uk.org)

[3] montgomery.pdf (rcog.org.uk)

[4] NHS England » Maternity Transformation Programme

[5] pi-shoulder-dystocia.pdf (rcog.org.uk)

[6] Overview | Intrapartum care for women with existing medical conditions or obstetric complications and their babies | Guidance | NICE

In this guideline, NICE recommends that healthcare professionals should:

*1.17.1 Explain to women in labour whose babies are suspected to be large for gestational age that:*

- *it is sometimes difficult to be certain the suspicion is correct until the baby is born*
- *when making decisions about mode of birth (for example, vaginal birth or caesarean section), this uncertainty needs to be taken into account.*

*1.17.2 Discuss with women in labour whose babies are suspected to be large for gestational age the possible benefits and risks of vaginal birth and caesarean section, including:*

- *higher chance of maternal medical problems such as infection with emergency caesarean section*
- *a higher chance of shoulder dystocia and brachial plexus injury with vaginal birth*
- *a higher chance of instrumental birth and perineal trauma with vaginal birth.*

*Explain to the woman and her birth companion(s) what it might mean for her and her baby if such problems did occur.*

*1.17.3 Offer women in labour whose babies are suspected to be large for gestational age a choice between continuing labour, including augmented labour, and caesarean section.*

I am informed by NICE that during the development of this guideline, NG121, NICE's committee acknowledged that there is no standardised definition of large for gestational age and so did not specify this in its recommendations.

In addition, NICE advises that there was no convincing evidence for one mode of birth over another for women in labour whose babies are suspected to be large for gestational age. The committee discussed the difficulty of estimating a baby's size when a woman is in labour and acknowledged that ultrasound is difficult to perform in labour and is less accurate at estimating a baby's weight than in the antenatal period. As such, they agreed that women should be told about this uncertainty.

Evidence showed an increased risk of maternal infection when women in labour had an emergency caesarean section. In the committee's experience, there was a risk of shoulder dystocia and perineal trauma with vaginal birth and the committee agreed that women should be provided with information so that they can make their own decisions about mode of birth when their baby may be large for gestational age.

It is the opinion of NICE that the guideline adequately covers the options and counselling that should be discussed with mothers with a suspected large baby.

NICE is currently consulting on an update to Clinical Guideline 70: *Inducing labour*[7], and the evidence review of the induction of labour for suspected fetal macrosomia[8]. The Guideline defines fetal macrosomia as "*a fetus that is believed to be large for its gestational age, defined for the purposes of this guideline as an estimated fetal weight above the 95th percentile, at or after 36 weeks of pregnancy*."

The aim of the evidence review was to determine if Induction of Labour for suspected fetal macrosomia at, or after, 35 weeks gestation, has benefits and reduces the risk of adverse outcomes for the mother and the baby, compared to expectant management. The review looked at all women apart from those with treated diabetes (pre-existing or gestational). The review looked at the following outcomes; third/fourth degree tears; shoulder dystocia; perinatal death; hypoxic ischaemic encephalopathy; maternal satisfaction; brachial plexus injury; and, caesarean birth.

The evidence review concluded that "*suspected large for gestational age babies (or babies with suspected macrosomia) are at an increased risk of having difficult births. Preventing babies from getting too large by having an earlier birth may mitigate the associated risks, however the available evidence was not sufficient to recommend inducing labour and having an early birth over managing the pregnancy expectantly and waiting until birth started spontaneously.*"

The draft update to Clinical Guideline 70 currently states:

> ***Suspected fetal macrosomia***
> *Offer women with suspected fetal macrosomia, and without diabetes, the choice of induction of labour or expectant management after a discussion of the benefits and risks of both options. Discuss that:*
>
> - *there is limited evidence that induction of labour could reduce the risk of shoulder dystocia*
> - *there is very limited evidence that induction of labour could increase the risk of third- or fourth-degree perineal tears*
> - *there is evidence showing no difference in the risk of perinatal death, brachial plexus injuries in the baby, or the need for caesarean birth between the 2 options*
> - *Base the choice of care on the woman's circumstances and her preferences and support her decision. Support recruitment into clinical trials, if available. (2021).*

In relation to glucose tolerance testing, I am advised by NICE that National Guideline NG3, *Diabetes in pregnancy*, published in 2015 and last updated in December 2020, recommends that women who have had gestational diabetes in a previous pregnancy should be offered:

> *1.2.6 For women who have had gestational diabetes in a previous pregnancy, offer:*

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[7] 1 (nice.org.uk)

[8] NICE Guideline Template

- *early self-monitoring of blood glucose or*
- *a 75-g 2-hour oral glucose tolerance test (OGTT) as soon as possible after booking (whether in the first or second trimester), and a further 75-g 2-hour OGTT at 24 to 28 weeks if the results of the first OGTT are normal.*

Healthcare professionals should offer women with any of the other risk factors for gestational diabetes (outlined in recommendation 1.2.2) a 75-g 2-hour OGTT at 24 to 28 weeks (recommendation 1.2.7). NICE advises that it does not consider that there is sufficient evidence to make a recommendation for OGTT at 26 weeks.

I am further advised by NHSEI that in clinical practice, glucose tolerance tests are routinely arranged to be performed at around 26 weeks gestation and that the 24-28 week recommendation allows some flexibility should there be a problem with the woman attending at exactly 26 weeks.

I hope this response is helpful.

**MARIA CAULFIELD**

**Minister for Primary Care**