

# **STAN: An introduction to its use, limitations and caveats**

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## **Introduction**

Intrapartum hypoxia and subsequent metabolic acidosis is associated with short term complications such as admission to neonatal unit, hypoxic ischaemic encephalopathy (HIE) and neonatal death or long term implications such as cerebral palsy or learning difficulties. The main aim of fetal monitoring is to timely identify and hence to salvage fetuses that are at risk of intrapartum hypoxic injury, whilst avoiding unnecessary operative intervention to fetuses that are normoxic.

Cardiotocograph (CTG) has been used for over 40 years to identify intrapartum hypoxia and when CTG was introduced into obstetric practice it was hoped that it would help reduce the cerebral palsy (CP) rate. Unfortunately, the incidence of cerebral palsy has remained fairly stable over the last 40 years whereas, there has been a significant increase in the incidence of operative delivery, since the introduction of CTG. The 4th Confidential Enquiries into Stillbirths and Deaths in Infancy (CESDI) Report concluded that issues with interpretation and failure to act when a CTG abnormality was detected may have contributed to over half of all intrapartum related deaths<sup>1</sup>. It is therefore essential to understand the pathophysiology of intrapartum fetal hypoxia to improve outcomes<sup>2</sup> and to explore better techniques of fetal assessment during labour.

## **Problems with traditional tests used for intrapartum fetal monitoring**

Cardiotocograph (CTG) has been used all over the world over the last 40 years to timely identify fetuses experiencing intrapartum hypoxic insults so that appropriate intervention could be taken to avoid cerebral injury. However, this test has several flaws.

### **a. Pattern Recognition**

CTG relies on pattern recognition and information management by midwives and obstetricians. Unfortunately, not all patterns that are associated with intrapartum fetal hypoxia are currently known. There is a vast degree of inter-observer and intra-observer variation in pattern recognition. The 4th CESDI Report concluded that lack of knowledge to interpret CTG traces was a major contributor to potentially avoidable intrapartum related deaths.

### **b. High false positive rate and poor positive predictive value of CTG for intrapartum hypoxia**

CTG has a very good sensitivity but a very poor specificity and positive predictive value for intrapartum hypoxic injury. Hence, the false positive rate is high. This means that even if CTG shows all the 'abnormal features' such as late decelerations, complicated baseline tachycardia and complicated variable decelerations, only 40-60% of fetuses actually have intrapartum hypoxia<sup>3</sup>. In other words, if operative intervention is undertaken, based on the observed CTG changes alone, 40-60% of fetuses will be born with normal cord blood gases without any evidence of metabolic acidosis. Positive predictive value of a pathological CTG for metabolic acidosis is approximately 30%<sup>4</sup>. This implies that if a clinician uses the CTG alone for intrapartum fetal monitoring, it is

likely that unnecessary operative interventions will be increased without any discernable benefit to perinatal outcome.

c. Requirement for additional tests of fetal wellbeing

In view of its very poor positive predictive value for metabolic acidosis and a high false positive rate, CTG requires additional tests of fetal wellbeing such as fetal scalp blood sampling, (FBS), fetal scalp lactate, fetal pulse oximetry and fetal electrocardiograph (fetal ECG also called STAN or ST-analyser).

d. Problems with CTG Classification

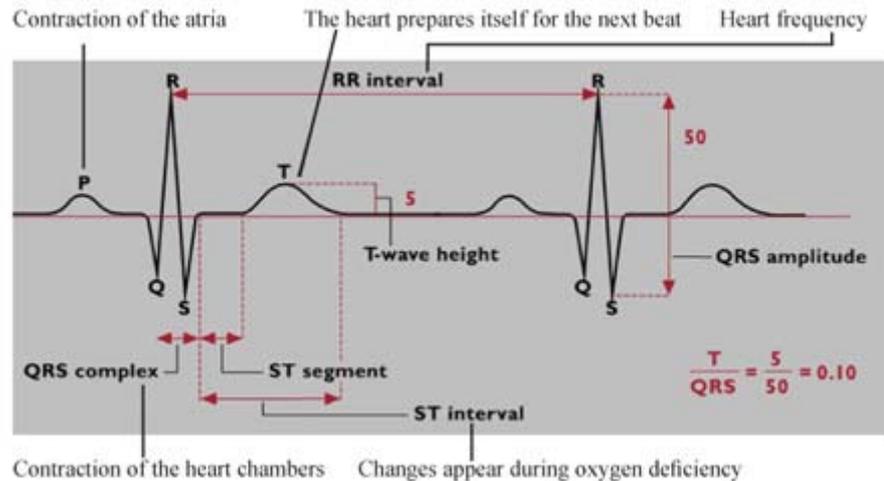
Six years after publication of the 4th CESDI Report that highlighted substandard care (which included lack of knowledge and failure to interpret CTG traces) in over 50% of babies who died due to intrapartum related causes, the Royal College of Obstetricians and Gynaecologists (RCOG) and National Institute of Health and Clinical Excellence (NICE) produced National Guidelines on Electronic Fetal Heart Rate monitoring (EFM) in 2015. This was a very welcome and much needed step in the right direction and it created a platform for universal classification of CTG into Normal, Suspicious and Pathological categories. Hence, varied terminologies such as 'good CTG' 'optimal CTG', 'sub-optimal CTG', 'bad CTG', 'non-reassuring CTG' etc, which caused much confusion among clinicians in the past, were avoided. However, this classification itself was riddled with many drawbacks. First of all, it over-simplifies the complex process of labour and assumes that there could be only three types of decelerations during labour (early due to head compression, variable due to cord compression and late due to utero-placental insufficiency). There has been no consideration to multiple events such as head and cord compression occurring together during uterine contractions or the importance of fetal reserve or its capacity to respond to hypoxia on the ultimate outcome.

Moreover, clinicians often reacted to 'CTG Patterns' described in the EFM Guidelines without considering the clinical picture. Electronic Fetal Monitoring Guidelines was subsequently revised by NICE in 2007 to include a 'time frame' for decelerations in order to reduce the likelihood of clinicians reacting and thereby instituting an unnecessary intervention to specific patterns noted in the CTG6. Hence, instead of intervening when one or two late decelerations are noted, the current classification allows late decelerations for 50% of contractions for up to 30 minutes to be present prior to be considered as an abnormal feature. Although, this is a vital step in the right direction, there has been no consideration of the type of hypoxia during labour (acute, sub acute, gradually evolving) or emphasis of other features such as pseudo-sinusoidal patterns, saltatory patterns, loss of cycling of fetal heart rate that may also reflect fetal compromise, in the current NICE Classification.

**Role of fetal ECG in intrapartum fetal monitoring**

Fetal electrocardiograph (ECG) refers to a graphic record of the summation of electrical activity of the myocardial cells. This in turn reflects oxygenation status of a central organ (i.e. myocardium of the heart), which is protected until very late stages of hypoxia by a fetus that mounts a compensatory response to lack of oxygen. Hence, indirectly, it provides information on the oxygen status of the fetal brain, which is also a central organ and is protected by compensatory mechanisms (re-distribution of blood from non-essential organs such as the kidneys, skin and liver to central 'essential' organs such as the heart, brain and fetal adrenal glands).

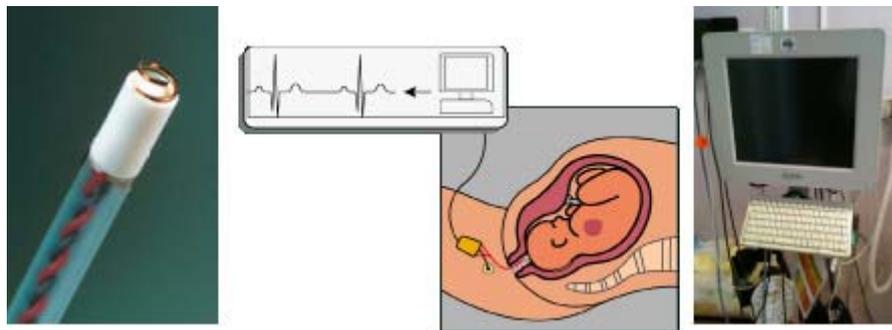
Figure 1. Fetal ECG Complex



### What is STAN (ST-Analyser)?

STAN analyses changes in the fetal ECG Complex that occur secondary to myocardial hypoxia. It is so named because it analyses the 'ST Segment' of the fetal ECG (Fig 1). 'ST Segment' and 'T wave' give an indication regarding the electrical changes that occur during the repolarisation of the myocardial cells, as they prepare for the next contraction. STAN also analyses the T/QRS Ratio (height of the T wave that reflects repolarisation of the ventricles and QRS Complex that reflects depolarisation of the ventricles) to determine an acute or longer lasting hypoxic insult to the myocardial cells.

Figure 2. Scalp electrode (a), connection to skin electrode on the maternal thigh (b) and STAN Machine (c)



### Why do we need STAN?

Cardiotocograph (CTG) has a high false positive rate of over 50%, which implies that if CTG is used alone, it would increase interventions such as emergency caesarean sections and operative vaginal births without any significant benefit to the perinatal outcome. Currently available additional tests of fetal well being (FBS, fetal pulse oximetry and fetal scalp lactate) determine evidence of hypoxia in peripheral tissue (fetal scalp) and hence they fail to provide information on the oxygenation of central organs (myocardium and brain). They do not help us determine the fetal responses to hypoxia, which vary from fetus to fetus. Moreover, FBS and fetal scalp lactate do not provide continuous information during labour and require repetition if the changes observed on CTG, which are suggestive of suspected fetal compromise, do not improve.

ST-Analyser (STAN) aims to overcome these shortcomings by assessing fetal response to hypoxic insults on myocardium, which is a central organ. It helps differentiate between a fetus exposed to hypoxia that is compensating well by continuing to perfuse its central organs from a fetus that is unable to compensate or has exhausted all the resources

available to deal with hypoxic insult. Moreover, STAN also provides continuous information throughout labour on fetal wellbeing.

### How does STAN get electrical signals from the fetal heart?

As shown in Figures 2, electrical signals from the fetal heart is captured through a fetal scalp electrode (Fig 2a), which is connected to a skin electrode on the maternal thigh (Fig 2b). The latter is connected to a computer that analyses the signals and displays it on the STAN Monitor (Fig 2c).

It is important to ensure good contact between fetal scalp electrode and the fetal scalp to obtain a good signal quality. Similarly, the skin electrode on the maternal thigh should also have sufficient contact to ensure optimum capture of fetal ECG signals by the computer. If there is poor contact (increased fetal hair or scalp or skin electrodes not applied appropriately), this will be flagged up on the monitor with a suggestion to 'check the electrodes'.

### How does STAN technology work?

As soon as a fetus is connected to the STAN Machine, the machine calculates the normal baseline T/QRS ratio for the individual fetus, by analysing the fetal ECG complexes that it receives through the fetal scalp electrode. In the presence of good signal quality, this usually takes approximately four to five minutes. Once this initial calculation is completed, the computer remembers this value as the 'normal baseline' for the individual fetus in question. Subsequently, the computer analyses every 30 fetal ECG complexes and compares with the original 'baseline value' and puts a cross ('x') on the monitor. Hence, if the fetal heart rate is 150 beats/minute, one should expect to see five crosses ('x') on the screen (Fig 3). If the computer determines that the recent information on fetal ECG after analysis is significantly different to its original calculation (i.e. the baseline T/QRS or ST Segment values obtained in the initial four minutes), this will be flagged up as a 'ST Event' for clinicians to take appropriate action. Figure 3 shows the appearance of fetal heart trace on the STAN Monitor which indicates the fetal heart rate (148/min), the standard CTG trace and the crosses ('x') that indicate ST Analysis.

Figure 3. Appearance on the STAN Monitor

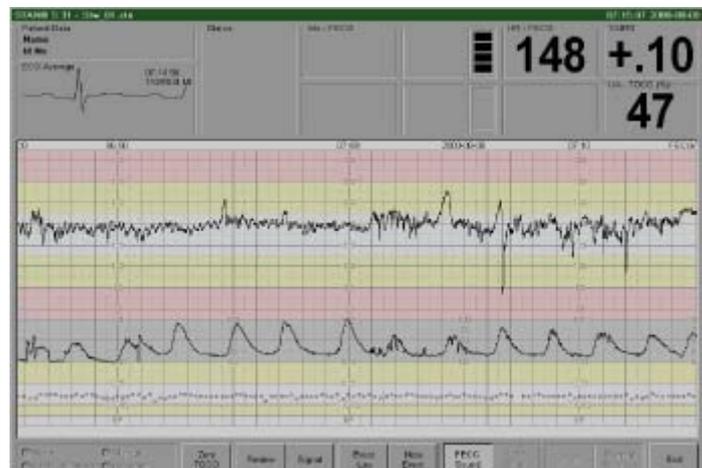


Figure 4. Classification of CTG using STAN Guidelines

	Baseline heart frequency	Variable Reactivity	Decelerations
<b>Normal CTG</b>	- 110-150 bpm	- Accelerations - 5-25 bpm	- Early uniform decelerations - Uncomplicated variable decelerations with a duration <80 sec and loss of >80 beats
<b>Intermediary CTG</b>	- 100-110 bpm - 150-170 bpm - Short bradycardia episode (<100 bpm for >3 min)	- >25 bpm (salvatory pattern) - <5 bpm >40 min with absence of accelerations	- Uncomplicated variable decelerations with a duration <80 sec and loss of >80 beats
<b>Abnormal CTG</b>	- 150-170 bpm and reduced variability - >170 bpm - Persistent bradycardia (<100 bpm for >3 min)	- <5 bpm for >60 min - Sinusoidal pattern	- Complicated variable decelerations with a duration of >80 sec - Repeated late uniform decelerations
<b>Preterminal CTG</b>	- Total lack of variability (<2 bpm) and reactivity with or without decelerations or bradycardia		

Figure 5. Suggested Course of Action based on ST Events noted and Classification of CTG based on STAN Guidelines

ST Events	Normal CTG	Intermediary CTG	Abnormal CTG	Preterminal CTG
Episodic T/QRs rise		>0.15	>0.10	
Baseline T/QRs rise	- Expectant management	>0.10	>0.05	- Immediate delivery
Biphasic ST	- Continued management	3 Biphasic log messages!	2 Biphasic log messages!	

Figure 3 shows the appearance of fetal heart trace on the STAN Monitor which indicates the fetal heart rate (148/min), the standard CTG trace and the crosses ('x') that indicate ST Analysis. Hence, the monitor

provides a continuous analysis of fetal ECG signals (i.e. an additional test of fetal wellbeing to avoid false positive rate) throughout labour.

### **What are the 'ST Events' produced by STAN Technology?**

STAN specifically analyses T/QRS ratios and 'ST Segment changes' of fetal ECG complexes and produces two types of 'ST Events': 'T/QRS ST Events' and 'Biphasic ST Events'.

#### **T/QRS ST Events**

These denote periods of myocardial hypoxia that results in an increase in 'T Wave' height. If the hypoxic insult is short lasting, it is termed 'Episodic T/QRS Rise' and if the hypoxia is long lasting, typically over 10 minutes duration, it is termed 'Baseline T/QRS rise'. The underlying mechanism appears to be a 'catecholamine surge' from the fetal adrenal gland (emergency hormone) that occurs secondary to hypoxic stress. Catecholamines increase the heart rate and also breakdown myocardial glycogen into glucose to increase the energy substrate for the myocardium to continue to function and to continue supplying the brain and fetal adrenal gland, both of which are essential for fetal survival.

This process of 'glycogenolysis' induced by catecholamines results in release of potassium ions along with glucose into the myocardial cell. Hence, the resultant local 'hyperkalemia' produces 'tall T Waves' and an increase in T/QRS ratio. It is vital to remember that excessive fetal movements that may result in catecholamine surges may also result in 'Episodic T/QRS ST events'. In this case, the CTG would be otherwise normal and would show accelerations and hence, ST events should be ignored.

#### **Biphasic ST Events**

As mentioned before, ST Segment reflects a period of quiescence when the myocardium 'rests' just after a contraction (depolarisation), prior to relaxation (repolarisation). Under normal circumstances, myocardial cell membrane should not allow transfer of any ions during this 'absolute refractory period'. Hence, the ST segment would be 'iso-electric' and will have a stable baseline. When there is a disturbance to myocardial pump function that may be secondary to hypoxic insults, infection, structural heart defects, myocardial dystrophies or prematurity (less contractile elements), the ST Segment of the fetal ECG segment may shift upwards or downwards leading to 'Biphasic ST Events'.

As the endocardium becomes ischaemic, sequence of repolarisation gets altered and the direction of current flow gets reversed. This results in depression of the ST segment of the fetal ECG complex with or without a negative T wave. Depending on the degree of such depression (i.e. negative ST segment due to reversal of current flow) Biphasic Grade 2 and Grade 3 ST events may be produced. These may become significant if the CTG is not normal. Breech presentation may also give rise to multiple biphasic ST events (as the heart is turned 'upside down' in relation to the maternal skin electrode that results in similar reversal in current flow in relation to the reference electrode), even though the fetus may not be hypoxic. STAN Machines have a 'breech mode' to rectify this problem and this should be activated if a decision has been made for assisted vagina breech birth and continuous electronic fetal heart rate monitoring is required.

#### **How to use STAN in clinical practice?**

Once a decision has been made for continuous electronic fetal heart rate monitoring, STAN Clip should be applied. As mentioned earlier, STAN technology works by determining the 'normal baseline ECG' for the index fetus and then compares

subsequent ECG complexes it obtains from the fetus with this calculated initial baseline. Hence, it is important to ensure that the fetus still retains its capacity to respond to hypoxia (i.e. can show a further change in the ECG complex, in response to hypoxia).

Therefore, analysing the initial CTG Trace prior to connecting a fetus to a STAN Machine is very crucial. If the CTG is pre-terminal or if there is total loss of variability, the fetus may have already exhausted all the reserves and resources available to respond to hypoxia. Hence, it is unlikely to show any further changes in the fetal ECG Complexes that may be determined by STAN Computer. This would mandate an immediate delivery to salvage the fetus. In all other cases (normal CTG, CTG showing decelerations with normal baseline heart rate and variability), the fetus is likely to have the capacity to respond further to hypoxia (i.e. show further changes in ECG complexes) and hence, could be connected to the STAN Machine.

Some advocate performing a fetal blood sampling (FBS) prior to connecting the fetus to the STAN machine if all four features of the CTG are not reassuring. As one gets more experience with the use of STAN Technology and with better understanding of pathophysiology of fetal hypoxic changes, it is possible to connect a fetus to STAN machine even in the presence of decelerations, if the baseline fetal heart rate and variability have remained normal.

### **How to Interpret STAN Events?**

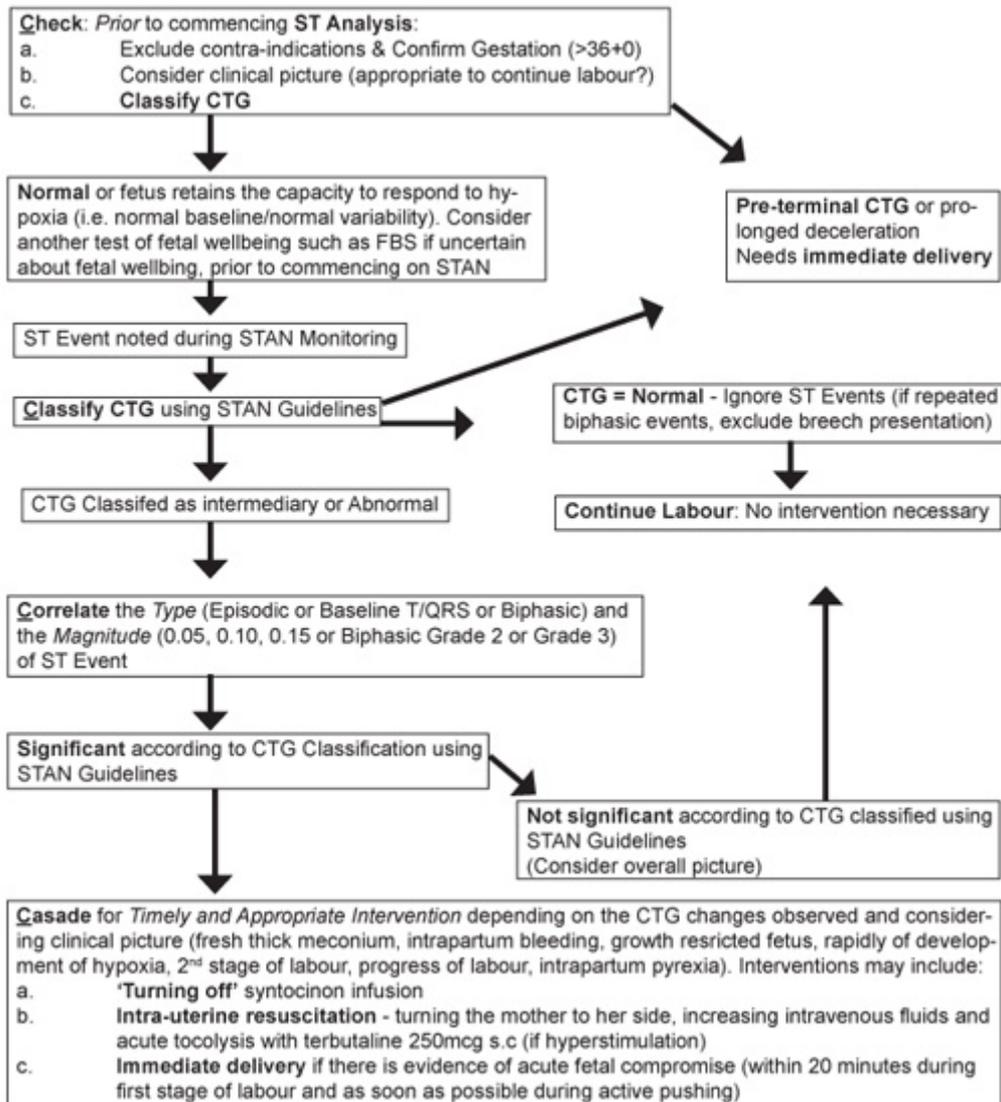
Whenever a ST Event is highlighted on the STAN Monitor, it is essential to classify the CTG (current and 30 minutes prior to the event). Classification is based on that adopted by the International Federation of Obstetrics and Gynaecology (FIGO) and is very similar to that recommended by National Institute of Health and Clinical Excellence (NICE), with minor differences. Figure 4 shows current STAN Guidelines on CTG Classification.

Once the CTG is classified using the STAN Guidelines into normal, intermediary or Abnormal, the size and magnitude of the ST Events should be noted. In the presence of a Normal CTG or pre-terminal CTG, ST Events should be discarded and labour continued in the former and immediate delivery carried out in the latter. Figure 5 illustrates application of STAN Guidelines based on the type and magnitude of ST Events.

For example, if the ST Event highlighted is 'Episodic T/QRS Rise 0.10; (type of event is Episodic T/QRS, magnitude of the event is 0.10), and the CTG of the index fetus is classified as 'Intermediary', this would not require any action. However, if the CTG has been classified as 'Abnormal', Episodic T/QRS rise of 0.10 would become significant and would therefore warrant an action (please see Figure 5).

Figure 6 illustrates an Algorithm for Interpretation of STAN Events and suggested actions. Essentially this consists of four C's (Check appropriateness for the use of STAN, Classify CTG, Correlate the observed STAN Events with the CTG to determine their significance and Cascade for timely and appropriate intervention).

Figure 6. Suggested Algorithm during use of STAN Technology



## Limitations of STAN Technology

### Does STAN Technology improve perinatal outcome?

Large randomised controlled trials (Plymouth<sup>7</sup> and Swedish<sup>8</sup>) have reported significant reductions in operative delivery for fetal distress and umbilical cord metabolic acidosis in fetuses monitored by STAN. A recent Cochrane Review considered five trials (10,628 women) on continuous fetal monitoring alone as compared to the use of STAN<sup>9</sup>. It reported that the use of STAN for intrapartum fetal monitoring resulted in fewer babies with neonatal encephalopathy (four trials, risk ratio (RR) 0.37), fewer fetal scalp samples during labour (four trials, RR 0.65) and fewer operative vaginal deliveries (five trials, RR 0.89). Recently, it has also been reported that STAN improves the inter-observer variation among clinicians, especially on the decision to intervene for an intermediary or abnormal CTG<sup>10</sup>.

### **Limitation for the use of STAN technology**

STAN can be used in clinical practice only after 36 +0 weeks of gestation. This is because preterm fetuses may have under-developed endocardial - epicardial inter-phase that may interfere with signal conduction, leading to multiple ST Events that are usually biphasic. STAN also cannot be used in fetuses with a structural or functional cardiac abnormality that may interfere with generation or transmission of fetal ECG Complexes. As it requires attachment of a fetal scalp electrode, any contra-indications to the use of such an electrode (risks of vertical transmission or known fetal bleeding disorders) would preclude its use. Rarely, in the presence of a large amount of fetal hair, it may not be possible to obtain sufficient electrical signals to rely on the technology and this may be highlighted by the STAN Machine. In this case, another additional test of fetal wellbeing should be carried out if the CTG is pathological (i.e. using NICE Guidelines as it is not possible to use STAN Guidelines in this case).

### **Use of STAN for intrapartum fetal monitoring: The caveats**

Development of fetal ECG as an additional test of fetal wellbeing appears to be a significant step in reducing the false positive rate of CTG and in improving perinatal outcome. No test is 100% perfect and it is estimated that STAN may have a false positive and negative rate of approximately 5%. Although the STAN technology is very advanced, it still requires visual analysis of complex information and institution of timely and appropriate management by attending clinicians. Hence, the system is open to human errors. In most cases where the STAN technology did not pick up an abnormality and the perinatal outcomes were poor, 'human factors' have been identified<sup>11</sup>. These include lack of knowledge (e.g. failure to recognise a pre-terminal CTG trace), failure to incorporate clinical picture (such as intrapartum pyrexia, fresh thick meconium, sentinel hypoxic events during labour) and failure to follow STAN Guidelines (including failure to take appropriate action and delays in action).

Other reported failures include the use of STAN technology in the presence of severe group B Streptococcal infection<sup>12</sup> thereby failure to recognise that hypoxia is not the only pathway for brain damage and that a co-existing infection may enhance the detrimental effect of hypoxia on the fetal brain. Following the reported three cases of adverse outcome, the STAN Guidelines have been revised (Figure 7).

*Figure 7. Revised STAN Guidelines*

- Intervention depends on the cause of fetal compromise and the stage of labour. It includes qualified assessment of FHR data, alleviation of cause(s) of fetal distress (such as over-stimulation or maternal hypotension) and delivery
- During second stage with active pushing, intervention means that immediate operative delivery is recommended unless spontaneous delivery is anticipated within the next five to 10 minutes
- Abnormal CTG pattern for more than 60 minutes, or less if the FHR deteriorates rapidly, with normal ST requires qualified assessment and checking for non-deteriorating fetal state
- With a preterminal CTG pattern intervention is always indicated, irrespective of ST data
- Pause in the recording or poor signal quality with gaps in the T/QRS ratios for more than four minutes may result in missed ST Events: management should be related to the CTG pattern and clinical situation
- In the presence of maternal pyrexia even intermediary CTG pattern may be regarded as significant in combination with ST Event

## Conclusion

Intrapartum fetal monitoring is aimed at identifying fetuses that are at increased risk of hypoxic brain damage so that timely and appropriate action could be taken to improve short term and long term outcomes. Substandard care with regard to fetal monitoring is associated with 'high-value' clinical negligence claims<sup>13</sup>. They have devastating effects on families and staff involved. Substandard care involving intrapartum fetal monitoring increases the financial cost to the healthcare systems besides resulting in a burden to the affected child, family and the society.

Use of STAN appears to reduce the risks of neonatal encephalopathy as well as reduce operative interventions. Clinicians should understand the limitations as well as the caveats, including the role of human error in the use and abuse of this technology. Computer analysis of the fetal heart rate and ST Event signals appears to increase the ability to predict neonatal acidaemia. Currently, a large European Multi-Centre trial is underway assess the role of computer analysis of STAN traces in assisting clinicians to take appropriate and timely interventions in order to improve perinatal outcome.

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