

Expert DataCare

Intelligent cord blood gas analysis - provides an objective measure of perinatal outcome.



Dedicated to Quality in Maternity Care

Our vision has been to bring midwives, doctors and technologists together to develop innovative solutions to improve maternity care for clinicians, mothers and their babies.

K2 Medical Systems have developed a portfolio of products that together form a powerful strategy to improve patient care in maternity and childbirth.

- Protection from obstetric litigation
- Audit tool for labour management
- Expert interpretation of cord blood gas analysis
- Diagnostic software for validation of paired cord samples
- Permanent database of results
- Permanent database of calibrations



Why cord blood gas analysis?

Assessment of the acid-base status of umbilical cord blood at birth provides an objective measure of the fetal response to labour and was recommended in 1993 by the 26th Study Group on Intrapartum Fetal Surveillance of the Royal College of Obstetricians and Gynaecologists¹. An international consensus statement in 1999 also regarded this as an essential requirement for assessing the outcome of labour². In May 2001 the Royal College of Obstetricians and Gynaecologists Evidence-based Clinical Guideline No.8 on 'The Use of Electronic Fetal Monitoring' has recommended that umbilical artery acid-base status be used as an intermediate outcome measure of fetal hypoxia in all hospitals³. These recommendations have been endorsed by the National Institute for Clinical Excellence⁴.

- Cord blood gas analysis provides an objective measure of neonatal condition at birth, as opposed to the Apgar score which is subjective, usually assigned retrospectively and is influenced by many factors other than hypoxia during labour.
- The presence of an arterial metabolic acidosis will identify those fetuses who have

experienced significant oxygen deficit prior to delivery, and who therefore may be at risk of neonatal problems such as hypoglycaemia.

- Normal blood gases are essential to defend litigation and acidotic blood gases an essential requirement for a diagnosis of hypoxic ischaemic encephalopathy.
- It encourages a physiological-based approach to intrapartum fetal assessment and helps clinicians to retrospectively review and learn from the fetal heart rate trace during labour.
- It is useful information to have when counselling parents of babies who encounter problems in the neonatal period.
- It provides an objective tool for the audit of intrapartum care and for risk management. The incidence of metabolic acidosis can be used as a quality measure of the standard of care.

Why do we need an objective measure of perinatal outcome?

The National Audit Office reported (May 2001) that medical malpractice claims against the NHS amount to £4 billion⁵. 80% is attributable to cerebral palsy and the majority of claim is therefore against obstetric care around labour. Individual cases

of cerebral palsy attributed to perceived mismanagement during labour routinely receive settlements of the order of £3million.

These figures are disproportionate and are exacerbated by the lack of an objective measure of perinatal outcome. All too often a case is decided on a subjective argument between two sets of experts. It is perhaps not surprising, given the subjectivity and a brain damaged infant, that a Court often finds for the plaintiff.

An outcome measure is needed that can reliably reflect the condition of the infant at birth and provide an indication of the level of oxygen deprivation **actually** sustained during labour. This objective knowledge, can better establish the timing of the cerebral injury (ante-partum, intrapartum or postpartum).

Why do we need Expert DataCare?

The NICE and RCOG Guidelines recommend that umbilical acid base status needs to be assessed by collection of paired samples from the cord artery and vein.

The Quality of Data without DataCare

However, the artery can be quite difficult to sample. If there is no mechanism to check the results at the time of sampling then often two vein samples are obtained instead of an artery and a vein pair⁶. A single sample has little clinical value and virtually no value in a court of law.

A review of supposed paired cord blood gas data from a multicentre trial in the UK and Europe without Expert DataCare, found that both artery and vein had only been obtained in 40% of cases. The remainder had duplicate vein samples. A success rate this low questions the value of the procedure.

In units where Expert DataCare is used, the success rate in obtaining true paired results can be greater than 90%. **Expert DataCare ensures Quality Data**

What is Expert DataCare?

Expert DataCare is a PC software package that connects to most blood gas analysers (Bayer, Chiron, Radiometer, Instrumentation Laboratory, AVL) and can be configured for others.

Expert System

Expert DataCare has in-built expert knowledge to interpret the cord blood gas results. It identifies whether both an arterial and venous sample have been obtained. The cord artery is the more difficult to sample. If two venous samples were mistakenly obtained then the user is given the opportunity to resample the artery before the cord is disposed of. This ensures that data is consistently collected and validated to the appropriate standard.

Expert Interpretation

A detailed interpretation of the results is displayed on screen and a brief summary comment is printed along with the results on to sticky labels for inclusion into the mother's and baby's notes. The clinician therefore has an immediate feedback.

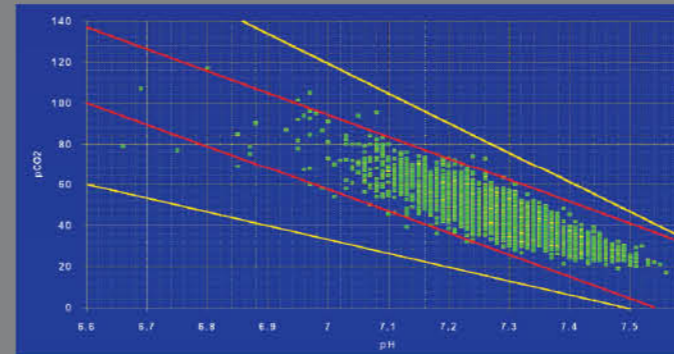
How does Expert DataCare work?

Recognition of sampling errors

Expert DataCare has in-built expert knowledge to enable it to recognise when an erroneous sample has been obtained. Sample errors are flagged at the time of sampling to enable an opportunity to obtain a better quality sample. Physiological error ranges have been identified based on our experience of using cord blood gases in many thousands of cases⁶.

Physiological errors cannot be detected by the blood gas analyser they can only be detected by Expert DataCare.

Graph of pH vs pCO2



DATE	TIME	TYPE	NUMBER
29/JUL/1997	14:28	Paired cord sample	267

ID	NAME	SURNAME
TESTING	FIRST NAME *****	SURNAME *****

SAMPLE	VESSEL	pH	pCO2	pO2	HCO3	BDecf
7289	Artery	6.98	62	98	13.2	15.1
94	Vein	7.38	37	98	12.3	2.6

Example of printed label

INTERPRETATION
Acute moderate acidemia with large A-V difference.
Possibility of neonatal metabolic maladaptation.

Expert interpretation of results

Acid-base balance is a difficult area and this is particularly so for umbilical cord acid-base measurements. The system uses the experience and knowledge of physiologists, obstetricians and paediatricians to interpret the results and identify infants who may experience problems in the neonatal period.

The validated results are interpreted using a database of rules and classified into one of 36 groups ranging from 'All results normal' to 'Severe arterial and venous metabolic acidosis'. A full and summarised explanation of the results is given.



Expert DataCare adjusts blood gas analyser results to make them applicable for the fetus rather than the adult.

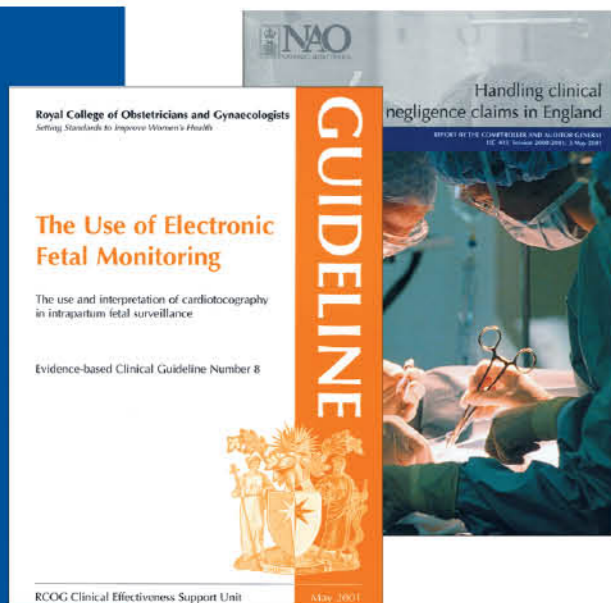
Most blood gas analysers calculate Base Deficit of the blood compartment which is correct for the adult but not for the newborn. Expert DataCare calculates Base Deficit of the extra-cellular fluid compartment which is the correct compartment for the neonate.

Database

Expert DataCare stores all results (cord blood gas data, fetal blood samples, miscellaneous samples and calibration and quality control samples) to a database. This allows a permanent record to be kept which can be linked to patient information for audit purposes and is useful to biochemists for maintaining calibration.

Defence against Litigation

Most cases of cerebral palsy now become the subject of litigation but it is widely accepted that only about 10% are attributable to intrapartum events. A normal validated paired sample (artery and vein) is an extremely powerful defence against litigation for clinical negligence during labour. Single vessel samples or paired samples which are subsequently both found to be venous are of no great value.



What is included in the Service Contract?

Training

We will provide all units with 1 day's training on the software and on the operational aspects of adopting routine cord blood gas analysis into your unit.

Software updates

All software updates and updates to the expert system knowledge will be provided free as part of the maintenance contract.

We anticipate this to be at least once per annum.

Customer Support

We have midwives working with K2 Medical Systems to provide you with quality customer support. They have in-depth product knowledge of Expert DataCare and much practical experience of cord blood sampling.

Clinical Audit

K2MS will provide a confidential annual report of your units' cord blood gas data. Every 6 months we will provide you with a clinical audit report that can be used to track changes in clinical performance. You can compare your unit's performance with the previous year and we will also provide you with data from a comparable unit (anonymous)

Frequently asked questions

Which vessel should we sample?

Both. Without both artery and vein samples you cannot be sure that you have the artery. It is the artery that reflects fetal acid-base balance but is more difficult to get. A single sample cannot be guaranteed to have come from the artery and so is of little value for audit or in a court of law.

Which deliveries should get cord blood sampling?

Ideally all deliveries. If you do cord blood gas analysis for audit purposes then you clearly need to know about your whole population of births, not just a sub-group. If you do cord blood gas analysis for defence against subsequent litigation then again, you need to do all births because there is no way of telling which cases might bring about a future claim. Some have suggested just doing sampling on cases with Apgar scores less than 7 at five minutes. The problem here is that Apgars are so subjective that they are easily challenged in a court. The only way to exclude intrapartum events as a cause of cerebral palsy and block litigation is to have the cord blood gas data from a validated paired sample.

Who should do cord blood gas analysis?

Anyone can be trained to get reliable cord blood gas results. In Plymouth the nursing auxiliaries take almost all samples after the cord has been clamped by the midwife. We have measured their performance and have found that they consistently achieve higher success rates for validated paired samples than either midwives or doctors. The important factor is the provision of good quality training so that staff are aware of the potential pitfalls in cord blood sampling.

Is routine cord blood gas analysis difficult to implement?

It is certainly not easy unless clinicians are provided with feedback. Expert DataCare does this. It is our experience that a routine sampling policy establishes a more reliable quality system than selective sampling. We have a wealth of experience that can help you establish a process in your hospital to allow you to realise the full potential of cord blood gas analysis. The key to success is a good workable system and good training with feedback.

References

1. Recommendations arising from the 26th ROG study group. In 'Intrapartum Fetal Surveillance'. Eds Spencer JAD and Ward RHT. RCOG Press, 1993
2. MacLennan A, for the International Cerebral Palsy Task Force. A template for defining a causal relation between acute intrapartum events and cerebral palsy: international consensus statement. *BMJ* 1999; 319 October 16, 1054-1059.
3. The Use of Electronic Fetal Monitoring. Royal College of Obstetricians and Gynaecologists. May 2001
4. The Use of Electronic Fetal Monitoring. National Institute for Clinical Excellence. May 2001
5. Handling Clinical Negligence Claims in England. National Audit Office 3rd May 2001
6. Westgate J, Garibaldi J, Greene KR. Umbilical cord blood gas analysis at delivery: a time for quality data. *Br J Obstet & Gynaecol*, 1994 101: 1054-63



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