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Recruitment Ads - Pages: 2 and 11

Neonatal Database – An Open Source Data Framework

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Keywords: Neonatal Database, Networking, Open source, Nurseries

A free Neonatal Data system is now available from the download centre hosted by the *Journal of Clinical and Diagnostic Research* (JCDR). The system houses data in a SQL Server (accessible over a network) in a Patient-centred relational table structure where most postnatal data is stored in Date-Timed records. The front end client runs in MS Access and has Clinical, Audit and Follow-up modules which view overlapping subsets of the data. The Clinical module of the Neonatal Database, is a quasi live data entry system designed to assist in day to day clinical management as well as generate discharge summaries (this system is NOT designed to be an EMR or electronic chart) (Table/Figure 1)

The traditional audit outcomes are automatically derived from the raw data after validation by a designated Audit Officer in the Audit Module. With a moderate prior knowledge of MS Access you are able to configure the system to your own local requirements.

Evolution of Clinical Neonatal Databases

In the early 1980's there was increasing development by interested clinicians of audit databases for use in the NICU[1] and commercial clinical systems were beginning to appear by the 1990's often guided by clinicians who had developed home grown systems[2]. In 1989 a survey was performed among the nurseries within the United States with regard to use of database. Of the 305 centers responding to the survey, 78% had a database in use in 1989 and 15% planned to develop one in the future[3]. The Vermont Oxford Network (VON) was established in 1988, the

Table/Figure 1.

Network is today comprised of over 700 Neonatal Intensive Care Units around the world[4]. This Network maintains a Database including information about the care and outcomes of high-risk newborn infants. Membership annual cost is $4000 USD per annum. Some countries now have formed a network to collect data into a national neonatal database. The Canadian Neonatal Network founded in 1995 maintains a standardized neonatal intensive care unit (NICU) database and includes members from 27 hospitals and 16 universities across Canada[5]; there is also input from an increasing number of International Hospitals. Similarly, Australia – New Zealand collaborate their data. Most of these databases only collect a very small number of summary data items.

Connecting Data Sources

There is an increasing mass of data being collected about healthcare delivery but up to now very little pooling of information from multiple sources. A hospital would dearly love to have a single database to run its business; however that just simply is not possible. Not only is the task huge with so many different stakeholders but it is also evolving and the data is needed well beyond the institutional needs. There have been attempts to use audit engine analysis of electronic text (discharge summaries) to look for keywords that can be detected[6,7]. However, in the future we will have enough data sources that our problems will be the large amount of electronic information rather than the paucity of it. There have been several publications from Newborn Screening Programs that look at the issues of large scale data and potential uses of data linkage[8,9,10]. There need to be analytical tools developed to allow for non-human interpretation of large datasets[11,12] this is both for clinical quality improvement[13,14] and also for administrative use such as the DRG[15]. The Internet is being increasingly used to submit cases to a Clinical Registry[16] and for enrollment into RCTs[17] and with appropriate security is now an option for patient identified information. Developed countries are now achieving population scale datasets[18], but it is increasingly possible for under-resourced countries to commence the collection of large scale data[19,20].

The Electronic Medical Record

Hospitals worldwide are moving towards paperless systems. The Electronic Medical Record (EMR) is being tackled on a large scale with large commercial implications by many different companies. The majority have their origin from Patient Information Systems and then have incorporated patient data / images from laboratory and imaging departments then added medication prescribing modules and if lucky some clinical information (low priority). In an intensive care environment like the NICU there is also a separate type of data system that is receiving data from many different types of equipment (monitors, ventilators, infusion pumps, incubators) and integrating this into an electronic charting system[21] for the nursing staff to use instead of paper charts.

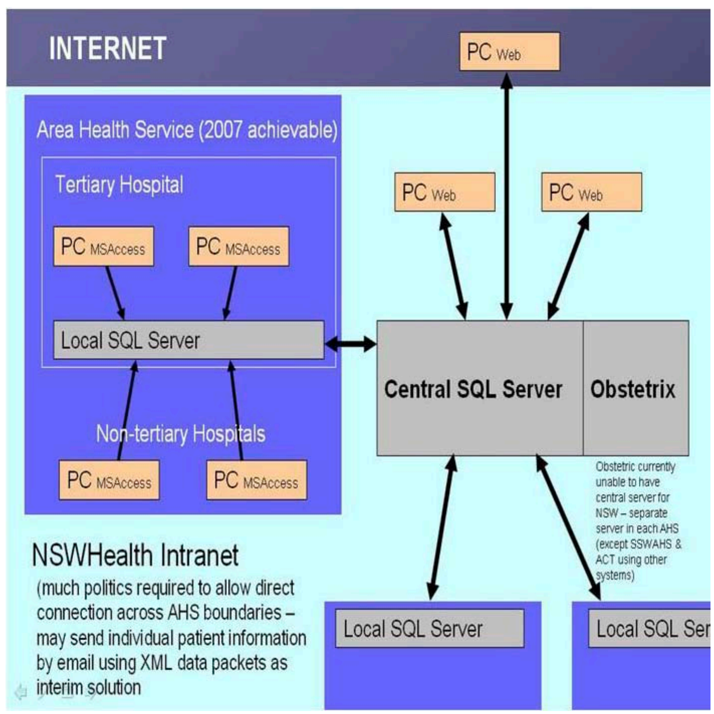
Most hospitals on this path encounter many hurdles. One of these is the lack of sensitivity of most HIS systems to individual units requirements with the one enterprise solution for all patients. These systems have not been designed to properly perform clinical audit. Audit databases have in the past expected users to enter data in retrospect by audit officers. The presented Neonatal database tries to answer these short comings. Firstly, it is clinician friendly and can be used as you go through the clinical rounds. Secondly, it gives end user rights to enmesh it with the hospital HIS system. Though sale of any EMR software which contains this software enmeshed is prohibited without prior permission of the developers.

The Neonatal Database Project (Table/Figure 2)

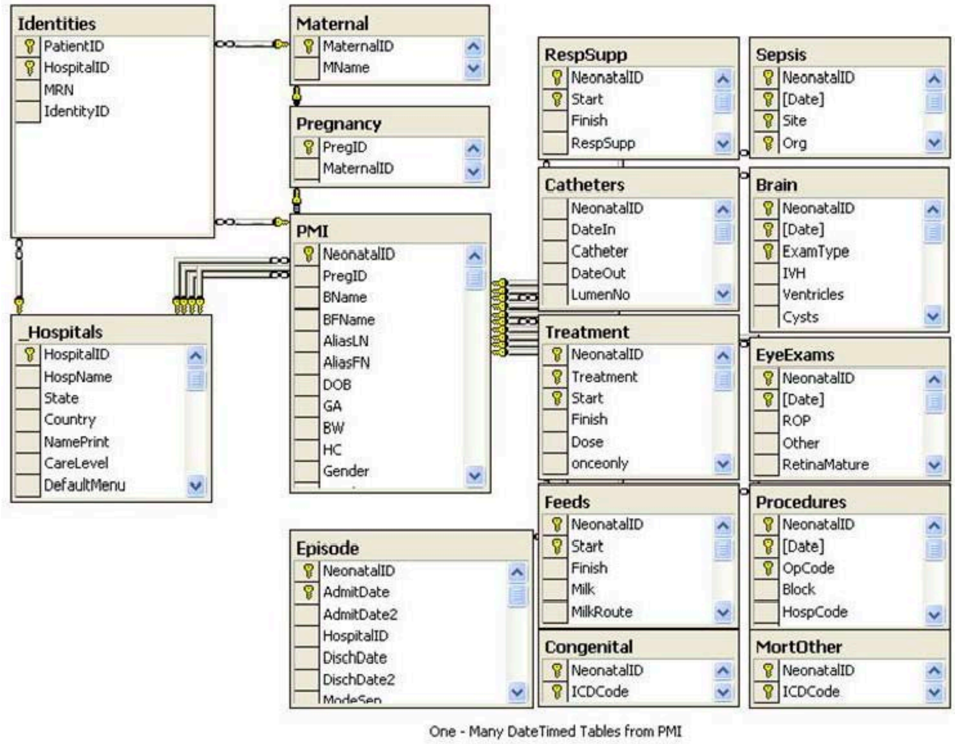
Timeline

The Neonatal Intensive Care Unit Study (NICUS) was formed in 1990 to collect audit data for New South Wales (and ACT) and now contributes about 1/3 of the babies in the ANZNN (Australia and New Zealand Neonatal Network) collection.

There was an extensive review of data system requirements and methodology commencing at the National Perinatal Data System



Table/Figure 2. Original Concept as Created in 2005.



Table/Figure 3.

"A free Neonatal Data system is now available from the download centre hosted by the Journal of Clinical and Diagnostic Research (JCDR)."

Planning Workshop in 2004. The new Neonatal Database has been constructed by NICUS members with minimal funding using MS SQL Data Server to house data, and MS Access as the user front end. The system has been implemented in all 10 member tertiary hospitals with no significant cost required; Historical NICUS Data has been loaded into the new database, and new NICUS data has been entered since the beginning of 2007. The majority of the units are also using the Clinical Module for patient management and it is expected that in early 2009 we will achieve full networking between all participating units in NSW, including another 5 intermediate nurseries that routinely provide CPAP.

Data Methodology (Table/Figure 3)

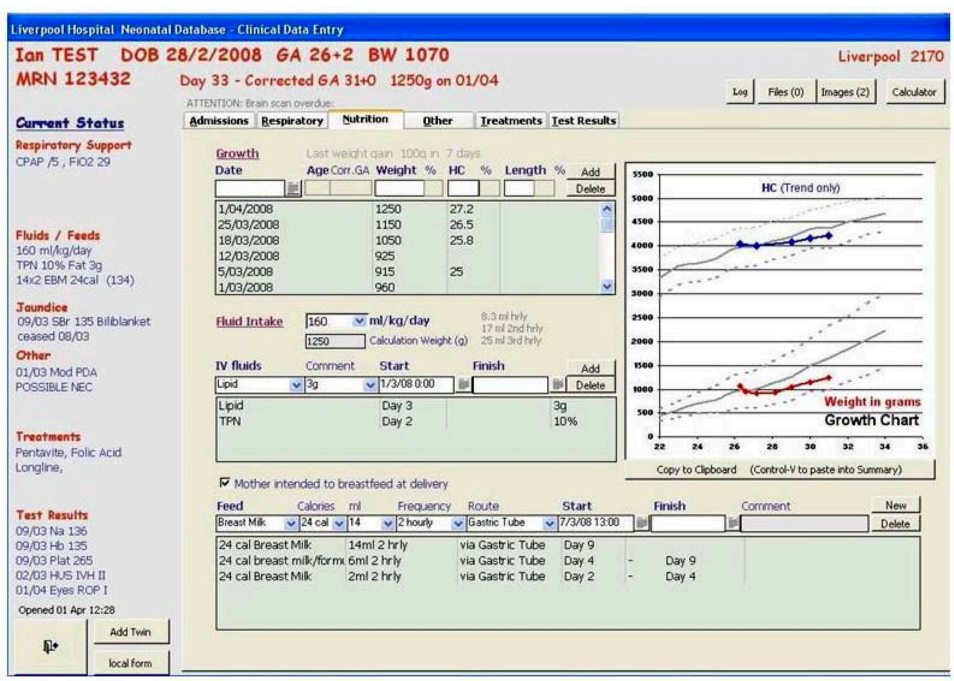
Maternal, Pregnancy, Patient (PMI) and Identity data are separated into related tables and then postnatal information is entered as Date-Timed records where possible, using the OHIO (Observational Historical Investigations Outcomes) Principle and Audit Outcomes are then derived.

There is every attempt to match a new baby / pregnancy with mothers who have had a previous baby in Neonatal Intensive Care in order to provide retrospective and longitudinal information. The majority of Hospitals in NSW are using the 'ObstetriX' system for collecting obstetric data and so an import program has been developed in order to seed patient data in the majority of cases. Importation from or connectivity with other data sources can be achieved with relative ease using the SQL Server.

Clinical Interface (Table/Figure 4)

Although the data is housed in a 'complex' but logical table structure, it is represented to the user via the MS Access frontend in a way that allows intuitive data entry. The vast majority of the patient information is contained within a single tabbed form that selectively shows / hides relevant data and contains hyperlinks where relevant. Parts of the dataset are summarised for review or graphed for trend analysis.

The clinical module is designed to be used 'quasi – live'; mostly this has been done on medical ward rounds using either a wireless laptop or bedside PC's. When the system is kept up to date then data entry is fast once the user is familiar with the system. Data changes are only needed to START or STOP treatments/ results / problems, and there are Date-Time short-



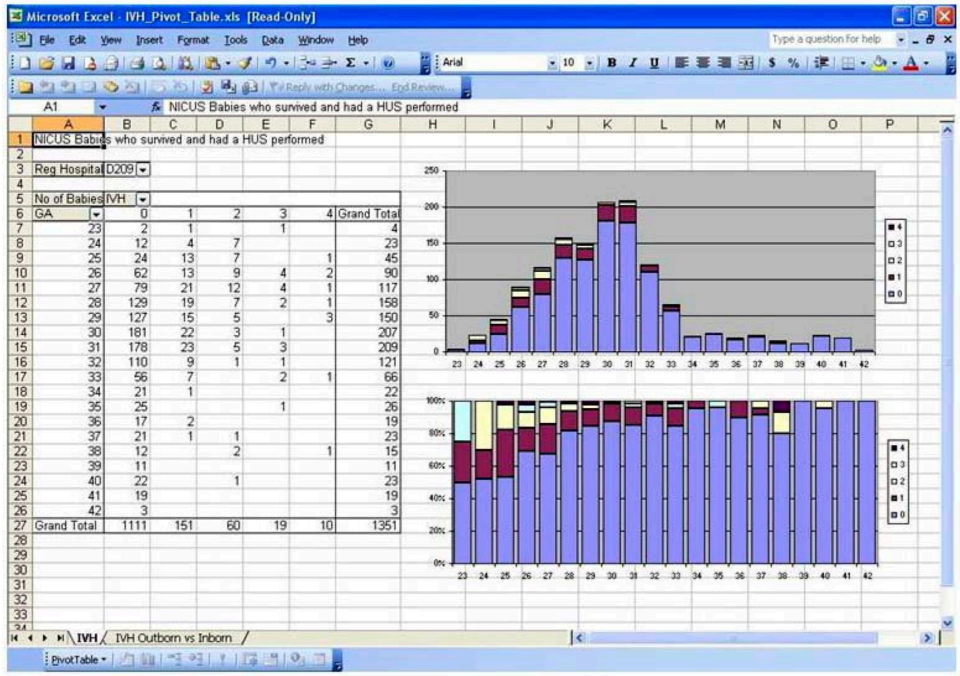
Table/Figure 4.

cuts that speed this up considerably. A Medical Discharge Summary is easily produced when data has been entered during the inpatient stay and is more comprehensive as well as more time efficient.

Neonatal Database - [AUDIT : Tab

Column Name	Data Type
NeonatalID	uniqueidentifier
NICBABY	smallint
L2BABY	smallint
DOB	smalldatetime
DOA	smalldatetime
BWPC	smallint
HCPC	smallint
NETS	smallint
NETSNO	nvarchar
MAge	smallint
MATDIS	smallint
ANCOMP	smallint
ROM	smallint
DROM	smalldatetime
RESTYPE	smallint
VENT	smallint
DMVENT	smalldatetime
HMECHV	smallint
HFVENT	smallint
HFOVDate	smalldatetime
HFOVHrs	smallint
CPAPDATE	smalldatetime
HCPAP	smallint
HVAPOTH	smallint
HOMECPAP	smallint
HOMEVAPOTH	smallint
endDtCPAP	smalldatetime
DATEO2	smalldatetime
CLD36	smallint
HOMEO2	smallint
HOMEVENT	smallint
AIRLEAK	smallint
ALDATE	smalldatetime

Table/Figure 5. Generated Summary Outputs.



GA	0	1	2	3	4	Grand Total
23	2	1		1		4
24	12	4	7			23
25	24	13	7		1	45
26	62	13	9	4	2	90
27	79	21	12	4	1	117
28	129	19	7	2	1	158
29	127	15	5		3	150
30	181	22	3	1		207
31	178	23	5	3		209
32	110	9	1	1		121
33	56	7		2	1	66
34	21	1				22
35	25			1		26
36	17	2				19
37	21	1	1			23
38	12		2		1	15
39	11					11
40	22		1			23
41	19					19
42	3					3
Grand Total	1111	151	60	19	10	1351

Table/Figure 6.

Audit Data Quality (Table/Figure 5)

The vast majority of quality Neonatal Audit is completely separated from clinical data systems which are known to be of dubious quality. The NICUS group has pride in the quality of the data being collected; there is a funded Audit Officer at each member Tertiary Hospital and a process for data quality assurance. The quality of the audit data has to be maintained when merging with a clinical system. For those hospitals using the clinical module, it is the practice of the nominated NICUS Audit Officer to perform data cleaning of a subset of the clinical data (plus addition of a small number of specific Audit data items) via the Audit Module after the patient has been discharged for several weeks (to allow for readmission). When the Audit officer is happy with the data quality the patient record is locked (still viewable from the clinical module). At the time of locking there is an automated data checking program and the generation of an output record of calculated summary items for that baby (same as entered manually in previous database). Once the patient record has been thus closed, the data is immediately available for analysis, and the NICUS group is currently looking at enabling 'live' inter-hospital benchmarking.

Reporting Functionality (Table/Figure 6)

Some reports are built into the MS Access frontend (e.g. Discharge Summary, Monthly Unit Report, NICUS Inter-hospital comparisons) but the most flexible reporting can be achieved using Ad Hoc Queries. In the same way as the MS Access frontend makes the table structure more easy to navigate, Queries (= Views) can represent data in a simple way from a complex underlying table arrangement, and can be saved and even used in further Queries as if they were another 'table.' These Queries can be viewed and created from MS Access (behind the user interface), and can also retrieve data directly from SQL Server to

"Within health organisations there is progressive implementation of electronic systems that reach beyond the role of Patient Administration System (PAS) and we are headed inevitably to the 'Electronic Medical Record', 'Electronic Charting' and 'Electronic Prescribing.'"

other outside programs such as Excel, Word or PowerPoint (tables, pivot tables, charts & mail merge), SPSS (or other statistics packages), Internet Explorer or other SQL Servers. The Open Source design makes anything possible without the need to pay for the software vendor to make changes for you.

Software, Hardware and Connectivity

The data sits on a single computer running SQL Server (Version 2000 or 2005); Microsoft has made available free Desktop versions of both – MSDE (desktop version of SQL2000) is available from the Neonatal Database Download Centre, and is capable of running over a small network. To purchase the full version of SQL2005 would cost around $US 2000 depending on local deals. However, it is very probable that your hospital already has SQL Server available to host the database, and this would be the preferable option if you wish to run a multi-PC environment.

Each Client PC would generally need to have MS Office Professional (including MS Access) 2000 or higher (2003 preferred) installed on it, although it is possible to have the Client PC act as a dummy terminal for a Citrix server that runs MS Office for multiple clients.

There is a free runtime version of MS Access 2007, but it has not been extensively tested by us.

The system runs over a typical hospital network, although some IT support may be required, particularly if not running a standard Windows Network. Multiple hospitals on the same network can automatically be connected to the same server. To connect hospitals from multiple networks, we would suggest that a central server connecting to peripheral servers be used, although a single WAN SQL Server could be used if the WAN was fast and reliable and the server capable of handling the simultaneous workload.

Data from other systems should be used to augment the system (and vice versa) when possible. As we have done for the ObstetriX program being used in NSW, importation of obstetric data to seed a neonatal admission is particularly useful. In this case we had the vendor create an ASCII text file output and wrote a conversion program (no different in principle to HL-7 import). If however external data is being held in a SQL accessible relational table structure then an automatic link / import from your SQL server would be ideal.

MERITS

Advances in Technology means that the Neonatal Units will increasingly have data downloaded from equipment, which will both replace paper and make data more accessible. Data from multiple sources will become 'connected' and will in turn offer the opportunity to audit data of a different magnitude, this includes longitudinal data (not just neonatal follow-up data but also data into adult life). Quality of the data needs to be considered when performing audit (even though the data item may be the same for clinical and audit use), but sheer quantity may still make some data (especially equipment derived) useful.

The current 'gold standard' of scientific evidence (RCT) is very expensive, time consuming, minutely focussed and often out of date at the time of publication. Audit data has in the past been considered by the research purist to be unworthy to be called "Evidence." If quasi real-time massive population (international) data collections can be analysed using data mining tools, then we have the capacity to detect associations well before detection would be possible by a human (if at all). In some cases the 'audit evidence' would be so strong that a RCT would not even be necessary.

Emerging countries with large populations but restricted finances (such as India) have the potential to collect audit data (if they have a PC and we give them free software) that if amalgamated would not only advance their own care but that of advanced countries because of scale.

The non-commercial neonatal database illustrated on the website is available for anyone who wants it (download or by arrangement on DVD with everything including instructional movies). This is to offer advanced audit capability (plus other trimmings) to those that would not otherwise be enabled to collect it, however our ultimate goal is the amalgamation of large scale audit data from any source, and for the recognition of the value of such collection by governments.

Merits Summary:

- Clinician Friendly
- Free download available
- Already in use for more than 2 years among various nurseries
- Open to local customization
- Allows itself to be linked to local hospital HIS
- Can be installed in local machine or across hospital network
- Gives user control over his own data
- Data can easily be accessed from Excel (refreshable)
- Development of the software continues in a collaborative environment

Project Support

As with any new initiative there have been teething troubles. Every attempt has been made to overcome these and we are keen to continuously improve the software. We wholly encourage the users to send us feedback so that the database evolves further, and is pertinent for the times. As the database is a free initiative and has been developed by clinicians with minimal IT support, the installation process is less automated. We encourage users who find the database useful to support the project through voluntary donations, spreading it in units they know or in any way they can contribute.

The Future

There has been incredible change in the use of computers and data in health care.

Within health organisations there is progressive implementation of electronic systems that reach beyond the role of Patient Administration System (PAS) and we are headed inevitably to the 'Electronic Medical Record', 'Electronic Charting' and 'Electronic Prescribing.' Large Database systems that try and perform all tasks for everybody are expensive and extremely slow to deliver what the clinician wants. In the Neonatal Intensive Care setting we have a relatively small number of patients connected to multiple machines capable of electronic output, being managed by a favourable ratio of staff who are becoming rapidly computer enlightened. There will continue to be evolution of parallel data systems, with some amalgamation along the way, but an increasing need to allow for data to be communicated between systems.

In the future, a box of obstetric medication being delivered to the pharmacy at Hospital A will become 'connected' to a neonatal saturation reading from a monitor at Hospital B – there will be common patient(s) and a temporal relationship. The sheer scale of data that will be available for analysis will mean that newer techniques will be needed, that do not depend on human inquisition. Data Mining techniques will be used to detect previously unknown associations (known associations would be adjusted for) in very large datasets. With such detection systems, both positive and negative effects of treatments could be noticed before a human could possibly notice an association. We should attempt to begin this process with the data available to us and increase the granularity of the data when we have the resources.

More information is available at the Neonatal Database Homepage: www.jcdr.net/NeoDB/NeoDB_Home.asp

"Advances in technology means that the Neonatal Units will increasingly have data downloaded from equipment, which will both replace paper and make data more accessible."

Conclusion

There is a demand for a Neonatal database which is clinician-friendly, captures most clinical data, and can be filled in along with routine clinical work (is not dependent on the audit officer), and is cost effective. Another need is the control over your data. A clinician should be able to with minimal expertise explore their data and draw conclusions. The Neonatal Database platform being offered by the journal fulfills these needs. This database has been in use in many nurseries around the world in the pre-launch trial period and has matured after valuable feedback. Since the Database is free it is hoped that its use becomes widespread and is not inhibited by subscription fees.

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Medical News, Products and Information

OxyAlert NIRSensor Correction and Current News

In the May 2009 issue of Neonatology Today, the news on Somanetics' OxyAlert NIRSensors for neonates and infants was in error. OxyAlert NIRSensors (pictured here) have been marketed since early 2008 for use with the INVOS System, which noninvasively monitors site-specific blood oxygen levels to help surgical and critical care teams protect patients against brain and vital organ area damage.

Current news surrounding the INVOS System includes an April 510(k) clearance for expanded labeling. The new labeling allows a claim of improved patient outcomes after surgery when the INVOS System is used to manage therapies in patients above 2.5 kilograms (kg). Additionally, its indications for use now reflect the INVOS System's ability to generate accurate real-time measurements of blood oxygen saturation.

"Our expanded indication reinforces the device's applicability for on-label treatment of patients at any weight," explains Bruce Barrett, Somanetics' President and CEO. "For patients above 2.5 kilograms – including adults, children and most infants – our proprietary algorithm generates accurate, real-time measurements for immediate use by the care team. In patients below 2.5 kilograms, which is extremely common in our neonatal market, clinicians may use our device on-label as a trend monitor."

These changes make the INVOS System the only commercially-available cerebral/somatic oximeter backed by an improved patient outcomes claim, and the only cerebral/somatic system (monitor and sensors) cleared for use on neonates less than 2.5 kg.

Additional new labeling states that, "In neonates, infants and children, cerebral and somatic regional oxygen saturation (rSO2) provide non-invasive indications of oxygen changes in the cerebral and peripheral circulatory systems and may provide an early indication of oxygen deficits associated with impending shock states and anaerobiosis."

The INVOS System's use in neonates was featured in 25 posters and presentations at the Pediatric Academic Societies (PAS) annual conference in May. The studies focused on early applications of the technology in the neonatal intensive care unit (NICU), including investigations of how cerebral/somatic blood oxygen data may correlate to severe conditions that are traditionally difficult to diagnose such as necrotizing enterocolitis (NEC) and patent ductus arteriosis (PDA).

NEC often arises unexpectedly due to largely unknown causes, and typically does not exhibit definitive signs until damage has already been done. When NEC is suspected, one standard response is to stop feedings so that the affected gut is not taxed.

"While useful to combat NEC, cessation of feedings has its own drawbacks such as stunting organ development in an already fragile neonate," explains Michael Wider, PhD, co-author of two of the PAS studies and Somanetics' vice president of technology and market development. "To better confirm which patients should not be fed, investigators are studying whether cerebral/somatic oximetry values have a correlation to feeding intolerance and the eventual development of NEC."

Six PAS studies explored the technology's role in caring for neonates with PDA. Studies are exploring how cerebral/somatic oximetry via the INVOS System may potentially be used to help detect oxygen deficits indicative of PDAs and to help determine whether surgical or drug intervention is required.

Another study examined four drugs, commonly used in the NICU to manage a range of severe conditions, and their effect on cerebral and somatic (e.g., abdomen, kidney area, muscle) rSO2. The INVOS System showed that each drug produced distinct medication-specific changes to rSO2, and that this pattern was also tied to dosage.

"While drug therapy is very successful at managing numerous conditions in the NICU, clinicians may not have fully appreciated its impact on vital and non-vital organ area oxygenation because this type of data was simply not available before," adds Wider. "Arming clinicians with this previously unavailable data gives them important additional information to consider when assessing neonates and care protocols."

NEONATOLOGY TODAY

Developing a Genetic Test for Pregnancy Risks

Newswise — University of Adelaide researchers in Australia are developing a world-first genetic test that can predict which pregnancies are at risk of complications long before symptoms arise.

Led by Associate Professor Claire Roberts, Senior Research Fellow in the University's new Robinson Institute, the researchers have identified subtle variations in specific genes within the mother, father or baby that indicate the mother is more likely to suffer from pregnancy complications.

This advance will permit tailored, and sometimes potentially life-saving, antenatal care and constitutes a quantum leap forward in the care of pregnant women and their babies.

The research has also identified potential therapies for use in early pregnancy to improve placental development and function and reduce the risk from pregnancy complications.

"Our findings show that it does actually take two for successful pregnancy," Associate Professor Roberts says. "Pregnancy success is determined by a complex interaction of maternal, paternal and environmental characteristics that together dictate how well the placenta develops and functions and how the mother adapts to pregnancy."

"Defects in how well the placenta develops and functions are implicated in common pregnancy complications ranging from miscarriage, through preeclampsia, pre-term birth and fetal growth restriction. The problem with complications is that we are unable to predict which women are at risk until symptoms develop, and then therapies can be too little, too late."

Prenatal Meth Exposure Linked to Abnormal Brain Development

Newswise — A first of its kind study examining the effects of methamphetamine use during pregnancy has found the drug appears to cause abnormal brain development in children. The research was published in the April 15, 2009, online issue of Neurology®, the medical journal of the American Academy of Neurology.

"Methamphetamine use is an increasing problem among women of childbearing age, leading to an increasing number of children with prenatal meth exposure," said study author Linda Chang, MD, with the John A. Burns School of Medicine, University of Hawaii at Manoa in Honolulu. "But until now, the effects of prenatal meth exposure on the developing brain of a child were little known."

For the study, brain scans were performed on 29 three and four-year-old children whose mothers used meth while pregnant and 37 unexposed children of the same ages. The MRI scans used diffusion tensor imaging to help measure the diffusion of molecules in a child's brain, which can indicate abnormal microscopic brain structures that might reflect abnormal brain development.

The scans showed that children with prenatal meth exposure had differences in the white matter structure and maturation of their brains compared to unexposed children. The children with prenatal meth exposure had up to four percent lower diffusion of molecules in the white matter of their brains.

"Our findings suggest prenatal meth exposure accelerates brain development in an abnormal pattern," said Chang. "Such abnormal brain development may explain why some children with prenatal meth exposure reach developmental milestones later than others."

Studies have shown that prenatal meth exposure can lead to increased stress and lethargy and poorer quality of movement for infants.

"While we don't know how prenatal meth exposure may lead to lower brain diffusion, less diffusion of molecules in white matter typically reflects more compact axonal fibers in the brain," said Chang. "This is consistent with our prior findings of smaller subcortical structures in children with prenatal meth exposure, which is the portion of the brain immediately below the cerebral cortex."

Long-term studies are underway to determine if the brain differences found in children with prenatal exposure to meth will normalize with age.

The study was supported by the National Institute on Drug Abuse, the National Center for Research Resources, the National Institute of Neurological Disorders and Stroke and the Office of National Drug Control Policy.

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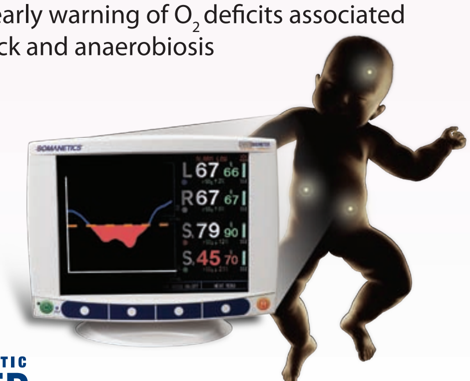

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