

VIII. DISSEMINATION OF KNOWLEDGE, CENTERS OF EXCELLANCE PROGRAM

A. Introduction

This section includes the proposal for and interim results from the EU sponsored program for the establishment of Centers of Excellence throughout Europe utilizing the STAN S21 Fetal Heart Monitor.

Specific objectives of this program:

1. With the aid of an improved system for monitoring the baby during delivery, the STAN S21 Fetal Heart Monitor together with a dedicated teaching and training package, we aim to improve the understanding of fetal reactions during labor among labor ward staff. As a consequence, the staff will be able to separate those babies not capable of handling the stress of birth and oxygen deficiency from those less affected.
2. This will be done by using a model whereby academic centers across Europe, as a joint effort, are made partners of a currently industry driven knowledge transfer process. These centers of excellence then become the regional hub of experience stimulating other units to follow in a structured fashion.
3. An important objective is to develop teaching and training tools that would stimulate to self-learning. This will be done by applying modern IT-based tools such as computer assisted learning, on-line user support together with hands-on experience with a rapid feed-back on goals achieved. The training process is supported by a system for user certification.
4. Thus, a system for continuous technology surveillance is developed, targeting a safe reduction in the number of operative interventions for threatening fetal oxygen deficiency without placing the baby at risk.

The reason for including this information in the PMA is that Neoventa intends to use this same approach to introduce the STAN system into the United States.

The education and training materials and user certification are included in Section IX of this PMA.

Dissemination of a knowledge based system for determining appropriate intervention during labour based on a qualified analysis of the fetal electrocardiogram.

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Objectives and expected achievements

General objective

The expectation of society is that the application of the results of health technology assessment will improve quality of care and ensure that available resources are used effectively. The objective of the proposal is to develop and validate a model whereby the user aspects are put to the fore to stimulate postgraduate training and an appropriate management structure.

Specific objectives

Fetal surveillance during labour constitutes a challenge in information management. To give birth is a natural process for women. For the child it may constitute a threat for intact survival and ominous changes may appear within minutes putting labour ward management to the fore front of medical high risk management. The nurse/midwife/obstetrician manages this complex situation by visual analysis of a host of information constituting clinical, as well as directly recorded data from the fetus in particular. ST waveform analysis of the fetal electrocardiogram has emerged as a valuable tool to diagnose adverse fetal events during labour.

1. With the aid of an improved system for monitoring the baby during delivery, the STAN@S 21 fetal heart function monitor together with a dedicated teaching and training package, we aim to improve the understanding of fetal reactions during labour among labour ward staff. As a consequence the staff will be able to separate those babies not capable of handling the stress of birth and oxygen deficiency from those less affected.
2. This will be done by using a model whereby academic centres across Europe, as a joint effort, are made partners of a currently industry driven knowledge transfer process. These centres of excellence then become the regional hub of experience stimulating other units to follow in a structured fashion.
3. An important objective is to develop teaching and training tools that would stimulate to self learning. This will be done by applying modern IT-based tools such as computer assisted learning, on-line user support together with hands-on experience with a rapid feed-back on goals achieved. The training process is supported by a system for user certification.
4. Thus, a system for continuous technology surveillance is developed, targeting a safe reduction in the number of operative intervention for threatening fetal oxygen deficiency without placing the baby at a risk.

Expected achievements

Some aspects of this training program has been applied as part of the preparation of an on-going Swedish multi-centre trial involving more then 300 labour ward staff. The tools so-far used have been introductory lectures followed by self studies from written and multi-media based teaching material including a computer based "trainer". This is a simulator displaying real recordings during labour using a library of more than 3000 cases.

Recently, an enquiry was made at one of the centres. The main purpose was to assess the reactions of the nursing staff to the new ST concept. 90% said the practical support provided was excellent. This support included on-demand individual and group teaching and direct support during the first 6 months of the trial by an expert fellow midwife.

Everyone said the automatic assessment of ST changes, the ST log was most useful and trusted its statements completely. 73% thought that the computer screen was useful and could be developed further as a means of displaying information. All midwives but one thought the clinical guidelines caused no problems and as a result of this overwhelmingly positive attitude, 71% said ST analysis gave an enhanced feeling of security because of an increased ability to identify fetuses at risk. Furthermore, everyone thought ST analysis had become a valuable complement to the standard CTG monitoring. It should be noted this enquiry was undertaken prior to any knowledge regarding the outcome of the.

Maybe such a positive response to a new technology could only be achieved at one key centre. However, we do not believe that to be the case and would like to take on the challenge of developing and validating new instruments for knowledge transfer within the field of perinatal medicine. This can only be done as a joint effort involving academic centres across Europe adapting the current ST programme to the local culture.

The success of this program will enhance the ability of the obstetric profession to understand more about how the baby reacts to the process of being born and to deliver improved services to the family and society.

Contribution to programme objectives.

The knowledge transfer process involves, in the first phase, knowledge transferred from the academic/research environment to industry, and in the second phase, from industry to the customer. It is our belief that there is a need to refine both these knowledge transfer processes. The closer to the customer we get the more important it becomes that the intention of the knowledge and the product is made clearly visible.

By definition the research based knowledge will always be at the forefront of current thinking. A support structure has to be developed to secure optimal use of the knowledge gained and scientifically proven. Therefore, as an SME (small/medium size enterprise) with an innovative product it seems logical to involve the professional academic community as experts on teaching and training as well as in the more conventional R&D aspects. The plan is to allow these key academic centres to obtain their own experience with, not only the device itself but also with the teaching and training package developed jointly.

The specific task of the current proposal "Dissemination of a knowledge based system for determining appropriate intervention during labour based on a qualified analysis of the fetal electrocardiogram" concerns the whole industrialised world where electronic fetal monitoring has become part of standard management during labour. The total instrument population in the EU has been estimated to more than 25000 units with 4160 sold per annum.

The project develops new teaching tools such as a trainer/simulator which allows midwives and doctors to earn their own experience from displaying real cases from our data base virtually. This enables exposure to rare but important cases otherwise not experienced and handled during ordinary training. A dedicated teaching module is developed to fit with the different cultural aspects. Staff certification becomes essential with continuous assessment of skills through dissemination of test cases. The ultimate test will be a surveillance of clinical outcome regarding frequency of interventions and cases born with biochemical evidence of fetal distress (umbilical cord metabolic acidaemia). This will be part of the research element.

The demonstration element contains the introduction to the labour ward of a medical device, STAN@S 21, required to obtain accurate information from the fetus.

Innovation aspects.

The Fetal Electrocardiogram

Similar to the adult stress test, ST waveform analysis of the fetal ECG, affected by the stress of labour, should provide key information about the ability of the high priority organ, the fetal heart to respond. This assumption seems to hold true and ST analysis has emerged, not as an alternative to cardiotocography but as a support tool to allow more accurate interpretation of intrapartum events along the lines depicted in *Figure 1*. Furthermore the fetal ECG is readily obtainable during labour from the same scalp electrode used to obtain the fetal heart rate and no alterations are required in the patient handling routines.

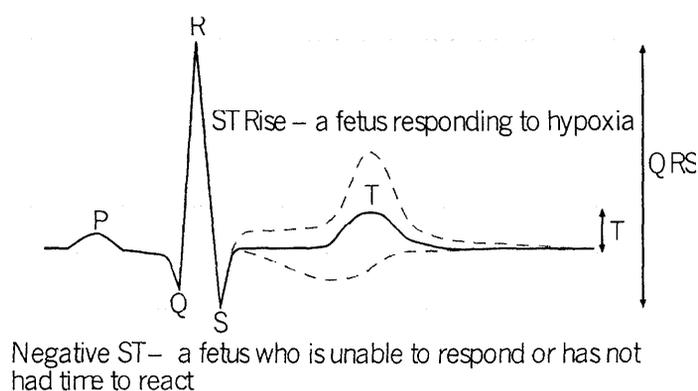


Figure 1 The electrocardiogram with a schematic presentation of hypoxia related changes. The T/QRS ratio measurement is also indicated.

Figure 1 indicates those parts of the ECG, which have provided specific information on the fetal response to hypoxia. The waveform marked P corresponds to the contraction of the atrium. The next sequence is the contraction of the ventricles, which is illustrated by the waveforms Q, R and S. The generation of these waveforms are passive events and thus very stable and easily detected which makes it well suited for fetal heart rate recording. The ST waveform changes, on the other hand, are more easily affected by signal noise, mode of ECG recording etc. Neoventa Medical AB has developed proprietary knowledge of how to avoid and handle these problems.

Dedicated research

The concept of ST analysis has been developed through a continuous validation process, starting with experimental research followed by bioengineering developments and the generation of a dedicated medical device.

Currently there are 10 MD and PhD thesis's from Sweden, the UK and Italy providing the scientific knowledge on basal physiology, bio-engineering, including modern digital signal processing and clinical usage.

The latest thesis describes the findings of a European multicentre trial of 320 high risk pregnancies. The cases were managed according to the routine CTG with blinded ST

information (data stored on a PC connected to a STAN® prototype unit). There were six cases of marked oxygen deficiency (hypoxia), all of which showed ST waveform changes of a magnitude to signify immediate delivery ^(Ref 27).

Another example of what could be achieved by using this CTG+ST technology was shown in the Plymouth randomised controlled trial of CTG only versus CTG+ST ^(Ref 25). This trial included 2.400 cases showing a 46% reduction in operative interventions for threatening fetal distress with indications of improved outcome among babies monitored by the STAN® prototype recorder. This achievement was made by improvements in the ability of the staff to interpret fetal reactions and save the hospital, £32.50 per delivery. Many of the obstetric centres involved in these initial assessments have now agreed to co-operate in the further dissemination of the CTG+ST methodology.

Not until today after more than 25 years of dedicated R&D, do we have the computing capacity and knowledge available for designing a modern instrument for intrapartum fetal monitoring. An example is the expert system approach applied whereby the computer incorporated into the new STAN®S 21 fetal heart function monitor recognises any relevant ST waveform changes and informs the operator by messages on screen and paper print-outs. This ST log function in combination with the CTG+ST clinical guidelines has recently been shown to accurately identify all 15 babies with marked oxygen deficiency among a group of 574 Swedish and Norwegian babies. Although conventional CTG monitoring was used to assess the condition of the baby, still these cases were missed. As a consequence three of these babies are likely to suffer permanent brain damage. Furthermore, there is also the SME with financial resources and industrial competence to take the ST-project further onto the international market.

Fundamentals of the project

The additional information gained from ST-analysis seems to add substantially to our understanding of how the fetus manage labour. The awareness of the current clinical situation has stimulated academic centres across Europe to form a consortium with Neoventa Medical, the SME responsible for the development of the ST concept. The challenge is now to take the knowledge forward.

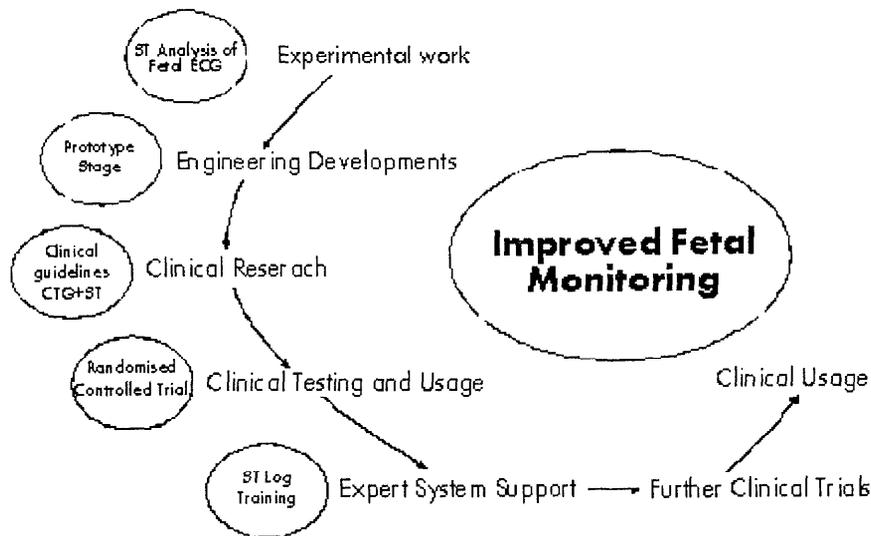
Should this project await further data or should the market introduction be of a more common design, e.g. a more commercially driven market introduction? The current CTG technology was introduced with very little understanding of how the technology would work in the labour wards. As a consequence fetal surveillance during labour has largely been a disappointing story which should not be repeated. The scientific basis of the ST concept is sound and the tools are now available whereby the firm clinical guidelines could be implemented more accurately provided a joint effort is made. Consistent training and market surveillance has to come to the fore as an essential component of market introduction. We believe that the consortium operating under the auspices of the EU will have a unique opportunity to achieve the goal of a safe introduction of a modern computer assisted system for intrapartum fetal surveillance based on a thorough understanding of the physiological and bio-engineering principles involved.

Project workplan

Introduction

The programme will bring a model of customer teaching and training from its current status of a programme operating in a few labour wards in Sweden and Norway to a phase of more general European dissemination. Leading academic centres (CoE) across Europe are provided with an opportunity to verify with their own experience the usability of the new system for fetal monitoring during labour.

The development of the ST concept of intrapartum fetal surveillance could be summarised according to the following graph.



The following work packages should be regarded as the components required to secure the relationship between clinical usage and the ultimate goal of improved fetal monitoring.

Work package no 1

Refinement of the teaching and training package

Objectives

1. To develop the simulator function by including more cases.
2. To upgrade the existing version and adapt it for international usage.
3. To enable the use of both PC and Macintosh platforms.
4. To undertake surveys of how the training is perceived and knowledge gained.
5. To develop a model for user certification.

Milestones and expected results

This WP interrelates very closely with WP 2 and 4. In principal the milestone related to WP1 will be software to include validated teaching, training and certification modules. The labour ward manager will have a tool whereby it should be possible to achieve knowledge transfer in a controlled fashion with a considerably improved understanding of the reactions of the baby to the stress and strain of labour. At the same time the staff will have a simulator tool to use not only when discussing cases among themselves but also to stimulate self-learning. Furthermore, this simulator module will include cases, not only generated within the department but also from other obstetric centres across Europe.

Work package no 2

Dissemination of the CTG+ST concept to academic CoE.

Objectives

The prime objective is to implement and test a model of knowledge transfer using the labour ward setting and the task of intrapartum fetal monitoring as a test site.

Other essential objectives will be:

1. To have a core group of doctors and midwives becoming local experts to guide the development of centres of excellence.
2. To disseminate the knowledge contained in the CTG+ST programme throughout the staff.
3. To conduct a demonstration project whereby a new medical device is made use of in a standardised way and at the same time undertake a study testing the feasibility of improving quality of care by implementing a strict clinical protocol.
4. To undertake a staff certification process.

Milestones and expected results

The key milestone will be the establishment of a centre of excellence to include the following:

1. Certified staff
2. Scientific data to confirm the potential of the CTG+ST concept
3. A process for continuous validation of the efficacy of the interaction between the staff and the technology.

The expected final result will be a reduction in the number of operative interventions without placing the baby at risk. In fact, there is the possibility that at the end of the first year pooled data analysis will show a reduction in the number of babies born with biochemical evidence of significant oxygen deficiency during labour.

Work package no 3

Development and testing of a system for assessment of clinical management.

Objectives

To obtain information on the relationship between the clinical situation (the appearance of risk situations) and clinical management on-line and retrospectively.

Milestones and expected results

The ability of the labour ward manager to have a close surveillance of the functioning of the monitoring system is of vital importance. This central monitoring function, developed within the project will provide full cover of emerging abnormalities in a most flexible way. It is envisaged that all clinical partners will be equipped with these facilities to cover the need for on-line system surveillance and key parameter data storage.

Furthermore, WP3 will provide firm indications of the amount of staff training required to enable optimal use of the CTG+ST technology.

Work package no 4

Further regional CTG+ST knowledge dissemination

Objectives

1. To disseminate the centrally and locally gained knowledge and experience.
2. To utilise the CoE structure for a safe and efficient knowledge transfer process.
3. To achieve substantial improvements in health care.

Milestones and expected results

Fetal surveillance during labour constitute a challenge in information management. On the basis of medical and socio-economic aspects, there is an urgent need to improve the quality of intrapartum care.

WP4 will provide a thorough test of a documented model of knowledge transfer. The model will be presented as a final report and utilised in the world wide dissemination of a knowledge based system for determining appropriate intervention during labour based on a qualified analysis of the fetal electrocardiogram.

The measurable milestone will be more appropriate interventions during labour based on a qualified analysis of the fetal electrocardiogram.

Furthermore, the project would have achieved

1. A dedicated SME with considerably improved staff skills.
2. An interactive model for safe and efficient dissemination of the knowledge jointly gained operated by an expanding of European centres of excellence.

C3 Management and resources

Project management

The programme utilises an already existing infra structure which holds extensive experience extending from product development, to knowledge based marketing and professional teaching. In particular, the consortium has vast experience in the field of intrapartum fetal monitoring. The project will be managed by the co-ordinating company Neoventa Medical. The company have been developed on the basis of the ST project with the documentation aspects at its heart. The company will allow key staff to focus their work on the successful implementation of the project. The strategy to build the marketing of the >2.000.000 ECU STAN® S 21 investment on development of C o E is a strategic company policy.

The academic centres all have outstanding research and teaching achievements in the field of fetal monitoring and they are all one of the leading centres in their country. They will enhance their role as centres of excellence even further and attract new staff to conduct research and training.

WP 1

WP1 will to great extent involve work utilising Neoventa staff with input from associate partners. The start of WP1 will be a 1½ day workshop where all participants would meet to be presented with the first version of the teaching and training package. Although most of the senior scientists are known to each other and are well acquainted with the ST project, it is important that a feeling of “ownership” of the project is created at an early stage. Much of the work packages are based on refining processes initially developed within the ST project and the Neoventa company over the years. The emphasis of the program is to allow this knowledge to be distributed throughout the perinatal community of Europe with a strong emphasis on customer feed-back. This implies a top-down management structure within the program. However, very little will be gained if not the individual CoE are allowed to put their expertise and experience into the final training package. The key progress monitoring measure will be the distribution of the teaching packages to the different centres.

WP 2

WP 2 will have more of a decentralised structure where the different activities will follow the time plan agreed upon. However, local factors may affect the time it will take before the training have been fully implemented. During this initial learning phase, it will be necessary that the C o E are visited on a regular basis by the co-ordinator. Regarding deliverables during WP2, number of recordings per day would be a useful indicator of progress monitoring initially. As the work package develops, clinical action according to CTG+ST guidelines becomes the ultimate tool to assess the success of the work package as the number of staff being certified.

WP 3

This work package will involve two main items:

1. The development of a model for continuous CTG+ST assessment through transmission of ST log information from the STAN® S 21 monitors to the labour ward manager. This

system will be developed by Neoventa Medical and will be a research component. It is envisaged that the “Bluetooth” technology developed by Ericsson Microwave system, as part of an international consortium will become a new standard for short distance data transmission and may serve as a flexible and cost efficient method by which the labour ward manager may, in a non intrusive way monitor ongoing events.

2. The development of a staff and CTG+ST system performance module. This part of the WP will be based on the joint assessment by a panel of C o E experts, that will intermittently monitor the results from using the STAN® S 21 monitors with the target of achieving a 50 % reduction in operative intervention for fetal distress as compared with conventional monitoring technique without placing the fetus at risk of significant oxygen deficiency.

WP 4

WP 4 will be developed by the C o E and the timing will depend on the assessment of staff and system performance according to WP 3. Due to local variations the start of WP 4 may vary somewhat but it is envisaged the a successful completion of WP 1, 2 and 3 should mean the five more centres per C o E will become fully certified for the use of the CTG+ST technology.

There is a quality assurance process built into every part of the program and the documentation of quality assessments, such as staff certification and successful protocol implementation should serve as methods by which the motivation is kept very high.

The legal aspects are well identified as the STAN® S 21 fetal heart function monitor will have received approval according to the EU Medical Device Directive prior to commencement of the clinical part of the programme. It is envisaged that all findings will become part of the public domain and published in scientific journals.

The partnership

Participant no 1

The co-ordinator Neoventa Medical is a young company based on 25 years of experience from bringing the ST project forward.

The management team consist of the following individuals:

Prof. KG Rosén, MD, co-ordinator, pediatrician and perinatal physiologist. Inventor and project leader of the STAN® development since more than 25 years. Between 1991 and 1994, KGR was the inaugural dean of the Plymouth Postgraduate Medical School, University of Plymouth, UK, where he is continuing as a visiting professor. KGR is frequently used as a consultant in various medical projects. His position at Neoventa is Medical director.

Arne Samuelsson, MSc. AS has been responsible for the technical development, quality control and service function of the STAN® system since 1988. AS has gained a lot of technical expertise within the field of signal processing as leading engineer at Ericsson

Microwave Systems. AS is now heading the implementation of STAN® S 21. AS serves as technical director at Neoventa.

Kent Olsson, University studies in marketing and business administration. KO has gained medical business expertise from years in executive positions in the pharmaceutical and diagnostics industry. He has served in well-reputed companies such as Johnson & Johnson, Glaxo-Wellcome, Pharmacia Upjohn and Abbott Diagnostics. KO holds the position managing director incl. responsibility for the marketing function.

The following obstetric departments have agreed to participate in the programme. They are all of the highest international standards and would, as part of a joint effort considerably enhance the likelihood of a successful completion of the project:

1. Department of Obstetrics and Gynaecology, Oestra Hospital, University of Gothenburg, Sweden (ass prof Henrik Hagberg).
2. Department of Obstetrics and Gynaecology, University of Turku, Finland (prof Risto Erkkola).
3. Department of Obstetrics and Gynaecology, Rikshospitalet, University of Oslo, Norway (Overlege, Dr Med Per Boerdal).
4. Department of Obstetrics, Gentofte Hospital, Copenhagen, Danmark (Overlege Karsten Lenstrup).
5. Department Obstetrics-Virchow-Klinikum, Charité, Berlin, Germany (prof Joachim Dudenhausen).
6. Department of Obstetrics and Gynaecology, Hospital Eduard Herriot, University of Lyon, France (prof Jean-Marie Thoulon).
7. Department of Obstetrics and Gynaecology, Derby City General Hospital, University of Nottingham, United Kingdom (prof S Arulkumaran).
8. Department of Obstetrics and Gynaecology, University of Perugia, Italy (prof Gian Carlo Di Renzo).
9. Department of Obstetrics and Gynaecology, University Hospital Utrecht/Wilhelmina Children's Hospital, University of Utrecht, The Netherlands (prof Gerhard Visser).
10. Department of Obstetrics and Gynaecology, Derriford Hospital/Plymouth Postgraduate Medical School, University of Plymouth, United Kingdom (prof Keith Greene)

Participant no 2

Department of Obstetrics and Gynaecology, Oestra Hospital, University of Gothenburg, Sweden (ass prof Henrik Hagberg).

This unit has been a key centre and today holds the most experienced staff. The department is currently involved in the large Swedish randomised controlled trial of CTG versus CTG+ST and has participated in several previous STAN® trials. The department has an important role in serving as the initial centre of excellence where staff from other European centres would get their initial training in practical device handling.

The department is the largest in Sweden and has two of its labour wards equipped with STAN® prototype systems covering 5000 - 5300 deliveries per annum.

The project is led by ass prof Henrik Hagberg who has achieved a position in the international scientific community because of his research into mechanisms of hypoxic brain damage in the new-born.

Participant no 3

Department of Obstetrics and Gynaecology, University of Turku, Finland (prof Risto Erkkola).

The Department has a longstanding interest in the field of fetal monitoring and has previously participated in the evaluation of the fetal ECG during labour. It has 3600 deliveries per annum and serves as a referral centre for high risk pregnancies. Prof Erkkola is well known and respected and has contributed to the development of perinatal medicine for many years.

Participant no 4

Department of Obstetrics and Gynaecology, Rikshospitalet, University of Oslo, Norway (Overlege, Dr Med Per Boerdal).

Rikshospitalet holds a central role in the Norwegian health care system. In the fall, the department will move into the newly built hospital with enhanced capacity for teaching and training. The labour ward unit has been involved in the preliminary evaluation of the CTG+ST methodology.

Participant no 5

Department of Obstetrics, Gentofte Hospital, University of Copenhagen, Denmark (Overlege Karsten Lenstrup).

The unit manages 2400 deliveries per annum and is well known as national teaching and training centre. Dr Lenstrup has been using the ST technology since its prototype stages and he has a proven interest and capacity in teaching his Danish colleagues and midwives.

Participant no 6

Department Obstetrics-Virchow-Klinikum, Charité, Humboldt University, Berlin, Germany (prof Joachim Dudenhausen).

Prof Dudenhausen has a longstanding interest in the fields of fetal physiology and fetal monitoring. He is editor-in-chief of J Perinatal Medicine, the leading European journal.

Participant no 7

Department of Obstetrics and Gynaecology, Hospital Edouard Herriot, University of Lyon, France (prof Jean-Marie Thoulon).

The labour ward unit has between 2800 and 3000 deliveries per year. It serves as a referral centre with many high risk pregnancies. The Cesarean section rate is 21%. There is a 24h service with obstetrician, anaesthesiologist and neonatologist.

Prof J-M Thoulon and his unit has previously participated in the validation work on fetal ECG waveform analysis. The unit serves as a regional centre for teaching and training.

Participant no 8

Department of Obstetrics and Gynaecology, Derby City General Hospital, University of Nottingham, United Kingdom (prof S Arulkumaran).

This is a rapidly developing academic unit that was set up 1½ years ago by prof Arulkumaran on his shift from Singapore University to University of Nottingham. The labour ward has approx 4000 deliveries per annum. Prof Arulkumaran is a leading name in international obstetrics and has been actively involved in the ST evaluation work since 1987.

Participant no 9

Department of Obstetrics and Gynaecology, University of Perugia, Italy (prof Gian Carlo Di Renzo).

From 1983 to 1994 he was Professor of Prenatal Medicine at the Postgraduate School of Obstetrics and Gynaecology at the University of Chieti and since 1992 he is Professor of Obstetrics and Gynecology; Prenatal Medicine and head of Obstetrics and of research laboratories at the Department of Gynecological, Obstetric and Pediatric Sciences at the University of Perugia.

His research interests have been focused on: prostaglandins and parturition, amniotic fluid, fetal lung maturity, childbirth organization, fetal monitoring, preterm labour, gynecologic endocrinology. He is principal investigator of several research projects for the National Research Council and for the Ministries of University and Health of Italy.

Participant no 10

Department of Obstetrics and Gynaecology, University Hospital Utrecht/Wilhelmina Children's Hospital, University of Utrecht, The Netherlands (prof Gerhard Visser).

Obstetrics is part of the Perinatology unit and serves as a regional center for high risk pregnancies. The department has 2000 deliveries and is located in a brand new hospital with all modern facilities. Prof Visser has contributed to our understanding of fetal reactions and response to hypoxia for more than 25 years.

Participant no 11

Department of Obstetrics and Gynaecology, Derriford Hospital/Plymouth Postgraduate Medical School, University of Plymouth, United Kingdom (prof Keith Greene)

The Perinatal Research group conducted the first randomised controlled trial on CTG+ST. Since then prof KR Greene has focused his research into the application of intelligent systems for the assessment of CTG and cord-acid base. The labour ward is one of the largest in the UK with approx. 5000 deliveries per annum.

C4 Community added values and contribution to EU policies

With the introduction of electronic fetal monitoring during the seventies there was the hope that we would see marked improvements in care during birth with appropriate intervention for oxygen deficiency in particular and less babies put at risk of hypoxic brain damage. Electronic fetal monitoring is an example of the limited use of the information available. Today, interpretation of clinical data during this high risk situation is still based on visual fetal heart rate analysis (CTG) according to thirty year old empirically based interpretation models. These interpretation models are known not to provide the information required and to not meet the demands of modern obstetric care. As a consequence operative deliveries are overly used for what is, often wrongly perceived as threatening oxygen deficiency. This frequently means unnecessary intervention with normal labour with an increased health risk for the mother and child as well as increased health expenditure. Another and even more serious consequence is that abnormal CTG-patterns are sometimes missed and babies are injured. In some EU countries the medico-legal costs are escalating as a consequence of uncertainty in interpreting the signals obtained from the fetus during birth. Thus, improvements in intrapartum fetal surveillance is still one of the challenges of modern medical technology.

The demonstration component is the dissemination of new fetal heart function monitor (STAN® S 21) which has been constructed and build according to the regulatory requirement of Europe - Medical Device Directive, MDD and the US - Quality System Regulations, QSR. It is of great importance that the well proven knowledge contained within the ST concept is made available to the end-user. Today there are no specific requirement regarding the implementation of a medical device knowledge transfer process. Action according to regulatory requirements is only required when things go wrong - obviously too late in a situation such as labour when oxygen deficiency may institute a threat to life and intact survival.

At the core of the programme is the trans European dissemination of knowledge and experience gained and validated in a few European countries. Neoventa has proven its ability to operate and develop the ST methodology working as a joint partner with well established health care institutions. Throughout this process the need for a thorough understanding of the physiological and clinical mechanisms involved have been well defined. To bring the ST technology into general use requires the creation of a critical mass of internationally and nationally recognised obstetric centres. For many years, European scientists have been dominating and it would be most relevant for the EU to support the commercialisation phase thereby safeguarding:

1. The introduction of a thoroughly validated, safe and cost-efficient health care technology.
2. The support of an SME with the potential of gaining world wide acceptance for its knowledge based technology.
3. The testing of a new management oriented method of knowledge and technology transfer.
4. The further enhancement of European centres of excellence.

C5 Contribution to Community social objectives.

Currently, it is known that between 5 and 10% of all pregnancies are exposed to operative interventions for what is perceived to be threatening lack of oxygen. The intention of the project is to promote the dissemination of a methodology based on a more thorough identification of fetuses at risk of oxygen deprivation during labour, thereby significantly reducing the risk of unnecessary operative interventions and less babies suffering.

The standard methodology of fetal surveillance (CTG) is generally regarded as one of the most difficult to interpret causing great concern among labour ward staff throughout Europe. From the enquiry into staff attitudes we have indications that the midwives appreciate a well designed support structure when introduced to something new. If successfully implemented the new IT based teaching and training module as well as the on-line user support should provide labour ward management with a more appropriately structured staff support. Obviously, if the CTG+ST technology meets with the requirements of modern health care, there would be the opportunity of a general dissemination to regions currently not involved in the scientific evaluation of new technologies.

C6 Economic development and scientific and technological prospects – Exploitation and dissemination plans.

The project focus on developing and validating a model for improving the accuracy of knowledge dissemination and thereby the interface between man and machine. If this is achieved, it is anticipated that the CTG+ST methodology will be applied generally throughout the industrialised world in managing one of the most high risk situations of normal health care – the process of being born.

We know from previous experience that the key to market acceptance is the weight of the scientific data and the support provided by academic centres of excellence. The ST project already today has achieved a strong scientific base with a unique premarketing opportunity to build a customer oriented support structure in anticipation of a more general market acceptance. Thereby, we hope to avoid problems related to an inappropriate usage. An illustration of this problem is the key-hole surgical technique introduced some 10 years ago. It earned a very rapid market acceptance followed by substantial claims for malpractice as the technology was used without to little customer support and training. Today, after 10 years of trial and error it is being applied more appropriately. Neoventa Medical realises that the ST technology has to be introduced with such experience in mind and the following pages illustrates how this could be achieved.