



FOBIS – Foresight studies on biomedical sensor

How will biomedical sensors shape the healthcare systems of the future? How can they impact the quality and cost of healthcare and what are the business opportunities in the Nordic region? A Nordic consortium headed by SINTEF (Norway) and with the participants VTT (Finland), FOI (Sweden), S-SENCE (Sweden), STC (Denmark) and MedCoast-Scandinavia is conducting a foresight study on Biomedical Sensors. The project is supported by the Nordic Innovation Centre. The project revolves around a series of workshops, the first on to be held in Copenhagen 6–7th October, the second in Oslo, 2nd November. More information is found on our web-site: www.nordic-fobis.net.

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The next FOBIS workshop will be held in Stockholm 3 March 2006 with the theme *How do we get there?*

Key note speakers are:

- Prof. Ingemar Lundström (Linköping)
- Prof. Brian MacCraith (Dublin)
- P-O Söderström (Umeå) (to be confirmed)
- Bengt Kasemo, (Göteborg)

Program & registration:

http://www.nordic-fobis.net/workshop/Workshop_3

Introduction

The health care systems of the industrialized countries are expected to undergo major changes within the next 10 – 15 years. The number of elderly people requiring treatment will grow considerably, so-called welfare diseases is increasing, and increasing use of new advanced treatments will occur. This will require a more efficient health care system offering better services. A number of new health care technologies will emerge and several will be adopted by the health care systems.

How will biomedical sensors shape the healthcare systems of the future? How can they impact the quality and cost of healthcare and

what are the business opportunities in the Nordic region?

This newsletter reports a summary of the two first workshops of the project.

Project objectives

- To enable a strategic understanding of the possibilities and implications of the use of biomedical sensors for healthcare purposes by establishing likely scenarios for technology, applications and markets.
- To provide for a framework for commercially viable exploitation of biomedical sensor penetration in the Nordic region by enhancing

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a network of competencies relevant to technology and applications.

The Workshops

The project revolves around a series of workshops, the first two being held in Copenhagen 6 – 7th Oct., the second in Oslo 2nd Nov. The next two will be held in Sweden and in Finland. The objectives of the workshops are to establish status, needs and perspectives for sensors in relation to health care and in particular the need for biomedical sensors.

1st Biomedical Sensors Foresight Workshop

Copenhagen 6 – 7 October, 2005

The workshop attracted 40 people from Sweden, Norway, Finland, and Denmark. The participants represented a cross-section of the relevant sectors and industries covering research institutions, granting agencies, companies addressing the health care sector and health care practitioners.

The workshop consisted of two sessions with invited presentations covering needs of the health care system, assessment of health care technology, security and defence, commercialization of sensors and diagnostic equipment, and the technology of the sensors for the health care industry.

Group work was performed covering the topics home care, defence, doctor's office and hospitals.

Program

Introduction

Ingrid Storruste Svagård from SINTEF is the project leader. She gave an introduction to the project as a whole and introduced the subject in general.

Lars Lading chaired the workshop and gave an introduction to the workshop and presented a

number of hypothesis concerning the future of health care that would have an effect on the need for and application of medical sensors.

Presentations

The main areas for the presentations were: Service, market, security and defence, technology

Jens F. Rehfeld from Copenhagen University Hospital gave a presentation "The Hospital Laboratory of the future", which described the current state of affairs and the future role and desired premises.

Hindrik Vondeling from Centre for Applied Health Services Research and Technology Assessment, University of Southern Denmark on "Health technology assessment: an introduction with emphasis on the clinical and economic evaluation of diagnostic tests".

Åke Sellström from The Swedish Research Defence Agency gave a presentation on needs and possibilities in relation to security and defence. The nuclear, biological and chemical threats were discussed.

Ulf Jönsson is CEO of Celectricon and former CEO of Biacore. Biacore is an example of a company that successfully has exploited a biosensing concept based on so-called surface plasmon resonance. Ulf Jönsson gave a presentation on "Marketing Biosensors".

Lars H. Pedersen from Bioneer gave a presentation of the technologies of sensors for medical applications.

Low tech screening market

"Your family history holds key information about your past and clues to your future health. Many of your physical traits (such as eye colour, hair colour, and height) are inherited. So, too, are risks for certain genetic conditions and health problems such as heart disease, diabetes, and some cancers. You may have noticed that some of your relatives are healthier and live longer than other relatives. You may also have noticed that some relatives

have the same health problems. By collecting your family's health history, you can learn what health problems you may be at increased risk for in the future and how to reduce your risks. For instance, people at increased risk for heart disease may be able to reduce their risk through not smoking, regular exercise and diet. Finding out your family history can benefit both you and your relatives...

http://www.geneticalliance.org/ws_display.asp?filter=resources_family_history

Group work

Group work and discussions were performed on the issues homecare/self testing, doctor's office, hospitals and defence and security.

Market issues

Summary points from *Ulf Jönsson*

Commercialization:

How important is the market? Consider a slower pace rather than shock-financing that will lead to a series of not so well thought through investments. Investors also have a responsibility to not allow too much money in too short a time.

Commercializing new technology is challenging, costly and requires sustainability: Biacore took nine years to breakeven with 500 MSEK accumulated loss.

The gene transfer market:

The market can be grouped in the research market and the emerging clinical market.

The "buzz" is currently dominated by RNAi (gene-silencing) in research but the hope is that methodologies will provide us with tools needed to gene manipulate against diseases.

As with other clinical tools, an emerging technology needs to be embraced by the research market in order to win clinical acceptance.

Summary points from *Lars H. Pedersen*

Glucose sensing currently represents the largest market for biosensors (approx. USD 2.5 billion).

The estimated number of units for *point-of-care* is estimated to 11.500 in the US alone.

The in vitro market is in 2005 estimated to USD 26 billion with the largest growth rates in cancer detection and blood processing.

The market for patient self-testing is considerable, but the current exploitation is marginal.

Service

Summary points from *Jens F. Rehfeld*

The hospital lab of the future is part of a larger centre for molecular diagnostics in the hospital.

In the centre, physical description and function should ensure a balance between optimal integration and presence of specialities.

The common denominator for the lab is the term "molecular" in thought and technology irrespective of whether the lab is biochemical, genetic, microbial or imaging.

The centre ensures a close link between the production of diagnostic results, research and development.

Many decisions are made in relation to perceived needs in a narrow context and may not comply with the general needs of a health care system.

Summary points from *Hendrik Vondeling*

Health technology assessment is a multidisciplinary and internationally oriented activity.

Diagnostic tests versus screening tests.

Diagnostic accuracy studies versus (among others) studies evaluating diagnosis as part of a patient management strategy in- or excluding issues of 'value for money'.

Diagnostic technology: rapid technological change, accompanied by rapid changes in assessment methodology”

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Security

Summary points from *Åke Sellström*

Peace-keeping operations has changed the risk scenario considerably, soldiers from stable affluent countries operate under conditions and in environments very different from their home countries.

Needs for both person and large area monitoring

An area very much dominated by politics

The US Homeland Security programme represents a massive effort

Research targeting security and space has high priority in the EU’s Seventh Framework Program for Research, which covers the period 2007 to 2013. Security and space combined are suggested to receive funding amounting to €4 billion during the period

Technology

Summary points from *Lars H. Pedersen*

The technology for medical sensing may be based on

- Chemical sensors
- Bioconversion sensors
- Biochemical affinity sensors

The may be designed as invasive sensors or non-invasive with contact sensing or remote (non-contact) sensing.

The dominating application of biosensors is for home monitoring of glucose in blood.

Surface Plasmon resonance sensors are primarily used in laboratory instruments with Biacore™ as the leading vendor of complete systems.

Several new bio-optical sensing schemes have emerged based on long range surface plasmons and photonic crystals.

Receiver Operating Characteristics (ROC) curves originally developed for radar signals are very useful for evaluating the performance of medical sensors.

Kiosk testing

“**QuesTest™ consumer health testing**, a service of Quest Diagnostics, is a revolutionary concept in consumer-driven health care that offers customers an important new way to take charge of their health through commonly ordered screening tests that they choose and receive results for themselves. QuesTest™ lab services help answer a broad need for consumers to obtain baseline personal health information.

Customers can walk into any participating Patient Service Centre and select QuesTest™ lab services from a menu of more than 20 popular health-screening tests. No appointment is necessary and during the visit, a small blood and/or urine sample is collected. QuesTest™ customers obtain their own

test results – which are private and confidential – usually available on-line in 2 to 3 days.”

More information:

http://www.questest.com/ch/get_started/get_started_process.jsp

Group work and discussions

Group works and discussions were performed on the following topics:

- Doctors office
- Home care/self testing
- Hospitals
- Defense and security

Some conclusions of the groups were:

Doctors office

- The General Practitioner medical doctor (GP) will face a more market driven situation. The patients will be more active and demanding which calls for quicker and more reliable services, which again implies more “on the spot” sensing and diagnostics.
- Screening of patients will be an increasingly important task.
- Tasks that are currently allocated to hospitals will be transferred to GPs.
- Preventive health care will most likely become more important than it currently is.
- Economic incentives are a main driver for change.

Home care/self testing

- The need for home care will increase drastically. This will necessitate an increased use of medical sensors, telemedicine, and remote consultation, diagnostics and decision making.
- Implantable devices where sensing and therapy are combined have a great

potential, but poses a number of legal and ethical issues

- Equipment must be developed in the form of simple, robust, and reliable kits.
- The public system as well as individuals will have to face a number of difficult problems in relation to defining priorities.
- Home care is currently the largest market for low-cost medical sensors and this will most likely also be the case in the future.
- Cross-validation and consistency will be increasingly important with a growing market for home-care solutions.

Hospitals

- They should be more service and production oriented! Greater attention to individuals would be required in the future.
- Point-of-care vs. central laboratories was discussed. Both would be needed in the future. However, more diagnostics must be performed at the point of care.
- Increased skills in relation to so-called distributed diagnostics would become more important. Distributed point-of-care systems puts pressure on the user friendliness of the systems.

Defence and Security

- Can be divided into two main areas, that of personal safety and that of public security.
- Key parameters: Solutions must be mobile, and portable: light to carry—and remote, eg sense at a distance. Devices that measure something, although not too accurate, have great potential in the private market. Another key word here is miniaturization! A potential future application: travel safe kit?
- Strength of the Scandinavian countries is our tradition for peacekeeping and our environmental credibility. Application for humanitarian purposes could be an area of interest.

2nd Biomedical Sensors Foresight Workshop

Oslo, 2 November, 2005

This workshop, which was the second in a series of four, attracted around 35 people from Sweden, Norway, Finland and Denmark, representing a cross-section of relevant sectors and care practitioners.

The workshop consisted of two sessions with invited presentations covering ethical issues, state of the art and future perspectives of biomedical sensors, technology of the sensors and market issues/business opportunities.

Group works were performed covering the topics home care, defence, doctor's office and hospitals.

Program

Introduction

Ingrid Storruste Svagård from SINTEF, the current project leader, gave an introduction to the project as a whole and introduced the subject in general.

Rita Westvik from SINTEF gave an introduction to the workgroups.

Presentations

Ole Johan Borge from Bioteknologinemnda in Norway gave a presentation "Ethical challenges in biosensor research and - applications".

Professor Tor Inge Tønnessen, Interventional Centre, Rikshospitalet, presented "Potential of biomedical sensors; state of the art, future perspectives"

Ralph Bernstein, Assistant Research Director at SINTEF ICT, department of Micro- and Nona technology, presented the current state-of the art and future roadmap for biomedical sensor technology.

Stein Lorentzen-Lund, CEO Alertis Medical AS, talked about market issues and business opportunities, and presented the biosensor from Alertis detecting ischemia.

Olav Flaten, Medical Director, GlaxoSmithKline AS, gave the last presentation "Biomedical sensors in the pharmaceutical industry - "killer application"?"

Group works and discussions

Group works and discussions were performed on the topics market, technology and ethical issues.

Market issues

Summary points from *Olav Flaten*

Rapidly expanding biosensor field:

- 60% annual growth
- Health care industry is driving
- Food quality appraisal
- Environmental monitoring
- World analytical market is about £12,000,000,000
- 30% in health care
- 0.1% is presently covered by products

Obstacles:

- Body interference
- Fibrotic capsule
- Toxicology: No clear outline yet
- Industry infrastructure
- ELSA

Ethical challenges

Summary points and comments from *Ole Johan Borge*

"Why should we consider ethical issues in relation to biosensors?"

"As responsible beings in a democratic society, we have a duty to evaluate the foreseeable consequences of the biosensor technology we are developing and hope will be applied in a high number of commonly used applications. This does not necessarily imply that you as a

scientist, company leader or one with particular interests in the field should start on such an attempt on your own, but such initiatives should be encouraged.

A public debate regarding biosensors will facilitate the acceptance and even accelerate the rollout of this new technology. This will also play a role in making the technology more socially robust and thereby reducing the likelihood of long-term serious set backs during the early phases of this technology.

A public, ethical debate will also facilitate a more comprehensive debate regarding the needs and requests to the potential users and this might therefore even open new avenues for research and product development.

Issues useful in identifying ethically challenging areas are:

The right to know and the right not to know are considered a fundamental right particular in relation to human health. At first glance, it seems that the right not to know is unproblematic. However, it might not necessarily be all that easy when working with biosensors because the biosensors might generate information that was not thought about when the patient started to use the biosensor. An example: a certain blood glucose measurement might also indicate a given genetic lipid disease. Thus, the patient receives more information than what he or she asked for and most likely consented to.

Hype and hope

When debating an emerging, technologically advanced field in public it is of high importance to be sincere and avoid overselling the benefits of the technology. The recent history with gene therapy, xeno-transplantation and stem cells are only but a few examples of overselling and that patient groups wrongfully have got the impression that a technological fix, for their condition, is just around the corner.

There is no sense in sensing something you can not do anything about. This is the

biosensor equivalent of the mantra in medical ethics that you should only diagnose conditions you either can treat or at least have something to offer the patient. I do not necessarily agree with this mantra because, in certain cases, it could be useful to contribute to the understanding of phenomena, which in the future may lead to possibilities for treatment.

Biomedical sensor technology

Summary points from *Ralph Bernstein*:

- Future medical sensors will require small low cost, low power sensors, remote power generation, wireless communication, nanotechnology and advanced functional and bio-compatible materials.
- Medical sensors and BioMEMS is a rapidly growing field. The development in microsystems is a key driving force: cost per function decreases with 25% every year, no. of bits per chip grow by a factor of 4 times every 3 years, processing speed is increased by a factor of 5 every 10 years.
- High research activity for medical MEMS is expected in the Cardiovascular area (e.g. sensor systems for rate adaptive pacing, cardiac well-being monitors) in Drug delivery (e.g. oral ticking tablets for timed delivery) and in Endocrinology (e.g. minimally invasive glucose monitoring).

Summary points from *Tor Inge Tønnessen*:

- Except for EKG, we do not have real-time detection of organ injury. Most organs reveal symptoms late. In the anesthetized patient and the ICU patients, symptoms are absent.
- Reliable biosensors are badly needed, for early detection and continuous measurements.
- Example of area of need is Ischemia. This is the most prevalent cause of mortality and morbidity in the Western world (myocardial

infarction, stroke, trauma)

Summary points from Stein Lorentzen–Lund

- Nordic Countries is a MedTech Cluster, carrying 30% of the European investment in Medical technology.
- The region has high quality Health Care, high quality research and Inexpensive academic workforce and a high number of med–tech companies.
- The potential market for small disposable sensors (like the Alertis bio–sensor for measuring ischemia), is large. Considerable market growth expected due to more advanced surgeries and ageing population. (First indications will be orthopedic and plastic surgery.) Large market potentials in for internal organ monitoring.

Group work and discussions

Group works and discussions were performed on the following topics:

- Technology
- Market
- Ethical and social issues

During the discussions, a number of important points were identified:

Technology trends:

- Personalized medication
- Multifunctional sensors
- Point of care diagnosis
- System biology and biosensors
- Enablers or showstoppers?
- Change in treatment politics
- Education and research
- Organ specific analysis
- Unrealistic expectations
- Long time and high cost to market
- Conservative attitude
- Product quality?

Market scenario for year 2020

- Preventive medicine
- Early detection
- Telemedicine
- Patient self testing

Ethical, societal, policies

Uncertainties:

- Acceptance of the technology
- Right to privacy
- The role of the policies
- Bio criminality
- Bioterrorism
- Wellness/wellbeing – preventive/treatment
- Innovation, priority
- Price/recourses; who affords to use the technology, western countries contra undeveloped countries
- Grade of interdisciplinary
- What kind of deceases to we diagnose/treat, what do we afford
- How is the word developing on an economical level, will effect health care/diagnosis
- Religious/cultural influence

The next workshop will discuss “How do we get there?” Don’t miss this event in Stockholm 3 March 2006.

Exhibition – biomedical sensors

We invite researchers, students and companies to exhibit products, prototypes, hands–on demos and/or posters related to biomedical sensors. Get in contact with Lars Österlund at FOI if you are interested of being part of this exhibition!
[*\(lars.osterlund@foi.se\)*](mailto:lars.osterlund@foi.se)