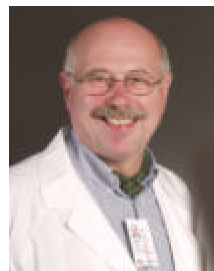
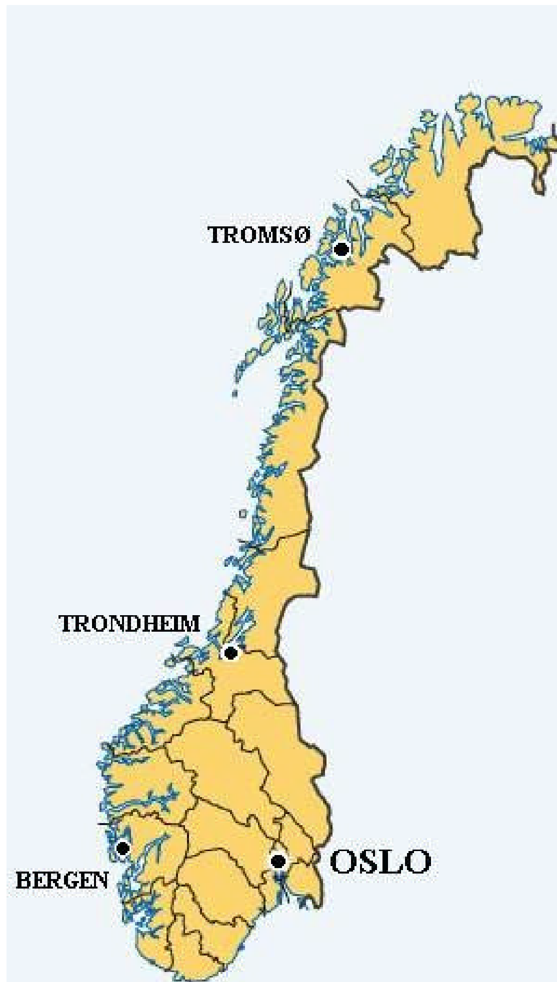


International Federation for Hospital Engineering
17 th Congress Bergen, Norway 13.5.2002

Clinical engineering in Norway – a paradigm shift from managing technology to managing economy?

Øystein Jensen, Clinical Engineering Manager,
Rikshospitalet University Hospital, Oslo, Norway



1 January 2002

Responsibility for all Norwegian hospitals transferred to the Government.

- Ownership of the hospitals is transferred to the Government sector, thereby placing responsibility with one owner.
- The hospitals are organised as enterprises. This means that they will be separate legal subjects and will thus not be an integral part of the central government administration.

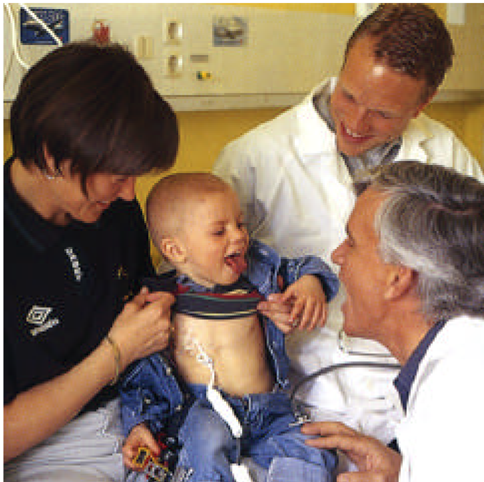
5 University Hospitals (2 in Oslo)

5 Regional Health Enterprises

My lecture adresses :

•the problems and challenges of running the services of a University Hospital Clinical Engineering Department (CED) in the transformed world of “enterprisition”

•new trends, projects and available analyses assisting the management of the CED, presenting some examples from Norway and Nordic countries.



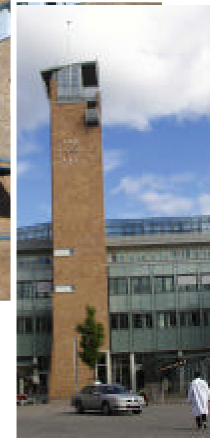
Rikshospitalet

Universitetsklinikk

Specialities: organ transplantation, children heart surgery, neurosurgery, basic medical research, R&D new medical methods.

Academic education, University of Oslo

40% of patients are children



Key figures 2001/2002

Rikshospitalet
Universitetsklinikk

Construction cost	5,9 billion NOK (2001)
Total area	130.000+ m^2
No. of rooms/beds/patient hotel	7.000/580/90
No. of employees	4.000 (2002)
Annual budget	2,8 billion NOK (2002)
In-patients/Daypatients/Outpatients	27562/15892/144108 (2001)
Medical equipment, device records	13.000+ (2002)
Medical equipment, accumulated cost	957 mill NOK (2002)
Medical equipment, mean age	6 year (2002)

Rikshospitalet Clinical Engineering Department

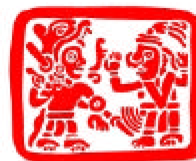
30+ engineers, technicians, researchers

Process-oriented organisation according to ISO6002-2000 and Nordmedteks recommendation ”Good Clinical Engineering Practice”

13.000+ records, NKKN version of GMDN - Global Medical Devices Nomenclature, Meridá inventory database system (Haukeland University Hospital)

Annually 5000 ”jobs” registered - service or preventive maintenance

Procurement process 2001: 64 mill NOK



MÉRIDA

Systemet for TotalLogistikk i helsesektoren

Medical devices population RH

29.04.2002

Accumulated procurement cost, incl. UiO, no index

Year	No	Cost (eks. VAT)	Incl. VAT
1955	1	12 500	15 500
1955	1	8 333	10 333
1960	7	66 825	82 863
1962	2	67 624	83 854
1965	10	477 662	592 301
1966	1	10 333	12 813
1967	1	10 000	12 400
1968	13	260 173	322 615
1969	7	76 041	94 291
1970	52	460 927	571 549
1971	9	186 569	231 346
1972	17	453 481	562 316
1973	11	100 101	124 125
1974	12	108 164	134 123
1975	33	374 381	464 232
1976	18	277 856	344 541
1977	52	547 507	678 909
1978	49	1 343 429	1 665 852
1979	32	521 472	646 625
1980	129	2 457 422	3 047 203
1981	33	984 019	1 220 184
1982	37	751 115	931 383
1983	71	1 901 262	2 357 565
1984	94	5 229 809	6 484 963
1985	266	6 002 484	7 443 080
1986	166	5 577 875	6 916 565
1987	157	7 220 782	8 953 770
1988	215	7 356 921	9 122 582

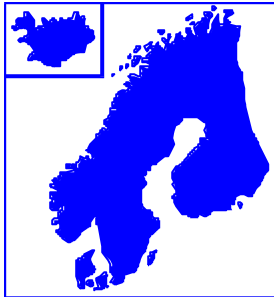
Accumulated procurement cost, incl. UiO, no index

Year	No	Cost (eks. VAT)	Incl. VAT
1989	254	12 550 809	15 563 003
1990	454	12 880 190	15 971 436
1991	247	11 849 380	14 693 231
1992	355	19 578 048	24 276 780
1993	412	17 555 707	21 769 077
1994	392	23 519 687	29 164 412
1995	631	25 251 298	31 311 610
1996	630	68 189 776	84 555 322
1997	604	27 394 389	33 969 042
1998	1535	90 816 435	112 612 379
1999	4030	283 105 921	351 051 342
2000	1651	82 243 213	101 981 584
2001	648	31 821 759	39 458 981
2002	81	4 436 675	5 501 477
	Total (NOK):	754 038 354	**935 007 559**

Management of the CED and Medical technology management

There are three essential targets to hit and control in order to achieve a cost-effective, efficient and safe use of medical devices:

- Safety issues
- Quality systems, organisation and competence
- Economy



NORDMEDTEK

NORDIC CO-OPERATIVE GROUP FOR MEDICAL TECHNOLOGY

NORDIC GUIDELINES FOR GOOD CLINICAL ENGINEERING PRACTICE

Draft - Version 3, October 2001

Complies with ISO 9001-2000

www.uas.se/NMT

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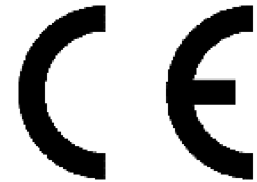

NORDIC GUIDELINES GCEP, REFERENCES

- European directive on Active Implantable Medical Devices, AIMDD,
- European directive on Medical Devices, MDD,
- European directive on In Vitro Diagnostics Medical Devices, IVDD
- EN 28402: 1991, Quality- Vocabulary.
- EN ISO 9001: 2000, Quality systems - Model for quality assurance in design, development, production, installation and servicing.
- EN 46001:1993 Quality systems - Medical devices - Particular requirements for the application of EN ISO 9001.
- ISO 9004-2: Quality systems- Guidelines for services.
- ISO 10011: Guidelines for auditing.
- ISO 10013: Guidelines for developing quality manuals.
- EN 540: Clinical investigation of medical devices for human subjects.

National regulations

NORDIC GUIDELINES GCEP
MAIN PROCESSES FOR CLINICAL ENGINEERING PRACTICE

The main processes are designed to satisfy the demands from the main CED customer(s). The processes are divided into different activities designed to improve the medical services. The main processes are parts of the infrastructure for successful use of medical devices in diagnoses, treatment and care. They are:

1. Strategic planning
2. Procurement
3. Device management and support in clinical use
4. Disposal of medical devices
5. Knowledge management
6. Research and development of medical devices

To perform safety assessments and inspection, preventive maintenance and documentation is a costly process that not can be compromised in the management of medical equipment. In an "enterprised model" of running business, where the "customer" is invoiced in some kind of transfer pricing system, the associated services must be basic, i.e. they can not be voluntary "to buy". A "flow of cost" is initiated by the procurement of the equipment, and in the keeping of a defined safety standard – even if the equipment is not used.

Based on data from 1975 – 1990, the Rikshospitalet/Haukeland (RH/HUH) index model predicts the reinvestment cost:

Reinvestment cost: C_{re}
Actual procurement cost for a device: C_o
Age, whole years: Y

$$C_{re} = C_o \bullet (1{,}072)^Y;\ Y = 0 \ldots 10$$

$$C_{re} = 2\ C_{o;}\ Y > 10$$

i.e. the annual growth of cost is 7,2% to ten years, then constant eq. doubled procurement cost

Depreciation and estimated lifetime
Medical equipment
Nordic datasets for estimated lifetime

	RH Health Region II (N)-1	Huddinge AB (SE)-2	Lands pitali (IS)-3	Landspital i (IS)-3	Landstin gs Förenin gen (SE)-4	**Norwegian official Initial balance**
Reference year	1998	?	1998	2001	2000	**2002**
Radiological equipment	10	7			7	**10**
Endoskopic equipment	4	5				**4**
Ultrasound, imaging equip.	7	5			7	**7**
Analysis and lab.equipment	9	5	7 (10)	5 (7)		**9**
ECG/Intensive care equipment	8	5			7	**8**
Unspecified Med. Equipment	11	5				**11**
Surgical instruments	15					**15**
Radiation therapy equipment	15					**15**

References
1-RH Health Region II, 1998, Norway: Det regionale helseutvalg II, 4.2.1998 (in Norwegian)
2-Huddinge AB, Sweden: Data from enterprise initial balance due to Price Waterhouse Coopers.
3-Lanspitali, 1998, Iceland: Initial opening balance of enterprise Landspitali. From Gisli Georgsson.
4-Landstingförbundet, Sweden 2000: Depreciation for counties and regions, from Nils-Gunnar Holmer

Cost of ownership RH

Applied on the 13.000+ population of Rikshospitalets medical equipment inventory register, the key figures are as follows:
Accumulated procurement cost: 957 mill NOK
Calculated reinvestment cost based on RH/HUH-model: 1.300 mill NOK
Capital depreciation cost in 2002: 95 mill NOK

Running cost of all RH CED processes (incl. preventive maintenance based on manufacturers spec or deviations based on internal risk assessment, subcontracted maintenance and unexpected breakdown, R&D and procurement): 28 mill NOK
Subcontracted Preventive maintenance on radiological equipment: 15 mill NOK

⇨ Total cost of running all CED processes and maintaining all medical equipment at Rikshospitalet: 43 mill NOK

Thus, in total, the management and running of medical equipment and CED quality, safety and competence processes at RH Health enterprise cost 4,5% - 3,3% of the equipment population's value – depending on the selection of accumulated procurement cost or calculated reinvestment cost as the basis.

So, how to divide the cost between the users, clinics and medical production line?

There are several unresolved problems, and different strategies.

- There is no modifier to users needs unless it cost money. Cost starts to run when equipment is acquired and kept in safe, working order during its lifetime.
- Transfer pricing is not necessarily the answer, varying amount of service may be demanded from a department or user during different periods of time (i.e. the breakdown of an expensive CT x-ray tube).
- Is the solution a contracted Service Level Agreement between the CED and clinical department on a cost-per-use the answer? CED owns the equipment, and the user has a contracted number of e.g. examinations in a kind of "insurance".

Some points in summing up:

The concept of the enterprised model for running a university hospital and its medical equipment is very inspiring. The capital depreciation method allows a reinvestment plan to be realised. Though – this implies that the depreciated capital really is invested in new equipment. Many details remain to be resolved; i.e. pricing and ownership models, but they are minute problems compared to keeping up the reinvestment in Norwegian hospitals.

It is essential to realise that a university hospital must be run with more perspectives than cost. With introduction of the recognized *Balanced Scorecard* approach, it is possible to bring into view both the financial perspective, the customer perspective, internal-business-process perspective and learning-and-growth perspective. This targets future performance of the organisation. The Norwegian Health Enterprises reform is still in its infant stage.

Acknowledgments
I appreciate my collegues Trond Strømme, Jan Olav Høgetveit and André Nygård for profound discussions and contributions, as well as the collective contributions to the analysis of CEDs quality indicators of the NORDMEDTEK group referenced in the Nordic guidelines at the web-site.