Fokus på forskning i spesialisthelsetjenesten
Habilitering
20170913

Frode Gallefoss
Forskningsjef SSHF
Lungelege, dr. med., professor, UiB
Research expenditure in Norway compared
Sørlandet Hospital

- 528 somatic beds, incl. patient hotel (63)
  - + 81 technical beds
    - Intensive Care Unit (ICU), post-operative og incubator
- 280 psychiatric beds incl. DPS
- 5 557 gross man-labour years
  - 7 270 employees
- Budget 6.350 billion NOK \(\rightarrow\approx 700\) mill EURO
2002: Historical expectations in the region

- The Sørlandet Knowledge Foundation (SKF) & the Aust-Agder foundation
- Plans for University of Agder
- a peripheral part of Norway that has ambitions
Hairy goals when the Clinical Research Department was founded in 2002

Within 10 years

- **100** articles in peer reviewed journals
- **10** PhD’s
Hairy goals when the Clinical Research Department was founded in 2002

Within 10 years it became

- **300** articles in peer reviewed journals
- **30** PhD’s
Established function for clinical research

- Infrastructure/offices/PC’s
- ICT og library support
- Statistics/methods seminars
- «The mini-research school»
- Project planning and follow-up
- Engagement for supervisors
- Internal controls and annual project reviews
- Financial management
- System development/documentation
The department of Clinical Research SSHF

- Chief of Clinical Research
- Economic management consultant
- Research administrator/-supervisor
- Project leader/international relations
- Secretary
- Biobank coordinator
Number of peer reviewed articles
Number of PhD’s

- 2003: 0
- 2004: 2
- 2005: 0
- 2006: 0
- 2007: 2
- 2008: 2
- 2009: 6
- 2010: 4
- 2011: 3
- 2012: 10
- 2013: 10
- 2014: 4
- 2015: 6
- 2016: 4
Scientific «points»

Years: 2003-2016

Points: 26, 23, 15, 15, 41, 30, 51, 40, 47, 73, 81, 67, 96, 98
Ongoing clinical research activity
20170912

- External finance:
  - 17 PhDs & 6 PostDocs
  - 4 PhDs with not longer external support

- Supported from clinical budget:
  - 4 PhDs
  - 15 PhDs (1° KPH)
## Ongoing clinical research activity

**20170912**

<table>
<thead>
<tr>
<th></th>
<th>External finance</th>
<th>Internal finance</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td><strong>PhDs</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>21 (4 without current support)</td>
<td>19 (1° KPH)</td>
<td>40</td>
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<tr>
<td><strong>PostDocs</strong></td>
<td>6</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td><strong>Supervisors</strong></td>
<td></td>
<td>9(10%), 17(20%), 2(40%)</td>
<td>510% stilling</td>
</tr>
</tbody>
</table>
Medical specialists engaged as professor at universities

- Åse Mygland, neurology  
  UiB
- Unn Ljøstad, neurology  
  UiB
- Sverre Steinsvåg, ENT  
  UiB
- Frode Gallefoss, Pulm Med  
  UiB
- Svein Gunnar Gundersen, intern. health  
  UiA
- Jon Skranes, pediatrics  
  NTNU
- Gudrun Rohde, QoL  
  UiA
- Terje Mesel, ethics  
  UiA
- Dagfinn Ulland, ethics/religion  
  UiA
Future visions

- Clinical research +++
- Support clinical quality improvements at SSHF
- Shall SSHF become a University Hospital?
- Increase the number of projects with cost-effectiveness analyses
- EU projects
  - Horizon 2020
Clinical research is important for the conduct of clinical skills

- New science
- Knowledge
- Logistics
- Finance
- Ethical guidelines
- Medical treatment
Correlations between treatment quality and clinical research

Svenska Cancerfonden 2009
Randomised controlled trials
Can it work? (under ideal conditions)

More pragmatic designs
Does it work? (in daily life)
RCT 'Ideal' conditions

‘Real world’ conditions
Randomised controlled trials
Can it work? (under ideal conditions)

More pragmatic designs
Does it work? (in daily life)
Quality is measured indirectly → we need an indicator

- Indicator
  - Indicare: indicate
  - Qualis: characteristics
- Observable phenomenon that indicates the condition of a non-observable phenomenon
International consensus on quality indicators

<table>
<thead>
<tr>
<th>Country</th>
<th>Mortality (&lt; 28-30 days)</th>
<th>Readmissions (28-30 days)</th>
<th>Injuries or Complications Acquired During Hospital Stay</th>
<th>Timeliness or Access to Appropriate Care</th>
<th>Patient Experience</th>
<th>Guideline Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>x</td>
<td>x</td>
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<td>UK</td>
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<td>Switzerland</td>
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<td>x</td>
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<tr>
<td>Denmark</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Netherlands</td>
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<td>x</td>
<td>x</td>
<td>x</td>
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<td>x</td>
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<tr>
<td>Canada</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>
Patient security campaigns
Quality improvement at SSHF

- The Knowledge Centre for the Health Services (part of the Norwegian Institute of Public Health)
  - 1-2 years delay
  - 30 day mortality…. 
- Dr Foster/Global Comparator Program
  - 4 months delay
  - OOPS: Hospital data only
- Statistical Process Control/PROMS
  - Daily data registration

Fresh data improves insight to quality
The coming spike

- **2015:** 4 employees pays for 1 retired
- **2040:** <2 employees pays for 1 retired

Source: ONS
United for Health (U4H)
- a EU program

- Collaboration with
  - SSHF, University of Agder, Devoteam og Kristiansand + 27 municipalities at Agder

- Also supported by the Norw. Research Council

- COPD:
  - Agder, Tromsø

- Diabetes

- Heart failure
Telemedicine

Psychiatry

- CIGNUS Glucometer
- Cardguard 1-12 Lead ECG
- Bloodpressure Meter
- Vitalograph Peakflow Meter
- Clever IR Ear-Thermometer
- Nonin Oxymeter
- IEM Scale
A joint telemedical system at Agder

Universal solutions in Telemedicine
Deployment for European HEALTH care, 2013-2015
ICT PSP call identifier: CIP-ICT PSP-2012-3

Point-of-Care Services Agder.
- Sub-Project financed by the Research Council of Norway, 2013-15

eHealth – Extended Care Coordination.
- Synergy Project financed by the Agder Research Fund, 2011-2014
TELMA
Joint telemedical system for 30 municipalities at Agder

- Extension of the U4H experiences
- 1.7 mill EURO from Norw. Research Council
- Extends to COPD, diabetes & heart failure and comorbidity
PhD → eksternal finance

- HSØ
- NFR
- Helse & Rehab/Ekstra
- Lokale kompetansefond fond
  - Sørlandets kompetansefond & Aust-Agderfondet
- Regionale forskningsfond Agder (NFR)
- EU
- D-stilling/fordypningsstilling
  - 50% forskning
Strong clinical research groups

- Cardiology at SSA
- Neurology/ tick born diseases
- Centre for Cancer Treatment (SFK)
- Psychiatry + Alcohol/drug abuse
- Rheumatology
- Gynecology
- Lung diseases
Normal ECG

ST Elevation

ST Depression

T Inversion

STEMI

NSTEMI
Strong clinical research groups

- Cardiology at SSA
- Neurology / tick born diseases
- Centre for Cancer Treatment (SFK)
  - cetuximab
- Psychiatry + Alcohol/drug abuse
- Rheumatology and osteoporosis
- Gastroenterology
- Gynecology and cancer
- Lung diseases
Ingen spesielle forskningsmidler til habilitering?
Hvorfor forskning innen habilitering?

- Sikre best mulig funksjons- og mestringsevne, selvstendighet og deltagelse sosialt og i samfunnet for personer med medfødt eller tidlig nedsatt funksjonsevne (St melding 21, 1998)
- Tilby den best dokumenterte oppfølging og behandling til enhver tid
  - for å finne ut hva som er best, må vi forske!
Spesialisthelsetjenestens kjerneoppgaver er:

1. Pasientbehandling
2. Pasientopplæring
3. Forskning
4. Utdanning
Utfordringer i habiliteringsforskning

- Medisinsk diagnose (ICD 10) vs funksjonsdiagnose (ICF), ”paraplybetegnelse”
- Hvordan skille vekst, modning og ”naturlig forløp” fra endring pga behandlingseffekt?
- Kombinasjon av ulike behandlingsmåter gjør det vanskelig å isolere en av gangen
- Dosering; intensitet, varighet, hyppighet, repetisjoner?
- Evaluering: → mangelfulle måleinstrumenter
- Etiske begrensninger ved forskning på barn
- Bivirkninger – tidsbruk – er det verd prisen?
Krav til habiliteringsforskning
Forskerutvalgsrapport til Shdir2006

- Fokus på kjerneinnholdet i habilitering
- Høy vitenskapelig kompetanse
- Tverrdisiplinær forskning
- Forske på virkninger av habiliteringsprosesser
- Nærhet til brukerorganisasjoner
- Nærhet til praksisfeltet
- Utvikle nasjonale og internasjonale nettverk
Hvordan forske innen habilitering?

- Forskning er å stille de gode spørsmålene
- Hvem får lov til å stille spørsmålene;
- Hvem bestemmer hva som er relevante spørsmål?
Nasjonalt forskningsnettverk innen habilitering

- Nasjonalt forskningsnettverk innen habilitering
  - Etablert i 2010 på OUS
  - Økonomisk støtte fra Hdir
  - Nasjonale årlige konferanser
  - Ingen har ennå oversikt over habiliteringsforskningen i HSØ eller i Norge
Nasjonalt forskningsnettverk innen habilitering

- **Målsetting**
  - Være en møteplass for forskere innen habilitering
  - Være kontaktpunkt mellom norske og internasjonale forskningsmiljøer
  - Være pådriver for formidling av forskningsresultater
  - Stimulere til prosjektutvikling og prosjektsamarbeid
What is the dilemma of public health information?

- Those who need it the most understand it the least
What is of core importance in lifestyle intervention?

- Motivation
What it’s all about..

How to elicit motivation?

MOTIVATION is generated from:
• Mastery
• When the negative aspects becomes clearer
Told, but not heard
Heard, but not understood
Understood, but not accepted
Accepted, but not put into practice
Put into practice, but for how long?

Konrad Lorenz
Patient education in asthma and COPD

INCLUSION CRITERIAS

Asthma:
- FEV1 > 80% of predicted
- 20% reversibility, variability or positive metacholine test

COPD:
- FEV1 < 80% of predicted with or without reversibility or variability

Exclusion:
- Serious medical disease:
140 patients with mild to moderate asthma (n= 78) and COPD (n= 62) at our out-patient clinic after having received ordinary consultation care

**RANDOMISATION**

**Study design:**

- **Control group**
  - Followed by GP for one year

- **Intervention group**
  - After intervention followed by GP for one year

**One-year follow-up**

**Intervention:**
- 2 x 2 hour group sessions
- Individual sessions
INTERVENTION PROGRAM

- PEF and symptom registration
- Written booklet on asthma
- 2 x 2 hour group sessions (5-8 patients)
- 1-2 x 40 minutes individual sessions by nurse and physiotherapist
- Treatment plan
SKIPPER
PÅ EGEN
SKUTE

Pasientinformasjon om
obstruktiv lungesykdom
med vekt på egenkontroll
Consultations at GP
during the one-year follow-up
Mean (SD)

Asthma n=39/32
COPD n=27/26

Control
Intervention

No of GP consultations

2,6 (3,6)
0,7 (2,0)
3,4 (5,5)
0,5 (0,9)

p<0,001*
p<0,0001*

* Mann Whitney U test
Days off work
during the one-year follow-up
Mean (SD)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma n=24/25</td>
<td>26 (SD 8)</td>
<td>8 (SD 32)</td>
</tr>
<tr>
<td>COPD n=14/13</td>
<td>18.5 (SD 1)</td>
<td>7 (SD 1)</td>
</tr>
</tbody>
</table>

p < 0.05*  
p < 0.64*

* Mann Whitney U test
Changes in FEV1 during the one-year follow up
Mean (SD)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Control</th>
<th>Intervention</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>-2.7</td>
<td>3.4</td>
<td>&lt;0.05*</td>
</tr>
<tr>
<td>COPD</td>
<td>2.9</td>
<td>5.6</td>
<td>0.61*</td>
</tr>
</tbody>
</table>

Asthma: n=39/32, COPD: n=27/26

* T-test
Inhalation steroid compliance during the one-year follow-up

Compliance = \( \frac{\text{collected DDD/PDD}}{\text{PDD}} \times 100 \)

Asthma n=38/30

- Control: 32%
- Intervention: 57%

COPD n=24/24

- Control: 58%
- Intervention: 50%

p < 0.04 (Asthma vs Intervention)
p = 0.56 (COPD vs Intervention)
Dispensed short-acting $\beta_2$-agonists during a one-year follow-up

Dispensed DDD among those who collected

---p=0.15---

---p=0.03---

(Mann Whitney U)

Percentiles
90th
75th
Median
25th
10th

n= 24 21 23 24

Asthma

Control group

Intervention group

COPD
Four questions on Health Related Quality of Life

A better year
Symptoms <2 times a week
Does not wake up
No impact on daily life

Percentage at the one-year follow-up

ASTHMA

- A better year: 81% (Control), 43% (Intervention)
- Symptoms <2 times a week: 81% (Control), 36% (Intervention)
- Does not wake up: 60% (Control), 94% (Intervention)
- No impact on daily life: 62% (Control), 88% (Intervention)

p=0.002*  p<0.001*  p=0.001*  p=0.017*

* Chi-square test
Number Needed to Educate to make one person experience

**ASTHMA**

95% confidence intervals

- 1.7 - 5.9
- 1.5 to 4.2
- 1.9 to 6.3
- 2.1 to 20

**NNE**

2.63 2.22 2.94 3.85

- A better year
- Symptom free days
- Symptom free nights
- No impact on daily life
Health Related Quality of Life
St. George’s Respiratory Questionnaire
Mean (SD)

SGRQ Total Score at the one-year follow-up

Asthma n=39/32
COPD n=27/26

* ANOVA

SGRQ

Control
Intervention

p<0.001*
p<0.54*
<table>
<thead>
<tr>
<th>Costs</th>
<th>Control n= 39</th>
<th>Intervention n= 32</th>
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</thead>
<tbody>
<tr>
<td>• Education</td>
<td>0</td>
<td>1 100 (50)</td>
</tr>
<tr>
<td>• Medication</td>
<td>3 300 (3 100)</td>
<td>3 700 (3 400)</td>
</tr>
<tr>
<td>• Doctor visits</td>
<td>700 (900)</td>
<td>200 (500)</td>
</tr>
<tr>
<td>• Hospital admissions</td>
<td>0</td>
<td>700 (2 700)</td>
</tr>
<tr>
<td>• Travel costs</td>
<td>63 (89)</td>
<td>100 (64)</td>
</tr>
<tr>
<td><strong>Direct costs</strong></td>
<td><strong>4 000 (3 800)</strong></td>
<td><strong>5 900 (4 800)</strong></td>
</tr>
<tr>
<td>• Production loss</td>
<td>11 600 (33 100)</td>
<td>3 400 (16 700)</td>
</tr>
<tr>
<td>• Time costs</td>
<td>300 (700)</td>
<td>1 300 (600)</td>
</tr>
<tr>
<td><strong>Indirect costs</strong></td>
<td><strong>11 900 (33 500)</strong></td>
<td><strong>4 600 (17 300)</strong></td>
</tr>
<tr>
<td><strong>Total costs</strong></td>
<td><strong>16 000 (35 400)</strong></td>
<td><strong>10 500 (20 500)</strong></td>
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</table>
## INCREMENTAL COST-EFFECTIVENESS RATIOES

<table>
<thead>
<tr>
<th>Activity</th>
<th>Adjusted incremental cost-effectiveness ratio</th>
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<tbody>
<tr>
<td>SGRQ * total scores at the one year follow-up</td>
<td>-3 400 per 10 unit improvement</td>
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<tr>
<td>FEV1 change in %</td>
<td>-4 500 per 5% improvement</td>
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<tr>
<td><strong>Adjusted incremental cost-effectiveness ratio of making one person have</strong></td>
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</tr>
<tr>
<td>A better year</td>
<td>-14 400</td>
</tr>
<tr>
<td>Symptom free days</td>
<td>-12 200</td>
</tr>
<tr>
<td>Symptom free nights</td>
<td>-16 100</td>
</tr>
<tr>
<td>No impact in daily life</td>
<td>-21 100</td>
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</table>

* SGRQ = St. George’s Respiratory Questionnaire
### Conclusion

Patient education

<table>
<thead>
<tr>
<th>Metric</th>
<th>Asthma</th>
<th>COPD</th>
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</thead>
<tbody>
<tr>
<td>GP visits</td>
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<td>↓</td>
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<tr>
<td>Days off work</td>
<td>↓</td>
<td>-</td>
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<tr>
<td>Steroid compl.</td>
<td>↑</td>
<td>-</td>
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<tr>
<td>$\beta_2$- agonists</td>
<td>-</td>
<td>↓</td>
</tr>
<tr>
<td>HRQoL</td>
<td>↑</td>
<td>-</td>
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<tr>
<td>FEV1</td>
<td>↑</td>
<td>-</td>
</tr>
<tr>
<td>Total costs</td>
<td>↓</td>
<td>↓</td>
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<tr>
<td>Cost Type</td>
<td>Control n= 27</td>
<td>Intervention n= 26</td>
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<td>-----------------------------</td>
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</tr>
<tr>
<td><strong>Education</strong></td>
<td>0</td>
<td>1 100 (50)</td>
</tr>
<tr>
<td><strong>Medication</strong></td>
<td>6 700 (4 400)</td>
<td>5 700 (3 400)</td>
</tr>
<tr>
<td><strong>Doctor visits</strong></td>
<td>1 000 (1 000)</td>
<td>100 (200)</td>
</tr>
<tr>
<td><strong>Hospital admissions</strong></td>
<td>6 300 (21 000)</td>
<td>2 400 (6 900)</td>
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<td><strong>Travel costs</strong></td>
<td>89 (200)</td>
<td>100 (30)</td>
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<tr>
<td><strong>Direct costs</strong></td>
<td>14 000 (23 300)</td>
<td>9 600 (8 500)</td>
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<tr>
<td><strong>Production loss</strong></td>
<td>5 500 (20 200)</td>
<td>300 (1 300)</td>
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<tr>
<td><strong>Time costs</strong></td>
<td>500 (1 400)</td>
<td>700 (700)</td>
</tr>
<tr>
<td><strong>Indirect costs</strong></td>
<td>5 900 (21 400)</td>
<td>1 100 (1 700)</td>
</tr>
<tr>
<td><strong>Total costs</strong></td>
<td><strong>19 900 (38 800)</strong></td>
<td><strong>10 600 (8 400)</strong></td>
</tr>
</tbody>
</table>
Cost-benefit

A cost-benefit ratio after patient education was calculated as follows:

- \((\text{Educational costs} + \text{patient time cost for educational programme})/ (\text{total costs} - (\text{Educational costs} + \text{patient time cost for educational programme})).\)

The mean difference in total costs were NOK 9 300, while the benefit in monetary terms when adapted for the calculation of a cost-benefit ratio was \((9 300 - 1600) = \text{NOK 7 700}.\) The cost benefit ratio for patient education thus became 1 600: 7 700, meaning that

- for every NOK put into patient education, there was a saving of 4.8.
Conclusion COPD

A one year follow-up indicates that patient education with emphasis on self-management in patients with COPD

• reduced the need for GP visits
• reduced the proportion of patients in need of GP visits
• improved patient satisfaction with GP
• reduced the need for rescue medication
• was cost-beneficial
• was cost-effective
Cost-effectiveness of individual smoking cessation after AMI
Russel, MAH: Effect of general practitioner advice against smoking
BMJ, 1979, 231-235

12-month follow-up

equals 25 long-term quitters / GP / year

all p’s < 0.001

n=2000
Estimated abstinence rates for various intensity levels of person-to-person contact

Meta-analysis, 43 studies,
Clinical Practice Guidelines, 2000, US Dep HHS

Estimated abstinence rates

- No contact: 11%
- Minimal counseling (<3min): 13%
- Low intensity (3-10min): 16%
- Higher intensity (>10min): 22%
Odds ratios and 95% confidence intervals (CIs) using a random effects model for reduction in mortality associated with smoking cessation after myocardial infarction. Asterisk indicates subgroup analysis from a randomized controlled study.
Randomised controlled trial of smoking cessation intervention after admission for coronary heart disease
Petter Quist-Paulsen, Frode Gallefoss

Abstract

Objective To determine whether a nurse led smoking cessation intervention affects smoking cessation rates in patients admitted for coronary heart disease.

Design Randomised controlled trial.

Setting Cardiac ward of a general hospital, Norway.

Participants 249 smokers aged under 76 years admitted for myocardial infarction, unstable angina, or cardiac bypass surgery. 118 were randomly assigned to the intervention and 122 to usual care (control group).

Intervention The intervention was based on a booklet and focused on fear arousal and prevention of relapses. The intervention was delivered by cardiac nurses without special training. The intervention was initiated in hospital, and the participants were contacted regularly for at least five months.

Main outcome measure Smoking cessation rates at 12 months determined by self report and biochemical verification.

Results 12 months after admission to hospital, 57% (n = 57/100) of patients in the intervention group and 37% (n = 44/118) in the control group had quit smoking (absolute risk reduction 20%, 95% confidence interval 6% to 33%). The logical approach, with specially trained nurses, and 29% of participants in the usual care group were lost to follow up.

Fear arousal messages are important in smoking cessation. AWe aimed to determine whether a nurse led smoking cessation intervention with emphasis on fear arousal affected smoking cessation rates after 12 months among patients admitted for coronary heart disease.

Methods

We invited to participate in our study all patients admitted to Vest-Agder Hospital, Kristiansand, Norway for myocardial infarction, unstable angina, or care after coronary bypass surgery performed at other hospitals. Eligible patients had to be under 76 years of age and daily smokers until the start of their present coronary symptoms. Patients who had undergone bypass surgery had to have been daily smokers until they received the date for surgery, and the cause had to be symptomatic coronary artery disease. Patients had to be sufficiently recovered to reliably receive the intervention, had to be able to read Norwegian, and had to live in Vest-Agder or Aust-Agder county. We excluded patients with serious illnesses associated with short life expectan-
En hjelp til røykeslutt
- for deg som virkelig trenger det

Det er viljen som det gjelder
Viljen frigjør eller feller
Henrik Ibsen
Sluttet å røyke
Fortsatte å røyke
Cumulative mortality (%)

Daly, BMJ, 1983. 498 pat.
Intervention (n=100)
Control (n=118)

57.0% 37.3%

p=0.004

NNT: 5.1

Intention to treat analyse:
50% mot 37% (p 0.045)
Table 2  Smoking cessation rates at various stages for patients assessable at 12 months’ follow up. Values are numbers (percentages) of patients unless stated otherwise

<table>
<thead>
<tr>
<th>Group</th>
<th>Hospital discharge</th>
<th>Six weeks</th>
<th>12 months*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention (n=100)</td>
<td>78 (78)</td>
<td>69 (69)</td>
<td>57 (57)</td>
</tr>
<tr>
<td>Control (n=118)</td>
<td>91 (77)</td>
<td>81 (69)</td>
<td>44 (37)</td>
</tr>
<tr>
<td>Difference (95% CI)</td>
<td>0.9 (-10.0 to 12.0)</td>
<td>0.4 (-12.0 to 12.7)</td>
<td>19.7 (6.4 to 33.0)</td>
</tr>
<tr>
<td>P value ($\chi^2$ test)</td>
<td>0.88</td>
<td>0.96</td>
<td>0.004</td>
</tr>
</tbody>
</table>

*Verified by low concentration of nicotine metabolites in urine.
Comparison of the cost effectiveness of the smoking cessation program after coronary revascularisation (low risk model) with other treatment modalities in patients with coronary heart disease. Estimates are in the life time perspective.