

Cover page

**EFFECTIVENESS AND CLINICAL OUTCOMES OF ADMISSIONS TO MUNICIPAL ACUTE
WARDS VERSUS A GENERAL HOSPITAL: A MULTICENTER, RANDOMIZED CONTROLLED
TRIAL IN ØSTFOLD COUNTY**

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EFFECTIVENESS AND CLINICAL OUTCOMES OF ADMISSIONS TO MUNICIPAL ACUTE WARDS VERSUS A GENERAL HOSPITAL: A MULTICENTER, RANDOMIZED CONTROLLED TRIAL IN ØSTFOLD COUNTY

1. INTRODUCTION

1.1 The challenge of providing alternatives to hospital treatment

Demographic changes in the Western world are expected to prompt a need for better organized and more efficient health care services (1, 2). In order to curb expenses, health care providers in many countries are searching for viable alternatives to hospitalizations. Norwegian white papers and reform documents presume that the municipalities will play a central role in meeting the growth in demand for health services (3-5). Central public policy documents and national research strategies highlight that we need pathways characterized by good quality and safe care, and which are responsive to needs, based on user involvement, continuity of care and successful collaboration within and between service levels (5-7). The 2012 Coordination Reform (CR) placed new responsibilities on municipalities in the delivery of primary health care services and on hospitals as deliverers of specialist services, as well as on the integration and collaboration between the two organizational levels (3). This reform mandates that all 428 Norwegian municipalities are obliged to establish Municipal Acute Wards (MAW, *Kommunale akutte døgnplasser*), so as to alleviate pressure on hospitals. However, the initiation of these units is based on political initiatives and not on high quality research. Hence, there is little information on the outcomes regarding the quality, cost-effectiveness, and patient-reported outcomes of this new level of care.

1.2 Our approach

The proposed study aims at assessing the outcome of admissions to MAWs compared to a general hospital for patients in need of acute care, such as acutely sick elderly and patients with exacerbations of chronic conditions, that can be treated at a lower and decentralized level of health care, with potentially less resources than traditional hospitalizations (8). The study will use a Randomized Controlled Trial (RCT) design. It builds on previous research and systematic reviews, and aims to assess several outcomes, including health-related quality of life (HRQoL), patient experiences, cost-effectiveness, and short-term mortality, and draws on linkages to national registers. A strength of the study is that it is interdisciplinary and cross-sectoral, and it is founded on national collaboration between researchers with relevant experience and representatives from both MAWs and hospitals. Moreover, this intervention is of particular interest for the municipalities, and a number of municipalities contribute to this project.

This study will provide essential knowledge for authorities, politicians, healthcare leaders and healthcare professionals when developing, implementing and refining decentralized acute healthcare services in MAWs, as an alternative to hospitalization. Moreover, it will be essential for user organizations, such as LHL, as thorough documentation when speaking up for users. Although the CR is a national reform, the results of the project will be of international interest to those working towards better ways of organizing healthcare delivery systems.

2. THE RESEARCH PROJECT

2.1 Background and status of knowledge

Several models have been developed to meet the future challenges of increased demand for hospital care, aiming to ensure integration of services and teamwork in primary health care services, for example integrated care units such as community hospitals (CH) and nurse-led units (NLU)(9-11). Findings from such units differ substantially: some studies indicate no reduction in hospital admissions (12), while others report reduction of early re-admissions and higher costs than for inpatient stays (13).

In Norway General Practitioner Hospitals (GPHs) or Community hospitals (CHs) represent a primary healthcare level, low technology unit for clinical observations, treatment, rehabilitation and care of patients in need of more intensive medical care than can be provided at home or at standard nursing homes when the patients do not need general hospital care (14, 15). E.g. GPHs have been shown to contribute to a reduction in hospital admissions, improved access to healthcare services in rural areas, and at a lower cost (16, 17). In spite of an awareness in many countries of the challenge of finding feasible alternatives to hospitalizations for acute care, and hence to reduce costs, there is little scientific evidence for, or evaluation of, alternatives to hospitalization. Studies that compare patient outcomes for patients acutely admitted to supplemented primary care units (e.g. MAWs) instead of a general hospital are scarce. A recent review (18) only identified one

small RCT conducted in Norway (19) and two observation studies conducted in England (20, 21). The review concluded: [1] It is possible that admission to a supplemented primary care unit compared with hospitalization provides slightly better patient satisfaction, but the quality of the evidence for this result is low; [2] There is insufficient scientific evidence to determine whether admission to a supplemented primary care unit compared to hospitalization affects patient outcomes, such as physical function and quality of life or affects the number of readmissions; [3] No prospective controlled studies that examined whether supplemented primary care units lead to fewer hospital admissions, or are associated with reduced expense were identified; [4] No studies that compared larger inter-municipal units with smaller were identified.

Some studies have suggested that patients prefer being treated in a less busy and harried environment than in stressful and hectic hospitals, and that patient experiences are more positive in small and rural hospitals than in larger and more urban hospitals (22, 23). Recently, a randomized study of 60 patients in rural Norway compared the health consequences of acute admission to a small community hospital unit (n=33) as an alternative to a general hospital (n=27). The study found no differences in daily functioning or health consequences between the groups, though the community hospital patients had fewer in-patient days at hospitals and nursing homes and less use of home nursing than those admitted to the general hospital (24). The study included few patients, resulting in no significant findings. This RCT can be seen as a “pilot” to our planned study, and the researcher of this RCT also takes part in this new study.

The municipalities will play a central role in meeting the growth in demand for healthcare services in Norway (4, 25). As of 1 January 2016, all Norwegian municipalities are obliged to have in place a MAW in order to reduce the pressure on hospitals. The MAWs are designed for patients diagnosed with conditions that can be managed with less advanced equipment than in hospital, without reducing treatment quality. These units offer 24-hour acute treatment and care service within the municipality, to people in need of necessary, urgent and immediate help, as wards with an anticipated length of stay less than 72 hours (26). A recent study reported that the establishment of MAWs in Norway reduced general hospital admissions, especially for people 80 years or above, and where the MAW was co-located with a casualty and had a physician present 24/7 (27). Moreover, MAWs have been shown to deliver safe and quality, patient-centered healthcare services from patients’ perspectives (28, 29). The MAWs represent somehow different services than the ICUs, GPHs and community hospitals, since the MAWs are meant to be an alternative to acute hospitalization, while the other units are services prior to and after hospitalization, or used for rehabilitation.

As far as we know, no other randomized, controlled studies have been conducted to compare healthcare services as offered in MAWs to those offered in hospital. The study will undertake an economic evaluation and study other outcomes of an intervention, using an RCT design, which is a strong study design. The study also includes measures of HRQoL and patient experiences.

2.2 Overall study design: a randomized controlled trial

Patients selected for treatment in a MAW are presumed to be less severely ill than those treated in the hospitals, and the staffing, diagnostic and monitoring facilities are more limited than in the hospital. Therefore there is a selection bias that represents a challenge when comparing treatment in MAWs and hospitals. In order to compare treatment between MAWs and adjust for observable and non-observable bias and confounding, an RCT would be feasible. RCTs are the most rigorous way of determining whether a cause-effect relation exists between an intervention and an outcome (30), yet such studies have been underutilized in the health care services research.

Therefore, the study is designed as an RCT of the effectiveness and quality of care in five MAWs, compared to one hospital in Østfold County. The study will be a large, open, parallel group RCT, which aims to include a minimum of 700 patients. In order to reduce the additional workload on the hospital, we shall use a 2:1 allocation to the MAWs and hospital, respectively.

2.3. The study’s objectives

The primary outcome of the study will be patient experience, as measured with the Nordic Patient Experience Questionnaire-The NORPEQ, which is a validated, reliable short form questionnaire including eight questions to measure patient experiences covering important aspects of the healthcare service delivery, such as communication, information, trust and care, as well as overall satisfaction (31).

The null hypothesis states that there is no difference in patient experiences between the two allocation groups.

In addition the study will compare a number of secondary outcomes between the study arms:

- Change in HRQoL from inclusion to 4 weeks, as assessed with the EQ-5D Index utility measure (32).
- 30-day mortality
- 30-day readmission rate (all causes)
- Length of stay and number of inpatient days over 3 months (all causes)
- Transfer of patients between the MAW and the hospital
- Patient experiences, using the NORPEQ questionnaire, 4 weeks after inclusion
- Health status as assessed with the RAND-12 instrument
- Costs and cost-effectiveness
- Variation in practice between the five MAWs

Moreover, the study will aim at further exploring General Practitioners' perspectives on these issues, and on the quality, safety and efficacy of the MAWs (see section 2.7).

2.4. Patient perspectives

There is a growing recognition that patients' perspectives are essential in designing health care services, and in the assessment of the effectiveness and quality of health care (33). The planned study will assess effectiveness using patient-reported outcomes.

At the time of admission, the patients will be asked to complete an interviewer-administered EQ5D-three level version (EQ-5D-3L) as a baseline measure. Four weeks after inclusion, the patients will be contacted by telephone to respond to the EQ-5D-3L and the NORPEQ questionnaires:

The *EQ-5D-3L* is a generic measure of health status that provides a simple descriptive profile and a single index value that can be used in the clinical and economic evaluation of health care, and in population health surveys. The EQ-5D-3L consists of the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS) (32). The items are aggregated to a utility index, the EQ-5D Index.

The *RAND-12* health status inventory (aka SF-12) is a commonly used health status instrument, which was developed as part of the Medical outcomes study in the 1980s. It uses 12 items from the SF-36 and can be aggregated to a physical health component score and an mental health component score.

2.5. User involvement

We have established close links with representatives from the health care services in the municipalities, including in the steering group, as well as users from Landsforeningen for Hjerte- og Lungesyke, LHL. For successful inclusion of patients in the project, it is crucial to have good support in the local communities.

Patient participation is increasingly recognized as a key component in the design of health care processes and in improving patient safety (34). In the planning of this project, patient representatives from LHL, and a representative from the Consumer board (*Brukerutvalget*) at Østfold Hospital Trust have participated and provided constructive input in project meetings. In addition, a patient representative from LHL will provide input and critique to the planning of the project, specifically patient information and inclusion procedures. Moreover, users will be essential when planning utilization and publication of the findings.

2.6. General Practitioners' perspectives

Patients admitted to MAWs are referred by a General Practitioner (GP), a casualty- or a nursing home physician. A recent study from Østfold found that GPs found several aspects of MAW services problematic, including challenges in deciding which patients were suitable for treatment at a MAW, whether patients could be regarded as medically clarified, and whether these services were sufficient and safe. GPs were also under pressure from several other stakeholders when deciding where to refer their patients. Moreover, the MAWs were viewed not merely as an alternative to hospitals, but also as a service in addition to hospitals (35). These aspects have an impact on whether MAWs are used as intended or not. Further investigation of GPs' perspectives on MAWs will be included in the Post-docs' research approach.

3. THE PROJECT PLAN, MANAGEMENT, ORGANIZATION AND COOPERATION

3.1. Project plan and data collection

Sample and inclusion

The study will be conducted in Østfold county, which include 17 municipalities belonging to the same

hospital catchment area of approximately 290 000 inhabitants. In Østfold, five MAWs have been established during the period 2012-2013. The MAWs consist of from six to 11 beds, and are located both rural and central.

In a pilot study all patients who are admitted to the five MAWs during 2 weeks, will be presented with patient information about a preliminary fictive study, whether they would be willing to participate in such a potential proposed (theoretical) study, asked to respond to some questionnaire items, and finally provide comments to the process. This to ensure that inclusion will be possible.

Statistics from the five MAWs in Østfold collected throughout the last five years, shows that approximately 60% of the patients are referred from one of the five casualties (Legevakt). All patients who otherwise would have been hospitalized, and who are judged to fulfill the criteria for admission at a MAW by a physician at the local Casualty (*Legevaktslege*) will be invited to participate. Those fulfilling the inclusion criteria will be randomized for admission either to a MAW or the hospital.

Inclusion criteria:

- Age ≥ 18 years
- Ability to provide written, informed consent
- Eligible for admission at a MAW according to established admission criteria
- Assessed and referred by a physician at the local Casualty (*Legevakt*) on the same day

Exclusion criteria:

- Psychiatric or cognitive impairment
- No Norwegian national identification number
- Patients admitted to the MAW via the *diagnostic loop*
- Previous admission to a MAW during the project period (to prevent patients being included more than once in the project)
- Insufficient Norwegian language skills to respond to the questionnaires

The *diagnostic loop* is a service by the hospital offering the GPs an opportunity to send patients to the hospital for examinations and diagnostic work-up, e.g. with x-rays, and then further to the MAW. Patients admitted via this pathway will be registered, but they will not be included in the RCT.

The referring physician will contact one of the five MAWs after having judged the patients' eligibility for inclusion, and received patients' written informed consent to participate. The MAWs will then randomize the patients to either the MAW or the hospital, using a simple randomization procedure with numbered sheets in sealed, opaque envelopes. The randomization will be done by personnel responsible for receiving referral by telephone, either a physician or a nurse, at the MAWs. The patients will then be transported to the MAW or hospital according to the random allocation procedure.

Variables collected

The referring physician will fill in a screening form before allocation, including date, time, age, sex, ICPC2 diagnosis and a checklist of the inclusion/exclusion criteria. These forms will be kept as part of the case report form (CRF) for those included, and as a reject log for those excluded. At admission to the allocated unit, a minimum of additional data will be collected: EQ-5D-3L profile and VAS by interview, *Modified Early Warning Score* including the raw data (MEWS; a measure to judge the severity of a patient's condition), demographic variables, ID of treating hospital department or MAW, and number of hospitalizations (and localization) during the past 6 months. At 4 weeks (range 3-6 weeks) after inclusion, the patients will have a follow-up by telephone, being interviewed with the EQ-5D-3L and the NORPEQ, and present location (home/nursing home/rehabilitation), and whether a proxy assisted with responding to the phone interview.

All included patients' electronic medical records at the MAWs and the hospital will be reviewed after discharge to record a number of variables, such as previous diagnoses (comorbidity), previous number of admissions and inpatient days during the past year, whether the patient was admitted from the home or nursing home, treatments given, diagnoses at discharge, re-admissions and deaths. In addition the project will ask for consent to use the national personal identification number (PIN) of each patient for linkage with information of the Norwegian Patient Register (*Norsk pasientregister, NPR*), the Cause of Death Register of Statistics Norway (*Dødsårsaksregisteret*), and the Norwegian Prescription Database (*Reseptregisteret*).

The *Charlson comorbidity index* (CCI), a method of predicting mortality by classifying or weighting comorbid conditions, will be used to control for comorbidity as a potential confounding variable when

comparing patient-reported outcomes in the MAWs and hospital wards. This method has been widely used by health researchers to measure burden of disease and case mix (35). In the present study, CCI will be scored on the basis of review of medical records at the MAWs and the hospital, and validated against diagnosis codes from previous hospital stays.

Costs will be estimated for the patients' hospital stays as

[*Actual inpatient-days**(*DRG cost/National average LOS for the DRG*)],

and for each admission to a MAW as

[*Actual inpatient-days***Total annual MAW cost/Total number of MAW inpatient-days*]).

Sample size

In a recent study (36) utilized the NORPEQ to validate the Picker Patient Experience Questionnaire (PPE-15) in Norwegian. In this study the mean score in MAWs was 0.83 (Standard deviation, SD, .13), while the score in hospital was 0.78 (SD .13). Following a superiority design, 2:1 allocation to the MAW and hospital respectively, power=0.8, alpha=0.05, we estimated the required sample size to be able to detect a mean difference between the groups of 0.25 standard deviation (SD). Adjusted for potential drop-outs (5% dead, 15% non-response to follow-up) this gives a sample size of 340 patients in MAWs and 160 patients in hospital. The mortality rate seems realistic, as over 2 months in 2015 the 30-day mortality rate was 5% in total for one of the largest MAWs in Østfold County.

Recruitment schedule

In 2018 about 2,300 unique patients were admitted to the five MAWs in Østfold county, and the annual number of admissions is expected to increase during the next years. Patients may not be eligible for inclusion, may be excluded, or may reject to participate because they have a preference for being treated in their local community (24), for the most advanced treatment, or the may opt to avoid unnecessary transport to another facility. Given extensive encouragement and support in the recruitment process, we anticipate that it is possible to include the needed amount of patients over 12 months. The duration of the inclusion period in the project will be a maximum of 15 months.

Statistical analysis

Groups will be compared using the Student's t test, Mann-Whitney U or chi-square test, as appropriate. Change in the EQ-5D-3L index (the primary outcome) will be compared using the Student's t test. The distributions of scores on the EQ-5D dimensions at follow-up will be compared using the Mann Whitney U test. 30-day mortality rate will be compared between groups using the chi square test or multivariable logistic regression analysis.

Similarly, average cost per disease episode will be compared between the two study arms using the t test. LOS will be compared using the Mann-Whitney U-test, or multivariable negative binomial regression analysis.

A priori, we assume a 20% crossover rate of patients from the MAWs to the hospitals. Analyses will be based on the *intention-to-treat* principle where possible. In some of the secondary analyses, we shall control for potential confounding factors such as gender, age and co-morbidity to reduce bias.

3.2. Project management and organization

The project has been established in collaboration between the Østfold Hospital Trust, Østfold College, the five inter-municipal MAWs, the 17 municipalities in the Østfold county, Helse Sør-Øst Centre for Health Services Research (HØKH, Akershus University Hospital), and the University of Oslo. The project has been planned by a working group in consultation with an advisory board consisting of experienced researchers, physicians from three of the MAWs in Østfold County and users. The project will be organized with a project group, project supervisors/investigators, and an advisory board. The researchers established contact with LHL at an early point, and user representatives have participated in project planning.

Statistical support is available at the Department of Research, Østfold Hospital Trust, HØKH, as well as the University of Oslo. HØKH has skilled researchers with a competence in methodology, health economics, and clinical medicine, and the project will draw on their expertise.

3.2.1 The project group and roles

The following positions will be funded by the project:

PhD student. Nystrøm will primarily be employed at the Østfold University College during the study. The student will take responsibility for applications for data linkage, data collection, including follow-up and support of the randomization and inclusion process, review of medical records, data analysis and publications, in addition to completing the mandatory courses for the PhD. She/he will be involved in follow-up of data collection in the Emergency department of the hospital and the MAWs in collaboration with the project coordinators/research assistants.

Project coordinators/research assistants. At each of the MAWs, we will aim at engaging a dedicated research assistant. They will be located at each of the MAWs and will be involved in randomization, data collection and general support, with a focus on daily follow-up with the PhD candidate, the Emergency department of the hospital and the MAWs.

3.2.2 Project supervisors/collaborators

Main supervisor. Dr Ann-Chatrin Linqvist Leonardsen, associate Professor Østfold University College and Post-doc at Østfold Hospital trust. Dr Leonardsen will be the main supervisor for the PhD student. She holds her PhD in health-service research and was one of the first Norwegian researcher focusing on the effects of the collaboration reform. She has excellent knowledge of the primary care health service in Østfold County and a well-renowned network within the field of health-service research. As a post-doc fellow at Østfold Hospital Trust (20%) dr. Leonardsen will assist during inclusion of patients and co-write relevant papers, as well as resume responsibility for 1-2 of the remaining papers.

Co-supervisor Tron Moger, Professor University of Oslo will be co-supervisor for the PhD student. Dr Moger has done extensive research within the field of health economics. He is specialized in the field of cost-effectiveness analyses. Dr. Moger will assist in data analyses and relevant scientific papers.

Co-supervisor Hilde Lurås, Associate Professor University of Oslo will be co-supervisor for the PhD student. Lurås has done extensive research within the field of effects of organization, patient pathways and collaboration in healthcare services, as well as in health economics. Dr Lurås will assist in data analyses, writing and publication.

Research collaborators:

Co-investigator. Professor Terje Hagen, University of Oslo. With his extensive research experience within the field of health service research and health economics, professor Hagen will contribute to this project in data analyses and scientific input on relevant papers.

Co-investigator. Professor Patrik Midløv University of Lund, Sweden. Professor Midløv has extensive experience in the field of health-service research, as well as in primary care research. He holds the position as professor and chief of primary care research at Lund University, Sweden. Professor Midløv will contribute to this project through data analyses and scientific input on the papers.

Co-investigator. Øystein Lappégard, MD, PhD. Dr. Lappégard took his PhD on «Acute admissions at Hallingdal sjukestugu: Can and should local medical centres play a role in Norwegian healthcare services for acute admissions of a specified group of patients?». His experience with complex health-service research designs will be valuable for the PhD student. Dr Lappégard will provide help in data analyses and interpretation of findings.

3.4 Budget

The PhD candidate will be financed through fundings from Extrasiftelsen. Leonardsen has received a finance guarantee for three years from Østfold Hospital Trust. Lurås and Moger will be financed through internal research time in their employments at UiO, respectively.

3.5 Time schedule

	2018	2019		2020		2021		2022	
	July-Dec	Jan-Jun	July-Dec	Jan-Jun	July-Dec	Jan-July	July-Dec	Jan-July	July-Dec
Project planning & protocol									
Applications									
Employment of PhD candidate-12/6-19									
Inclusion period									

PhD courses,									
Data cleaning, analysis									
Presentations/abstracts									
Paper I:									
Paper II:									
Paper III:									
PhD thesis									
Paper IV (post-doc)									

4. KEY PERSPECTIVES AND RELEVANCE TO HELSEVEL

4.1 Compliance with strategic documents

The study builds on recent research on MAWs in Østfold county, and on an established collaboration between researchers and participants from both municipalities, hospital and educational institutions as well as research groups both nationally and internationally. The study includes measures of HRQoL and patient-experiences, as well as data from national registers, and has a comparative approach. The project incorporates users from LHL and the hospital consumer board in the planning of the project, which may contribute better acceptance of and a successful completion of the project. This proposal addresses key aspects of the CR and other national strategic documents (3, 7, 37). Finally, health services research is a prioritized area for the owners of the Østfold Hospital Trust, HSØ.

4.2 Relevance and benefit to society

The study will provide important knowledge about structural, organizational and economic aspects of acute healthcare services, exploring the effectiveness and outcomes in MAWs versus a general hospital, including HRQoL, quality of care, cost-effectiveness and patient experiences/satisfaction, as well as GPs perspectives on these issues. These outputs will be important for authorities, politicians, health care leaders, and professionals as well as researchers involved in developing, implementing and refining decentralized acute health care services as an alternative to hospitalization. In addition these outputs are important documentation for user organizations (such as LHL), when speaking up for their members.

The project outputs will be of international interest, in particular in countries with national health insurance with broad coverage, as in the Nordic countries, the UK, Canada and Australia that have previously undertaken similar but different approaches to decentralize health care and reduce the costs of acute hospitalizations.

4.3 Ethical perspectives

Ethical approval has been granted from the Regional Committee for Medical Ethics (reference no. 2018/687), as well as the Norwegian Center for Research Data (NSD, reference no. 340271). The project will be based on the principles stated in the declaration of Helsinki. All data will be anonymized and treated in strict adherence to prevailing regulations. All participants will be informed that participation is voluntary and of their right to withdraw at any stage, and fully informed consent will be collected prior to their enrolment and randomization. The consent will include that the researchers are allowed to gather needed information from the patients' medical records in the MAW and Norwegian hospitals, and through linkage to national registers.

4.4 Gender issues

The results of this project will be of relevance to both women and men. The research team has a good gender balance and will endeavor to maintain this when employing the PhD candidate, Post-doc. candidate, and co-workers.

5. DISSEMINATION AND COMMUNICATION OF RESULTS

The study will lead to at least five high quality scientific publications in peer-reviewed journals in English, of which three articles will be part of fulfillment for the PhD thesis of the PhD candidate.

Some tentative titles for publications from the study that relate to the objectives described above:

- (1) Health-related quality of life after admissions to municipal acute wards versus a general hospital: a multicenter, randomized controlled trial

- (2) Patient experiences following admissions to municipal acute wards versus a general hospital: a multicenter, randomized controlled trial
- (3) Cost-effectiveness of admissions to municipal acute wards versus a general hospital: a multicenter, randomized controlled trial
- (4) Comparison of 30-day mortality and health care utilization for admissions to municipal acute wards versus a general hospital: a multicenter, randomized controlled trial
- (5) Variations in structure, processes and healthcare utilization between municipal acute wards in Østfold County. GPs' perspectives and impact.
- (6) Variations in health-related quality of life and patient experiences between five municipal acute wards: a descriptive study

The project group includes merited researchers, thus ensuring that publication in high-impact journals is achievable. The protocol, planning, progress reports, and results from the study will be presented as oral presentations or posters at national and international conferences. The target audience will be scientific peers, administrators, government, and politicians, as well as representatives for various patients' consumer groups. A web-site and social media, such as Facebook, will also be used to spread information about the progress and results from the study to users and the general public. An anticipated time schedule for the various study outputs is shown above in the project plan (item 3.5.)

6. ADDITION INFORMATION REQUESTED IN THE CALL FOR PROPOSALS

Expected benefit. The CR has mandated the establishment of MAWs all over Norway as of 2016, without any strong scientific documentation of cost-effectiveness. The study builds on data from previous research, stating that there is a need for more solid documentation about intermediate level acute hospital care. The proposed study will assess the effectiveness, cost-effectiveness and several aspects of quality of care and will contribute useful information for evaluation and future planning of MAWs, as an alternative to hospitalization. Therefore we think this project is timely. The MAWs in Østfold County are small to medium-sized and are expected to be representative for the majority of MAWs in Norway, and therefore of interest to smaller cities and rural areas. In a national health service striving to curb expenses of hospital care, the study results on cost-effectiveness will be of particular interest and have a benefit for the authorities, politicians, and healthcare professionals when developing that are engaged in implementing and refining the MAW concept.

User involvement. In this project the patients, relatives, municipalities and their representatives constitute the users. The project has established close links with representatives from the healthcare services in the municipalities that have participated in project planning and expressed strong support to the project. The municipalities' healthcare personnel will participate in the inclusion of patients, and this commitment is crucial for the success of the project. The municipalities are also represented in the advisory board. Patient participation is a key component in the design of health care processes and in improving patient safety (34). In the planning of this project, patient representatives from LHL and a representative from the Consumer board (*Brukerutvalget*) at Østfold Hospital Trust have participated and provided constructive input. In addition, patients will provide input and critique to the patient information and inclusion procedures.

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