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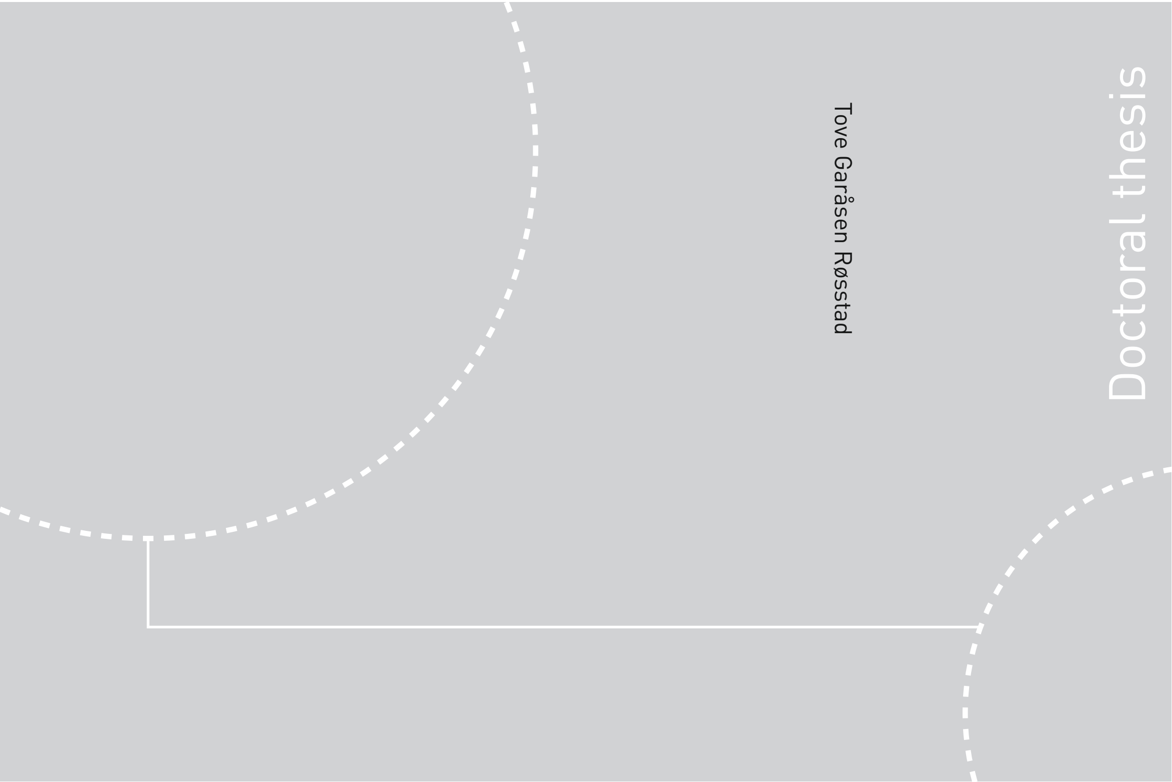

Tove Garåsen Røsstad

Doctoral thesis

Doctoral theses at NTNU, 2016:238

NTNU
Norwegian University of
Science and Technology
Thesis for the Degree of
Philosophiae Doctor
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Department of Public Health and
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Generic Care Pathway for Elderly Patients in Need of Home Care Services after Hospital Discharge

A cluster RCT with nested qualitative studies of development and implementation

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Norsk sammendrag

Generisk pasientforløp for eldre pasienter med behov for hjemmetjenester etter utskriving fra sykehus – utvikling, implementering og effekt

Vestlige land står overfor et økende antall eldre pasienter som bor hjemme med mange sykdommer og redusert funksjonsevne. Sykehusoppholdene blir stadig kortere, og oppfølging og rehabilitering i primærhelsetjenesten må skje på et stadig tidligere stadium i sykdomsforløpet. For å sikre gode pasientforløp kreves god informasjonsoverføring, kompetanseoverføring og koordinering mellom helsetjenestenivåene. Utvikling og bruk av strukturerte pasientforløp er en strategi for å skape sammenhengende og effektive helsetjenester av god kvalitet, men bruken har så langt i hovedsak vært begrenset til sykehus.

Denne avhandlingen utforsket et strukturert pasientforløp for eldre pasienter med behov for hjemmetjenester etter et sykehusopphold, utviklet av helsepersonell fra sykehus og primærhelsetjenesten i samarbeid med representanter fra pasientorganisasjoner. Pasientforløpet integrerer utreiseplanlegging og oppfølging ved hjemmetjenesten og fastlegen i de fire første ukene etter utskriving fra sykehus. Hovedformålet med avhandlingen var å bidra med kunnskap om utviklingen av et integrert pasientforløp for eldre pasienter som involverte både spesialist- og kommunehelsetjenesten og videre kunnskap om implementeringen og effekten av dette pasientforløpet.

Det ble gjennomført tre studier. De to første studiene som hadde et kvalitativt design, undersøkte prosessen med å henholdsvis utvikle og implementere pasientforløpet. Den tredje studien var en kluster randomisert studie som undersøkte effekten på pasientnivå.

Den første studien viste at de organisatoriske og kulturelle forskjellene mellom spesialist- og kommunehelsetjenesten gjorde det vanskelig å utvikle et felles strukturert pasientforløp. Ansatte fra sykehusene fant det naturlig å utvikle diagnosebaserte forløp i tråd med vanlig praksis i sykehus. Bruk av slike diagnosebaserte pasientforløp ble imidlertid funnet lite hensiktsmessige i hjemmetjenesten for målgruppen som var eldre

og ofte hadde flere sykdommer. Arbeidet med diagnosebaserte forløp ble forlatt til fordel for ett generisk pasientforløp gitt navnet **H**elhetlig **P**asientforløp i eget **H**jem (HPH, PaTH på engelsk). For å sikre nødvendige observasjoner og kompetanseoverføring ble det utviklet sjekklister som ble brukt ved definerte milepæler i pasientforløpet, blant annet ved kommunikasjon mellom hjemmetjeneste og sykehus eller fastlege.

Den andre studien undersøkte implementeringen av HPH i hjemmetjenesten. Den viste at det var krevende å implementere og integrere en kompleks intervensjon som HPH i en organisasjon i full drift. Sammenlikning av implementeringsprosessen mellom kommuner som fortsatte å bruke HPH etter forsøksperioden og de som ikke gjorde det, viste at tydelig ledelse og et omfattende arbeid over tid med tilrettelegging for bruk i det daglige arbeidet og tilstrekkelig trening av ansatte var nødvendig for å skape tilstrekkelig forståelse, engasjement og forpliktelse for å implementere HPH i daglig bruk. I de kommunene der pasientforløpet ble en del av det daglige arbeidet, opplevde de ansatte at de var bedre forberedt når pasienten kom hjem fra sykehus. Dette gav dem større oversikt over pasientens tilstand, og de ble mer proaktive ved ny oppståtte problemer. Lederne i disse kommunene opplevde HPH som et nyttig lederverktøy for å bedre kvaliteten på tjenestene.

Den tredje studien var en kluster randomisert kontrollert studie av effekten av HPH i løpet av 12 måneder. Bruken av de fire sjekklistene som utgjorde kjernen i HPH var mangelfull; tre eller flere sjekklister ble dokumentert brukt for bare 36 % av pasientene i de hjemmetjenestene som innførte HPH, men bruken bedret seg over tid. Pasientene i intervensjonsgruppen hadde signifikant flere konsultasjoner hos fastlegen sammenliknet med kontrollgruppen og det var indikasjoner på flere dager hjemme. Vi fant ingen statistisk signifikant forskjeller mellom gruppene på funksjonsnivå eller reinnleggelse (primære utfallsvariabler), helsetjenesteforbruk i sykehus og kommunale institusjoner, dødelighet eller livskvalitet (sekundære utfallsvariabler).

Avhandlingen viste at helsepersonell i kommuner der HPH var blitt en del av daglig virksomhet, opplevde at et slikt integrert, generisk pasientforløp kunne gi bedre

koordinering og kvalitet på tjenestene. Implementering av denne komplekse intervensjonen var imidlertid krevende. Utilstrekkelig innkjøringsperiode medførte at HPH ikke ble brukt i tilstrekkelig omfang og med tilstrekkelig kvalitet i perioden hvor effekten ble studert. I denne avhandlingen kan man derfor ikke trekke noen endelig konklusjon om hvorvidt et integrert pasientforløpet som HPH, er effektivt på pasientnivå.

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English summary

Generic care pathway for elderly patients in need of home care services after hospital discharge

Western countries are facing an increasing number of elderly patients with multimorbidity and functional impairments living at home. Hospital stays become shorter, which means that follow-up and rehabilitation in primary care must take place at an increasingly earlier stage of the patient trajectory. Adequate transfer of information and knowledge as well as coordinated services across the collaborating health care providers are required to ensure safe patient trajectories. Development and implementation of integrated care pathways is a strategy to ensure coherent and effective health care provision of high quality, but this have so far mainly taken place within hospitals.

This thesis investigated an integrated care pathway for elderly patients in need of home care services after hospital discharge, developed by health care professionals in hospitals and primary care in cooperation with representatives from patient associations. The care pathway integrates discharge planning and post discharge support and follow-up by the home care services and GPs during the first four weeks after discharge. The aim of this thesis was to provide knowledge about developing an integrated care pathway for elderly patients involving specialist and primary care services, and furthermore, knowledge about its implementation and effectiveness.

Three studies were conducted. The first two studies had a qualitative design and explored the process of developing and implementing the care pathway. The third study was a cluster randomised controlled trial, investigating the effectiveness of the care pathway on patient level.

The first study revealed significant organisational and cultural differences between the health care professionals in the hospitals and municipalities that made development of care pathways across care levels challenging. The hospital professionals found it

appropriate to develop disease-specific care pathways, which were common in hospitals. However, such disease-specific care pathways were found to be unsuitable for use in home care services for the target population characterised by old age and multimorbidity. Instead, a generic care pathway (**Pa**tient **T**rajectory for **H**ome-dwelling elders - PaTH) was developed, which could be used for patients with different diseases. To ensure adequate observations and assessments of the patients and sufficient information transfer, checklists were developed for use at defined stages in the patient trajectory.

The second study explored the implementation of PaTH within the home care services. This study revealed that it is demanding to implement and integrate a complex intervention like PaTH in an organisation in full operation. When comparing the implementation process between municipalities that used PaTH and those that discontinued using it after the study period, it became evident that engaged leadership and extensive work over time ensuring practical facilitation of the work processes and sufficient training of employees, was needed to create sufficient understanding, engagement and commitment to implement PaTH. In the municipalities where PaTH became part of daily work, the employees told that they were better prepared before the patients came home from hospital. This made them more aware of the patients' condition and challenges, and they became more proactive when the patients' condition deteriorated. The home care managers and head nurses in these municipalities experienced PaTH to be a useful tool to improve the quality of home care services.

The third study was a cluster randomised controlled trial where the effectiveness of PaTH was studied during a 12 months follow-up period. Use of the four core checklists of PaTH was insufficient; three or more checklists were used on only 36 % of the patients in the intervention group, but adherence improved over time. The patients in the PaTH group had statistically significant more consultation with the GPs compared to the control group and there were indications of more days at home. No statistical significant differences were found on functional level and readmissions (primary outcomes), health service utilisation in the hospitals and municipal institutions, mortality, or quality of life (secondary outcomes).

The thesis demonstrates that health care professionals in the municipalities where PaTH was integrated in daily work, experienced that such an integrated, generic care pathway could improve coordination and quality of care. However, implementation of this complex intervention was challenging. Insufficient run-in-time resulted in patients being included in the study before the intervention was provided with sufficient quantity and quality. Therefore, this thesis cannot draw a final conclusion on whether this integrated care pathway was effective on patient level.

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Acknowledgements

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List of papers

This thesis is based on the following original research papers:

Paper 1:

Røsstad T, Garåsen H, Steinsbekk A, Sletvold O, Grimsmo A: Development of a patient-centred care pathway across healthcare providers: a qualitative study.

BMC Health Serv Res. 2013 Apr 1;13:121. doi: 10.1186/1472-6963-13-121

Paper 2:

Røsstad T, Garåsen H, Steinsbekk A, Håland E, Kristoffersen L, Grimsmo A: Implementing a care pathway for elderly patients, a comparative qualitative process evaluation in primary care.

BMC Health Serv Res. 2015 Mar 4;15:86. doi: 10.1186/s12913-015-0751-1

Paper 3:

Røsstad T, Salvesen Ø, Steinsbekk A, Grimsmo A, Sletvold O, Garåsen H: Generic care pathway for elderly patients in need of home care services after discharge from hospitals. A cluster randomised trial.

Resubmitted to BMC Health Serv Res. January 2016

Abbreviations

ADL	Activities of Daily Living
CI	Confidence Interval
cRCT	cluster Randomised Controlled Trial
CCM	Chronic Care Model
CGA	Comprehensive Geriatric Assessment
HER	Electronic Health Record
EPA	European Pathway Association
GEU	Geriatric Evaluation Unit
GP	General Practitioner
HPH	**H**elhetlig **P**asientforløp i eget **H**jem (Translated to PaTH, see below)
IADL	Instrumental Activities of Daily Living
ICC	Intraclass Correlation Coefficient
IPLOS	Individuell Pleie- og OmsorgsStatistikk (individual care statistics)
MCS	Mental Component Summary (in SF 36)
NEADL	Nottingham Extended ADL scale
NEXES	EU project: Supporting Healthier and Independent Living for Chronic patients and elderly
NPT	Normalisation Process Theory
NTNU	Norwegian University of Science and Technology
PaTH	**Pa**tient **T**rajectory for **H**ome-dwelling elders (corresponds to the Norwegian "Helhetlig Pasientforløp i eget Hjem" (HPH))
PCS	Physical Component Summary (in SF 36)
PCMH	Patient-Centred Medical Home
QoL	Quality of Life
SD	Standard Deviation
SF-36	Short Form 36 (Health related quality of life)
STC	Systematic Text Condensation

Definitions

Municipality is a district, town or city that possesses local self-government and has an elected political government body (local municipal authority).

Primary care in Norway includes health and social care services including home care services, GPs, physiotherapists, occupational therapists, social services, rehabilitation, and long-term care. Primary care is the responsibility of the local municipal authorities.

Home care services, as defined in this thesis, are primary health and social care services including nurses and nursing assistants making home visits to provide nursing procedures (e.g. medication, palliative care) and personal assistance (e.g. personal hygiene, dressing, toileting, and preparing meals) for those who cannot cope on their own due to disease or functional impairments. Home care services also include home-helpers providing house cleaning, but the home-helpers were not involved in this study. Physiotherapists and occupational therapists do also make home visits, but are not part of the home care services as defined in this thesis.

General practitioners (GPs) are primary care physicians providing general healthcare (preventive and curative) to a defined population. All inhabitants are entitled to a regular GP. The GPs are on contract with the municipality. They are usually organised in small private enterprises and work independent of other health and care services in the municipality.

Long-term institutional care / nursing homes are nurse-managed care institutions for patients in need of care services due to cognitive and / or physical disabilities caused by age or chronic diseases.

Community hospitals are low technology, primary care institutions (short-term) for clinical observations, treatment, rehabilitation, and care for patients in need of more intensive medical care that can be provided at home or at a standard nursing home (1)

General and university hospitals provide specialised health care. The hospitals are owned by the government and managed by four regional health authorities.

Complex interventions are interventions containing several interacting components (2). Degree of complexity varies and relates to factors like the number of interacting components, the number of groups or organisational levels targeted by the intervention, the degree of behavioural change required from those providing or receiving the intervention, and the degree of local adaptations permitted.

Cluster: A cluster is a social or organisational unit or individuals sampled within sites (the site being the cluster), e.g. home care units, GP practices, neighbourhood (3).

1 Introduction

As a primary care physician during 30 years, I have been experiencing inadequate exchange of information and subsequent insufficient follow-up of elderly patients after discharge from hospital. Elderly patients characterised by multimorbidity and functional decline are particularly dependent on continuity of care between collaborating partners. One period I was a physician at a community hospital in Trondheim, which was evaluated through a randomised controlled trial (4, 5). The trial found improved outcomes to elderly patients in need of aftercare who got a transitional stay in the community hospital after discharge from the general hospital. In the community hospital, they got close medical follow-up and were encouraged to practice on basic self-care activities. Furthermore, discharge to their homes was thoroughly planned. I reflected on whether a structured discharge and follow-up program by home care services and GPs might give similar results when addressing elderly patients discharged directly to their own homes from the general hospital.

At that time there was a general recognition among health care authorities and professionals that collaboration between health care levels and across health care providers in Norway was inadequate to patients with complex conditions, and a coordination reform was under way. This – together with my own reflections – gave rise to designing a project with the purpose of developing and implementing an integrated care pathway across care levels. The target population was elderly patients in need of home care services after hospital discharge, and the care pathway was to include structured discharge preparations and post-discharge follow up by home care services and general practitioners.

2 Background

2.1 Challenges facing health and social care

Population aging affects most developed countries around the world, but is particularly rapid in Europe and other OECD countries where the share of population aged 80 years and above is expected to rise from 5 % in 2010 to 11 % in 2050 (6). In Norway the number of elders aged 80 and above is expected to rise from 220 000 in 2014 to more than 550 000 in 2050 while the proportion of the population in working age, compared to elderly, decline from 5.4 to 2.7 (7, 8). The prevalence of multimorbidity, defined as two or more chronic conditions in the same individual, and functional decline become more common with age (9-13), and the growing proportion of elderly people will increase the pressure on health care and long-term services in the municipalities. However, the degree of pressure will depend on the health status of people as they get older. Two scenarios are possible; years gained increase time with ill-health, or morbidity and disability is postponed to a time closer to death (6, 14, 15). Recent studies suggest that more people are living longer without severe disability, and that need for health and social services increases most during the last months / years before death, independent of actual age (16-19). Improved health in old age is partly due to increased standard of living, but new technologies that increase the number of diseases that can be treated up to old age, also contribute to this development (7, 11).

In many Western societies both primary health and social care services as well as specialist health care are under severe financial pressure (6). To meet the increased demand, improve efficiency, and control costs, in-hospital stays in OECD countries are increasingly being replaced by treatment in outpatient settings. Furthermore, the number of hospital beds is being reduced, hospital stays are becoming increasingly shorter, and more responsibility is transferred from the hospitals to the municipalities (6, 7, 20). This implies an increased need for support in transition and follow-up after discharge, increasing the necessity of adequate communication routines to ensure patient safety. However, several studies have identified deficits in communication and information transfer between hospitals and primary care providers (21-25). This adds a substantial risk of adverse events during transition from hospital to home and subsequent follow-up in primary care, leading to rehospitalisation, disability, premature long-term care, and even death.

Different perspectives on care, different culture, organisation and funding cause fragmentation and make collaboration challenging, both between care levels and within specialist and primary care (26). Fragmentation of medical care, can lead to burdensome and potentially inappropriate treatment for patients with several chronic conditions (27-29). Integrating health care and social services has therefore got increasing attention in the EU (26, 30). Integration of services is requested both vertically between hospitals and primary health and social care as well as horizontally across the different providers of health care and social services within the communities. Several strategies will be presented that have been developed in hospitals and in primary care in order to improve continuity of care.

2.2 Measures to improve continuity of care

2.2.1 Predominantly hospital based interventions

Interventions developed in hospitals to improve transitional and post-discharge care for elderly and chronically ill patients have primarily aimed to improve patient level outcomes and prevent (re)hospitalisation (23, 25, 31-37). This includes geriatric assessment programs, discharge planning schemes, post-discharge support arrangements, and self-management and educational programs. These are partly overlapping interventions, and discharge arrangements incorporating both pre- and post-discharge interventions seem to be most effective in reducing post-discharge adverse events (23, 31, 37, 38).

Comprehensive geriatric assessment programs (CGA), a cornerstone in geriatric care, have a multidisciplinary and multidimensional nature determining the medical, psychosocial, functional, and social resources and problems of an elderly person in order to develop a coordinated plan for treatment and follow-up (39, 40). Discharge planning is an important component of inpatient CGA, but the main focus is on improving functional health status and independent living through medical intervention and rehabilitation (37). The implementation of CGA has shown beneficial effect in hospital settings increasing the likelihood for survival and being discharged to their own homes after an emergency admission to hospital (40-42).

Discharge planning schemes include interventions where a discharge coordinator or a discharge liaison nurse assesses, plans, coordinates, and provides post-discharge follow-up in cooperation with a hospital physician, other team members, and the patient's formal or informal caregivers (37, 43). While the discharge coordinator usually is a specialised hospital nurse, the discharge liaison nurse comes from the municipality, but is based at the hospital (43, 44). The assessment is usually comprehensive, including the nature and severity of the health problem, physical and mental function, social support, and discharge goals. Trials suggest that such interventions may result in reduced length of hospital stays and lower readmission rates; and again, best effects are found when discharge planning is combined with post-discharge follow-up (23, 45-47).

Post-discharge support arrangements include a broad range of partly overlapping interventions with varying complexity. This includes among others post-discharge telephone programs (48) and home visitor programs performed by single hospital professionals, usually nurses (49, 50). Telephone and visitor programs may be linked to case management schemes (51). Case management can be defined as the coordination of services on behalf of an individual person, often including health care, rehabilitation, nursing and social care. It is a somewhat fluid term and different authors use it to describe different initiatives (52). The concept may have some overlap with care pathways, which will be described in further detail in chapter 2.2.3. Other post-discharge support arrangements include interdisciplinary consultation or rehabilitation teams (21, 53-55), sometimes in collaboration with primary health care services (56).

Self-management and educational programs range from rather simple interventions provided to improve self-medication (like patients with asthma and diabetes) to education as part of complex discharge support interventions including e.g. post-discharge telephone calls and home visits. The programs may be directed at the individual patient (57) or at groups of patients with the same condition (58, 59). In Norway patient education is a hospital duty (60), but generic self-management programs have also been developed in primary care addressing patient with different chronic diseases (61). Best effect seems to be when self- management and educational programs are part of multi-component discharge support to groups of patients with single diseases (37, 62).

2.2.2 Predominantly primary care based interventions

The overarching goal of primary health care strategies addressing elderly patients is to maintain health and autonomy and to prevent disability and subsequent admissions to long-term institutional care (63). To achieve this, several strategies aim to improve post-discharge follow-up (36, 64) as well as to coordinate health and social care providers in the municipalities (26). This includes transitional care units in primary care for patients being discharged from hospital, multidisciplinary teamwork, chronic care models, patient-centred medical home, and interventions aiming at improving functional ability and support self-care. These strategies are presented in further detail below.

Transitional and intermediate care units based in primary care have been developed to ensure sufficient post-discharge support to elderly, frail patients when hospital stays become shorter (4, 65-68).The purpose is to fulfil medical treatment, observe, mobilise or rehabilitate the patients before they return to their own homes (20, 68). Intermediate care units have documented a potential of reducing readmissions to hospital, increase survival and independence (4, 5). However, such arrangements further increase the fragmentation in primary care by representing a new link in the chain of care. In Norway, the Coordination Reform has also introduced 24/7 municipal emergency bed services in primary care as an alternative to hospital admissions (69, 70). The target group is mainly elderly patients with acute illnesses or exacerbation of chronic illnesses who have become too ill to be treated at home, but yet not in need of specialised health care services in hospitals (7). The effect is debated, but there is some evidence that acute treatment at intermediate level to suitable patients do not lead to negative health consequences (71) and slightly reduce the number of readmissions to general hospital provided close follow-up by primary care physicians (70).

Multidisciplinary teamwork is a strategy increasingly brought forward as a means to coordinate health care services for elderly and chronically ill patients in primary care (72, 73). It represents one of the main measures in a Norwegian White Paper from 2015 on future primary healthcare (74). The Norwegian White Paper suggests the GP practices supplemented by nurses to be the core of multidisciplinary teams. However, such teams may be composed of a range of health care professionals functioning under one professional organisational umbrella or by professionals from different organisations forming a unique team for follow-up of individual patients with complex conditions (73). An example of effective multidisciplinary teamwork is found in a Danish study where GPs and home care nurses provided joint comprehensive follow-up to elderly patients during the first weeks after hospital discharge, achieving improved patient level outcomes and reduced health care utilisation (75). In Italy, multidisciplinary teams have been organised in geriatric evaluation units (GEU) in primary care. These are coordinated by a geriatrician and otherwise including community based home care nurses, social workers and physiotherapists in close collaboration with the patient's general practitioner. The GEUs are addressing elderly persons receiving home health care services or home assistance programmes and have documented effect in reducing functional decline, reducing the risk of hospital admissions, and reducing the length of stay in hospitals or long-term institutional care in the municipalities (76, 77). Involvement of the GPs is found to be a necessity in well-functioning multidisciplinary teams (78). Still, GP involvement has been a recurring challenge, described in Nordic countries and Canada, as GPs consider teamwork to be too time consuming, their role has been unclear, and they have been reluctant to take the responsibility expected of them in the teams (72, 79).

In *the chronic care model (CCM)* the focus is on chronic care management, primarily in GP practices, by transforming care from acute and reactive to proactive and planned (80, 81). CCM was initially developed in the United States, but has spread to countries worldwide. The components of a chronic care model have varied across different sites, but the main strategies of CCM include increasing the providers' knowledge and skills, supporting self-management of patients and their families, making care delivery more planned and team-based , and making better use of decision support and clinical information systems (82). Studies suggest that implementation of CCM improves the outcomes for patients with various chronic illnesses. However, redesigning the practice in accordance with CCM is comprehensive and requires highly motivated practices. In most cases, CCM has been applied on patients with a single chronic condition, diabetes mellitus being the most common (81). There is limited evidence on whether practice changes become sustained and spread to the care of other illnesses or to less motivated practices (82).

The patient-centred medical home (PCMH) is a measure to redesign primary health care from highly fragmented and uncoordinated to continuous, comprehensive and coordinated medical care of high quality. The model is developed in the United States and the precursor, 'medical home', was first used in 1967 by the American Academy of Paediatrics to 'describe a concept of a single centralised source of care and medical record for children with special health care needs' (83). PCMH has a patient-centred orientation towards the whole person. Care is to be coordinated across all health care levels and health care providers, including also preventive and health promoting activities in the patient's community. As in the CCM model, care is to be team-based (83, 84). CCM and PCMH is partly overlapping concepts, but while the PCMH model describes what patients should expect and how the practice can meet those expectations, the CCM model describes how care should be structured and delivered (85).

Preventive home visits have received much attention the last decades and have been part of national policy in several countries, including Denmark, UK, and Australia, as a measure to prevent functional decline and premature admission to long-term institutional care (86, 87). Some programs focus on one risk factor like e.g. falls (88). Others include multidimensional geriatric assessment to assess and improve medical, functional and social problems and resources (63, 88, 89). Multidimensional assessments with clinical examinations are found to have a potential of preventing functional decline, first and foremost among the elderly population at low risk of functional impairment. For patients with high risk of impairment, intensive, long standing home-based intervention program focusing primarily on improving underlying impairments in physical abilities has been found to be necessary to reduce functional decline (90). Yet the scheme for preventive home visits is debated, as they tend to be resource-demanding interventions, and as it proves difficult to identify what distinguishes effective programs from ineffective programs on mortality and institutionalisation (88).

2.2.3 Care pathways

In 1985 Hornbrook et al argued that by taking the patient's perspective through a patient trajectory, organisational dysfunctions and barriers to cooperation across different health care providers and care levels might be identified and solved (91). He claimed that analyses of health care episodes − defined as a period of time during which an illness, health care problem, diagnostic process or treatment process is present − could form a useful basis of health service research as well as planning and managing health care services. Health care episodes can be seen as the conceptual precursor to care pathways. Care pathways, also known as e.g. integrated care pathways, clinical pathways, critical pathways, patient trajectories or case management plans, were introduced in the United States in the late 1980s and have later spread worldwide, mainly for use within hospitals as a method for improving coordination and quality of care as well as optimising use of resources (92). A care pathway can be defined as a structured multidisciplinary care plan used by health care professionals to detail essential steps in the care of patients (93-95). This is a complex intervention which include several health care providers and many potential active ingredients (96). Care pathways are usually developed for defined groups of patients with specific medical conditions and a predictable clinical course, and are based on clinical evidence (93, 97). A Cochrane review from 2010 concluded that care pathways are associated with reduced in-hospital complications, improved documentation, decreased length of stay, and reduction in hospital costs (95). This reflects a hospital management perspective, but do not address the full health care episode, from the patient gets ill at home until the patient has returned home and has resumed his daily activities.

The Norwegian Coordination reform, launched in 2009, recommends care pathways across care levels as a means to improve care coordination and quality of care (7). However, to elderly multimorbid patients, traditional disease-specific care pathways are considered neither suitable nor effective due to the unpredictable clinical course for these patients (93, 98). Suman et al describes an alternative ‘generic’ care pathway model in hospitals addressing acutely admitted elderly patients with different diagnoses (99), but we have not found generic models across care levels in the literature.

There was thus a need for research to increase our knowledge of cross-border care pathways as a means to improve coordination and quality of care across care levels and within primary care in order to improve outcomes for elderly patients.

2.3 The Norwegian health care context

The Norwegian Coordination reform (7) was addressing the fragmentation in care and the barriers to collaboration between hospitals, GPs and other primary care services related to ownership, management, funding, legislation, information systems, and professional aims.

Most hospitals, which are responsible for specialist care, are *owned and funded* by the Government and managed by four regional health authorities as public enterprises with a steering group and a chief executive officer (100). A few small, private owned hospitals operate on contract with the regional health authorities. The local municipal authorities (municipalities) are responsible for providing primary health and social care. This includes regular GPs who usually run private enterprises on contract with the municipality. In contrast to hospitals with line management from the Ministry of Health, a local democratically elected council is responsible for priorities and funding of all services in the municipalities. The municipalities have a large degree of freedom on how they want to prioritise and organise their services. This implies that planning and priorities of health care services at primary and secondary level are not always attuned. *Separate laws* to specialist care and primary care reinforces this tendency.

Separate electronic health record systems (EHRs) are also an obstacle to coordinated care. Shared health records between different organisational units (e.g. GP practices, hospitals, home care services) have been illegal in Norway due to strict rules for protection of privacy. At the time of the introduction of the Coordination Reform, electronic exchange of information was limited to referral and discharge letters between the GPs and the hospitals and some test results from hospitals to the GPs. This made communication between collaborating partners ineffective as they were working at different locations (in most cases) and had to communicate by post and by fax or phone in urgent cases. A new legislation about EHR and electronic communication (101) came into force in January 2015 implying that sharing EHR systems across organisations and exchange of patient information will be easier ahead.

Finally, *different professional aims and perspectives* represent barriers for integrated care. In hospitals, there is increasing specialisation of services and focus on efficient trajectories and high quality, evidence-based treatment of the diseases causing the admittance (9). The main aim in primary health and social care services is to support people to manage their life as independent as possible and maintain quality of life taking into account functional ability, social situation and care for all the diseases the patients might have; thus caring for the person rather than caring for the disease. Such different perspectives and aims represent an obstacle to information flow as one party might not know or take into account the information needed by collaborating partners (102, 103).

In this context, the framework of an integrated cross-boundary care pathway was outlined by healthcare managers in the City of Trondheim in cooperation with St. Olavs University Hospital and researchers from Department of Public Health and General Practice at NTNU. It was primarily a quality improvement project addressing elderly people in need of home care services after hospital discharge. The care pathway, which was named Patient Trajectory for Home-dwelling elders (PaTH), was to include discharge arrangements and post-discharge follow- up in order to improve coordination and quality of care and thus support elderly patients to stay in their homes as long as possible with high quality of life. It became part of the project “Samhandlingskjeden kronisk syke” (Integrated Care Services for the Chronically Ill Patient) (104). The management level in six municipalities and three hospitals in the Central Region of Norway agreed to take part in the project. Furthermore, it was decided to do a scientific study of the development and implementation process and to analyse effectiveness on the target population (home care recipients).

3 Objectives, aims and hypotheses

The objective of this thesis was to provide knowledge about the development of an integrated care pathway for elderly patients involving specialist and primary care services, and furthermore, knowledge about its implementation and effectiveness. This was investigated by conducting studies with the following aims:

Paper 1: To explore the process of developing the integrated care pathway that was going to be implemented in the project.

Paper 2: To investigate the process of implementing the integrated care pathway into everyday practice by comparing the joint experiences of health care professionals and managers in home care services between the municipalities where it had been introduced.

Paper 3: To establish the effectiveness of PaTH on patient level – compared to usual care – for elderly patients in need of home care services after discharge from a general hospital, regarding primarily the patients' functional level and readmissions, secondarily use of health care service, mortality and quality of life.

The following hypotheses were defined for Paper 3:
An integrated care pathway targeting elderly home care recipients will result in:
H1: Decline in the patients' functional level (ADL scores) will be reduced
H2: Health care utilisation will be reduced

- Number of readmissions to general hospital will be reduced
- Number of hospital admissions and days of inward hospital care will decrease
- Need for long-term institutional care in the municipalities will be postponed
- Number of admissions to and days in short-term and long-term community institutional care will decrease

H3: Number of GP consultations will increase
H4: Mortality will be reduced
H5: Patients will get more days at home

H6: Patients will get higher level of health related quality of life

4 Material and methods

Evaluation of complex interventions should include randomised controlled trials to be able to conclude on effect (105). However, evaluation is demanding, and process evaluation is considered an essential part of designing and testing complex interventions (106, 107). The UK Medical Research Council (108) recommends use of both quantitative and qualitative research methods; quantitative research methods alone are considered insufficient (108) as they only answer questions that can be measured and counted (109). Evaluation of a complex intervention like care pathways, also need to explore questions like: what are the active ingredients in the care pathway, how are they excreting their effects, how feasible is the intervention in daily work, was the intervention implemented and delivered as intended, and what were the reasons for the findings of the trial (110, 111). These questions can best be answered by qualitative research methods which aim to explore, interpret, or obtain an in-debt understanding of the phenomenon or the attitudes, expectations, motivation, or experiences of particular individuals or groups (112, 113). Qualitative and quantitative research strategies can thus be seen as complementary (114).

This thesis therefore comprises three integrated studies, presented in three papers: a cluster randomised controlled trial with nested qualitative studies of the development and implementation of the care pathway.

The study was approved by the Regional Committee for Medical and Health Research (REK 4.2009.670) and the Ombudsman for Research and Social Science Data Service (NSD 215289). The trial was registered in Clinical Trials.gov NCT01107119. All informants in the process evaluations and patients in the cRCT were informed about the study and its purpose, that their anonymity would be ensured and that they could withdraw from the study at any time. They all signed an informed consent before participation. We did not consider the intervention or study to represent potential harm to patients or informants.

4.1 Qualitative studies

Study 1. Development of a patient-centred care pathway across health care providers: a qualitative study

Study 2. Implementing a care pathway for elderly patients, a comparative process evaluation in primary care

4.1.1 Study design and material

A qualitative design was used in the development study and the implementation study in order to explore the experiences, expectations, motivations, and attitudes of the health care professionals involved in developing and implementing the integrated care pathway. Interviews were the main data source and minutes, notes, and observations were mainly used to supplement the interviews, assisting in analysing the meaning of the informants' experiences.

In the **development study** data were collected through

- observations of discussion and work in regional and local working groups
- minutes and notes from working groups
- individual and focus group interviews performed after the development process

In the **implementation study** data were collected through

- minutes from telephone conferences during the early implementation process
- individual and focus group interviews during early implementation process and two and three years after the care pathway was introduced in the municipalities
- review of the electronic patient records two years after the introduction of PaTH in order to assess how the checklists were integrated in the electronic health records

The interviews were semi-structured; the interview guides had open-ended questions allowing the participants large degree of freedom about what they would talk about and emphasise (Table 1).

Table 1. Topics included in the interview guides

Development study
Understanding of the care pathway concept
Responsibilities and cooperation in a care pathway
Expectations and attitudes during the development process
Challenges in the development process
Other important issues appearing during the development work
Appraisal of the final version of the care pathway
Implementation study
How the informants had been involved with the care pathway
Their initial expectations to the care pathway
How it had been introduced at their workplace
The efforts invested to take it into use
Challenges and promoting factors during implementation
Assessments of benefit
If and why it was dismissed or integrated and sustained in daily use

4.1.2 Informants

Twenty-three informants (four focus groups) were recruited to the development study (Paper 1), and 60 informants (12 focus groups) were recruited to the implementation study (Paper 2) (Table 2). In addition, there were some individual interviews of informants who were not able to participate in the focus group interviews or informants who belonged to the management level. In Paper 1, the focus groups had four to seven informants and the interviews were held (except for the GP group) at each of the three hospitals. The groups (except for the GP group) were mixed with informants from the hospitals and adjacent municipalities (Table 2 in Paper 1). In Paper 2, the focus groups had three to eight informants. The interviews in 2012-2013 were performed at the local workplaces of the home care professionals.

Table 2. Participants in the interviews 2010 and 2011-2013

			Focus groups	Individual interviews	Total number of participants
Paper 1					
	2010	Mixed primary and specialist care and patient associations	3	1	19
		GPs	1		4
Paper 2					
	2011	Management level primary care	2	0	13
	2012	Management level primary care	2	2	7
		Frontline nurses and nursing assistants primary care	6	0	26
	2013	Management level primary care	1	0	6
		Frontline nurses and nursing assistants primary care	1	0	0
		Total	**16**	**3**	**83**

The development study

The researcher recruited the informants to the development study using two selection criteria; the informants should have participated actively throughout the development project, and all hospitals and municipalities should be represented by at least two participants. The informants represented two patient associations, five of the six municipalities, the three hospitals, and the Central Norway Regional Health Authority. One small municipality was not represented in the interviews due to problems with capacity, and they temporarily pulled out of the project. The informants constituted about half of those that had been active in the regional and local workgroups. One nurse was not able to participate in the focus group and was interviewed individually to ensure at least two representatives from each hospital. Few GPs took part in the development process, and none of them were able to take part in the mixed focus group interviews. Collaboration between home care services and GPs was, however, an important topic both in the development process and in the interviews. Therefore, an additional focus group of four GPs was recruited to elaborate collaboration from their perspective as physicians. Of these four, only one had taken part in the actual development process.

The implementation study
The care pathway (PaTH) was to be implemented in the three hospitals and six municipalities (including 48 GP practices) that had taken part in the development work. Due to available time and resources, the study of the implementation process was limited to the home care services. The researcher recruited every home care manager and head nurse in the home care units where PaTH had been introduced. The head nurses / home care managers recruited in turn frontline nurses and nursing assistants ensuring both professional groups from all municipalities. To be selected, the informants should have been employed in the home care services from the first introduction of PaTH and have experience in using the checklists.

In **both the qualitative studies**, the interviews lasted for one to two hours, were audio recorded and transcribed verbatim. The researcher performed all the interviews and transcribed half of the interviews. The rest was transcribed by research assistants, but the researcher checked all transcripts against the audio-file.

4.1.3 Analytical method and theoretical framework

The interviews in both studies were analysed using systematic text condensation. In the implementation study, the Normalisation Process Theory was applied to systematise the comparison between the municipalities in order to facilitate understanding of the factors of importance as to why PaTH was integrated and sustained in the home care services in some municipalities and not in others.

Systematic text condensation
Systematic text condensation (STC) was developed by Malterud (115) and inspired by Giorgi's psychological phenomenological approach (116). Phenomenological analyses seek to catch the meaning and essences of an event through examination of individual experiences, which was the purpose of the qualitative studies. STC represent a pragmatic approach, applicable for use with different theoretical frameworks.

The data from the interviews in the qualitative studies were organised and analysed according to the four steps of STC (115). In the *first step,* the research group read the whole material to get an overall impression, and the main researcher identified preliminary themes. In the *second step,* the researcher reviewed the text systematically line for line and identified units of meaning, which is text fragments containing information about the research question. The meaning units were classified into code groups, mainly related to the preliminary themes. The whole research group reconsidered and refined the code groups. In the *third step,* the meaning units in the code groups were further classified into subgroups. Furthermore, a condensate was made, representing the content of all meaning units in one subgroup, and illustrative quotations were identified for each subgroup. In the *fourth step,* the researcher wrote an analytic text based on the condensates and quotations, presenting the most salient content and meaning of the phenomenon under study.

Normalisation process theory

In the implementation study (Paper 2), we searched for a theory explaining what is necessary for implementing and integrating the care pathway into daily working practices. We also wanted a theory that could make a framework for comparing the participating municipalities. Among several implementation theories, we found the Normalisation Process Theory (NPT) to be most applicable to our needs. NPT was developed and presented by Carl May, Tracy Finch and colleagues in 2009 as a framework for understanding processes by which complex interventions become, or do not become, part of normal practice (117). Initially NPT was developed from studies of health technology implementation (118), but has during the last years been tested, refined and applied in studies conducted across diverse settings in hospitals as well as in primary care (118, 119). The theory is useful for evaluating implementation of complex intervention as well as to design and judge the implementation potential of new interventions (120). The focus of NPT is not only on early implementation, but beyond this to a point where the intervention is integrated and sustained as a natural part of daily work (120). This makes the theory useful alongside randomised controlled trials to assess whether an intervention is feasible and sustainable beyond the project setting.

Four core constructs define essential conditions and processes for new working practices to become a natural part of daily work: coherence (making tasks meaningful and understandable), cognitive participation (building commitment and engagement), collective action (efforts and resources invested to make the intervention work), and reflexive monitoring (assessment of benefit). These four constructs of the NPT framework were used to map the subcodes in the last step of the STC process. The relationship between the constructs is not linear, they influence each other mutually, and implementation work is necessary within all four constructs for a complex intervention to be integrated and sustained in daily work (117).

4.2 Cluster randomised controlled trial

Study 3: Generic care pathway for elderly patients in need of home care services after discharge from hospital: A cluster randomised controlled trial

4.2.1 Study design

A cluster randomised controlled trial (cRCT) design was chosen to study the effectiveness of the integrated care pathway. The home care service units were the unit of randomisation and were randomised to either use the intervention or their usual procedures (control group). Outcomes were assessed at the level of the individual home care recipients.

Senior medical officers in an independent organisation (Ministry of Health) were drawing lots, identifying one home care cluster in every municipality to start as intervention clusters. Initially a step-wedge design (121) was planned in each municipality. The plan was that the control clusters should gradually implement the care pathway in a predetermined manner. To avoid contamination of the control patients, inclusion of patients was planned to be stopped two months before introduction of the care pathway. However, implementing PaTH was experienced to be far more demanding than expected, and except for one cluster in Trondheim, all the initial control units remained controls throughout the study period of the cRCT.

In order to test feasibility and acceptability of the intervention, a test period of three months, involving one home care unit, was preceding the main trial. Only some minor details were changed before it was introduced to all intervention clusters.

4.2.2 Clusters and study population

Twelve clusters were formed, each consisting of one to three home care units. The total number of home care recipients in the different clusters varied considerable, ranging from 80 to 750. Eligible patients were at least 70 years of age and in need of home care services after discharge from hospital. They were to be discharge directly to their homes or via a transitional stay in a short-term community institution anticipated to be less than four weeks. Exclusion criteria were participation in another intervention study or cognitive impairment to such an extent that the patient was not able to sign an informed consent.

From January to April 2010, after the test period, patients were included in the trial successively at all intervention sites after a one-day introduction course to all employees. The patients were recruited in either a discharge meeting at the hospital by municipal case managers (in Trondheim) or immediately after returning home by a home care nurse (all municipalities).

4.2.3 Outcomes and data collection

Functional ability was chosen as one of our two primary outcomes as disability has major implications in older patients regarding quality of life, need for support and need for long-term care, either at home or in long-term institutions in the municipalities. Functional ability is generally assessed through self-report or proxy report on difficulties or need for help related to basic self- care tasks, mobility or more complex tasks for living independently in the community (115). Most commonly used are measures of daily living (ADL) and instrumental activities of daily living (IADL) (115). ADL is related to basic self-care tasks and include bathing, dressing, transferring form a bed to a chair, using a toilet and eating (115, 116). Measuring ADL works well to identify the most severely disabled individuals. IADL refer to more complex tasks like shopping, preparing food, housekeeping, laundry, using transportation, taking medications, handling money and using telephone (115, 117). In the cRCT two measures of physical ability were used – IPLOS and Nottingham extended ADL scale (NEADL). IPLOS**,** a Norwegian individual-based, standardised, national registration system describing patient disability and limitations, was used to check for baseline similarities and to estimate sample size. It includes 17 topics on ADLs and mobility as well as IADLs (122). It is mandatory for use on individuals receiving public health and social services, but is not a validated tool within research. Instead, NEADL was used to measure changes in functional level (123). NEADL is a validated research tool that has proved to be useful when evaluating treatment for stroke (124), hip fractures (42) and rehabilitation (125) of elderly. It measures mobility and IADLs within the domains kitchen, domestic, and leisure. In study 3, NEADL was used to measure functional level at baseline and at six and 12 months. It was considered easy to understand and score, which was of important since NEADL was to be used by several people at different sites.

The other primary outcome was readmissions, which is a common outcome when testing the effectiveness of transitional care (32, 45). Readmission was defined in this thesis as acute unplanned admission of any cause within 30 days. Secondary outcomes were numbers and length of inpatient hospital and nursing home admissions, days before long term care in nursing homes, consultations (including home visits) with the GPs, deaths at six and 12 months, days at home, and quality of life (SF36). SF 36 (Short Form 36) is a multipurpose, generic short-form health survey measuring health related quality of life (126). The 36 questions yield an eight-scale profile of functional health and well-being scores as well as physical and mental health summary measures. The SF-36 has proven useful in surveys of general and specific populations and in differentiating the health benefits produced by a wide range of different treatments (126).

All data were collected from registers and health records except for NEADL and SF-36, which was completed by health personnel in the home care services or a research assistant (city) in dialog with the patients, or by the patients themselves. The researcher extracted demographics, diagnoses, patient outcomes and consumption of health care services from health records of the home care services, GPs and hospitals.

The adherence to PaTH was explored by reviewing the health records of the home care services and assessing how many of the four core checklists that was applied on the individual patient (Appendix 13.6 and Table 1 in Paper 3).

4.2.4 **Statistical analyses**

4.2.4.1 Sample size estimation

The study has two primary outcomes, readmissions and functional level. Sample size estimation was first based on readmissions, but due to unforeseen problems as explained below, readmissions were replaced by functional level as a base for sample size estimation.

Initially, the sample size estimation was based on data on readmissions from two former studies in Trondheim. In the first study on patient flow between primary and secondary care, Anthun et al (127) found a readmission rate for an unselected home care population to be 16 % within 28 days and 24 % within 60 days for patients known to the home care services. For patients *new* to the home care services, the readmission rates were 24 % within 30 days and 32 % within 60 days. These differences between new and established users of home care services could indicate insufficient information transfer from the hospital to the home care services and gave rise to an assumption that readmission rates could be improved, especially to those who were new to the home care service. In the second study on the effect of an intermediate care unit after hospital discharge for elderly patients, Garåsen et al (4) found that close follow-up in the post-discharge period could improve readmission rates; the readmission rate was 36 % within 60 days (same disease) in the control group and 20 % within the intervention group. To get a reduction in 60 days readmission rate from 35 % to 20 % (Garåsen study), sample size was estimated to a total of 120 patients (60 patients in each group, α

0.05, power 0.8) discharged from hospital to follow-up by home care services for the first time. In order to account for the cluster effect, the number of patients needed was increased by 50 % to 90 patients in each group.

During the first months of the study, it was obvious that the newcomer group was smaller than indicated before the study. We also found that due to early discharge from hospital, several patients needed a short-term stay at a municipal rehabilitation facility or nursing home before returning home. Furthermore, the national standard had defined readmission to apply to the first 30 days after discharge, for any diagnosis (128). The difference between intervention and control groups was less for 30 days readmission rate. All this made readmissions less fitted for sample size calculations.

Instead, it was decided to use functional level, a main predictor of independent living (129), as a base to estimate sample size. We did not have data on changes in functional level in this patient group measured by NEADL before the study, and as a proxy, mobility data in IPLOS was chosen a base for estimation of sample size. In a survey of 2300 home care recipients during 12 months in the city of Trondheim, we found a mean mobility level at baseline on 2.3, a standard deviation of 0.80 and a decline in mobility on 11.5 % during 12 months. When estimating the sample size, we wanted to identify a difference in mobility of at least 0.3 (e.g. 2.3 in control and 2.0 in the intervention group) assuming the intervention and control groups to be independent samples of equal size with equal standard deviation of 0.8. We set power to 0.90, α to 0.05. Sample size was estimated to 151 patients per group (302 in total) by applying a t-test in STATA. Due to a misunderstanding, the cluster model was not taken into account.

4.2.4.2 Statistical analyses

The effectiveness of the intervention was analysed applying linear mixed models (NEADL and SF 36), logistic mixed models (health care utilisation) and Cox regression with shared frailty (days to long-term care and days to death). Mixed models are especially suitable for analyses of correlated data, either due to grouping of subjects or to repeated measures on each subject over time (130). Furthermore, mixed models are robust to missing values as long as data meet the missing - at - random definition (131), and allow for analyses of non-normal distributed outcomes, which were characterising our data. Mixed models use fixed and random effects in the same analysis. Fixed effects represent the levels of primary interest while random effect parameters represent the general variability among the subjects or clusters (130). Site and patient ID were set as random factors when applying linear and logistic mixed models.

The main analysis was an intention-to-treat- analysis. A subgroup analysis was performed excluding patients who died before discharge, remained in nursing homes > 4 weeks after discharge, did not receive home care or did not receive intervention (Figure 2 in Paper III). Two other subgroup analyses were performed including patients where minimum two and three of the four registered checklists had been applied during the patient trajectory. A fourth subgroup was analysed on readmissions including only patients that were discharged directly home from the general hospitals without an intermediate stay in a nursing home.

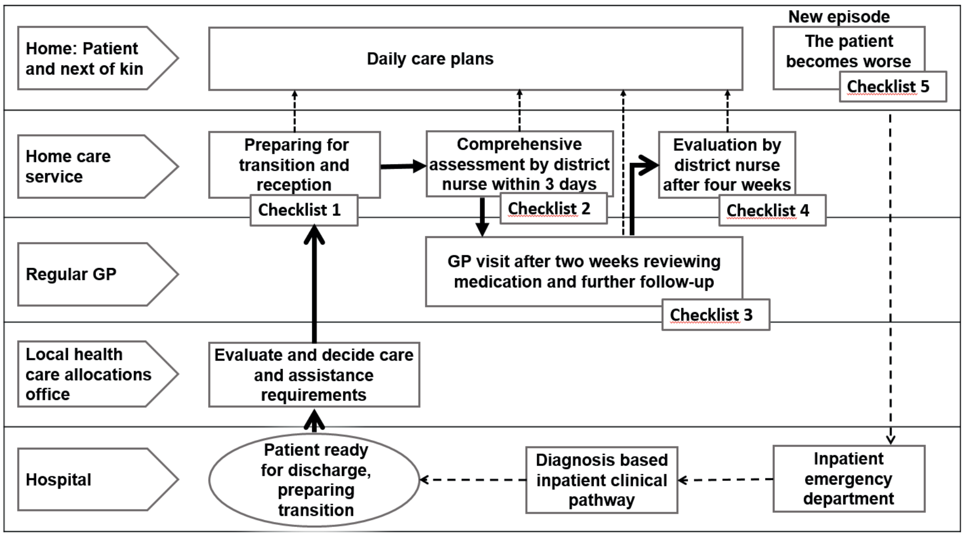
5 Description of the intervention (PaTH)

The care pathway (**Pa**tient **T**rajectory for **H**ome-dwelling elders, PaTH) that was used as the intervention in the cRCT was developed in a bottom-up process including home care professionals, GPs, representatives from patient associations, and hospital nurses and physicians from six participating municipalities and three hospitals. It was based on a predefined framework, but the participants in the development process defined the detailed content of the care pathway after identifying challenges in transitional care and follow-up in primary care. Supervisors from the Central Norway Regional Health Authority were teaching process facilitators, representatives from all municipalities and hospital departments, on how to develop care pathways. The process facilitators ran the development process locally in the municipalities and hospitals.

PaTH comprised transition from hospital to follow-up in primary care (Figure 1). It was generic, implying that it could be used for most patients within the home care services. The care pathway was designed as a chronological trajectory of procedures to be evoked in patients' meeting with different parts of health care in order to ensure adequate information transfer and follow-up by home care services and GPs. The care pathway implied that assessments, observations and collaborations with external partners were structured. Checklists were introduced at defined stages in the patient trajectory (Figure 1) to ensure a closer follow-up of the patients' medical condition and a more equal practice between the home care professionals.

The checklists in PaTH (content detailed in Appendix 13.5 / 13.6) included practical issues (e.g. whether assistive devices had been ordered and when they would be installed), health issues (e.g. review of medication), social conditions (e.g. if the present accommodation was appropriate for the patients' level of functioning) and physical and cognitive functioning (e.g. ability to climb stairs, reduced memory). The first checklist was common to both hospital and primary health care professionals to ensure that relevant information was collected and communicated. No other checklists where developed to be used within the hospitals, but PaTH implied that the hospital physicians and nurses were to provide clear recommendations in the discharge letters on issues needed to be followed up by primary care. Furthermore, all changes in medication were to be clearly marked in the medication lists. One checklist was made for GPs (checklist 3B), some checklists were used by home care nurses only (checklist 1 and 2), while others were used by nursing assistants as well (checklist 4 and 5). All of the issues on the lists were not necessarily relevant for all patients, and the nurses and nursing assistants had to use their professional insight to decide what to assess and how to follow-up. Critical information from all checklists was included in the daily care plan in the electronic health record, which was available to all home care professionals.

Figure 1. Patient-centred care pathway for home dwelling elders (PaTH)



6 Summary of results

6.1 Qualitative studies

Paper 1: Development of a patient-centred care pathway across health care providers: a qualitative study.
Aim paper 1: To explore the process of developing the integrated care pathway that was going to be implemented in the project.

The ambition was to understand the factors of importance for agreement on the content of a care pathway across health care levels by exploring the expectations, motivations, attitudes and experiences of the multidisciplinary group of health care personnel in municipalities and hospitals who participated in the development process.

The process of developing an integrated care pathway across health care levels was experienced as challenging due to different organisational structures and different professional perspectives between the health care providers. In specialist care, the main objective was efficient assessment and treatment of the disease causing the admission. In contrast, the home care professionals in primary care focused more on the person and the support needed for the person to be able to cope with daily living. Their main attention was put on functional ability, social situation, and the patient’s preferences, and they did not consider disease-specific care pathways to be feasible for use in the home care services. The home care professionals argued that diseases being common in the hospital wards had low volume in the home care services, and several disease-specific care pathways would cause confusion or be forgotten. Moreover, most of their patients had several medical conditions that all had to be attended to. Still, the home care professionals acknowledged the need for closer follow-up of the patients’ medical conditions, but argued that the recommendations for follow-up needed to be designed to the individual patient’s needs and preferences and not according to standardised disease specific care pathways.

Finally, a generic care pathway was developed comprising transition between hospital and home and follow-up in primary care. It was merging the disease perspective of the hospital professionals and the broader care perspective of the home care professionals by structuring information flow and follow-up; taking into consideration functional ability, social situation, and patient preferences as well as follow-up of the disease(s). The home care professionals became the main contributors in the care pathway. Disease-specific care pathways were kept for use within the hospitals.

Paper 2: Implementing a care pathway for elderly patients, a comparative qualitative process evaluation in primary care

Aim paper 2: The aim was to investigate the process of implementing PaTH into everyday practice by comparing the joint experiences of health care professionals and managers in home care services between the municipalities where it had been introduced.

The ambition was to explore the factors of importance for implementing the integrated care pathway into everyday practice in the home care services by comparing the expectations, motivations, attitudes, and experiences of the home care professionals in the participating municipalities.

Home care professionals in all of the municipalities expected that PaTH would meet their needs of improving cooperation with the hospitals and GPs as well as improving quality of follow-up and were enthusiastic to start using it. However, the implementation work was demanding, and two to three years after the onset of the project PaTH was integrated in daily work in two of the six municipalities. In two municipalities some elements of PaTH were used, but occasionally and not by all staff. In the last two municipalities, PaTH was discontinued.

The Normalisation Process Theory was used to compare the implementation process in the municipalities and identifying barriers and facilitators for integrating PaTH in daily working activities. We found that the municipalities that integrated PaTH in daily work were characterised by active involvement of the executive municipal management and strong managerial focus on creating engagement and commitment among all professional groups in home care services. Continuous practice and guidance was found to be necessary to make the regular home care staff understand how to use the care pathway as it implied a change in perspective from mainly supporting the elderly persons in their daily life to structured observations and assessments of the their medical, functional and social conditions. This was especially the case to the nursing assistants who constitute the majority of the employees. Furthermore, practical facilitation of working processes was essential to succeed as well as a stable organisation without major competing priorities. Finally, PaTH was only sustained in the municipalities were the home care professionals experienced it as useful. In the two municipalities where PaTH was integrated in daily work, the care pathway was found to be useful to management level as well as frontline professionals as a tool to improve collaboration, structure provision of services, and improve knowledge and skills.

6.2 Cluster randomised controlled trial

Paper 3: Generic care pathway for elderly patients in need of home care services after hospital discharge: a cluster randomised controlled trial

Aim paper 3: The aim was to establish the effect of PaTH on patient level – compared to usual care – for elderly patients in need of home care services after discharge from a general hospital, regarding primarily the patients' functional level and readmissions, secondarily use of health care service, mortality and quality of life.

Twelve clusters were randomised to six intervention and six control clusters, each cluster consisting of one to three home care units. One hundred sixty-three patients were allocated to the intervention group and 141 patients were allocated to the control group (Figure 2 in Paper 3). All six intervention clusters used PaTH during the study period, but to a varying degree. In total 129 patients (79 %) received complete or parts of the intervention, but only 36 % of the patients were assessed by at least three of the four core checklists (Table 4 in Paper 3).

Odds ratio and hazard ratio was generally in favour of the PaTH group (Table 3) and the intervention group had significantly more consultations with the GPs. However, we found no statistically significant differences between the PaTH group and control group with regard to the primary outcomes (functional level and number of readmissions) or the other secondary outcomes. Only analyses to the intention- to treat groups are presented, as the sub group analyses did not provide additional information.

Table 3. Hypotheses and results

Hypothesis		Test	Conclusion
H 1	Decline in the patients' functional level will be reduced	Table 3 in Paper 3	Hypothesis not supported
H 2	Health care utilisation will be reduced	.	Hypothesis not supported
H 2.1	Number of readmissions to general hospital will be reduced	OR[1] 0,9, 95 % CI: 0.4-1.7, p 0.7	Hypothesis not supported
H 2.2	Number of hospital admissions will be reduced	OR 1.0, 95 % CI: 0.2-1.3, p 0.8	Hypothesis not supported
H 2.3	Number of days of inward care at general hospitals will decrease	OR 0.8, 95 % CI: 0.5-1.4, p 0.4	Hypothesis not supported
H 2.4	Number of admissions to community institutional care will be reduced	OR 0.9, 95 % CI: 0.7-1.3, p 0.6	Hypothesis not supported
H 2.5	Number of days in community institutional care will be reduced	OR 0.7, 95 % CI: 0.2-2.2, p 0.6	Hypothesis not supported
H 2.6	Need for long-term institutional care will be postponed	HR[2] 1.5. 95 % CI: 0.8 – 3.0, p 0.2	Hypothesis not supported
H 3	Number of consultations with the GPs will be increased	OR 1.4, 95 % CI 1.0-1.8, p 0.04	Hypothesis supported
H4	Days to death will be increased	HR 0.9,95 % CI 0.6-1.6, p 0.8	Hypothesis not supported
H 5	Patients will get more days at home	OR 1.8, 95 % CI: 0.9-3.4, p 0.08	Hypothesis not supported
H 5	Patients will get higher level of quality of life	Table 3 in Paper 3	Hypothesis not supported

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[1] Odds ratio (OR) is estimated for PaTH group vs control group.

[2] Hazard ratio (HR) is estimated control group versus intervention group

7 Discussion of design and methods

This thesis comprises a cluster randomised controlled trial with nested qualitative studies of the development and implementation of the care pathway, and discussion of methods is divided in a qualitative and quantitative part.

7.1 Paper 1 and 2 – qualitative process evaluations

Qualitative research methods were applied in the two first papers as they focused on experiences, expectations, motivation, and attitudes of the participants in order to get an understanding of the process and results of the development and implementation of PaTH. Qualitative research methods are especially relevant to such research questions (113, 115). In order to ensure scientific quality when applying qualitative research methods, Malterud propose to look at validity, reflexivity, and relevance (114). In the following, the qualitative studies will be discussed in relation to these concepts.

Validity

Internal validity

According to Malterud (114) internal validity in qualitative research 'asks whether the study investigates what it is meant to'. To strengthen the internal validity, several different data sources (source triangulation) were applied in both the qualitative studies; observations, interviews, minutes / notes from meetings and conference calls, and review of the electronic health records to assess how PaTH was integrated in the electronic health records. In addition, researcher triangulation was ensured by having several researchers with different professional backgrounds (physicians, sociologists, nurse) taking part in the analyses. The main data source was the focus group interviews, which are useful in studies of experiences, views and attitudes in a working environment where many people interact, but may also inhibit divergent viewpoints (113). In the development study (Paper 1), one nurse was interviewed individually, primarily because she was not able to take part in one of the focus group interviews. She had, however, very divergent views and attitudes from the rest of the informants, which made an individual interview beneficial for her to be free to present her experiences.

Most focus groups had four to eight participants which is considered to be ideal for the group dynamics (113). In the implementation study (Paper 2), frontline staff and the managerial level were interviewed in different groups to ensure the informants to have common experience (113) and to make them speak more freely.

In qualitative research, the richness of the information needs to be large enough for data saturation (132) which means that no new themes, concepts or problems are presented in subsequent interviews. Several factors may influence the number of informants needed. Malterud et al recently introduced the concept 'information power' to guide the decision of the number of informants needed (133). Fewer informants are needed when the study aim is narrow, when the informants hold the experiences, knowledge and properties needed in the study, when the study is supported by a relevant theory, and when the quality of the dialog in the interviews is strong. In our studies, the aims were rather broad, but the experience, knowledge and properties of the informants were in general highly specific to the needs of the study. The informants were collected through so-called 'purposeful sampling' (134). This implies that informants are selected to ensure that they have relevant experience. About half of all who had participated in the development process were interviewed in the development study. In the implementation study, all home care managers and head nurses and a sample of frontline staff in all municipalities were interviewed. The head nurses or home care managers selected the frontline staff, which implied an inherent risk of selection bias by recruiting those being most positive or failing to recruit persons with relevant experience. In some municipalities, the informants were recruited in advance while in other municipalities informants were recruited from those being at work at the day of the focus group interviews. This resulted in some frontline informants lacking relevant experience in two of the municipalities. This limitation was counteracted by the large number of informants in total. Furthermore, frontline staff informants with relevant experience represented both municipalities were PaTH was sustained as well as municipalities were PaTH was discontinued. There were no indications that the most positive employees were being selected as the participants advocated both frustrations as well as enthusiasm.

In the implementation study there was a period of two to three years from the introduction of PaTH in the municipalities to the last interviews (Table 2 in Paper 2). This may have caused a recall bias of the early phases of the implementation process and use of PaTH. Especially to the frontline staff who was only interviewed once, their recollection is likely to have been coloured by the present implementation status. The contact with the management level had been closer throughout, starting with the conference calls in the early implementation stage, thus counteracting recall bias in the last interviews. The long observation period was otherwise a strength to assess whether PaTH had actually been integrated in daily work in a sustainable manner.

The results were presented to a process facilitator in each of the three mixed focus groups in the development study (Paper 1) and to all home care managers in the implementation study (Paper 2). Some minor misinterpretations on engagements of physicians in the development study, and value for leaders in the implementation study were revealed and corrected.

External validity

Validity also concerns external validity, that according to Malterud 'asks in what context the finding can be applied' (114). In qualitative research, the term 'transferability' is often used instead of external validity (135), referring to the degree to which the results of qualitative research can be generalised or transferred to other contexts or settings. The results in the qualitative studies would not necessarily be the same if the development and implementation took place in another context. Many factors influence such complex processes, like e.g. the experiences, motivations, commitments, and ability of the people involved in development and implementation. The findings should thus be interpreted cautiously before transferring them to other settings, especially across countries where there are major differences in organisation of health care. Still findings in the qualitative studies point to general challenges of cooperation across health care levels and factors important for implementation of complex interventions (136, 137) that have been thoroughly discussed in the literature. This includes different perspectives on care (138), insufficient transfer of information (138, 139), and issues important for the implementation like acceptance and understanding of the intervention (140-142), engagement and commitment (137), sufficient resources, skills and training (140, 143), and positive impact on daily work and interaction between professionals (137, 143, 144). The findings in the studies are therefore found to have external validity, meaning that they can be transferable to other settings.

Reflexivity

Reflexivity concerns how the researcher's background and perspectives may influence the processes under study and the collection and analyses of the data (114). The researcher participated in two of the three regional meetings and most local meetings in two of the three local sites during the development study. This implied mainly a non-participating observation, although the researcher explained the premises in the research protocol when it came to questions about specific details. The researcher's presence as a primary care physician and a generalist can have influenced the discussions in the development process where the working groups and focus groups were mixed, containing health care professionals from the hospitals as well as from primary care. The researcher's background may have been experienced as moral support and strengthened the self-consciousness of the primary care participants. However, there was congruence between the two local working groups were the researcher had been present and the third group regarding the experiences of the development process and the perspectives of the care pathway, indicating that the researcher's presence had been of subordinate importance.

In the interviews, the researcher explicably told all informants that all their experiences and reflexions were of interest, negative as well as positive. Still there is chance that the informants would portray that the process was more successful than it was, especially the management level whom the researcher had been in touch with during a period of two to three years. In fact, the interviews of the frontline staff and review of the electronic health records did indicate that the management level had overrated the degree to which PaTH had been implemented in daily work. This underscored the importance of varied data sources.

The researcher performed all interviews and transcribed or checked all transcripts against the audio-file. Even if the researcher had solid knowledge of transitional care and the work-setting of the home care professionals, the background as a physician might colour the understanding and coding of the interviews. To counteract bias, researchers with different professional backgrounds (physicians, sociologists, nurse) read the interviews in both qualitative studies independently. There was a common understanding of the main themes in the data material and the interpretation of the results.

Relevance

Relevance is whether the resulting knowledge from the research is important in a wider setting (113). The studies of development and implementation of PaTH was highly relevant for several reasons: Coordination of health care services and use of care pathways as a coordinating tool are on the agenda both nationally and internationally (7, 95), and knowledge of the challenges in developing care pathways across care levels is important when developing future similar projects (107). For complex interventions like PaTH, exploration of the implementation process is important to understand the complexity and the core components of the intervention. Furthermore, the challenges in the implementation process need to be understood if the intervention is to be deployed and tailored into another context.

7.2 Paper 3 – evaluation of the effectiveness of PaTH

A randomised controlled design was used to study the effect of PaTH on patient level outcomes as randomisation ensures a control for unmeasured and unknown confounders (110). This allows for an investigation of the causal relationship between the intervention and outcome (2, 105, 145). Challenges to RCT design on complex interventions include problems of standardisation of the intervention and implementation difficulties. Furthermore, the cluster model represents challenges when designing the study and analysing the data. These issues will be further discussed below.

The challenges of standardisation of the intervention

PaTH was a multicomponent complex intervention involving different health care levels and many health care providers. Moreover, it was consisting of several components with checklists at defined stages in the patient trajectory. The intervention was not identical across the sites as the topics on the checklists could differ slightly due to local needs. Furthermore, the health care providers had to use their professional knowledge and judgement on how to assess the issues on the checklists. The intervention delivered could therefore differ somewhat from site to site and from person to person implying that neither the intervention itself nor the delivery of the intervention could be strictly standardised. According to Hawe et al. (145), complex intervention cannot be strictly standardised as the intervention cannot be considered independent of the context in which the intervention is provided; it must be considered as a product of the components of the intervention and the context. Since controlled trial design traditionally requires that an intervention is replicable and can be recognised at different sites, the standardisation challenges have caused a debate on whether controlled trials are a suitable evaluation method for complex interventions (105, 145, 146). Hawe et al argue that there is a possibility for standardisation also for complex interventions. However, instead of standardising the components of the intervention, the 'change process' that the elements are meant to facilitate should be defined as a standard (145). Regarding PaTH, the topics on the checklists can be understood as the components while the change process that the checklists should facilitate is the structured assessments and information transfer to ensure that relevant issues are taken care of in order to support, maintain or improve health and functional ability for the home care recipients. Checklists leading to structured assessments and information transfer can thus be identified as the core element or active ingredients, while the specific content within the checklists can vary due to local context and needs.

The cluster design

As PaTH was a complex and comprehensive intervention implying a new way of performing home care services in each home care unit (Paper 2), a cluster design was chosen due to the inherent risk of contamination of the control group with an individualised RCT design. This is a strength of the study and in line with recommendation for complex interventions implying changes in organisation or service provision (2). Cluster randomised trials are, however, vulnerable to changes on the organisational level which may affect the service provision in the cluster causing incomplete exposure to the intervention. In worst case, entire clusters and not just individuals may be lost to follow-up. In the cRCT (Paper 3), all intervention clusters used PaTH, but the use of the intervention varied across the sites. By combining the findings in Paper 2 and 3, we found that low adherence to the intervention was connected with loss of key professionals in some of these clusters.

A cluster model sets other requirements when estimating sample size and analysing the data than studies on individuals. Observations from the same cluster are usually more similar than observations from different clusters as the individuals may share similar characteristics or be exposed to the same external factors (3, 147). The individuals can thus not be considered independent of each other. Dependence leads to loss of statistical power and need for increased sample size compared to RCTs on individuals (148). Intraclass Correlation Coefficient (ICC) is a general measurement of the correlation among observations within a cluster (3). If the variance within the clusters is less than the total variance, this should be taken into account when estimating sample size and analysing the data (3). Nevertheless, sample size was not increased taking the cluster effect into account in our study (see section 4.2.4.1). This is a methodological limitation as it represented a risk for the study to be underpowered (148). The additional design effect (DE) of a cluster randomised trial can be estimated by the formula $DE = 1 + (n-1)\rho$,where n = mean number of individuals per cluster and ρ = ICC (147). ICC is usually between 0.01 - 0.02 in clinical studies (149). By applying ICC to be 0.015 and $n = 25,3$ (mean number of individuals per cluster in our study), we would get $DE = 1.36$. By multiplying the design effect with sample size estimated by an individual randomised design (302 patients), sample size for the cluster design would have increased to 412 patients.

We accounted for the cluster model when analysing the data by applying linear (repeated measures within individuals) and logistic mixed models (3). The statistical analyses revealed no cluster (site) effect for the primary outcomes, functional level (measured by NEADL) and readmissions. Also for most other outcomes, the cluster effects observed in the material were ignorable. This implies that lack of counting for the cluster model when estimating sample size did not lead to an underpowered study.

Potential biases

There is a possibility for selection bias in the trial regarding the enrolled patients. We do not have information of the patients being eligible who were not asked or who declined to participate, but there was gradually a declining recruitment rate in the PaTH clusters as well as the control cluster, indicating that there was an increasing number of patients who were not asked to participate in the study. One likely reason for this could be that patients were included by ordinary staff in busy running organisation, and as the recruitment procedure added to their workload, recruitment was likely to slow down over time. There were few exclusion criteria in this study and the researcher got informal feedback from some of those including patients that they were uncomfortable including patient with short life expectancy. This included both intervention and control units, and we got no indications that this led to systematic differences between the groups.

There was no blinding of outcomes assessment, which causes a risk for detection bias; i.e. systematic differences in how outcomes are determined (150). However, except for functional level (NEADL) and quality of life (SF 26), outcomes were collected from health registers and ordinary electronic health care records, minimising the risk for systematic differences between the groups.

Incomplete use of the intervention

The real life setting of this study may give indications on the feasibility of the PaTH, but may also pose a limitation on the possibility of detecting effect (108). Several people were involved in inclusion of patients and a large number of participants were to be trained in performing the assessments and procedures in PaTH in full time running organisations. Inclusion of patients started shortly after the introduction of PaTH and before it was properly settled in the organisations. Paper 2 revealed challenges ranging from teething problems to more permanent implementation problems in the home care districts. Paper 3 included a quantitative process evaluation measuring to what extent the intervention was provided. This disclosed that for 21 % of the patients in the PaTH group, no checklists were used while another 16 % were only assessed by one of the four core checklists. This insufficient use of PaTH represented a major limitation of the possibility to detect effects of PaTH.

8 General discussion

The thesis consists of a cluster randomised controlled trial with nested qualitative studies in line with recommendations from the UK Medical Research Council when evaluating complex interventions (108). The first qualitative study elucidated the factors of importance for developing an integrated care pathway across health care providers and health care levels for elderly patients in need of home care services after hospital discharge (Paper 1). This study of the development process created an understanding of rationale and content of the intervention, showing that the active components were checklists to guide information transfer between collaborating partners as well as guiding observations and assessments of the home care recipients' medical, functional and social needs after discharge. The second qualitative study explored hindrances and factors of importance for succeeding in implementing the integrated care pathway into every day practice in six different municipalities, thus elucidating the feasibility of the care pathway in different contexts (Paper 2). This study also investigated how the home care professionals valued PaTH, and found that the front line staff as well as the management level found PaTH to be beneficial to improve quality of services, provided the care pathway was properly implemented. Together, these qualitative studies shed light on 'what' works and 'how'. The randomised, controlled study (Paper 3) explored the effectiveness of PaTH, and did also include a quantitative process evaluation component investigating to which degree the different components of PaTH was actually used, thus revealing that the intervention was not delivered to such an extent as intended (106). Paper 3 could not document differences between the PaTH group and the control group except for more GP consultations in the PaTH group (hypothesis H3, Table 3) and indications that the PaTH group got more days at home (hypothesis H4, Table 3). However, there were clear indications that patients were included in the study before the intervention was provided with sufficient quantity (Paper 3) and quality (Paper 2).

Can a generic care pathway be effective?

Complex interventions can have effects across a range of domains, and it has been argued that there is a risk that the predefined outcomes do not provide adequate assessment of the success (2). The first step when designing an intervention is thus to collect evidence that the intervention might have the desired effect on the outcomes chosen (105). One recommended strategy is to draw on existing theories when developing complex interventions. Other strategies can be to base the intervention on 'experience' or 'common sense' (106). The development of PaTH was primarily based on former studies (‘experience’) of care pathways (151), transitional care (23, 37) and post-discharge primary care interventions (4, 5, 152). Introduction of care pathways is a well-accepted way to improve efficiency and quality of care in hospitals by implementing evidence based guidelines in daily work to patients with specific diagnoses (153) and have documented effect on various outcomes like quality of life, patient satisfaction, readmissions, and health care costs (98). To ensure that the intervention was feasible in the context where it was going to be used, the main content and details of the care pathway was developed in a bottom-up process by health care professionals caring for elderly patients in the hospitals and in the municipalities. During this process, a disease-specific care pathway model, which are most commonly used in hospitals (93), was abandoned in favour of a generic model as this was considered by the home care professionals in primary care to be most feasible for follow-up care for elderly, multimorbid home care recipients. Evidence based guidelines for patients with multimorbidity hardly exists (154) and therefore the participants in in the first study developed their own generic ‘guidelines’ operationalised by preparing checklists defining what kind of issues to assess at the different stages in the patient trajectory. PaTH contained no recommendation on follow up of specific diseases; the hospitals physicians and the GPs had to tailor the recommendations according to the individual patient, taking into account multimorbidity, functional decline and the patient’s preferences. Greenhalgh et al claim that such a patients-centred approach is the future for follow-up of multimorbid patients (154). She warns about the trend of focusing on evidence based follow-up of single diseases and letting the guidelines determine the process of examinations and treatment without taking the patient’s total situation and goals into consideration. Still, evaluation of such generic, patient-centred, and integrated care pathways have been difficult to find in literature.

Some disease-specific cross-boundary care pathways have been described. A Belgian mixed method study from 2013 on cross-boundary care pathways for breast and prostate cancer (155) found enhanced care coordination and positive effect on exchanging information and clarifying common goals, roles, expectations, and competencies. Paper 1 and 2 indicate similar experiences of our generic model. The Belgian study did not provide data on the effectiveness of the care pathway and implementation challenges were hardly mentioned. A Norwegian study from 2015 explored the development of cross boundary care pathways for COPD and hip fractures addressing elderly patients (156). The main part of the care pathway was to be used in primary care, and representatives from primary care and hospitals developed the care pathways together. The study revealed that the hospital participants, who had experience in developing care pathways in hospitals, had the main influence on the design and content. This is the likely reason that when it came to implementation, the primary care leaders did not find the care pathways relevant in the municipality setting and implementation failed. In our development study (Paper 1), the home care professionals claimed that different disease-specific care pathways would be impossible to integrate in daily work; diseases being common in hospitals would not occur frequently to the individual home care professional who would thereby get little training in how to use the care pathways. This is supported by a submitted article by Grimsmo et al (157) which found that individual home care nurses has on average 0.5 patients hospitalised with COPD, 0.3 with heart failure, 0,2 with stroke and 0,4 patients with hip fracture each year. Furthermore, they found that > 90 % of these patients had two or more chronic diseases. The study concludes that it is questionable whether disease-specific guidelines are feasibility and sustainable for multimorbid patients needing care coordination in primary care (157).

The two Scandinavian studies on post-discharge interventions forming a base for our study (4, 152) documented that a generic approach can have positive effect on readmissions, independence and death. However, in these studies, the primary care physicians played an active role performing close follow-up of the medical situation during the first few weeks after discharge. Paper 1 and 2 showed that the physicians had a subordinate role in both developing and using PaTH. The PaTH procedure implied that the home care services performed the main follow-up and initiated the GP consultations. Even if PaTH implied a stronger focus on follow-up of medical situation by the home care professionals, their main perspective had traditionally been on social care, supporting the elderly person to manage their daily lives (Paper 1), indicating that this perspective might still be dominant. The home care recipients were characterised by multimorbidity and functional decline (Table 2 in Paper 3), and the risk of adverse medical events in the vulnerable post-discharge period is considerable (158). In light of former studies, a question thus remains on whether the GP role in a generic model like PaTH is too passive, and whether the follow- up of the medical situation too weak to improve patient level outcomes.

Implementation challenges

Paper 2 revealed that there were several barriers to implementation even if the development process had created a general enthusiasm to PaTH and the home care professionals had had a major influence on the design and content of the intervention according to their needs (Paper 1). During the three months test period before PaTH was introduced to all intervention cluster (Paper 3), one highly motivated home care unit tested PaTH and approved the intervention. Only some minor changes in the checklists were recommended to make them more understandable, and the intervention was considered as both feasible and acceptable to the home care professionals. The test period did not reveal that substantial efforts were needed to make the frontline staff use the checklists in PaTH, which was later disclosed in Paper 2. Thus, the complexity of the implementation process was underestimated. This demonstrates the need of performing process evaluations, not only in the early test or pilot periods, but also when the intervention is introduced to all participating sites to evaluate potential teething problems, feasibility and acceptability across different contexts as well as to explain the findings of the RCT in the end (106).

We found the Normalisation Process Theory (NPT) (159, 160), useful to compare and understand the implementation process in the different municipalities. However, it has been recommended to analyse the implementation potential and requirements before the main trial, in order to ensure that adherence to the intervention will be sufficient to conclude on effect (105). Murray et al (120) argue that NPT can be useful also for this purpose and recommend that topics related to the four main constructs in NPT (Table 4) is explored before proceeding to the implementation. Had this been done before introducing PaTH to all participating sites, questions on understanding to all staff, compatibility with existing work, and training of staff would have needed some closer consideration (Paper 2).

Paper 2 gave indirectly information regarding implementation status at the hospitals and GPs through the experiences of the home care services; neither the hospitals nor the GP practices were prepared when PaTH was implemented in the home care services. The lack of implementation within the hospitals and among the GPs can be understood in light of the Normalisation Process Theory. From Paper 1 it was clear that neither the hospitals nor the GPs experienced the same needs for implementing the integrated care pathway as the home care professionals. This made the task less meaningful and led to low engagement and commitment. Such lack of coherence is often pointed to as important challenges to implementation processes (141, 142).

Table 4. Use of NPT when exploring implementation potential (120)

NPT components	Examples of questions to consider within the NPT framework
Coherence (Makes sense)	Does the intervention have a clear purpose? Who will benefit from the intervention? Are the providers / users likely to value these benefits? Will the providers easily understand the intervention?
Cognitive participation (Engagement and commitment)	Will the intervention fit the overall goals and activity of the organisation? Are the providers and user groups likely to think it is a good idea? Are the providers prepared to invest time and work in this?
Collective action (Facilitation for use)	How will the intervention affect health care providers and users? Is it compatible with existing work practices? Will the providers need extensive training before they can use it?
Reflexive monitoring (Appraisal of value)	Are the providers / users likely to appreciate the interventions when it has been used for a while? Can the intervention be improved on basis of experience and feedback?

Effectiveness

When analysing the result in the cRCT (Paper 3) in light of the implementation study (Paper 2) it is not possible to conclude that PaTH does not improve patient level outcomes. In Paper 3 (and Paper 2), we found that the intervention was not delivered as intended, and that the use of checklists was less than planned. Our studies further revealed that that adherence to the intervention (Paper 3) and the quality of performance (Paper 2) improved over time, indicating a learning curve. This implied that a run-in time would have been necessary to ensure that the intervention was delivered efficiently (105). Insufficient run-in time is generally a challenge when implementing complex interventions due to the limited timeframe for most intervention studies (161). If inclusion of patients to the main trial is carried out too soon after introduction of the intervention, like in our case, the full effect might not be observed within the study period as such interventions need time before the intervention is provided in the desired quantity and quality (162).

Yet another explanation of the sparse effect on patient level outcomes can be the fact that there had been improvements in provision and coordination of care between hospital care and primary care in the participating city (where most patients were included) during the last 10 years. Even if the development process had identified deficiencies in care coordination and follow-up, the contrast between PaTH and care as usual may have been too small to detect an effect on patient level outcomes. However, we do not expect this to be the case as the home care professionals at the sites where PaTH was integrated in daily work, experienced that they were much more alert and prepared to follow-up and intervene if the patient's health condition deteriorated.

9 Conclusion

- Primary care professionals within the home care services did not find disease-specific care pathways across care levels to be feasible for follow-up of elderly multimorbid patients. Instead, a generic care pathway was developed including checklists and procedures for discharge and follow-up by primary care.
- Implementation of PaTH was challenging and required high priority and engaged leadership in order to facilitate for daily use, create engagement and commitment, and ensure sufficient guidance and practice.
- Health care professionals in the municipalities where PaTH was integrated in daily work experienced that this integrated, generic care pathway improved the provision of home care services and collaboration with the GPs.
- The home care managers in these municipalities found PaTH to be useful as a management tool to effect change and improve knowledge and skills.
- No statistical significant differences were found on patient level between the intervention and control groups except for increased number of consultations with the GPs. However, it is not possible to draw a final conclusion on whether or not PaTH had effects on patient level as patients were included in the RCT before the intervention was provided with sufficient quantity and quality.
- For complex interventions, there is a need of process evaluations alongside the RCT to check the quantity and quality of the intervention provided to ensure that the intervention is delivered efficiently before including patients in the study.

10 Implications for practice

Highly motivated practices, strong prioritisation and engaged leadership was found to be necessary to integrate PaTH in daily working practices (Paper 2). Except for one municipality, no extra resources were provided within the home care services. The extensive efforts that were found to be necessary to succeed with the implementation indicates that PaTH in its present form can be too comprehensive for it to be deployed generally in other municipalities, at least without additional resources. Still, PaTH has got considerable attention throughout Norway as a means to improve quality of transition from hospital to home as well as follow-up in primary care (163, 164), and several municipalities consider implementing PaTH. From our experiences, a thorough analysis of the prerequisites for successful implementation is strongly recommended before introducing PaTH into new settings.

Furthermore, PaTH needs to be tailored to the local context to fit the local needs. The core elements in PaTH are checklists at defined stages in the patient trajectory ensuring information continuity (165) across care levels and between health care professionals. However, the topics on the checklists need to vary according to local requirements. Vanhaecht et al state that introducing a care pathway without a local process involving health care professionals to adapt the care pathway to the local context, can be 'unsafe and ineffective'(153). Håland et al claim even more categorical that care pathways should be 'treated as prefabricated tools' and that the local process of developing, customising and introducing the care pathways is crucial for making them work (166). The Normalisation Process Theory is recommended in this work to identify the potential and requirements for implementation.

In the two municipalities that integrated the care pathway in daily work, PaTH is still in use six years after being introduced. Continuous efforts have been necessary to support and adjust it to contextual changes, work considered to be necessary for complex interventions to be sustained in daily practice (167).

11 Suggestions for further research

- A cost effectiveness analysis based on health service utilisation is recommended to analyse whether the resources needed are acceptable compared to what is achieved.
- A study on patient satisfaction in the two municipalities where PaTH is still in use or in municipalities planning to use PaTH. Relevant research methods could be use of questionnaires, interviews or a combination of the two.
- Based on our findings and assessed against the former mentioned Scandinavian studies (4, 75), we would also suggest a more extensive study by testing arrangements with joint assessments by GPs and home care nurses to elderly patients with multimorbidity and disability in the early discharge phase.

12 References

1. Garåsen H. The Trondheim Model [dissertation]. Trondheim: NTNU; 2008.
2. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.
3. Grace-Martin K. The Intraclass Correlation Coefficient in Mixed Models. The Analyzes Factor [Internet]. [cited 2016 Jan 6]. Available from: http://www.theanalysisfactor.com/the-intraclass-correlation-coefficient-in-mixed-models/.
4. Garåsen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomized controlled trial. BMC Public Health. 2007;7:68.
5. Garåsen H, Windspoll R, Johnsen R. Long-term patients' outcomes after intermediate care at a community hospital for elderly patients: 12-month follow-up of a randomized controlled trial. Scand J Public Health. 2008;36(197).
6. OECD: Health at a Glance 2013. OECD Publishing; 2013. [cited 2015 Jun 15]. Available from: http://dx.doi.org/10.1787/health_glance-2013-en.
7. The coordination reform. Proper treatment - at the right place and right time. Oslo: Norwegian Ministry of Health and Care Services; 2008-2009 (47).
8. Population projections, 2014-2100. Statistisk sentralbyrå. [cited 2015 Oct 1].Available from: https://www.ssb.no/statistikkbanken/. Norwegian.
9. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. Lancet. 2012;380(9836):37-43.
10. OECD. Long Term Care for Older People. Paris: 2005.
11. Hakkinen U, Martikainen P, Noro A, Nihtila E, Peltola M. Aging, health expenditure, proximity to death, and income in Finland. Health economics, policy, and law. 2008;3(Pt 2):165-95.
12. Marengoni A, Angleman S, Melis R, Mangialasche F, Karp A, Garmen A, et al. Aging with multimorbidity: a systematic review of the literature. Ageing Res Rev. 2011;10(4):430-9.
13. Fried LP, Ferrucci L, Darer J, Williamson JD, Anderson G. Untangling the concepts of disability, frailty, and comorbidity: implications for improved targeting and care. J Gerontol A Biol Sci Med Sci. 2004;59(3):255-63.
14. Jagger C, Matthews R, Spiers N, Brayne C, Comas-Herrera A, Robinson.T., et al. Compression or expansion of disability?: forecasting future diability levels under changing patterns of disease. Kings's fund; 2006.
15. Caley M, Sidhu K. Estimating the future healthcare costs of an aging population in the UK: expansion of morbidity and the need for preventative care. J Public Health (Oxf). 2011;33(1):117-22.
16. Christensen K, Doblhammer G, Rau R, Vaupel JW. Ageing populations: the challenges ahead. Lancet. 2009;374(9696):1196-208.
17. Sanderson WC, Scherbov S. Demography. Remeasuring aging. Science. 2010;329(5997):1287-8.
18. Spijker J, MacInnes J. Population ageing: the timebomb that isn't? BMJ. 2013;347:f6598.

19. Otnes B. Tjenestebehov og hjelpetilbud. Oslo: Statistisk sentralbyrå; 2011.Norwegian.
20. Ayyar A, Varman S, De Bhaldraithe S, Singh I. The journey of care for the frail older person. Br J Hosp Med (Lond). 2010;71(2):92-6.
21. Mesteig M, Helbostad JL, Sletvold O, Rosstad T, Saltvedt I. Unwanted incidents during transition of geriatric patients from hospital to home: a prospective observational study. BMC Health Serv Res. 2010;10:1.
22. Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. The incidence and severity of adverse events affecting patients after discharge from hospital. Ann Int Med. 2003(138):161-7.
23. Mistiaen P, Francke AL, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: a systematic meta-review. BMC Health Serv Res. 2007;7:47.
24. Preyde M, Brassard K. Evidence-based risk factors for adverse health outcomes in older patients after discharge home and assessment tools: a systematic review. J Evid Based Soc Work. 2011;8(5):445-68.
25. Hesselink G, Schoonhoven L, Barach P, Spijker A, Gademan P, Kalkman C, et al. Improving patient handovers from hospital to primary care: a systematic review. Ann Intern Med. 2012;157(6):417-28.
26. Leichsenring K. Developing integrated health and social care services for older persons in Europe. Int J Integr Care. 2004;4:e10.
27. Tinetti ME, Bogardus ST Jr., Agostini JV. Potential pitfalls of disease-specific guidelines for patients with multiple conditions. N Engl J Med. 2004;351(27):2870-4.
28. Caughey GE, Roughead EE, Shakib S, McDermott RA, Vitry AI, Gilbert AL. Comorbidity of chronic disease and potential treatment conflicts in older people dispensed antidepressants. Age Ageing. 2010;39(4):488-94.
29. Boyd CM, Darer J, Boult C, Fried LP, Boult L, Wu AW. Clinical practice guidelines and quality of care for older patients with multiple comorbid diseases: implications for pay for performance. JAMA. 2005;294(6):716-24.
30. Grone O, Garcia-Barbero M. Integrated care: a position paper of the WHO European Office for Integrated Health Care Services. Int J Integr Care. 2001;1:e21.
31. Rennke S, Nguyen OK, Shoeb MH, Magan Y, Wachter RM, Ranji SR. Hospital-initiated transitional care interventions as a patient safety strategy: a systematic review. Ann Intern Med. 2013;158(5 Pt 2):433-40.
32. Leppin AL, Gionfriddo MR, Kessler M, Brito JP, Mair FS, Gallacher K, et al. Preventing 30-day hospital readmissions: a systematic review and meta-analysis of randomized trials. JAMA Intern Med. 2014;174(7):1095-107.
33. Allen J, Hutchinson AM, Brown R, Livingston PM. Quality care outcomes following transitional care interventions for older people from hospital to home: a systematic review. BMC Health Serv Res. 2014;14(1):346.
34. Kripalani S, Theobald CN, Anctil B, Vasilevskis EE. Reducing hospital readmission rates: current strategies and future directions. Annu Rev Med. 2014;65:471-85.
35. Philp I, Mills KA, Thanvi B, Ghosh K, Long JF. Reducing hospital bed use by frail older people: results from a systematic review of the literature. Int J Integr Care. 2013;13:e048.

36. Mitchell GK, Burridge L, Zhang J, Donald M, Scott IA, Dart J, et al. Systematic review of integrated models of health care delivered at the primary - secondary interface: how effective is it and what determines effectiveness? Aust J Prim Health. 2015;21:391-408.
37. Parker SG, Peet SM, McPherson A, Cannaby AM, Abrams K, Baker R, et al. A systematic review of discharge arrangements for older people. Health Technol Assess. 2002;6(4):1-183.
38. Linertova R, Garcia-Perez L, Vazquez-Diaz JR, Lorenzo-Riera A, Sarria-Santamera A. Interventions to reduce hospital readmissions in the elderly: in-hospital or home care. A systematic review. J Eval Clin Pract. 2011;17(6):1167-75.
39. Conroy S, Ferguson C, Woodard J, Banerjee J. Interface geriatrics: evidence-based care for frail older people with medical crises. Br J Hosp Med (Lond). 2010;71(2):98-101.
40. Ellis G, Whitehead MA, Robinson D, O'Neill D, Langhorne P. Comprehensive geriatric assessment for older adults admitted to hospital: meta-analysis of randomised controlled trials. BMJ. 2011;343:d6553.
41. Saltvedt I, Saltnes T, Mo ES, Fayers P, Kaasa S, Sletvold O. Acute geriatric intervention increases the number of patients able to live at home. A prospective randomized study. Aging Clin Exp Res. 2004;16(4):300-6.
42. Prestmo A, Hagen G, Sletvold O, Helbostad JL, Thingstad P, Taraldsen K, et al. Comprehensive geriatric care for patients with hip fractures: a prospective, randomised, controlled trial. Lancet. 2015;385(9978):1623-33.
43. Dukkers van Emden DM, Ros WJ, Berns MP. Transition of care: an evaluation of the role of the discharge liaison nurse in The Netherlands. J Adv Nurs. 1999;30(5):1186-94.
44. Jowett S, Armitage S. Hospital and commuity liason links in nursing: the role of the liason nurse. J Adv Nurs. 1988;13(5):579-87.
45. Shepperd S, Lannin NA, Clemson LM, McCluskey A, Cameron ID, Barras SL. Discharge planning from hospital to home. Cochrane Database Syst Rev. 2013;1:Cd000313.
46. Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. JAMA. 1999;281(7):613-20.
47. Scott IA. Preventing the rebound: improving care transition in hospital discharge processes. Aust Health Rev. 2010;34(4):445-51.
48. Kotb A, Hsieh S, Wells GA. The effect of telephone support interventions on coronary artery disease (CAD) patient outcomes during cardiac rehabilitation: a systematic review and meta-analysis. PLoS One. 2014;9(5):e96581.
49. Naylor MD, Brooten DA, Campbell RL, Maislin G, McCauley KM, Schwartz JS. Transitional care of older adults hospitalized with heart failure: a randomized, controlled trial. J Am Geriatr Soc. 2004;52(5):675-84.
50. Watkins L, Hall C, Kring D. Hospital to Home: A Transition Program for Frail Older Adults. Prof Case Manag. 2012;17(3):117-23.
51. Takeda A, Taylor SJ, Taylor RS, Khan F, Krum H, Underwood M. Clinical service organisation for heart failure. Cochrane Database Syst Rev. 2012;9:Cd002752.

52. Zwarenstein M, Stephenson B, Johnston L. Case management: effects on professional practice and health care outcomes (Protocol). Cochrane Database of Systematic Reviews. 2011;2000(4).

53. Hansen FR, Poulsen H, Sorensen KH. A model of regular geriatric follow-up by home visits to selected patients discharged from a geriatric ward: a randomized controlled trial. Aging (Milano). 1995;7(3):202-6.

54. Stewart S, Pearson S, Luke CG, Horowitz JD. Effects of home-based intervention on unplanned readmissions and out-of-hospital deaths. J Am Geriatr Soc. 1998;46(2):174-80.

55. Avlund K, Jepsen E, Vass M, Lundemark H. Effects of comprehensive follow-up home visits after hospitalization on functional ability and readmissions among old patients. A ranomized controlled study. Scand J Occup Ther. 2002;9:17-22.

56. Fjaertoft H, Indredavik B, Lydersen S. Stroke unit care combined with early supported discharge: long-term follow-up of a randomized controlled trial. Stroke. 2003;34(11):2687-91.

57. Sogaard AJ, Forde OH. [Health education directed toward the individual. Can consultation be used?]. Tidsskr Nor Laegeforen. 1986;106(31):2657-60. Norwegian.

58. Gallefoss F, Bakke PS. Cost-benefit and cost-effectiveness analysis of self-management in patients with COPD--a 1-year follow-up randomized, controlled trial. Respir Med. 2002;96(6):424-31.

59. Zwerink M, Brusse-Keizer M, van der Valk PD, Zielhuis GA, Monninkhof EM, van der Palen J, et al. Self management for patients with chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2014;3:Cd002990.

60. Lov om spesialisthelsetjenesten m.m. Lovdata; 2001. [cited 2016 Apr 2].Available from: https://lovdata.no/dokument/NL/lov/1999-07-02-61?q=Spesialisthelsetjenesteloven . Norwegian.

61. Solberg HS, Steinsbekk A, Solbjor M, Granbo R, Garasen H. Characteristics of a self-management support programme applicable in primary health care: a qualitative study of users' and health professionals' perceptions. BMC Health Serv Res. 2014;14:562.

62. Lagger G, Pataky Z, Golay A. Efficacy of therapeutic patient education in chronic diseases and obesity. Patient Educ Couns. 2010;79(3):283-6.

63. Huss A, Stuck AE, Rubenstein LZ, Egger M, Clough-Gorr KM. Multidimensional preventive home visit programs for community-dwelling older adults: a systematic review and meta-analysis of randomized controlled trials. J Gerontol A Biol Sci Med Sci. 2008;63(3):298-307.

64. Smith SM, Soubhi H, Fortin M, Hudon C, O'Dowd T. Managing patients with multimorbidity: systematic review of interventions in primary care and community settings. BMJ. 2012;345:e5205.

65. Meads G. Rediscovering community hospitals. Br J Gen Pract. 2001;51(463):91-2.

66. O'Reilly J, Lowson K, Green J, Young JB, Forster A. Post-acute care for older people in community hospitals--a cost-effectiveness analysis within a multi-centre randomised controlled trial. Age Ageing. 2008;37(5):513-20.

67. Baillie L, Gallini A, Corser R, Elworthy G, Scotcher A, Barrand A. Care transitions for frail, older people from acute hospital wards within an integrated healthcare system in England: a qualitative case study. Int J Integr Care. 2014;14:e009.

68. Dahl U, Steinsbekk A, Johnsen R. Effectiveness of an intermediate care hospital on readmissions, mortality, activities of daily living and use of health care services among hospitalized adults aged 60 years and older-a controlled observational study. BMC Health Serv Res. 2015;15(1):351.
69. Lov om kommunale helse- og omsorgstjenester m.m. Lovdata; 2011. [cited 2016 Apr 2]. Available from: https://lovdata.no/dokument/NL/lov/2011-06-24-30?q=helse-og omsorgstjenesteloven. Norwegian.
70. Swanson JOJ, Alexandersen N, Hagen TP. Førte opprettelsen av kommunale akutte døgnplasser til færre innleggelser ved somatiske sykehus? Oslo: Institutt for helse og samfunn, UIO; 2016. Norwegian.
71. Lappegard O, Hjortdahl P. Acute admissions to a community hospital - health consequences: a randomized controlled trial in Hallingdal, Norway. BMC Fam Pract. 2014;15:198.
72. Hansson A, Friberg F, Segesten K, Gedda B, Mattsson B. Two sides of the coin - general practitioners' experience of working in multidisciplinary teams. J Interprof Care. 2008;22(1):5-16.
73. Hickman LD, Phillips JL, Newton PJ, Halcomb EJ, Al Abed N, Davidson PM. Multidisciplinary team interventions to optimise health outcomes for older people in acute care settings: A systematic review. Arch Gerontol Geriatr. 2015.
74. Fremidens primærhelsetjeneste - nærhet og helhet. Oslo: Norwegian Ministry of Health and Care Services; Meld St 26, 2014-2015. Norwegian.
75. Rytter L, Jakobsen HN, Ronholt F, Hammer AV, Andreasen AH, Nissen A, et al. Comprehensive discharge follow-up in patients' homes by GPs and district nurses of elderly patients. A randomized controlled trial. Scand J Prim Health Care. 2010;28(3):146-53.
76. Bernabei R, Landi F, Zuccala G. Health care for older persons in Italy. Aging Clin Exp Res. 2002;14(4):247-51.
77. Bernabei R, Landi F, Gambassi G, Sgadari A, Zuccala G, Mor V, et al. Randomised trial of impact of model of integrated care and case management for older people living in the community. BMJ. 1998;316(7141):1348-51.
78. Vedel I, De Stampa M, Bergman H, Ankri J, Cassou B, Mauriat C, et al. A novel model of integrated care for the elderly: COPA, Coordination of Professional Care for the Elderly. Aging Clin Exp Res. 2009;21(6):414-23.
79. Kokko S. Integrated primary health care: Finnish solutions and experiences. Int J Integr Care. 2009;9:e86.
80. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. JAMA. 2002;288(14):1775-9.
81. Davy C, Bleasel J, Liu H, Tchan M, Ponniah S, Brown A. Effectiveness of chronic care models: opportunities for improving healthcare practice and health outcomes: a systematic review. BMC Health Serv Res. 2015;15:194.
82. Coleman K, Austin BT, Brach C, Wagner EH. Evidence on the Chronic Care Model in the new millennium. Health Aff (Millwood). 2009;28(1):75-85.
83. Jackson GL, Powers BJ, Chatterjee R, Bettger JP, Kemper AR, Hasselblad V, et al. Improving patient care. The patient centered medical home. A Systematic Review. Ann Intern Med. 2013;158(3):169-78.
84. Akinci F, Patel PM. Quality improvement in healthcare delivery utilizing the patient-centered medical home model. Hosp Top. 2014;92(4):96-104.

85. Wagner EH, Coleman K, Reid RJ, Phillips K, Sugarman.J.T. Guiding transformation: How medical prctices can become patiwent-centered medical homes. The Commonwealth Fund; 2012.
86. Stuck A, Kane RL. Whom do preventive home visits help? J Am Geriatr Soc. 2008;56(3):561-3.
87. Stuck A, Egger M, Hammer A, Minder C, Beck J. Home visits to prevent nursing home Admissions and Functional Decline in Elderly Peiople. JAMA. 2002;287:1022-8.
88. Mayo-Wilson E, Grant S, Burton J, Parsons A, Underhill K, Montgomery P. Preventive home visits for mortality, morbidity, and institutionalization in older adults: a systematic review and meta-analysis. PLoS One. 2014;9(3):e89257.
89. Stuck AE, Minder CE, Peter-Wuest I, Gillmann G, Egli C, Kesselring A, et al. A randomized trial of in-home visits for disability prevention in community-dwelling older people at low and high risk for nursing home admission. Arch Intern Med. 2000;160(7):977-86.
90. Gill TM, Baker DI, Gottschalk M, Peduzzi PN, Allore H, Byers A. A program to prevent functional decline in physically frail, elderly persons who live at home. N Engl J Med. 2002;347(14):1068-74.
91. Hornbrook MC, Hurtado AV, Johnson RE. Health care episodes: definition, measurement and use. Med Care Rev. 1985;42(2):163-218.
92. De Bleser L, Depreitere R, De Waele K, Vanhaecht K, Vlayen J, Sermeus W. Defining pathways. J Nurs Manag. 2006;14(7):553-63.
93. Campbell H, Hotchkiss R, Bradshaw N, Porteous M. Integrated care pathways. BMJ. 1998;316(7125):133-7.
94. Vanhaecht K, Sermeus W, Peers J, Lodewijckx C, Deneckere S, Leigheb F, et al. The impact of care pathways for exacerbation of Chronic Obstructive Pulmonary Disease: rationale and design of a cluster randomized controlled trial. Trials. 2010;11:111.
95. Rotter T, Kinsman L, James E, Machotta A, Gothe H, Willis J, et al. Clinical pathways: effects on professional practice, patient outcomes, length of stay and hospital costs. Cochrane Database Syst Rev. 2010;3:CD006632.
96. Vanhaecht K, Ovretveit J, Elliott MJ, Sermeus W, Ellershaw J, Panella M. Have we drawn the wrong conclusions about the value of care pathways? Is a Cochrane review appropriate? Eval Health Prof. 2012;35(1):28-42.
97. European Pathway Association. Clinical / Care Pathways. [cited 2016 Jan 7]. Available from: http://e-p-a.org/care-pathways/.
98. Allen D, Gillen E, Rixson L. Systematic review of the effectiveness of integrated care pathways: what works, for whom, in which circumstances? Int J Evid Based Healthc. 2009;7(2):61-74.
99. Suman S, Lockington TJ. Generic care pathway for acute geriatric care and rehabilitation as a tool for care management, discharge planning and continuous clinical audit. J Integr Pathways. 2003;7(2):75-9.
100. Ringard Å, Sagan A, Saunes I, Lindahl A. Norway: Health systems in Transition. Copenhagen: European Observatory on Health Systems and Policies; 2013.
101. Lov om behandling av helseopplysninger ved ytelse av helsehjelp. Lovdata; 2014. [updated 2015 oct 1; cited 2016 mar 20]. Available from: https://lovdata.no/dokument/NL/lov/2014-06-20-42?q=elektronisk. Norwegian.

102. Paulsen B, Romoren TI, Grimsmo A. A collaborative chain out of phase. Int J Integr Care. 2013;13:e008.
103. Paulsen B, Grimsmo A. God vilje - dårlig verktøy. Om samhandling mellom sykehus og kommunale omsorgstjenester ved utskrivninger av omsorgstrengende eldre. Trondheim: Sintef; 2008.Norwegian.
104. Hernandez C, Alonso A, Garcia-Aymerich J, Grimsmo A, Vontetsianos T, Garcia Cuyas F, et al. Integrated care services: lessons learned from the deployment of the NEXES project. Int J Integr Care. 2015;15:e006.
105. Campbell M, Fitzpatric R, Haines A, AL K, Sanderock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. BMJ. 2000;321.
106. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015;350:h1258.
107. Moore G, Audrey S, Barker M, Bond L, Bonell C, Cooper C, et al. Process evaluation in complex public health intervention studies: the need for guidance. J Epidemiol Community Health. 2014;68(2):101-2.
108. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: new guidance. Medical Research Council, 2008.
109. Malterud K. The art and science of clinical knowledge: evidence beyond measures and numbers. Lancet. 2001;358(9279):397-400.
110. Lewin S, Glenton C, Oxman AD. Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study. BMJ. 2009;339:b3496.
111. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised controlled trials of complex interventions. BMJ. 2006;332(7538):413-6.
112. Greenhalgh T, Taylor R. How to read a paper: Papers that go beyond numbers (qualitative research). BMJ. 1997;315(740).
113. Malterud K. Kvalitative metoder i medisinsk forskning. Oslo: Universtitetsforlaget; 2008. Norwegian.
114. Malterud K. Qualitative research: standards, challenges, and guidelines. The Lancet. 2001;358(9280):483-8.
115. Malterud K. Systematic text condensation: a strategy for qualitative analysis. Scand J Public Health. 2012;40(8):795-805.
116. Giorgi A, editor. Sketch of a psycological phenomenological method. In Phenomenology and psycological research. Pittsburg, PA: Duquesne University Press; 1985.
117. May C, Finch T. Implementing, Embedding, and Integration Practices: An Outline of Normalization Process Theory. Sociology. 2009;43(3):535-54.
118. Finch TL, Rapley T, Girling M, Mair FS, Murray E, Treweek S, et al. Improving the normalization of complex interventions: measure development based on normalization process theory (NoMAD): study protocol. Implement Sci. 2013;8(1):43.
119. McEvoy R, Ballini L, Maltoni S, O'Donnell CA, Mair FS, Macfarlane A. A qualitative systematic review of studies using the normalization process theory to research implementation processes. Implement Sci: 2014;9:2.

120. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. BMC Med. 2010;8:63.
121. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. Contemp Clin Trials. 2007;28(2):182-91.
122. About IPLOS – a register for statistics on municipal health and care services. Oslo: Norwegian Directorate of Health; 2013 [cited 2014 Sep 15].Available from: http://helsedirektoratet.no/kvalitet-planlegging/iplos-registeret/about-iplos/Sider/default.aspx. Norwegian.
123. Nottingham extended ADL scale. The University of Nottingham; [cited 2016 may 2]. Available from: http://www.nottingham.ac.uk/search.aspx?q=Nottingham+extended+ADL+scale.
124. Wu CY, Chuang LL, Lin KC, Lee SD, Hong WH. Responsiveness, minimal detectable change, and minimal clinically important difference of the Nottingham Extended Activities of Daily Living Scale in patients with improved performance after stroke rehabilitation. Arch Phys Med Rehabil. 2011;92(8):1281-7.
125. Parker SG, Oliver P, Pennington M, Bond J, Jagger C, Enderby P, et al. Rehabilitation of older patients: day hospital compared with rehabilitation at home. Clinical outcomes. Age Ageing. 2011;40(5):557-62.
126. Ware JE. SF-36 health survey update. Spine. 2000;25(24):3130-9.
127. Anthun K, Paulsen B. [Collaboration between hospitals and community health care on discharge of eldery patients. Patient flow analysis]. SINTEF, 2007; A1798. Norwegian.
128. Reinnleggelse blant eldre 30 dager etter utskriving. Direktoratet for ehelse; 2014. [cited 2015 Dec 7] Available from: https://helsenorge.no/Kvalitetsindikatorer/kvalitetsindikator-sykehusopphold/reinnleggelse-blant-eldre-30-dager-etter-utskrivning.Norwegian.
129. Beswick AD, Rees K, Dieppe P, Ayis S, Gooberman-Hill R, Horwood J, et al. Complex interventions to improve physical function and maintain independent living in elderly people: a systematic review and meta-analysis. Lancet. 2008;371(9614):725-35.
130. Seltman HJ. Mixed models. In: Experimental design and analyses . Carnegie Mellon University; 2009. [cited 2015 nov 12]. Available from http://www.stat.cmu.edu/~hseltman/309/Book/
131. Twisk J, de Boer M, de Vente W, Heymans M. Multiple imputation of missing values was not necessary before performing a longitudinal mixed-model analysis. J Clin Epidemiol. 2013;66(9):1022-8.
132. Francis JJ, Johnston M, Robertson C, Glidewell L, Entwistle V, Eccles MP, et al. What is an adequate sample size? Operationalising data saturation for theory-based interview studies. Psychol Health. 2010;25(10):1229-45.
133. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. Qual Health Res. 2015.
134. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. Adm Policy Ment Health. 2015;42(5):533-44.
135. Trochim WMK. Qualitative validity. [cited 2015 Dec 15]. Available from: http://www.socialresearchmethods.net/kb/qualval.php

136. Prior M, Guerin M, Grimmer-Somers K. The effectiveness of clinical guideline implementation strategies--a synthesis of systematic review findings. J Eval Clin Pract. 2008;14(5):888-97.
137. Mair FS, May C, O'Donnell C, Finch T, Sullivan F, Murray E. Factors that promote or inhibit the implementation of e-health systems: an explanatory systematic review. Bull World Health Organ. 2012;90(5):357-64.
138. Hellesø R, Fagermoen MS. Cultural diversity between hospital and community nurses: implications for continuity of care. Int J Integr Care. 2010;10:e036.
139. Coleman EA, Berenson RA. Lost in transition: challenges and opportunities for improving the quality of transitional care. Ann Intern Med. 2004;141(7):533-6.
140. Bamford C, Poole M, Brittain K, Chew-Graham C, Fox C, Iliffe S, et al. Understanding the challenges to implementing case management for people with dementia in primary care in England: a qualitative study using Normalization Process Theory. BMC Health Serv Res. 2014;14(1):549.
141. Bamford C, Heaven B, May C, Moynihan P. Implementing nutrition guidelines for older people in residential care homes: a qualitative study using Normalization Process Theory. Implement Sci. 2012;7:106.
142. Lloyd A, Joseph-Williams N, Edwards A, Rix A, Elwyn G. Patchy 'coherence': using normalization process theory to evaluate a multi-faceted shared decision making implementation program (MAGIC). Implement Sci.2013;8(1):102.
143. Murray E, Burns J, May C, Finch T, O'Donnell C, Wallace P, et al. Why is it difficult to implement e-health initiatives? A qualitative study. Implement Sci.. 2011;6:6.
144. Finch TL, Mair FS, O'Donnell C, Murray E, May CR. From theory to 'measurement' in complex interventions: methodological lessons from the development of an e-health normalisation instrument. BMC Med Res Methodol. 2012;12:69.
145. Hawe P, Shiell A, Riley T. Complex interventions: how "out of control" can a randomised controlled trial be? BMJ. 2004;328(7455):1561-3.
146. WHO. Health promotion evalution: recommendations to policy-makers. Copenhagen: World health organization, Regional office for Europe, 1998.
147. Rutterford C, Copas A, Eldridge S. Methods for sample size determination in cluster randomized trials. Int J Epidemiol. 2015;44(3):1051-67.
148. Campbell MK, Mollison J, Steen N, Grimshaw JM, Eccles M. Analysis of cluster randomized trials in primary care: a practical approach. Fam Pract. 2000;17(2):192-6.
149. Sedgwick P. Cluster randomised controlled trials: sample size calculations. BMJ. 2013;346(f2839).
150. Higgins J, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.0 ed: The Cochrane Collaboration; 2011.
151. Rotter T, Kugler J, Koch R, Gothe H, Twork S, van Oostrum JM, et al. A systematic review and meta-analysis of the effects of clinical pathways on length of stay, hospital costs and patient outcomes. BMC Health Serv Res. 2008;8:265.
152. Hansen FR, Spedtsberg K, Schroll M. [Follow-up home visits to elderly patients after hospitalization. A randomized controlled study]. Ugeskr Laeger. 1994;156(22):3305-7, 10-1. Danish.

153. Vanhaecht K, Panella M, van Zelm R, Sermeus W. An overview on the history and concepts of care pathways as complex interventions. Int J Care pathways. 2010;14:117-23.
154. Greenhalgh T, Howick J, Maskrey N. Evidence based medicine: a movement in crisis? BMJ. 2014;348:g3725.
155. Van Houdt S, Heyrman J, Vanhaecht K, Sermeus W, De Lepeleire J. Care pathways across the primary-hospital care continuum: using the multi-level framework in explaining care coordination. BMC Health Serv Res. 2013;13:296.
156. Meese J, Rønhovde L. [Organizing a project]. NOS. 2015;17(3):86-108. Norwegian
157. Grimsmo A, Løhre A, Røsstad T, Gjerde I, Heiberg I, Steinsbekk A. Disease-specific clinical pathways - are they feasible and sustainable in primary care? A mixed methods study. BMC Health Serv Res (Resubmitted. 2016)
158. Krumholz HM. Post-hospital syndrome--an acquired, transient condition of generalized risk. N Engl J Med. 2013;368(2):100-2.
159. Rosstad T, Garasen H, Steinsbekk A, Haland E, Kristoffersen L, Grimsmo A. Implementing a care pathway for elderly patients, a comparative qualitative process evaluation in primary care. BMC Health Serv Res. 2015;15:86.
160. May CR, Murray E, Finch T, Mair F, Treweek S, Ballini L, et al. Normalization Process Theory On-line Users' Manual and Toolkit 2010 [cited 2014 Jan 13]. Available from: http://www.normalizationprocess.org/.
161. Shcherbatykh I, Holbrook A, Thabane L, Dolovich L. Methodologic issues in health informatics trials: the complexities of complex interventions. J Am Med Inform Assoc. 2008;15(5):575-80.
162. Ovretveit J. The future of care pathways. Int J Care pathways. 2010(14):76-8.
163. Grimsmo A. Veien frem til helhetlig pasientforløp: Norsk helsenett; [cited 2016 Mar 6]. Available from: https://www.nhn.tema/helhetlig-pasientforlop/Sider/default.aspx.Norwegian.
164. Eldre og kronisk syke. Læringsnettverk for gode pasientforløp i kommunene: The Norwegian Knowledge center for the Health Services (Kunnskapssenteret); 2015 [cited 2016 jun 3]. Available from: http://www.kunnskapssenteret.no/kvalitet-og-pasientsikkerhet/kvalitetsforbedring/pasientforlop/eldre-og-kronisk-syke. Norwegian.
165. Gjevjon ER. Kontinuitet i hjemmesykepleien - vanskelige vilkår, men gode muligheter. Tidsskift for omsorgsforskning. 2015;1:18-26. Norwegian.
166. Håland E, Røsstad T, Osmundsen TC. Care pathways as boundary objects between primary and secondary care: Experiences from Norwegian home care services. Health (London). 2015;19(6):635-51.
167. Vanhaecht K, De Witte K, Panella M, Sermeus W. Do pathways lead to better organized care processes? J Eval Clin Pract. 2009;15(5):782-8.

13 Appendix

13.1 Information to health care professionals about inclusion of patients

NTNU
Det skapende universitet

Inkludering i studien; Helhetlig Pasientforløp i eget Hjem[1]

Hvem som skal inkluderes som intervensjons- eller kontrollpasient

Formål med rutinen

Kvalitetssikre inklusjon av pasienter i studien: Helhetlig pasientforløp i eget hjem.

Omfang:

Det inkluderes både intervensjons- og kontrollpasienter i hver kommune - 30 pasienter i hver gruppe. Selv om man ikke har nådd dette antallet, stopper man inkludering i studien når det har gått 6 måneder. Ideelt sett bør det derfor gå 6 måneder mellom innføring av programmet i hver kommunedel.

Prosjektledelsen i Trondheim vil lage egne forskningskonvolutter for hver pasient som inneholder alle nødvendige papirer for inkluderingen.

Arbeidsbeskrivelse:

1. Vurdering av om pasienten fyller inklusjonskriteriene for å bli intervensjons- eller kontrollpasient:

- En definert person i hjemmetjenesten i kommunen vurderer om pasienten kan inkluderes i studien ut fra utvelgelseskriteriene (jfr utvelgelseskriterier – se under og eget vedlegg).
- Viktig punkt å ha med i lokal sjekkliste er:

---

[1] Eksempel fra landkommune

- Sjekk at pasienten ikke tidligere er inkludert i studien som intervensjons- eller kontrollpasient.
- Pasienter kan ikke delta i studien dersom de er med i andre større studier som innebærer intervensjon i kommunens hjemmetjeneste.
- Studien inkluderer også pasienter med en viss kognitiv svikt, men pasienten må være i stand til å kunne forstå hva deres deltagelse innebærer når de blir informert, og også være i stand til å undertegne en samtykkeerklæring. Det må legges vekt på at den muntlige informasjonen tilpasses den enkeltes kognitive funksjon.
- Brukeren i intervensjonssoner inkluderes i studien i forbindelse med 3 dagers besøket ved sykepleier.
- Brukere i kontrollsoner må også inkluderes innen 3 dager. Den enkelte kommune må vurdere hvordan dette gjøres.

Inklusjonskriterier (eget skjema)

- Pasienten skrives ut fra døgnopphold på sykehus.
- Pasienten har behov for tjenester fra hjemmesykepleien (praktisk bistand person).
- Pasienten har bostedsadresse NN kommune og får tjenester fra xx hjemmetjeneste.
- Pasienten er 70 år eller eldre.
- Pasienten har gitt sitt samtykke (forutsetter at pasienten er samtykkekompetent.).
- Pasienten skal hjem etter sykehusoppholdet (enten ved direkte hjemreise eller via korttidsopphold i sykehjem (4 uker eller mindre).
- Pasienter som tilhører hjemmetjenester der programmet er tatt i bruk, inkluderes som intervensjonspasient. Pasienter som tilhører de øvrige hjemmetjenestene inkluderes som kontrollpasient og kan ikke senere inkluderes som intervensjonspasient i oppfølgingsperioden (12 måneder etter inkludering i studien).

2. **Informasjon og samtykke:**

- Pasientene i både intervensjonsgruppen og kontrollgruppen informeres muntlig og skriftlig. Skriftlig informasjon til både kontrollpasient og intervensjonspasient ligger i forskningskonvolutten.
- Alle pasientene skal signere samtykkeskjemaet. Disse sendes fortløpende i forskningskonvolutten til kommuneoverlegen i Trondheim ved Helge Garåsen. Konvolutten har påtrykt adresse.

3. **Kartlegging i kommunen spesifikt for studien:**

- Alle pasienter som inkluderes i studien (både intervensjon og kontroll) kartlegges ved hjelp av skjemaet:" Kartlegging av evne til å utføre dagligdagse aktiviteter" (Nottingham extended ADL scale).
- Alle nybrukere av hjemmetjenestene (både intervensjon og kontroll) skal få utlevert et skjema for kartlegging av livskvalitet (SF 36) med ferdig adressert svarkonvolutt som går til kommuneoverlegen i Trondheim. Det er meningen at den enkelte bruker skal fylle ut skjemaet selv – evt ved hjelp av pårørende.

4. **Føring i Gerica (eller annet pasientjournalsystem):**

- Det må merkes tydelig i journal om pasienten er inkludert i studien som kontroll eller i intervensjonsgruppe. I Trondheim gjøres dette ved at det merkes i brukerkortet i Gerica. Dette gjøres under fanen" Personalia", velg HPH intervensjon eller HPH kontroll. Hver kommune kan velge egne løsninger bare det merkes tydelig i pasientjournal.
- Alle notat som gjøres som ledd i det nye programmet (pasientforløpet) må skrives på samme journalnummer (f. eks statusrapport) og ikke på daglig journalføring.

6. **Oppbevaring av skjema:**

- Samtykkeskjema og utredningsskjemaet om dagligdagse aktiviteter ("Nottingham") sendes kommuneoverlegen i Trondheim v/Helge Garåsen, i forskningskonvolutten.

- Pasient sender selv livskvalitetsskjemaet i den frankerte konvolutten i forskningskonvolutten.
- Utfylt utvelgelsesskjema lagres i pasientens mappe i basen for hjemmetjenesten for å sikre egen oversikt.

7. Forskningskonvolutten inneholder: (se vedlegg)

1. Rutine for inkludering i studien
2. Informasjonsskriv til intervensjonspasienter
3. Informasjonsskriv til kontrollpasienter
4. Samtykkeskjema
5. Utvelgelseskriterier
6. Kartlegging av evne til å utføre daglige aktiviteter (Nottingham Extended ADL scale)
7. SF 36 (opptrykt skjema) + frankert konvolutt

13.2 Selection criteria

NTNU
Det skapende universitet

Utvelgelseskriterier for pasienter til studien:

Helhetlig pasientforløp i eget hjem

Pasientens navn:

Fødselsnummer:

Postadresse:

Følgende spørsmål skal vurderes på alle pasienter

	Ja	**Nei**
Pasienten skrives ut fra sykehus		
Pasienten er bosatt i kommunen		
Pasienten er 70 år eller eldre		
Pasienten har behov for tjenester fra hjemmetjenesten		
Pasienten har gitt skriftlig samtykke (må være samtykkekompetent)		
Pasienten skal hjem etter sykehusoppholdet*		

*) Enten ved direkte hjemreise eller via ett korttidsopphold i sykehjem (≤ fire uker).

Hvis ja på alle spørsmål, og pasienten tilhører en hjemmetjenesteenhet som har tatt i bruk programmet, inkluderes pasienten i studien i intervensjonsgruppen.

Øvrige pasienter inkluderes i kontrollgruppen dersom de ellers fyller inklusjonskriteriene.

NB: Pasienten kan ikke samtidig delta i andre større studier som involverer hjemmetjenesten.

Dette skjemaet legges i pasientens journal på enheten.

Dato: ……………

Navn/kommune på utfyller: …………………………….

13.3 Information letters to the patients in intervention and control clusters

NTNU
Det skapende universitet

Til deg som pasient

Forespørsel om å delta i en studie som vurderer effekten av styrket oppfølging av hjemmetjenestene etter sykehusinnleggelse.

Mange eldre pasienter opplever at den første tiden etter et sykehusopphold kan være utrygg både med tanke sykdommen, hvor mye man orker og hvor god oppfølgingen blir av kommunens helse- og velferdstjenester.

Sykehuset og den kommunen du bor i vil prøve ut en ny ordning med bedre oppfølging av pasienter over 70 år etter sykehusopphold. Kommunene vil gjøre en vitenskapelig undersøkelse sammen med NTNU for å vurdere effekten av tiltakene. Det betyr at ca. halvparten av pasientene vil bli trukket ut til å få et nytt oppfølgingsprogram, mens de øvrige vil få oppfølging på vanlig måte fra hjemmetjenestene og fastlegen.

<u>Du er trukket ut til å prøve det nye programmet.</u> For deg som pasient innebærer dette at du vil bli bedt om å fylle ut et spørreskjema når du reiser fra sykehuset og etter ca. ett år. I skjemaene vil du bl.a. bli spurt om hvordan du opplever din egen livssituasjon. Du vil også være med i en spørreundersøkelse der vi spør hvordan du opplever kvaliteten på kommunens tjenester før og etter vi har satt i gang prosjektet.

For pasienter som blir trukket ut til å delta i dette nye oppfølgingsprogrammet, vil vi sette i verk følgende:

1. Pasienter som reiser hjem med vedtak om hjemmesykepleie, vil i løpet av 3 dager få besøk av en kontakthjemmesykepleier som vurderer tilstanden og legger en plan for videre oppfølging sammen med deg og med fastlegen din.

2. Innen 2 uker vil du ha en oppfølgingstime hos fastlegen dersom det er anbefalt fra sykehuset, du har begynt med nye medisiner eller er ny bruker av hjemmetjenesten.
3. Du vil etter ca. 4 uker motta tilbud om et nytt hjemmebesøk fra hjemmetjenesten hvor det vil bli vurdert mulighetene for forebyggende tiltak.

For at vi skal kunne gjøre en vitenskapelig vurdering av effekten, vil vi ha behov for noen opplysninger om din sykdom i din journal på sykehuset, hos fastlegen og hos hjemmetjenesten i din kommune. Dette gjelder din diagnose og hvor mye du benyttet deg av spesialisthelsetjenester og kommunale tjenester. I tillegg vil vi gi deg noen spørreskjemaer hvor du beskriver selv hvordan du har det. Opplysningene vil bli behandlet konfidensielt, og ingen enkeltpersoner vil kunne kjenne seg igjen i publikasjoner og rapporter der studiens funn gjengis. Opplysningene anonymiseres når studien er ferdig, innen utgangen av 2012.

Det er frivillig å være med, og du har mulighet til å trekke deg når som helst underveis uten å måtte begrunne dette nærmere. Dersom du trekker deg, vil alle innsamlede data om deg bli slettet.

Studien er meldt Norsk Samfunnsvitenskapelig Datatjeneste, og den er godkjent av Regional Komité for Medisinsk og Helsefaglig forskningsetikk, Midt-Norge.

Du kan stille flere spørsmål om prosjektet til stipendiat Tove Røsstad (tel 917 60 270), kommuneoverlege Helge Garåsen i Trondheim kommune (tel 911 12 656) eller til hjemmetjenestene der du bor.

Trondheim 01.10.09

Tove Røsstad	Helge Garåsen	Rolf Windspoll
Stipendiat	Kommuneoverlege	Samhandlingssjef
ISM, NTNU	Trondheim kommune	St. Olavs Hospital

NTNU
Det skapende universitet

Til deg som pasient

Forespørsel om å delta i en studie som vurderer effekten av styrket oppfølging av hjemmetjenestene etter sykehusinnleggelse.

Mange eldre pasienter opplever at den første tiden etter et sykehusopphold kan være utrygg både med tanke sykdommen, hvor mye man orker og hvor god oppfølgingen blir av kommunens helse- og velferdstjenester.

Sykehuset og den kommunen du bor i vil prøve ut en ny ordning for oppfølging av pasienter over 70 år etter sykehusopphold. Kommunene vil gjøre en vitenskapelig undersøkelse sammen med NTNU for å vurdere effekten av tiltakene. Det betyr at ca. halvparten av pasientene vil bli trukket ut til å få et nytt oppfølgingsprogram, mens de øvrige vil få oppfølging på vanlig måte fra hjemmetjenestene og fastlegen.

Du er trukket ut til å være såkalt kontrollpasient, dvs. at du vil få oppfølging på vanlig måte fra hjemmetjenesten og fastlegen. For deg som pasient innebærer dette at du vil bli bedt om å fylle ut et spørreskjema når du reiser fra sykehuset og etter ca. ett år. I skjemaene vil du bl.a. bli spurt om hvordan du opplever din egen livssituasjon. Du vil også være med i en spørreundersøkelse der vi spør hvordan du opplever kvaliteten på kommunens tjenester før og etter vi har satt i gang prosjektet.

For at vi skal kunne gjøre en vitenskapelig vurdering av effekten, vil vi ha behov for noen opplysninger om din sykdom i din journal på sykehuset, hos fastlegen og hos hjemmetjenesten i din kommune. Dette gjelder din diagnose og hvor mye du benyttet deg av spesialisthelsetjenester og kommunale tjenester. I tillegg vil vi gi deg noen spørreskjemaer hvor du beskriver selv hvordan du har det. Opplysningene vil bli behandlet konfidensielt, og ingen enkeltpersoner vil kunne kjenne seg igjen i publikasjoner og rapporter der studiens funn gjengis. Opplysningene anonymiseres når studien er ferdig, innen utgangen av 2012.

Det er frivillig å være med, og du har mulighet til å trekke deg når som helst underveis uten å måtte begrunne dette nærmere. Dersom du trekker deg, vil alle innsamlede data om deg bli slettet.

Studien er meldt Norsk Samfunnsvitenskapelig Datatjeneste, og den er godkjent av Regional Komité for Medisinsk og Helsefaglig forskningsetikk, Midt-Norge.

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Trondheim 01.10.09

Tove Røsstad	Helge Garåsen	Rolf Windspoll
Stipendiat	Kommuneoverlege	Samhandlingssjef
ISM, NTNU	Trondheim kommune	St. Olavs Hospital

13.4 Informed consent

NTNU
Det skapende universitet

Helhetlig pasientforløp i eget hjem.
Et systematisk utskrivings- og oppfølgingsprogram for pasienter i hjemmetjenesten

SAMTYKKEERKLÆRING
Navn:
Adresse:
Postnr. / sted:
Telefon

Jeg har fått skriftlig og muntlig informasjon om undersøkelsen som skal vurdere effekten av bedre oppfølging av hjemmetjenestene av pasienter etter sykehusopphold.

Jeg gir herved mitt samtykke til å delta i undersøkelsen, og at journalopplysninger både i sykehus, hos fastlegen og i omsorgstjenestene om meg blir benyttet til å vurdere kvaliteten og effekten av de tiltakene som blir satt i verk.

Samtykket er frivillig, og jeg er innforstått med at samtykket kan trekkes tilbake når som helst.

Trondheim;

…………………………………..
(Pasientens underskrift)

Samtykket sendes kommuneoverlege i Trondheim, Helge Garåsen i vedlagt konvolutt.

13.5 Original PaTH checklists in Norwegian

13.5.1 Checklist 1

Helhetlig pasientforløp i eget hjem.
Et systematisk utskrivings- og oppfølgingsprogram for pasienter i hjemmetjenesten

HPH 1 FORBEREDELSE HJEMKOMST

1. Navn på avdeling / ansatt, og telefonnummer:
2. Hjelpebehov / endret behov:
3. Hvis endring; Er helse- og velferdskontoret varslet?
4. Avtalt dato og klokkeslett for hjemkomst:
5. Spesielle observasjoner som vi skal foreta; skal fremkomme i sykepleiesammenfatning / foreløpig epikrise:
6. Sammenlign medikamentliste i foreløpig epikrise med gjeldende medikamentliste på Gerica, med tanke på nye, endrede og seponerte medikamenter.
7. Kontroller at det foreligger evt. Marevan-dosering for de første døgnene.
8. Bruker kommer hjem til kl. 13, hvis ikke skal foreløpig epikrise og sykepleiesammenfatning fakses til hjemmetjenesten innen kl. 13.
9. Sjekk at sykehuset sender med nødvendige resepter, evt. medisiner for 1 døgn / helg.
10. Hvis bruker har vært i kommunal korttidsavdeling, få bekreftelse at oppdaterte opplysninger er lagt inn i Gerica.
11. Er nødvendige hjelpemidler skaffet / bestilt? Hvilke hjelpemidler, bestilt av hvem, leveres når?
12. Er pårørende informert om tidspunkt for utskrivelse?
13. Behov for bolignøkkel? Vil den bli levert av pårørende?
14. Sørg for at bruker kommer på arbeidsliste, og at det er samsvar mellom vedtak og tjenester. Legg inn nødvendige opplysninger som er kommet fram i denne samtalen på oppdragets art.

15. Gi beskjed til samarbeidspartnere om utskrivelse.
16. Bestill time hos fastlege etter en eller flere av følgende kriterier:
    a. Pasienter som har fått endring av faste medisiner
    b. Pasienter som har fått anbefalt oppfølging av fastlege fra sykehuset

    Timen skal være 2 uker etter utskrivelse. Avklar om bruker trenger hjemmebesøk, og om bruker trenger følge til lege.
17. Foreløpig epikrise fakses fastlege når den er mottatt. Merk fax om bruker har Multidose.
18. Legg inn på huskeliste at vi skal fakse informasjon til fastlege dagen før legetime, samt påminnelse om legetimen.
19. Bestem tid for besøk av sykepleier (innen 3 dager). Dette bestemmes i samråd med arbeidslisteskriver.
20. Oppnevn primærkontakt, og legg inn i Gerica

13.5.2 Checklist 2

Helhetlig pasientforløp i eget hjem.
Et systematisk utskrivings- og oppfølgingsprogram for pasienter i hjemmetjenesten

HPH 2 STRUKTURERT OPPFØLGING AV SYKEPLEIER INNEN 3 DAGER ETTER HJEMKOMST

1. Gå gjennom foreløpig epikrise / medikamentliste og sykepleiesammenfatning før samtale med bruker.
2. Aktuelle diagnoser:
3. Har bruker startet med nye medisiner? (Vær obs i forhold til virkning / bivirkning).
4. Kontroll av medisindosett / multidose som bruker har i hjemmet/på sonekontor:
5. Avklar administrasjonsmåte i forhold til medikamenthåndtering, må komme tydelig fram på arbeidsliste.
6. Er seponerte medisiner fjernet fra hjemmet?
7. Nødvendige hjelpemidler / utstyr på plass?
8. Blir utstyret brukt riktig?
9. Har bruker trygghetsalarm? Er bruker i stand til å forstå bruken? Test alarmen.
10. Føler bruker seg trygg?
11. Kjenner bruker at han mestrer hverdagen?
12. Forvirringstilstand?
13. Hukommelsesproblemer?
14. Angstlignende reaksjoner, nedstemthet, irritasjon eller mistenksomhet?
15. Søvnmønster natt / dag:
16. Beskriv matlyst og næringsinntak (Kvalme? Behov for kostveiledning?):
17. Eliminasjon:
18. Utholdenhet / trettbarhet:
19. Fysisk aktivitet:
20. Forflytningsevne, ute – inne. Balanse, fallrisiko og fallfeller:

21. Muskelstyrke håndtrykk:
22. Smerter / tilstrekkelig smertelindring?
23. Symptomer på infeksjon?
24. BT (sittende og stående) / puls / sirkulasjon / respirasjon:
25. Brannrisiko?
26. Hvilke forhold må spesielt følges opp, knyttet til observasjoner, mestringsevne, forebyggende tiltak, aktuelle sykdommer og behandling? Legg inn i oppdragets art.
27. Er epikrise fulgt opp?
28. Behov for andre / økte tjenester?
29. Skriv inn i Gerica huskelister for videre doseringer / utlevering av multidose / utlevering av neste dosett / korrigering av Multidose.
30. Gjennomgang av innholdet i oppdragets art med hensyn til vedtak og observasjoner. Dette gjøres fortrinnsvis sammen med arbeidslisteskriver og primærkontakt.
31. Planlegg 4 ukers samtale for bruker / primærkontakt. Dette skal planlegges sammen med arbeidslisteskriver og legges inn på huskeliste;
32. Skriv ut ny hjemmejournal. Skal ligge i skap lengst til høyre på kjøkkenet hjemme hos bruker.

13.5.3 Checklist 3 A

Helhetlig pasientforløp i eget hjem.

Et systematisk utskrivings- og oppfølgingsprogram for pasienter i hjemmetjenesten

HPH 3A PLANLEGGE BESØK TIL FASTLEGE INNEN 2 UKER

1. Hjemmesykepleien ved ansvarlig sykepleier / fagkoordinator bestiller time hos fastlege når sonen får beskjed om utskriving.
2. Ansvarlig sykepleier / fagkoordinator vurderer om bruker kan møte på legekontoret eller har behov for hjemmebesøk.
3. Hjemmetjenesten skal informere skriftlig om de observasjoner som er gjort vedrørende pasientens helsetilstand, funksjon og mestringsevne (Gerica mal: **Informasjon fra hjemmetjenesten til fastlegen** i journal 311).
Dette skal gjøres av **fagkoordinator** dagen før legebesøk.

Viktig kontaktinfo som navn og telefonnummer til primærkontakt, ansvarlig sykepleier / fagkoordinator samt fax må noteres.

4. Tilsvarende prosedyre som punkt 3 ved seinere legekontakter.

Selve konsultasjonen / sykebesøket:

1. Fokus på pasientens helsetilstand, funksjonsevne og mestringstilstand samt evt behov for rehabilitering og forebyggende tiltak.
    a. Legen vil vurdere hva konkret hjemmetjenesten skal observere.
    b. Legen vil vurdere hva som skal skje dersom pasienten blir dårligere av evt kronisk tilstand.

2. Legen vil avtale ny legetime og hyppighet av videre legekontroller.

3. Legen leverer / fakser kopi av journalnotatet til hjemmesykepleien.

4. Legen leverer / fakser oppdatert medikamentliste til hjemmesykepleien og evt apoteket (ved multidose) også dersom det ikke er foretatt endringer.

Prosedyre for gjensidig oppdatering fastlege – hjemmesykepleien følges også ved seinere konsultasjoner av pasienter som er inkludert i studien.

Bakgrunnsinformasjon

MÅ LEVERES FASTLEGE I DAG!	
Legesenter:	Fastlege:
Faksnr.:	
Bruker:	Fødselsnummer:
Tidspunkt for legetime:	
Fastlegebesøk etter utskrivelse fra sykehus?	
Bakgrunn / Problemstilling:	
Observasjoner gjort av hjemmetjenesten:	
(Fysisk, psykisk, sosialt)	
Antall besøk fra hjemmetjenesten per dag:	
Andre kommunale tjenester:	
Fastlegens anbefaling til hjemmetjenesten for videre behandling og oppfølging:	
- Spesielle observasjoner / oppfølging:	
- Hva bør iverksettes ved forverring:	
Vennligst gi tilbakemelding til	
Hjemmetjeneste:	
Fagkoordinator:	
Faksnr.:	
Telefon:	
Mobilnr.:	
Vedlegg: Medikamentliste fra Gerica	

13.5.4 Checklist 3 B

Helhetlig pasientforløp i eget hjem. Et systematisk utskrivings- og oppfølgingsprogram for pasienter i hjemmetjenesten

HPH 3B MOMENTLISTE VED OPPFØLGING HOS FASTLEGEN TO UKER ETTER UTSKRIVING FRA SYKEHUS

(utarbeidet av fastleger i Trondheim / Orkdals regionen og godkjent av LSU)

Alle punkter vil ikke være aktuelle for alle pasienter. Legen skriver et journalnotat på vanlig måte ut fra hva legen mener er relevant informasjon, men det er viktig at rådene til hjemmetjenestene blir med. Hjemmetjenesten fakser sine observasjoner og evt. problemstillinger til legen et døgn før konsultasjon / sykebesøk. Legen fakser kopi av sitt journalnotat til hjemmetjenesten i de tilfellene hjemmetjenesten ikke følger pasienten (hjemmetjenesten følger pasienter som ikke selv kan gjøre rede for seg).

<u>Pasientens fortelling, vurderinger og spørsmål etter innleggelse:</u>

Har pasienten skjønt hva som skjedde under sykehusoppholdet?
Hvordan opplever pasienten sin situasjon etter sykehusoppholdet?

<u>Legens undersøkelse og vurdering:</u>

Gjennomgang av foreliggende dokumentasjon:

- Epikrise, rapport fra hjemmesykepleien

Undersøkelser og prøver:

- Ut fra det pasienten og hjemmesykepleien forteller
- I følge anbefalinger i epikrisen

Gjennomgang av legemiddellisten:

- Effekt? Bivirkninger?
- Noe som kan seponeres eller gjøres enklere?
- Har pasienten forstått nye medisiner / doseendringer?

- Trenger pasienten evt. hjelp eller opplæring for å håndtere sine medisiner, evt. egnet for multidose?

Pasientens egenmestring

- Behov for tiltak for å styrke pasientens egenmestring (f.eks. trening)?

Tiltak / plan for videre behandling og oppfølging:

Resepter og oppdatering av legemiddelliste og kopi til hjemmesykepleien / evt. apotek (ved multidose)

Rekvisisjon av undersøkelser og behandling

- Rehabilitering / fysisk trening / hjelpemidler?

Råd / veiledning (evt. utskrift fra NEL)

Avtale om videre kontroller hos fastlegen

Anbefalt råd /oppfølging til hjemmetjenesten

- Hva som evt. bør observeres (effekt av behandling, bivirkninger, mat / drikke, vekt, avføring / vannlating, ødemer etc.)
- Hva som evt. bør gjøres ved forverring / tidlig intervensjon (bruk evt. NEL). Spesifiser tiltak som hjemmetjenesten evt. kan starte

Lever / faks kopi av journalnotatet til hjemmetjenesten + evt. kopi av legemiddelliste (når hjemmetjenesten håndterer pasientens medikamenter)

13.5.5 Checklist 4

Helhetlig pasientforløp i eget hjem. Et systematisk utskrivings- og oppfølgingsprogram for pasienter i hjemmetjenesten

HPH 4 FIRE-UKERS SAMTALE / REVURDERING AV BRUKER

Helse:

1. Diagnose siste sykehusinnleggelse og andre kroniske tilstander:
2. Endring i brukers helse og hjelpebehov det siste halve året:
3. Videre oppfølging etter siste fastlegekontroll: Spesielle observasjoner framover?
4. Plan for videre kontakt med fastlege:
5. Ernæringstilstand: (Variert / ensidig kosthold. Mengde, hyppighet av måltider. Vekttap siste halvår? Behov for oppfølging under måltid?)
6. Tannhelse (Egne tenner? Veltilpasset protese? Behov for bistand til munnhygiene?):
7. Smerter / tilstrekkelig smertelindret?
8. Eliminasjon (Urin / Avføring):
9. Syn / Hørsel:

Daglige beslutninger:

10. Beskriv brukers hukommelse:
11. Beskriv brukers ressurser til å planlegge / ta ansvar for daglige gjøremål:
12. Oppleves brukers atferd som adekvat? Mistanke om forvirringstilstand?
13. Har bruker forståelse for sin egen situasjon? (Hvis nei; kontakt fastlege for å få brukers samtykkekompetanse vurdert).
14. Er brukers hjemmesituasjon forsvarlig (**B**rann, sikkerhet, helsetilstand)?
15. Er det spesielle utfordringer i forhold til brannsikkerheten (Hvis ja - følg prosedyre ‘Forebyggende brannvern for brukere i hjemmetjenesten’. Denne prosedyren skal i tillegg gjennomgås minimum 1 gang per år):

Sosialt nettverk/aktiviteter:

16. Hjelp fra og kontakt med pårørende og venner?
17. Hvilke interesser / aktiviteter har bruker deltatt i tidligere?
18. Behov for bistand til sosial deltagelse?
19. Informasjon: Ta med mappe med informasjon om aktivitets- og kulturtilbud.

Mestringsevne

20. Opplever bruker trygghet i hverdagen?
21. Dersom bruker har trygghetsalarm, test alarmen.
22. Har bruker forståelse for å bruke trygghetsalarmen?
23. Opplever bruker at hun mestrer hverdagen?
24. Nedstemthet, angstlignende symptomer, irritasjon eller mistenksomhet?

Funksjon / ADL:

25. Beskriv brukers bevegelse innendørs (opp og ned av stol, inn og ut av seng, balanse, gjennomføre toalettbesøk, gå trapp):
26. Har bruker falt de siste 4 uker? Evt. iverksett fallforebyggende tiltak.
27. Behov for tilpassing av leilighet (f.eks. fjerne dørstokker, gulvtepper, gode lysforhold? Er alt på ett plan?):
28. Har bruker nødvendige hjelpemidler? Behov for veiledning i riktig bruk?
29. Personlig stell: Hva mestrer bruker selv? Behov for bistand?
30. Trenger bruker tilrettelegging / bistand til av- og påkledning?
31. Mestrer bruker å lage mat, tømme søppel, vaske kopper, vaske klær, innkjøp?
32. Rengjøring av bolig; hva mestrer bruker selv? Bistandsbehov? Hvem bistår?
33. Kan noe gjøres for å styrke brukers funksjonsnivå og brukers egenmestring?
34. Er det noe bruker gjerne ønsker mestre, men som han / hun i dag ikke klarer?
35. Er det funksjoner som er i ferd med å svikte, men som kan styrkes?
36. Er bruker motivert til opplæring / trening / sosiale tiltak?
37. Oppdater oppdragets art.
38. Oppdater og skriv ut hjemmejournal, skal ligge i skap øverst til høyre på kjøkkenet.
39. Er brukers tjenestebehov i samsvar med eksisterende vedtak?
40. Har bruker behov for nye vedtak?

41. Revurdering skal utføres etter behov eller minimum hver 6 mnd. Legg inn på huskeliste.

13.5.6 Checklist 5

Helhetlig pasientforløp i eget hjem.

Et systematisk utskrivings- og oppfølgingsprogram for pasienter i hjemmetjenesten

HPH 5 BRÅ ELLER GRADVIS ENDRING / TAP AV FUNKSJON:

Ved akuttsituasjon RING113.

Konferer med sykepleier / vernepleier under utfylling av sjekklisten.

BRÅ ENDRING / TAP AV FUNKSJON (timer / dager / uke)
Bevissthetstilstand (forvirring?):
Mental svikt?
Respirasjon (rask? surklete? anstrengt?):
Blodtrykk / puls:
Vektendring (ved hjertesvikt)?
Hevelse i beina?
Hud (farge / tørr / varm / klam):
Tegn til infeksjon (temperatur, urinstiks, forvirring, luftveissymptomer, skarpt avgrenset rød hud)?
Medisiner (tar bruker sine medisiner? riktig dose?):
Smerter (hvor / styrke)?
Svimmel? Fall?
Eliminasjon (urin / avføring):
Matlyst / væsketilførsel:
Søvnmønster:
Atferdsendring (nedstemthet, engstelse)?
Behov for å kontakte fastlege / legevakt? (Bruk sjekkliste ved rapportering)
Behov for økte / endrede tjenester?
Informer pårørende.

Ved sykehusinnleggelse, eller ved legetilsyn skal Hjemmejournal legges fram eller sendes med ambulanse.

GRADVIS ENDRING / TAP I FUNKSJONSNIVÅ (uker, måneder)

Mental svikt?
Søvnmønster:
Adferdsendring (nedstemt, engstelig, mistenksom, aggressiv)?
Vekttap (hva og hvor mye spiser / drikker bruker):
Blodtrykk / puls:
Medisiner (tar bruker medisiner? riktig dose?):
Smerter (hvor / styrke)?
Gangfunksjon:
Svimmelhet?
Falltendens?
Eliminasjon (urin / avføring):
Kontakt pårørende (hvis samtykke):
Kontakt fastlege.
Kontakt helse- og velferdskontor dersom behov for endrede tjenester:

MAL I GERICA: BRÅ ELLER GRADVIS ENDRING / TAP AV FUNKSJON:

Beskriv situasjonen, og de observasjoner som er gjort etter sjekkliste" **BRÅ ELLER GRADVIS ENDRING/TAP AV FUNNKSJON**":	
Tiltak som ble iverksatt umiddelbart:	
Hvilke tiltak bør iverksettes for å forebygge nye hendelser, eller forebygge tap av funksjon:	

13.5.7 Checklist 6

Helhetlig pasientforløp i eget hjem.

Et systematisk utskrivings- og oppfølgingsprogram for pasienter i hjemmetjenesten

HPH 6: INFORMASJON TIL SYKEHUS VED INNLEGGELSER

1. Hjemmetjenesten sender med 'hjemmejournal' ved innleggelse i sykehus.

2. Legevakt må være kjent med at 'hjemmejournal' blir oppbevart i kjøkkenskap øverst til høyre, i de tilfeller hjemmetjenesten ikke er involvert i innleggelsen.

3. Hjemmetjenesten kontakter aktuell sykehusavdeling pr. tlf innen 24 timer / første virkedag etter sykehusinnleggelsen for overføring av informasjon, sjekker at avdelingen har mottatt 'hjemmejournal'.

4. Hjemmetjenesten skriver en oppsummering over siste dagers observasjoner i journal 311, etter følgende mal:

HPH 6: INNLEGGELSE SYKEHUS, INFORMASJONSOVERFØRING FRA KOMMUNE:

Innlagt avdeling: Dato: Ansatt:
Siste dagers observasjoner, før innleggelse: Fax hjemmejournal. Kvalitetssikre at pårørende og samarbeidspartnere er varslet. Kvalitetssikre at tjenester er stoppet.

Denne fakses eller sendes elektronisk til sykehusavdeling innen 24 timer/ første virkedag, evt. sammen med 'hjemmejournal' om denne ikke er mottatt tidligere.

13.5.8 Daily care plan

Helhetlig pasientforløp i eget hjem.

Et systematisk utskrivings- og oppfølgingsprogram for pasienter i hjemmetjenesten

STRUKTUR FOR OPPDRAGETS ART I GERICA, MED VEILEDER.

MAL:	VEILEDER
Tidspunkt	Når hjelp er avtalt.
Diagnose:	Beskriv sykdomssituasjon, aktuelle diagnoser, evt. situasjon etter siste utskrivelse.
Andre hensyn:	Har hund, ikke ring på døren, skal på dagsenter osv.
Medikamenter:	Viktig å være presis og detaljert i beskrivelsen for å unngå avvik. Marker tydelig om det er hjemmetjenesten som deltar i medikamenthåndteringen, eller om bruker har ansvaret selv. Oppbevares medisiner på sonekontor, eller hjemme hos bruker? Har bruker Multidose, dosett, eller begge deler?
Spesielle observasjoner:	Etter anbefaling fra sykehus / fastlege
Hva gjør vi ved forverring:	Etter anbefaling fra sykehus / fastlege, evt. oppgi nummer til sykehusavdeling, har bruker åpen innleggelse osv.
Oppdrag: **- Hva mestrer bruker selv:** **-Forebyggende tiltak:** **-Kompenserende tiltak:**	Oppdragstekst som skal gjenspeile vedtak, og hva vi konkret skal hjelpe bruker med, eventuelt hva bruker mestrer selv.
Varsling ved forsinkelse ja/nei	Skal bruker kontaktes hvis vi blir forsinket?

13.6 Core PaTH checklists (summary in English)

13.6.1 Checklist 1

Discharge call from hospital to home care services at the day of discharge.

(Checklist to be used by the head nurse)

1. Name and telephone number to the ward / person calling from the hospital.
2. What kind of support is needed after discharge? Has this changed during the present hospital admission?
3. If there is a change in need for municipal health and social care, has the hospital contacted the local health care allocation office?
4. Agree on date and time for discharge.
5. Are there any specific conditions to be observed by the home care staff after discharge? This must be documented in the discharge letter.
6. Compare the list of medication used in the hospital with the list of medications in the electronic health record (EHR) of the home care services to check for new, changed or discontinued medication.
7. Make sure there is a dose-plan for warfarin the first three days.
8. Make sure that the discharge letter will be sent by fax to the home care service before 1pm at the day of discharge.
9. Make sure that the hospital provides necessary prescriptions and medications for one day / weekend.
10. If the patient has had an intermediate stay in a nursing home / rehabilitation facility, make sure that information is updated in the EHR.
11. Have necessary assistive devices been ordered? What kind of devices? Who has ordered? When will it be delivered?
12. Has the family been informed about the discharge?
13. Does the home care staff need a key for the patient’s house? Will this be delivered by the family?
14. Make sure the patient is enrolled on the work list and that services are planned according to the decision of the local health care allocation office.
15. Make sure important information is registered in the daily care plan.
16. Inform cooperating partners about the discharge.

17. Fax information about medication and immediate follow-up needs to the GP.
18. Book an appointment with the GP within 14 days if there have been changes in the medication plan during the present hospital stay or if follow-up by the GP is recommended by the hospital. Clarify whether the patient can meet at the GP practice or need a home call by the GP.
19. Make a reminder in the EHR that updated information is provided to the GP one day before the appointment.
20. Decide on time for a follow-up visit by a home care nurse.
21. Appoint a primary contact person (nurse or nursing assistant) within the home care services.

13.6.2 **Checklist 2**

Post-discharge assessments by a home care nurse within three days after discharge

1. Check discharge letter from the hospital.
2. Document current acute / chronic diseases and medical conditions.
3. Check if medication list in the EHR is updated (new, changed or discontinued medication).
4. Check how medication is to be administered.
5. Observe effects / side effects of medication
6. Remove outdated medication from the patient’s home.
7. Check that necessary assistive devices are in place in the patient’s home and that they are being used correctly.
8. Does the patient have a safety alarm? Does he understand how to use it? Does it function properly? (Test it).
9. Does the patient feel secure?
10. Does the patient cope with the situation at home?
11. Confusion about time and place?
12. Reduced short-term or long-term memory?
13. Anxiety or depressive symptoms? Paranoid symptoms?
14. Sleeping pattern:
15. Eating well? Nutritious meals? Nausea? In need of diet guidance?
16. Proper bowel function? Urinary incontinence / retention?
17. Endurance – fatigue?
18. Physical activity.
19. Ability to walk indoors and outdoors. Risk for falls?
20. Muscle strength by hand shaking.
21. Pain?
22. Signs or symptoms of infection?
23. Blood pressure (sitting and standing), pulse, circulation, respiration.
24. Make sure the recommendations in the discharge letter is being followed up.
25. What kind of conditions are especially in need of follow-up (diseases, ADL, preventive measures)? Document this in the ‘daily care plan’ in the EHR.
26. Check whether there is need for other municipal health and social care services or increased home care services.
27. Update the daily care plan.

28. Plan for the four-week assessment together the patient’s primary contact person in the home care service.

13.6.3 **Checklist 3A**

Procedure and information provided before examination by the GP within two weeks after discharge (home care checklist)

1. Head nurse / nurse in charge book an appointment with the GP when they are informed of the discharge.
2. Head nurse / nurse in charge clarify whether the patient can meet at the GP practice or need a home call by the GP.
3. The day before the appointment, the head nurse informs the GP in written about observations done by the home care staff on the patient's health situation, physical and cognitive functional level and the patient's ability to master daily activities.
4. This procedure is to be followed also at later consultations.

Information from the home care services to the GP (Template in the EHR)

Name of GP practice / GP:

Fax no:

Name of the patient:

Date of birth / identification number:

Time for appointment:

Need for home call by the GP? (Yes / No)

Current problem:

Observations on physical, mental and social condition performed by home care staff:

Number of visits by home care staff per day:

Other municipal health and social care services:

Contact information home care services:

Name of home care unit:

Name of head nurse:

Fax no.:

Phone: /Mobile:

Please provide feedback on conditions to be observed by the home care staff, plan for further follow-up, and advice on measures in case of exacerbations of chronic diseases

Attachment: Medication list from the EHR

13.6.4 Checklists 3B

GP checklist for consultation two weeks after discharge

Not all issues are relevant to all patients. The GP documents as usual what is considered to be relevant information, but advice to home care services on further follow-up of medical condition is mandatory. The GP will receive updated information on observations and assessments from the home care professionals the day before the consultation. The GP informs at home care professionals on conclusions and plan for further follow-up after the consultation.

- Check whether there is a need for further examination / test in the discharge report or the report from the home care services.
- Check the medication list
    - Effect or side effects of medication?
    - Can medication be reduced or simplified?
    - Has the patient understood changes in the medication list?
    - Does the patient need help to handle her / his medication?
    - Is there a need to improve the patient's self-management related to diseases or medication?
    - Check whether there is a need for new prescriptions.
    - Make sure the medication list is updated, and information passed to the pharmacy and home care services provided they are handling the patient's medication.
- Does the patient need rehabilitation measures?
- Agree on further follow-up consultations and inform the home care services.
- Make a follow-up plan for the home care services including
    - What to observe (e.g. cognitive functioning, effect of treatment, side effects, nutrition, weight, blood pressure, oedema. etc.).
    - How to act if the chronic medical conditions deteriorates.

13.6.5 Checklist 4

Post-discharge assessment by a home care professional (nurse or nursing assistant) within four weeks after discharge.

Health

1. Document current acute / chronic diseases and medical conditions.
2. Document changes in patient's health condition last six months.
3. Is the plan for follow-up after the last GP consultation attended to?
4. Is there a plan for further follow-up by the GP?
5. Eating well? Nutritious meals? Nausea? In need of diet guidance? Weight loss last six months? In need of help during meal?
6. Dental health (own teeth?). How is the oral hygiene? In need of a dentist?
7. Pain?
8. Proper bowel function? Urinary incontinence / retention?
9. Vision and hearing.

Ability to make decisions on daily activities

10. Reduced short-term or long-term memory?
11. Confusion about time and place?
12. How is the patient's ability to plan and follow up daily activities?
13. Anxiety or depressive symptoms? Paranoid symptoms?
14. Does the patient have competence to consent to treatment?
15. Are the home conditions satisfactory (security, health, functional level)?
16. Does the patient have a safety alarm? Does he understand how to use it? Does it function properly? (Test it).
17. Does the patient feel secure?
18. Does the patient cope with the situation at home?

Social network and activities

19. Does he get any help from family / friends?
20. What kind of social activities did he use to attend earlier?
21. Does he need any help for participating in social activities?

22. Provide oral and written information about local social activities.

Activities of Daily Living (ADL)

23. Ability to walk indoors (walking to and from a chair, bed, toilette and staircase) and outdoors.
24. Any falls last four weeks? In need of fall-preventing measures?
25. Needs for improvements in the house due to functional impairment (e.g. remove carpets and doorsteps, better lighting)?
26. Sufficient assistive devices? Check whether they are being used correctly.
27. Personal hygiene? What can he manage himself? Need of support?
28. In need of help to dress / undress?
29. Able to prepare meals, wash dishes and cloths, do shopping, get rid of trash?
30. Able to clean his flat? If no, who is helping him?
31. Can something be done to strengthen the patient's ADL / coping of daily activities?
32. Is there anything that the patient wants to master, but is not able to do?
33. Can something be done to reverse functional decline?
34. How is the patient's motivation for exercising or social activities?
35. Check whether there is need of other municipal health and social care services or increased home care services
36. Update daily care plan

13.6.6 **Daily care plan**

- Time for assistance
- Relevant medical conditions
- Medication
- Observations recommended by the hospital or GPs
- What to do if the condition deteriorates
- What can the home care recipient manage himself?
- Preventive measures
- Assistance given by the home care professionals

13.7 Nottingham extended ADL scale.

Kartlegging av evne til å utføre dagligdagse aktiviteter.

Følgende spørsmål gjelder dagligdagse aktiviteter. Et kryss for hvert svar. Skriv hva du faktisk har utført siste 2 uker – inkludert sykehusopphold (ikke hva du tror eller ønsker du kan gjøre)

Navn:
Fødselsdato:
Dato for utfylling / utfylt av:

	Har du?	**Nei**	**Med hjelp**	**Alene med vansker**	**Alene**
1	Gått omkring utendørs?				
2	Gått i trapper?				
3	Kommet deg inn og ut av bilen?				
4	Gått på ujevnt underlag?				
5	Krysset veier?				
6	Reist med offentlig transport?				
7	Spist selv?				
8	Laget varm drikke?				
9	Tatt med varme drikker fra et rom til et annet?				
10	Tatt oppvasken?				
11	Laget et enkelt varmt måltid til deg selv?				
12	Håndtert dine egne penger når du er ute?				
13	Tatt små vask / håndvask?				
14	Gjort husarbeidet selv?				
15	Gjort innkjøpene selv?				
16	Tatt en hel klesvask?				
17	Lest aviser eller bøker?				
18	Brukt telefonen?				
19	Skrevet brev?				
20	Gått ut for sosialt samvær?				
21	Stelt din egen hage?				
22	Kjørt bil?				

13.8 IPLOS

IPLOS	**Utgjør intet problem**	**Ikke behov for assistanse**	**Middels behov for assistanse**	**Store behov for assistanse**	**Fullt behov for assistanse**
Alminnelig husarbeid					
Skaffe varer / tjenester					
Personlig hygiene					
På- og avkledning					
Toalett					
Lage mat					
Spise					
Bevegelse innendørs					
Bevege seg utendørs					
Ivareta egen helse					
Hukommelse					
Kommunikasjon					
Beslutninger i dagliglivet					
Sosial deltagelse					
Styre adferd					
Syn					
Hørsel					

14 Original papers I-III

Paper I

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RESEARCH ARTICLE Open Access

Development of a patient-centred care pathway across healthcare providers: a qualitative study

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Abstract

Background: Different models for care pathways involving both specialist and primary care have been developed to ensure adequate follow-up after discharge. These care pathways have mainly been developed and run by specialist care and have been disease-based. In this study, primary care providers took the initiative to develop a model for integrated care pathways across care levels for older patients in need of home care services after discharge. Initially, the objective was to develop pathways for patients diagnosed with heart failure, COPD and stroke. The aim of this paper is to investigate the process and the experiences of the participants in this developmental work. The participants were drawn from three hospitals, six municipalities and patient organizations in Central Norway.

Methods: This qualitative study used focus group interviews, written material and observations. Representatives from the hospitals, municipalities and patient organizations taking part in the development process were chosen as informants.

Results: The development process was very challenging because of the differing perspectives on care and different organizational structures in specialist care and primary care. In this study, the disease perspective, being dominant in specialist care, was not found to be suitable for use in primary health care because of the need to cover a broader perspective including the patient's functioning, social situation and his or her preferences. Furthermore, managing several different disease-based care pathways was found to be unsuitable in home care services, as well as unsuitable for a population characterized by a substantial degree of comorbidity. The outcome of the development process was a consensus that outlined a single, common patient-centred care pathway for transition from hospital to follow-up in primary care. The pathway was suitable for most common diseases and included functional and social aspects as well as disease follow-up, thus merging the differing perspectives. The disease-based care pathways were kept for use within the hospitals.

Conclusions: Disease-based care pathways for older patients were found to be neither feasible nor sustainable in primary care. A common patient-centred care pathway that could meet the needs of multi- morbid patients was recommended.

Keywords: Care coordination, Continuity of patient care, Healthcare disparities, Multi-morbidity, Patient discharge, Primary care, Home care services, Interdisciplinary communication, Organizational culture, Health services for the aged

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Background

In Norway, as in most Western societies, health authorities consider health and social services to be fragmented; especially challenging is a lack of continuity of care for elderly and chronically ill patients [1-4]. More outpatient care, fewer hospital beds and shorter inpatient stays redirect more rehabilitation and follow-up to primary care at an increasingly earlier stage of treatment [2,5]. Studies show that there is a considerable risk of adverse events in relation to the transition of patients between hospitals and primary care services and that information provided is often insufficient [6-8]. Thus, there is a growing need for better care coordination between primary and specialist health care services to ensure patient safety and continuity of care [1,9].

Many countries have focused attention on improving the coordination of their health and social care services [10,11]. In some European countries, models for hospital-at-home regimens have been developed as a beneficial alternative to inpatient care for selected patients [12,13]. Treatment and follow-up takes place in the patient's home, with an ambulatory team from the local general hospital remaining responsible for patient care. Other models describe care pathways that aim to ensure adequate follow-up after discharge, involving both specialist and primary care services [14,15]. Most studies in the field evaluate models that have been initiated by specialist care services and are based on treatment of single diseases like stroke, heart failure and COPD [16-18]. Some studies describe care pathways for hospitalized elders more generally [19]. In these studies, hospital-based practice nurses or multidisciplinary teams are usually involved in the discharge process and for a limited post-discharge period. In Denmark an intervention was developed within primary care by GPs and home care services that reduced the risk of readmissions and improved medication control for newly discharged elderly patients [20].

Models have also been developed to improve the follow-up care of patients with chronic conditions in primary care. The Chronic Care Model has been introduced at several sites but targets mostly single diseases [21,22]. More recently, the Patient-Centered Medical Home model has been launched in the US [23].

Cultural differences between specialist care and primary care are not unknown [24]. However, we have not found studies investigating the potential implications that the different professional cultures might have on the process of developing care pathways across care levels.

In Central Norway a primary-care initiated project was set up where the main objective was better care coordination and follow-up during and following discharge from hospital to home by developing integrated care pathways. Being a cluster-randomised complex intervention, a process evaluation nested inside the trial was started in order to clarify causal mechanisms and to identify obstacles or other contextual factors contributing to the variation, success, or failure of the interventions [25]. The aim of this paper was to explore the process of developing the integrated care pathways that was going to be implemented in the project.

Methods

This study used a qualitative design that included observations and interviews. The study was conducted from spring 2009 until spring 2010. It was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway and the Ombudsman for Research at the Norwegian Social Science Data Service. The randomized trial was registered in Clinical Trials.gov NCT01107119.

All informants were informed about the study both in writing and orally by the first author and signed a written consent. They were informed that the interviews would be handled confidentially, that citations would be anonymous, and that they could ask for statements to be deleted.

Setting

In Norway the general and university hospitals are owned by the government and managed through four regional health authorities. Primary care services, comprising for example general practitioners (GPs), home care services, nursing homes and community hospitals, are the responsibility of local authorities [26-28]. All citizens are entitled to have a GP who is responsible for providing general health care, including medical follow-up after discharge from hospital. These are usually organized as small private enterprises. Home care services are organized in district units employing nurses and aides who offer nursing and therapeutic procedures, medical services, personal care, social care and terminal care. Home care services may be offered several times a day and at night, when needed, and can even be provided continuously for 24 hours a day for shorter periods.

The framework for the project being studied was outlined by healthcare managers from the city of Trondheim in cooperation with St. Olavs Hospital and researchers from the Norwegian University of Science and Technology (NTNU) based on a literature search on care pathways across care levels for older patients.

Two general hospitals, one university hospital and six municipalities took part in the project, represented by people with experience in cooperation across care levels. Participants from all of the organizations met three times as part of a regional working group during a period of four months. They were given an introduction to the aims and tasks of the project and taught how to run the development process in their own organisations as local process facilitators (Table 1). They were guided by two supervisors from the Central Norway Regional Health Authority who had extended experience in coaching for developing clinical pathways within hospitals. The methods taught by the supervisors were based on the concepts Patient Process Redesign [29] and LEAN [30]. The participants in the regional working groups also formed three local working groups that met in between the regional sessions. These groups were led by one of the process facilitators and were organized around each of the participating hospitals and its adjacent municipalities. The local working groups were extended to involve additional nurses, physicians, physiotherapists, occupational therapists and participants from patient organizations. In addition, the local process facilitators arranged local meetings involving the staff at their workplace. The working groups were first asked to identify the risks for adverse events and potential obstacles during admission, discharge and follow-up at home, and to evaluate information flow, roles and responsibilities. Based on these analyses, they were challenged to develop care pathways for patients with COPD, heart failure and stroke. At the outset, the plan was to use the hospital-developed pathways and extend them into primary care by developing procedures for transition between the care levels and for follow-up in primary care.

Informants

Nineteen people (Table 2) were organized in three focus groups based on the local working groups. The informants were recruited by the first author and represented two patient organizations, five of the six municipalities, the three hospitals and the Central Norway Regional Health Authority. One small municipality was not represented in the interviews due to problems with capacity, and they temporarily pulled out of the project. The selection criteria were that the participants had participated actively throughout the development project in the regional and local working groups and that, in addition, all occupational groups were represented. Half of the informants had been local process facilitators, and two of them had managed the local working groups. All hospitals and municipalities were represented by at least two participants, and they made up about half of those who had been active in the regional and local working groups. Few GPs took part in the development process. However, collaboration between home care services and GPs was an important topic both in the process and the interviews. Therefore, a fourth focus group of four GPs was recruited; of these four, only one had taken part in the actual development process.

Table 1 Local process facilitators (N = 27)

Participants	Clinicians	Case handler	Managers
Hospital nurses	10		
District nurses in home care services	8		3
Health and social administration, primary care		4	
Occupational therapists, primary care	2		

Table 2 Participants in the interviews (N = 23)

	Participants	Age (mean/range)	Years of working experience
Primary care	10	45 (30–62)	18 (6–37)
Hospital/Regional health administration	7	50 (36–59)	21 (9–36)
Patient organizations	2	67 (64–69)	
GPs	4	55 (51–61)	29 (25–33)

Data collection

A semi-structured interview guide was used in the interviews (Table 3). The main question asked was: How did you experience the process of developing an integrated care pathway for older patients? Four focus groups were considered sufficient, as the representational spread was satisfactory, and the last interviews did not bring up new themes. All interviews were carried out by the first author. An independent co-moderator was present at two of the focus group interviews. The first author also participated as an observer at one regional meeting and at most of the meetings in the local working groups. Written material from all of the working groups, such as minutes, notes from flip-overs and proposed pathways, was collected and studied as well.

Table 3 Semi-structured interview guide

Main question	Subordinate topics
How did you experience the process of developing an integrated care pathway for older patients?	• Understanding of care pathways • Important topics in development work • Challenges regarding care pathways for older people • Responsibilities and collaboration in a care pathway • Expectations and attitudes in the development process • Challenges in the development process • Appraisal of the final solution

Analyses

The interviews were recorded and transcribed verbatim by the first author. In the analyses we applied Malterud's systematic text condensation, which is inspired by Giorgi's phenomenological approach [31,32]. The authors studied the interviews independently in order to get a general sense of all the material and to identify the main themes. They then met to discuss and refine the identified themes. The first author then identified units of meaning related to the main themes, and the coding of these was discussed in subsequent meetings with the other co-authors. The original themes were re-evaluated throughout this process.

Additionally, six researchers familiar with qualitative studies and who had not been part of the project read the transcripts of the first focus-group interview independently and identified central themes. There were no major differences between these and the central themes already identified. The main results of the analyses were finally presented to informants from all geographical sites to uncover any apparent misunderstandings. The final analysis was studied and approved by the authors. The citations used are chosen to illustrate and complement the description of the findings.

Results

The results were categorized into five main themes: The overall experience with the process is described under the heading "process experiences." The details of the experience are described under the following headings: a tug of war between professional goals; disjointed collaboration in primary care; primary care perspectives gain ground; and merging of perspectives.

Process experiences

The first regional meeting was described by the informants as confusing. For teaching the process method, all examples were taken from developing clinical pathways in hospitals, and the representatives from the municipalities were not able to relate the examples to their daily work. The participants from the hospitals and primary care understood the task at hand differently and struggled to understand each other's point of view. They were able to identify several risks of adverse events, especially related to insufficient information flow both between the care levels as well as within primary care. However, on trying to develop a model for transition and follow-up, differences in professional objectives and perspectives between specialist care and primary care became very obvious and proved to be challenging. This influenced the first local meetings as well, and the participants could not agree on which perspective should form the basis of the care pathways.

> *At one stage we were uncertain if and how we could continue the process. We were miles apart. We didn't understand each other's point of view. (Nurse primary care, local process facilitator, city)*

The project management was asked to intervene to get the process back on track, and this conflict of perspectives was a main theme in the next regional meeting. Furthermore, a geriatric nurse who had a great deal of working experience in both hospital and primary care joined the discussions and helped to bridge the gap between the participants from the hospitals and municipalities. These initiatives brought the process forward. The rest of the process was seen as constructive, and the dialogue was perceived as mutually respectful.

> *Gradually we accepted that each group had a completely different approach to the problem; that we came from different areas of expertise. The geriatric nurse helped us to speak the same language. That made things much easier, and then it became really fun. (Nurse primary care, local process facilitator, city)*

A tug of war between professional goals

The participants then started discussing discharge routines and follow-up for COPD, heart failure and stroke as proposed in the initial assignment. However, the strong focus on these single diseases was met with scepticism from most of the nurses in primary care. Their main concern, especially in the transition phase, was to assess the patient's functional abilities and social situation in order to prepare for the necessary level of assistance and support needed at home.

> *I felt as if we were expected to be preoccupied with diagnoses. However, we were more concerned with the patient's functional ability. (Nurse primary care, local process facilitator, city)*

This made some hospital nurses feel that the district nurses were uninterested in the patients' diagnoses. In the working group discussions, hospital nurses argued that many exacerbations of chronic conditions leading to hospital admissions might have been prevented had primary care done a closer follow-up of the disease. They said they were worried about the possible outcome of a care pathway that did not closely adhere to specific guidelines for each disease.

> *I wonder if a medical focus will be completely missing in the primary care program; it seems to have been given a back seat; it would appear that what I think is most important for the patient, follow-up of the disease, is wasted. (Hospital nurse, local process facilitator)*

The representatives from the patient organizations acknowledged the perspectives from both parties telling that their attention changed from focus on disease in hospital into resuming daily activities when coming home.

These different perspectives caused confusion and consternation. However, even if the district nurses considered functional ability as the most important factor in the transition phase, they were also concerned about their patients' chronic conditions in the follow-up at home. But they found that being restricted to assessment of single diseases for the three chosen diseases was unsatisfactory. Their patients rarely had only one single disease. In addition, diseases that were common in hospital might be infrequent for each nurse in primary care. They had to deal with the whole spectrum of diseases.

These concerns from the district nurses led to the proposal of developing discharge and follow-up routines applicable to most medical conditions, and common to all clinical hospital departments. This was met with astonishment by the majority of the hospital nurses.

> *There was an enormous difference between specialist care and primary care in how they approach care pathways. We found it difficult to understand why you [primary care] weren't really interested in care pathways for specific diseases, and how you could think that one common care pathway might suit many diseases. (Supervisor, Regional Health Authority)*

Disjointed collaboration in primary care

The district nurses, in cities and rural areas alike, expressed a need for closer collaboration with both specialist care and GPs, as well as routines to regulate this collaboration. In recent years they had experienced that the medical needs of their care recipients had become increasingly more complex. They often felt that they had insufficient information about their patients to provide the necessary follow-up. They could therefore feel unsure as to what to observe and how to react to changes in the patients' health.

> *When a patient is discharged the information we get is inadequate. And we can't call the GP all the time either. To be able to know that we are doing a good job, nurses need to have a proper idea of the patient's condition. I'm uncomfortable not having that type of control. (Nurse, primary care, rural area)*

At the same time, the GPs complained that home care services reacted too slowly when patients' health situations deteriorated.

> *And I've noticed that the district nurses aren't always very good at monitoring patients. I have on several occasions experienced that they have seen the patient for one or two weeks without noticing that the patient is getting very ill. (GP, city)*

The district nurses and GPs felt that there were organizational barriers to their collaboration such as geographic distance thus hindering a face-to-face relationship.

> *Nurses and doctors work closely and are on first-name terms when patients are in hospital. When the patients have had a minimal recovery, they are sent home. The possibilities for giving a good and coordinated follow-up then are completely different; in primary care, district nurses and GPs are geographically separated, might never have met each other and may not even know each other's names. The present system means that all home care service units may have to collaborate with all GPs in the municipality. (GP, city)*

Primary care perspectives gain ground

During the development process, it became evident that the primary care perspective was gaining ground; this was also apparent from the interviews. Primary care representatives were in the majority because there were more municipalities than hospitals participating in the process. In addition, primary care was represented by three experienced managers of home care services, whereas the hospitals were not represented by the management level in any of the working groups. The challenges faced in daily work in primary care and home care services and in collaboration across care levels were therefore well illustrated in the discussions. Furthermore, the representatives from primary care appeared to have a more autonomous position. The hospital nurses did not feel that they had been given a mandate to propose changes in discharge routines for the whole hospital. In the discussions, they thus focused on the disease-related content of the care pathways. This was seen as being a very narrow approach by the district nurses.

> *The primary care representatives expected us to represent the whole hospital. We were shocked. We hadn't been given a mandate to speak for the whole hospital. (Hospital nurse, local process facilitator)*

The physicians played a lesser role in the process, both in the hospitals and in primary care.

> *Even when the doctors took part in the meetings, they were only there for some of the time, and they were focused on the follow-up of single diseases. (Nurse primary care, local process facilitator, rural area)*

Merging of perspectives

In the end the participants reached a consensus. The disease-based clinical pathways in the hospital were kept as before, while a common care pathway able to include most diagnoses was designed for the transition between hospital and primary care and for the follow-up in primary care (Figure 1). In the final phase of the process, the focus was on developing structures for collaboration and the flow of information. It became evident that there was a need for detailed descriptions of procedures, responsibilities and information flow with checklists for all situations that had been identified as critical in the risk-identification phase (Figure 1).

> *Quality control of a patient's discharge and follow-up is simplified by using checklists no matter the diagnosis. They help us to remember to ask all the questions that need to be asked to ensure a proper follow-up. (Nurse primary care, local process facilitator, city)*

Discussion

Starting from the initial idea of using a disease-based model with several different care pathways, objections from primary care representatives led to the development of one common care pathway suitable for most common medical conditions covering admission and discharge from hospital as well as follow-up in primary care. However, different objectives and perspectives on patient care caused tension and obstacles between specialist care and primary care representatives in the joint process of designing clinical pathways. Table 4 summarizes how we interpret the differences that were uncovered. Primary care and hospital care pursue different professional goals and might not be fully aware of the needs and challenges of the other arena [24]. This study provides new insight into the ways in which different professional cultures play out in development processes.

Fragmentation in primary care

The increasing development of new specialties has contributed to fragmentation in health care [4,33]. Several publications have therefore pointed to primary care to ensure the continuity and integration of patients' needs and care [34]. However, the interviews in this study confirmed that there is also significant fragmentation in primary care [28]. This problem has been accentuated as the home care services in Norway have developed from being primarily a social service providing practical help and support to becoming a healthcare service with an

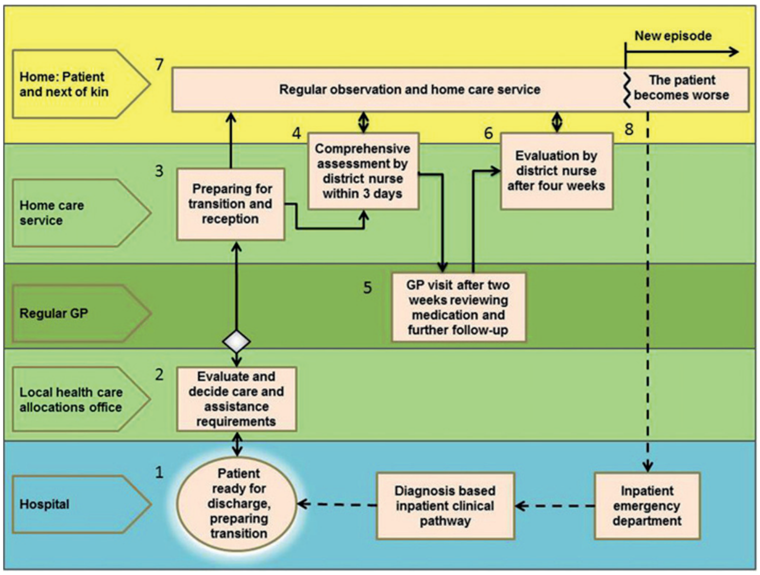

Figure 1 Common care pathway for transition from hospital and follow-up of home care recipients. The boxes represent procedures and checklists and the arrows the flow of information between involved parties. It starts with the patient being reported as ready for discharge and information is exchanged (**1** and **2**). Home care services are established (**3**), and within three days a district nurse performs a thorough and structured assessment (**4**). The patient has a consultation with the GP 14 days after discharge (**5**), and a nurse or aide performs an extended assessment during the first four weeks (**6**). A daily care plan is continuously updated (**7**), and if the patient's condition gets worse, the home care service has a routine for what to observe, whom to contact, and which information to pass on (**8**).

Table 4 Cultural differences found between specialist care and primary care for patients with home care needs

Activity	Specialist care	Primary care
Planning	Short perspective – major changes in a short time	Long perspective – small changes over time
Assessment	Diagnosis with advanced technology	Functional ability, patient preferences and degree of self-management
Diseases	Attention to one disease at a time	Simultaneous attention to all of the diseases patients have; a majority of patients have multiple diseases
Clinical guidelines	Strong adherence to clinical guidelines	Clinical guidelines for multi-morbidity hardly exist
Patient role	Passive; health personnel decide what has to be done	At home the patient decides; focus is on resuming daily activities
Decision making	Often in teams, many involved, and in a confirmed hierarchical structure	Often by health personnel alone or by few; more autonomous

important role as well in advanced medical follow-up of chronic somatic and mental conditions [35,36]. However, better care coordination between GPs and home care services has been difficult to achieve thus far [37,38]. One important measure proposed in this study, therefore, was a mandatory GP visit for all patients who are discharged from hospital and need home care services (Figure 1).

Clinical disease-based care pathways: sustainable in primary care?

The district nurses in our study were doubtful as to the usefulness of disease-based care pathways in primary care, as in their experience a large proportion of their patients had considerable co-morbidity. The prevalence of patients with multiple medical conditions increases with age and is substantial in the older population [39,40]. The specialist care informants gave an impression of district nurses not being interested in the treatment of the individual diseases. However, based on statements from the district nurses, there are reasons to believe that this was a misinterpretation. The impression was probably caused by the broad scope of measures that district nurses were concerned with in addition to treatment. They actually promoted a patient-centred approach that included functional ability, patient preferences, self-management and social needs [41]. They described that patients with chronic diseases have more common rather than differentiated needs. This, combined with the great prevalence of multi-morbidity, prepared the ground for one common clinical pathway for transition from hospital to follow-up in primary care. In the literature, care pathways based on a single medical condition are also found to be unsuitable for this patient group. This is because disease-based care pathways are founded in studies that largely exclude patients with co-morbid conditions [42]. Following clinical guidelines for individual diseases for patients with co-morbidity might even lead to potential treatment conflicts [43].

The development process

Abandoning the disease-based model in favour of a patient-centred model was not an obvious result of the process. The supervisors from the regional health authority coaching the process were familiar only with diagnosis-based clinical pathways within hospitals, and the initial idea in the project was to develop care pathways for three diagnoses, which indicated that the representatives from the hospitals would be the experts. In addition, the GPs felt most comfortable with the disease-based model. However, the lack of participation by physicians in the working groups lessened their influence on the process.

Several other factors influenced the result. This was both a top-down and bottom-up process considered to be important in such development work [44], and the project had a broad representation from hospitals, primary care and patient organizations to ensure that all the different perspectives were taken into consideration. This is believed to be important both to overcome any asymmetry between primary care and the usually dominant hospital care [24] and to obtain a result with a patient perspective that could be sustainable both within specialist and primary care.

Strengths and limitations

The results of this study came from experiences within a single regional setting. Any generalization of the findings should be made with caution. It is well known that there are major organizational differences in health care across countries that will influence and set limitations for what may be achievable and even legal. Norway has, compared to many countries, a well-developed primary care sector with an expenditure of approximately the same size as specialist care. However, the findings point to general challenges of cooperation in health care that have been thoroughly discussed in the literature [3,24,45].

A strength of the study is the use of triangulation: source triangulation by combining observations, written information from the workshops and interviews, and investigator triangulation by having several researchers with different backgrounds analyse the data and thus counteracting bias. The findings were finally validated by presenting the analyses to three of the informants, representing each of the three local working groups.

Conclusion

In this study, it was found that the merging of primary care and specialist care perspectives led to a change from developing several separate, disease-based care pathways to one patient-centred care pathway suitable for most common diagnoses. The findings in this study challenge the sustainability of the current situation where most of the care pathways across specialist and primary care are disease based. The effect on patient outcome of a patient-centred care pathway for older patients needs to be studied.

Abbreviations

COPD: Chronic obstructive pulmonary disease; GP: General practitioner; PC: Primary care.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

TR, HG, and AG designed the research. TR collected data and drafted the manuscript. TR, AG, HG, and AS participated in the data analyses. All authors provided input on the manuscript and read and approved the final version.

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References

1. *The coordination reform. Proper treatment - at the right place and right time.* Oslo: Norwegian Ministry of health and care services; 2008–2009. vol. Report no 47 to the Storting.
2. Morris J, Beaumont D, Oliver D: **Decent health care for older people.** *BMJ* 2006, **332**(7551):1166–1168.
3. Coleman EA, Berenson RA: **Lost in transition: challenges and opportunities for improving the quality of transitional care.** *Ann Intern Med* 2004, **141**(7):533–536.
4. Stange KC: **The problem of fragmentation and the need for integrative solutions.** *Ann Fam Med* 2009, **7**(2):100–103.
5. Conroy S, Ferguson C, Woodard J, Banerjee J: **Interface geriatrics: evidence-based care for frail older people with medical crises.** *Br J Hosp Med (Lond)* 2010, **71**(2):98–101.
6. Mesteig M, Helbostad JL, Sletvold O, Rosstad T, Saltvedt I: **Unwanted incidents during transition of geriatric patients from hospital to home: a prospective observational study.** *BMC Health Serv Res* 2010, **10**:1.
7. Payne S, Kerr C, Hawker S, Hardey M, Powell J: **The communication of information about older people between health and social care practitioners.** *Age Ageing* 2002, **31**(2):107–117.
8. Moore C, Wisnivesky J, Williams S, McGinn T: **Medical errors related to discontinuity of care from an inpatient to an outpatient setting.** *J Gen Intern Med* 2003, **18**(8):646–651.
9. Dancy M: **Bridging the treatment gap: the secondary care perspective.** *Heart* 2005, **91**(2):ii32–34. Discussion ii43-38.
10. Vedel I, Monette M, Beland F, Monette J, Bergman H: **Ten years of integrated care: backwards and forwards. The case of the province of Quebec, Canada.** *Int J Integr Care* 2011, **11**:e004.
11. Rudkjobing A, Olejaz M, Birk HO, Nielsen AJ, Hernandez-Quevedo C, Krasnik A: **Integrated care: a Danish perspective.** *BMJ* 2012, **345**:e4451.
12. Shepperd S, Doll H, Angus RM, Clarke MJ, Iliffe S, Kalra L, Ricauda NA, Tibaldi V, Wilson AD: **Avoiding hospital admission through provision of hospital care at home: a systematic review and meta-analysis of individual patient data.** *CMAJ* 2009, **180**(2):175–182.
13. Shepperd S, Doll H, Broad J, Gladman J, Iliffe S, Langhorne P, Richards S, Martin F, Harris R: **Early discharge hospital at home.** *Cochrane Database Syst Rev* 2009, **1**:CD000356.
14. Naylor MD, Sochalski JA: **Scaling up: bringing the transitional care model into the mainstream.** *Issue Brief (Commonw Fund)* 2010, **103**:1–12.
15. Smith SM, Allwright S, O'Dowd T: **Effectiveness of shared care across the interface between primary and specialty care in chronic disease management.** *Cochrane Database Syst Rev* 2007, **3**:CD004910.
16. Naylor MD, Brooten DA, Campbell RL, Maislin G, McCauley KM, Schwartz JS: **Transitional care of older adults hospitalized with heart failure: a randomized, controlled trial.** *J Am Geriatr Soc* 2004, **52**(5):675–684.
17. Fjaertoft H, Indredavik B, Lydersen S: **Stroke unit care combined with early supported discharge: long-term follow-up of a randomized controlled trial.** *Stroke* 2003, **34**(11):2687–2691.
18. Bolibar I, Plaza V, Llauger M, Amado E, Anton PA, Espinosa A, Dominguez L, Fraga M, Freixas M, de la Fuente JA, *et al*: **Assessment of a primary and tertiary care integrated management model for chronic obstructive pulmonary disease.** *BMC Publ Health* 2009, **9**:68.
19. Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS: **Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial.** *JAMA* 1999, **281**(7):613–620.
20. Rytter L, Jakobsen HN, Ronholt F, Hammer AV, Andreasen AH, Nissen A, Kjellberg J: **Comprehensive discharge follow-up in patients' homes by GPs and district nurses of elderly patients. A randomized controlled trial.** *Scand J Prim Health Care* 2010, **28**(3):146–153.
21. Bodenheimer T, Wagner EH, Grumbach K: **Improving primary care for patients with chronic illness: the chronic care model, Part 2.** *JAMA* 2002, **288**(15):1909–1914.
22. Coleman K, Austin BT, Brach C, Wagner EH: **Evidence on the Chronic Care Model in the new millennium.** *Health Aff (Millwood)* 2009, **28**(1):75–85.
23. *Patient-centered medical home.* [http://pcmh.ahrq.gov/portal/server.pt/community/pcmh__home/1483/pcmh_home_v2]
24. Hellesø R, Fagermoen MS: **Cultural diversity between hospital and community nurses: implications for continuity of care.** *International Journal of Integrated Care* 2010, **10**:e036.
25. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M: **Developing and evaluating complex interventions: the new Medical Research Council guidance.** *BMJ* 2008, **337**:a1655.
26. Garasen H, Hendriksen C: **Health care for the elderly–perspectives in relation to implementation of results from intervention studies in Norway and Denmark.** *Scand J Public Health* 2009, **37**(3):223–226.

27. *The Regular GP Scheme has now been introduced.* http://www.regjeringen.no/en/dep/hod/documents/veiledninger_og_brosjyrer/2001/The-Introduction-of-a-Regular-GP-Scheme.html?id=419359.
28. Johnsen JR: In *Health Systems in Transition.* Edited by Bankauskaite V. Norway: World health Organization; 2006:187.
29. *Patient process redesign.* http://www.npc.nhs.uk/improvement_tools/process/less_than_sixty.php.
30. *What is Lean.* [http://www.lean.org/whatslean/]
31. Malterud K: **Qualitative research: standards, challenges, and guidelines.** *Lancet* 2001, **358**(9280):483–488.
32. Giorgi A: *Sketch of a psycological phenomenological method, in Phenomenology and psycological research.* Pittsburg, PA: Duquesne University Press; 1985.
33. Barondess JA: **Specialization and the physician workforce: drivers and determinants.** *JAMA* 2000, **284**(10):1299–1301.
34. Stange KC, Ferrer RL: **The paradox of primary care.** *Ann Fam Med* 2009, **7**(4):293–299.
35. Romøren TI: **[Community nursing - a shift in responsibilities and target groups].** *Aldring og livsløp* 2007, **1**:9.
36. Brevik I: *The new home care services - far more than old age welfare services,* Volume 2. Oslo: Norwegian Institute for Urban and Regional Research; 2010.
37. Kalseth B, Midttun L, Paulsen B, Nygård L: *[Development in municipal and hospital health care - service development and interaction]*, Sintef rapport. Trondheim: Sintef; 2004:145.
38. *[Medical services to recipients of non- institutionalised local authority assistance].* Oslo: Norwegian Directorate of Health; 2006.
39. Valderas JM, Mercer SW, Fortin M: **Research on patients with multiple health conditionns: different constructs, different views, one voice.** *Journal of Comorbidity* 2011, **1**:1–3.
40. Wolff JL, Starfield B, Anderson G: **Prevalence, expenditures, and complications of multiple chronic conditions in the elderly.** *Arch Intern Med* 2002, **162**(20):2269–2276.
41. Robinson JH, Callister LC, Berry JA, Dearing KA: **Patient-centered care and adherence: definitions and applications to improve outcomes.** *J Am Acad Nurse Pract* 2008, **20**(12):600–607.
42. Tinetti ME, Bogardus ST Jr, Agostini JV: **Potential pitfalls of disease-specific guidelines for patients with multiple conditions.** *N Engl J Med* 2004, **351**(27):2870–2874.
43. Caughey GE, Roughead EE, Shakib S, McDermott RA, Vitry AI, Gilbert AL: **Comorbidity of chronic disease and potential treatment conflicts in older people dispensed antidepressants.** *Age Ageing* 2010, **39**(4):488–494.
44. Stein KV: *The Cause for Action? Decision Making and Priority Setting in Intergrated Care,* Doctoral Thesis. Vienna: Vienna University of Economics and Business Administration; 2010.
45. Plsek PE, Greenhalgh T: **Complexity science: The challenge of complexity in health care.** *BMJ* 2001, **323**(7313):625–628.

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Implementing a care pathway for elderly patients, a comparative qualitative process evaluation in primary care

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Abstract

Background: In Central Norway a generic care pathway was developed in collaboration between general hospitals and primary care with the intention of implementing it into everyday practice. The care pathway targeted elderly patients who were in need of home care services after discharge from hospital. The aim of the present study was to investigate the implementation process of the care pathway by comparing the experiences of health care professionals and managers in home care services between the participating municipalities.

Methods: This was a qualitative comparative process evaluation using data from individual and focus group interviews. The Normalization Process Theory, which provides a framework for understanding how a new intervention becomes part of normal practice, was applied in our analysis.

Results: In all of the municipalities there were expectations that the generic care pathway would improve care coordination and quality of follow-up, but a substantial amount of work was needed to make the regular home care staff understand how to use the care pathway. Other factors of importance for successful implementation were involvement of the executive municipal management, strong managerial focus on creating engagement and commitment among all professional groups, practical facilitation of work processes, and a stable organisation without major competing priorities. At the end of the project period, the pathway was integrated in daily practice in two of the six municipalities. In these municipalities the care pathway was found to have the potential of structuring the provision of home care services and collaboration with the GPs, and serving as a management tool to effect change and improve knowledge and skills.

Conclusion: The generic care pathway for elderly patients has a potential of improving follow-up in primary care by meeting professional and managerial needs for improved quality of care, as well as more efficient organisation of home care services. However, implementation of this complex intervention in full-time running organisations was demanding and required comprehensive and prolonged efforts in all levels of the organisation. Studies on implementation of such complex interventions should therefore have a long follow-up time to identify whether the intervention becomes integrated into everyday practice.

Keywords: Care pathway, Continuity of patient care, Checklists, Primary care, Home care services, Implementation, Complex intervention, Process evaluation, Health care quality, Normalization Process Theory

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Background

The complexity of elderly patients' health situation requires more coordinated health care across health care levels than what is currently offered, especially in the transitional phase between hospital discharge and primary care [1-3]. Several strategies, including a range of interventions, have been developed to improve continuity of care across care levels; e.g. individualised discharge planning [4], liaison nurses and discharge coordinators [5], enhanced multidisciplinary team work [6], transitional and intermediate care units [7], integrated care pathways [8] and integrated medical and social care [9]. These are complex interventions including multiple components and personnel, often across different organisations and care levels. A successful implementation may be crucial for the effect. Thorough analysis of the implementation process is therefore called for when introducing new interventions [10].

In 2009, a generic care pathway (**Pa**tient **T**rajectory for **H**ome-dwelling elders – PaTH, Figure 1), intended to improve continuity of care and reduce the need of institutional care, was developed and introduced in six municipalities in Central Norway. PaTH was the result of a bottom-up process in which home care professionals, general practitioners, patient organisations, and hospital employees (nurses and physicians) defined challenges and proposed solutions in transitional care and follow-up [2].

The aim of this study was to investigate the process of implementing PaTH into everyday practice by comparing the joint experiences of health care professionals and managers in home care services between the municipalities where it had been introduced.

Methods

Design

This was a qualitative study where the process of implementing PaTH was compared in six municipalities through individual and focus group interviews of leaders and regular staff, supported by reflexive field notes and minutes from meetings.

Setting, informants and ethics

In Norway health care and social care services are universally accessible, and are mainly financed by and

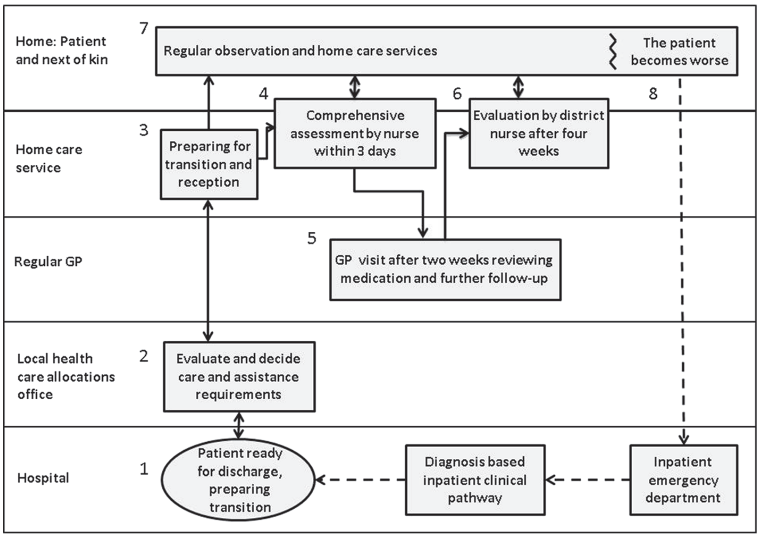

Figure 1 Generic care pathway (PaTH), for transition from hospital and follow-up of home care recipients [2]. The boxes represent procedures and checklists and the arrows the flow of information between involved parties. It starts with the patient being reported ready for discharge and information is exchanged (1, 2 and 3). Within three days a home care nurse performs a thorough and structured assessment (4). The patient has a consultation with the GP 14 days after discharge (5), and a nurse or nursing assistant performs an extended assessment during the first four weeks (6). A daily care plan is continuously updated (7), and if the patient's condition gets worse, the home care service has a routine for what to observe, whom to contact and which information to pass on (8). The checklists included practical issues (e.g. whether assistive devices had been ordered and when they would be installed), health issues (e.g. review of medication), social conditions (e.g. if the present accommodation was appropriate for the patients' level of functioning) and physical and cognitive functioning (e.g. ability to climb stairs, reduced memory). Some checklists were to be used by nurses only (3 and 4), while others were also to be used by nursing assistants (6 and 8). All of the issues on the lists were not necessarily relevant for all patients and the nurses and nursing assistants had to use their professional insight to decide what to assess and how to follow-up.

provided within the public sector [11]. Local authorities (municipalities), the lowest level of public administration, are responsible for providing primary health care, including home care and medical services [11] (Table 1).

PaTH was introduced in the municipalities in the period October 2009 – March 2010. All home care staff received detailed instruction about PaTH at the time of introduction in the form of a one-day course where four of the authors of the present article (TR, LK, AG and HG) gave lectures during the introduction course. The home care managers were responsible for further training in the home care units. To monitor progress of the implementation of PaTH, TR had monthly conference calls with the head nurses or home care managers in each of the municipalities. LK was a manager in one of the participating municipalities, but was not involved in the interviews.

All other home care managers and all head nurses in the home care units that introduced PaTH participated in the interviews in the current study. Furthermore, they recruited regular staff (nurses and nursing assistants) who had worked in home care since the introduction of PaTH.

Home care managers received written information about the study before the interviews. TR explained the purpose of the study to all the informants, that citations would be anonymous, that they could ask for statements to be deleted, and that the interviews would be handled confidentially. All informants signed an informed consent document before participation. The study was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway and the Ombudsman for Research and Social Science Data Service.

Data collection

Focus group interviews and individual interviews were the main data sources. Managers and head nurses from all home care units participated in two focus group interviews in November 2011, 20 – 25 months after the introduction of PaTH (Table 2). The other focus group interviews took place in each municipality from March 2012 to February 2013 and included regular staff as well as the management level. Management and regular staff were interviewed separately for the informants to speak more freely. TR led all interviews and co-author EH participated in the two last focus group interviews.

A semi-structured interview guide, used during the interviews, included the following topics: how the informants had been involved with the care pathway, their initial expectations, how it had been introduced at their workplace, the efforts invested to take it into use, challenges, promoting factors, assessments of benefits, and if and why it was dismissed or integrated and sustained in daily use.

Data sources, in addition to interviews, were minutes from the monthly conference calls with the head nurses or home care managers during the first year. Furthermore, TR made reflexive field notes on the overall impression of the implementation process when visiting the municipalities in 2012. The field notes were based on the interviews, assessments on how PaTH was integrated in the electronic health records, and informal discussions with the home care managers.

Theoretical framework

Among the many different frameworks used in implementation studies [12-16], we chose the Normalization Process Theory (NPT) to guide our analyses, as it offers

Table 1 Ambulant home care services and general practices in six Norwegian municipalities (A-F) introducing PaTH

Information about the municipalities	A	B	C	D	E	F
	City	Rural area	Small town	Rural area	Rural area	Rural area
Inhabitants	180 000	6000	11 000	4000	7000	10 000
Home care recipients[1]	3000	160	350	170	300	200
Home care units[2]	12	1	1	1	1	1
Home care managers[3]	12	1	1	1	1	1
Head nurses[4]	12	1	2	1	5	3
Regular staff[5]	337	24	42	29	53	28
General practices	38	1	2	1	2	2
General practitioners (GPs)[6]	140	6	8	4	6	7

[1] Persons who receive health and social care because of reduced functional level. Care may be provided several times a day and at night in their own homes.

[2] Every municipality has one or more home care units, which are divided in teams serving the population in a geographical area.

[3] Responsible for economy, personnel and quality in home care services.

[4] Responsible for daily professional activities, including guidance and supervision of staff.

[5] Includes nurses and nursing assistants. The numbers refer to full-time equivalents.

[6] Medical services to home-dwelling inhabitants are delivered by GPs who usually work in group practices. GPs operate independently of the home care services. Due to the inhabitants' right of free choice of a regular GP, the GPs may have patients in common with all home care units in the municipality where they work and also in home care units in neighbouring municipalities.

Table 2 The number and type of interviews and informants by year

Year	Type of informants	Number of focus group interviews	Number of individual interviews	Total number of informants
2011[1]	Home care managers and head nurses	2	0	13
2012[2]	Home care managers and head nurses	2	2	7
	Nurses and nursing assistants	6	0	26
2013[2]	Home care managers	1	0	6
	Nurses and nursing assistants	1	0	8
Total		12	2	60

[1]Focus group interviews with representatives from all municipalities in November 2011.
[2]Focus group interviews and individual interviews in every municipality March 2012 – January 2013.

a framework for evaluation of complex interventions and for comparing the implementation processes across different sites [17-19]. It helps to explain the processes by which complex interventions become, or do not become, integrated in everyday health care practice (i.e. 'is normalised') which was the ambition when introducing PaTH [20]. NPT has four core constructs which are all seen as essential for new working practices to become a natural part of daily work: *coherence* (making tasks meaningful and understandable), *cognitive participation* (building commitment and engagement), *collective action* (efforts and resources invested to make the intervention function), and *reflexive monitoring* (assessment of benefit).

Data analyses

The interviews were audio-recorded and transcribed verbatim, checked, anonymised, and corrected against the audio files by the first author (TR). In accordance with Malterud's method for systematic text condensation [21], all the authors independently first read all the interviews to get an overview of the material and to identify preliminary themes associated with implementation of PaTH. The preliminary themes were first discussed by the authors TR, EH, HG and LK. TR identified 'meaning units' that were classified into themes and subthemes. These were subsequently refined through discussions among all the authors in an iterative process. TR wrote a summary of the subtheme contents and identified illustrative quotations. In the last step, the NPT framework was used to map the themes to facilitate a systematic comparison between the municipalities. The comparison is based on what was perceived to be the common understanding of the implementation process among the informants from each municipality 24 or 32 months after PaTH was introduced. Minutes from conference calls together with the reflexive field notes, supplemented the analyses of the interviews.

TR and EH re-read the interviews, field notes, and the minutes after the analyses to validate whether the synthesis and illustrative quotations still reflected the original context appropriately. The results were presented to the home care managers in all municipalities for identification of any apparent misunderstandings. A few details on value for managers and user friendliness in one municipality were commented on and subsequently corrected.

Results

Home care professionals in all municipalities used PaTH when interviewed in 2011. At the time of the interviews in 2012/2013, PaTH was used in full scale in daily work in municipalities A and B (Table 3). Some elements of PaTH was used in two municipalities (C and D), but occasionally and not by all staff, and in the last two municipalities (E and F) PaTH was discontinued. Key themes and subthemes of importance for the implementation process, mapped onto the four main constructs of NPT, are summarised in Table 3 and are further detailed below.

Makes sense

As home care professionals in all participating municipalities had been involved in development of PaTH according to their own perceived needs for improvements, informants from all municipalities expected PaTH to be useful; i.e. to improve collaboration with GPs and hospitals and the quality of service delivery within the home care services. However, the process of creating a collective understanding of responsibilities and how to use PaTH was found to be more demanding than expected:

> *A lot of people seem to have trouble understanding what actually has to be done. There is an enormous need for guidance. At first we thought it had been understood and would be used, but.... Experience has shown that an awful lot of supervision and guidance is needed so that they really understand the how's and why's of the pathway. (Head nurse, municipality A)*

The main challenge was said to be uncertainty regarding how to observe, assess, act, and document issues on the checklists; especially for nursing assistants who were facing new roles and responsibilities. Their

Table 3 Differences in implementation status and implementation process in six municipalities (A-F)

	Municipalities					
	A	**B**	**C**	**D**	**E**	**F**
	PaTH in use in full scale[1]		**Elements of PaTH in use**[1]		**PaTH not in use**[1]	
Makes sense (coherence[2]**)**						
Expecting PaTH to be useful	Yes	Yes	Yes	Yes	Yes	Yes
Regular staff understood how to use PaTH	Mixed	Mixed	Mixed	Mixed	Mixed	Mixed
Commitment and engagement (cognitive participation[2]**)**						
Sustained leadership	Yes	Yes	No	No	No	No
Practice in using checklists	Intensive	Intensive	Minimal	Minimal	Minimal	Minimal
General attention to PaTH at workplace	Yes	Yes	No	Nurses only	No	No
Facilitating use of PaTH (collective action[2]**)**						
Extra personnel resources	Yes	Yes	No	Yes	No	No
Major competing priorities	No	No	No	No	Yes	Yes
Usability in electronic health record	Good	Fair	Poor	Poor	Poor	Poor
Working schedule facilitated for PaTH	Yes	Yes	No	No	No	No
Checklists incorporated in daily routines	Yes	Yes	No	No	No	No
Value of PaTH (reflexive monitoring[2]**)**						
Impact on collaboration with the hospital	Mixed	Mixed	No	No	No	No
Impact on collaboration with GPs	Yes	Yes	No	Yes	No	No
Impact on service quality	Yes	Yes	No	Yes	No	Yes
Value for individual nurse/nursing assistant	Yes	Yes	No	No	No	No
Valued as a management tool	Yes	Yes	No	Yes	No	No

[1] Assessed 24 months (B-F) and 32 months (A) after introduction of PaTH in the municipalities.
[2] Core constructs of the Normalization Process Theory.

traditional role was mainly to assist patients with practical issues, so they were not familiar with systematic observations, assessments, and documentation of health and functional issues. Some municipalities did not succeed with involving nursing assistants or did not prioritise it.

Engagement and commitment

Some home care managers underlined the necessity of sustained strong leadership in building and maintaining engagement, understanding and commitment of PaTH:

> *We're not only introducing checklists but also changing the way we think and the way we do things. We have to change our habits, which means that we have to think long-term.* (Home care manager, municipality F)

The head nurses who were expected to drive the implementation work, all described this as very laborious and time consuming. Involving the regular staff was especially difficult in municipalities C-F due to unexpected loss of key personnel, too much work for the head nurses, or too little support from the home care managers:

> *We were pretty pushed for time and to make matters worse this came on top of everything else. Maybe the checklists weren't given priority. Then we just have to fit it in when we can. It's frustrating when you have to fit it in between everything else. (Head nurse, Municipality C)*

Engagement and commitment was clearly affected by the attention given to PaTH at the workplaces. All informants said they received individual guidance when needed, but informants from three municipalities (C, E and F) were not able to recall any general attention to PaTH at the workplace after the introduction course. In municipality D, PaTH was discussed only at nurse meetings. Informants from the municipalities A and B said that PaTH was on the agenda in all common meetings at the work place, and that it was referred to in many other settings; e.g. discussions of complicated patient cases, unwanted incidents, and collaboration with the hospital and GPs:

> *We have to keep it in focus and I make sure that it is an issue in all of our meetings. The only way to ensure that people really understand is to continuously repeat yourself. I try to point out, by using examples, how*

> *negative the consequences may be if you don't use the checklists, how much extra work it can mean. (Head nurse, Municipality A)*

The amount of practice with using PaTH checklists was also considered important. Informants from four of the municipalities (C-F) were only able to recall having used a checklist once or twice themselves and never really got used to them:

> *We were more optimistic in the beginning. We were going to manage this! But motivation waned as we didn't use the checklists very often. I think it would have been better if we had used them a lot straight away so that we could have gotten used to them and had them at our fingertips. (Head nurse, municipality E)*

In the municipalities A and B, management decided that to get practice, all staff were to use the checklists both for patients discharged from hospital and for all other home care recipients. Therefore, the staff got much more training in using and understanding the elements of the checklists than at the other sites, and in particular nursing assistants were involved to a greater extent. In these municipalities the main effort during the first year was to get the staff to use the checklists and familiarise themselves with them. Later, the focus was shifted to the content and the quality of documentation related to the checklists. The informants from these municipalities found that the quality of assessments and measures improved over time.

Facilitating use of PaTH

In municipalities A, B and D the executive municipal management was said to be a driving force by setting clear requirements for the implementation and supplying extra personnel resources to facilitate implementation of the care pathway and guide the staff. In municipalities A and D support was provided at the administrative level, while in municipality B extra personnel was provided in the home care unit. In municipalities E and F, the implementation work was complicated by concomitant economic cutbacks and major reorganisations in the municipalities.

Efforts made to ensure usability of PaTH in daily working practices differed between the municipalities. The checklists were incorporated into electronic health records (EHR) in all of the municipalities, but accessibility of PaTH in the health records varied:

> *The check lists were in the wrong place in the health records and it took ages to find them when you needed to use them. (Nurse, municipality E)*

In municipality A the informants described a system where the templates in the EHR were adapted to the checklists in PaTH. This made the checklists easy to find and complete. The informants considered such facilitation as important for the success of the implementation.

Facilitating the working schedule to PaTH was also considered crucial for implementing the care pathway in daily working practices. In municipalities C-F the use of PaTH was simply added on top of the normal workload. The individual staff member had to create space for this extra work by asking their colleagues to take over some of their other tasks. In municipalities A and B dedicated personnel were responsible for creating space on the task lists for all staff:

> *Initially we had to make time ourselves to be able to do it. That was a bit frustrating. We had to organise things in the morning and ask colleagues to take over some of our patients to make time. That caused contention because they already felt that they had more than enough to do. But now we only have to let the people who allocate duties know and they sort it out. It works well now. (Nurse, municipality B)*

Nurses and nursing assistants in municipalities A and B, who had more experience with the checklists than in the other municipalities, found ways to further incorporate the use of checklists in daily routines. The informants said that they had first slavishly gone through each item on the checklist during one home visit. They found this to be excessively time-consuming, and eventually changed their approach. They found that several issues could just as easily be observed while they were providing their normal services. Furthermore, items in some of the checklists could be evaluated over subsequent visits. This way the checklists were more naturally incorporated into daily routines and were perceived as less of a burden.

Value of PaTH

Opinions as to the benefits of PaTH differed. In municipality E the primary objective of implementing PaTH had been to achieve improved collaboration with the hospital and GPs. Their motivation to use PaTH waned when they experienced that the hospitals and GPs showed little or no interest in the new, agreed procedures:

> *Collaboration with the hospital [about the care pathway] didn't really get started. The hospital never had the information we asked about, they hadn't collected it. That was desperately frustrating. We began to lose faith and we felt it might not be worth the effort. We felt that it [the pathway] had just become an obstacle. (Head nurse, municipality E)*

A lack of awareness within the hospitals was reported by all the informants, and this was not found to improve.

However, some informants said that they still felt that they managed to get more relevant information during transition between care levels as they kept on insisting on being given information in accordance with the agreed procedures in PaTH. They found this to save them considerable work later and they experienced that unwanted incidents during transition, especially related to medication errors, were reduced.

In municipalities A, B and D informants reported that both collaboration and the exchange of information with GPs had improved; in the other municipalities informants reported that this was unchanged.

Informants from municipalities A, B, D and F reported that PaTH had an impact on the service quality: The new routines and use of the checklists made them more observant and helped them to a greater extent to detect and prevent potential problems to their home care recipients:

> *We are more on the ball now and pick things up much earlier than before. And because of that we are better at intervening earlier so that we avoid people being admitted to hospital. (Nurse, municipality B)*

In the two municipalities were PaTH was integrated in daily working practices (A and B), PaTH was found to be valuable both for the regular staff and the managers. The informants said they felt that their professional standard had been raised and that their jobs were now more interesting. The home care managers found PaTH useful for getting an overview of skills and needs for guidance among the staff. As staff in home care services work alone in the patients' homes, their professional competence in observing, assessing, and documenting health issues had been difficult to evaluate. Now, the managers were able to uncover individual and collective strengths and weaknesses to a greater extent by checking individual patient assessments through the structured documentation in the EHR. This helped them to better adapt individual and collective training and guidance to actual needs and thus improve knowledge and skills. Furthermore, PaTH was valued as a useful management tool to achieve a more efficient organisation:

> *A consequence of PaTH is that the unit is now well organised. Peoples' responsibilities are clearer. This has reduced the number of discrepancies and quality is better. The unit now works much more like a piece of well-oiled machinery. (Home care manager, group A)*

Discussion

The municipalities that gave the implementation high and persistent priority within all core constructs of NPT succeeded in incorporating the care pathway in daily working practices; i.e. two of the six municipalities in our study. The implementation of PaTH was found to be demanding and the amount of work needed for successful implementation generally underrated; the two municipalities that experienced major competing priorities during the implementation period ended up discontinuing PaTH despite initial enthusiasm and high expectations. The factors that most clearly differentiated the municipalities from each other were strong management focus on creating engagement and commitment and on practical facilitation for use of PaTH. However, the study demonstrated that all factors identified to embed the new practice mutually influenced each other: When work processes were facilitated (collective action) and intensive work was invested to ensure that all employees gained experience with the checklists (cognitive participation), the employees got a better understanding of their roles and responsibilities and how to use the tool (coherence) and found a way to incorporate the checklist in daily work (collective action). Furthermore, by getting more experience both managers and regular staff found that the new procedures were useful for the patients, the individual professionals, and the organisation of services (reflexive monitoring). This increased motivation, engagement, and commitment both at the staff and management levels (coherence and cognitive participation).

This non-linear relationship and dynamic interplay of factors in NPT was underlined by May and Finch when they presented the theory [17]. Still, studies applying NPT often highlight issues within one of the constructs as the most important challenges or crucial drivers in the implementation [22-25]. Lack of coherence is often pointed to as an important challenge to implementation processes; the intervention does not make sense or is met with conflicting attitudes [22,23]. Implementation studies on integrated care models from France and Sweden [26,27], argue that for new care models to be accepted, integrated, and sustained in daily work, they must be experienced as effectively dealing with real problems in everyday practice. The same studies conclude that bottom-up processes with collaborating parties, as in our study, are effective in developing such care models.

Our study shows that bottom-up processes and enthusiasm is not enough. Complex interventions like PaTH also have to be actively supported by the management levels to be implemented in the organisation in a sustainable manner. This is supported by other implementation studies [27,28] which find that active involvement by the executive management can be crucial to achieve organisational change, not least to ensure that the intervention matches strategic and organisational priorities. Furthermore, support from the executive level signalises the importance and prestige of the work [27].

For new procedures or organisational change to be embedded and sustained, it must be experienced as useful [29,30]. In the municipalities where PaTH sustained, it was valued both by the regular staff and the managers as a means to raise professional standards and organisation of care. PaTH was thus found to have a potential of fusing professional and managerial concerns in primary care. A study from the UK found, correspondingly, that when care pathways were successfully implemented in hospitals, both managerial and professional needs were met; the care pathways provided a means for managers to better plan and evaluate care processes while the patient-centred focus was valued by professionals [31].

Methodological strengths and limitations

The main strength of this study was the number of informants and that interviews were done in several rounds and up to three years later. This allowed for a thorough investigation of the feasibility and sustainability of the care pathway. The last interviews were carried out two and three years after the introduction of PaTH, which may increase the risk of recall bias from the early introduction phase. The interviews were, however, supplemented by minutes from conference calls during the first year to ensure valid results.

The selection procedure of regular staff informants by the head nurses or home care managers had an inherent risk of ending up with those who were most positive. We found no indications that this was the case, as the staff advocated both frustrations and enthusiasm. One member of the research group (LK) managed one of the home care units in the project. To avoid bias, LK did not take part in the data collection and several researchers with different professional backgrounds analysed the data. LK's participation in the research group was considered to strengthen the analysis as she had detailed understanding of the context of the home care services. The findings were also validated by presenting them to and getting approval from all the home care managers in all municipalities.

We consider findings regarding the implementation process to be valid beyond our study, as the identified factors were recognisable from other studies and within the theoretical framework of NPT, a theory that has proved to be valid in different contexts in other countries [19]. PaTH itself may however not be a feasible care pathway in countries other than Norway, as health care is organised differently.

Implications of findings

Our findings illustrate how a comparative process evaluation and use of the NPT framework may help to identify hindrances and facilitators in the implementation process. This is important both to understand the implementation process, to assess the implementation potential before deciding on further deployment of the care pathway and to identify contextual factors of importance when evaluating the effect in a randomised controlled trial [30,32].

Conclusion

The generic care pathway for elderly patients has a potential of improving follow-up in primary care by meeting professional and managerial needs for improved quality of care, as well as more efficient organisation of home care services. However, implementation of this complex intervention in full-time running organisations was demanding and required comprehensive and prolonged efforts in all levels of the organisation. Studies on implementation of such complex intervention should therefore have a long follow-up time to identify whether the intervention becomes integrated in everyday practice.

Abbreviations

EHR: Electronic health record; GP: General practitioner; NPT: Normalization process theory; PaTH: Patient trajectory for home–dwelling elders; UK: United Kingdom.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

TR, HG and AG designed the research. TR collected all data from interviews and electronic patient records, performed the analyses, and drafted the manuscript. EH was co-moderator in two interviews. HG, AS, EH, LK and AG participated in data analysis and provided input on the manuscript. All authors read and approved the final version.

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References

1. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. Lancet. 2012;380(9836):37–43.
2. Rosstad T, Garasen H, Steinsbekk A, Sletvold O, Grimsmo A. Development of a patient-centred care pathway across healthcare providers: a qualitative study. BMC Health Serv Res. 2013;13:121.
3. Stange KC. The problem of fragmentation and the need for integrative solutions. Ann Fam Med. 2009;7(2):100–3.
4. Mistiaen P, Francke AL, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: a systematic meta-review. BMC Health Serv Res. 2007;7:47.
5. Jolly K, Bradley F, Sharp S, Smith H, Mant D. Follow-up care in general practice of patients with myocardial infarction or angina pectoris: initial results of the SHIP trial. Southampton Heart Integrated Care Project. Fam Pract. 1998;15(6):548–55.
6. Smith SM, Soubhi H, Fortin M, Hudon C, O'Dowd T. Managing patients with multimorbidity: systematic review of interventions in primary care and community settings. BMJ. 2012;345:e5205.
7. Garåsen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomized controlled trial. BMC Public Health. 2007;7:68.
8. Van Houdt S, Heyrman J, Vanhaecht K, Sermeus W, De Lepeleire J. Care pathways across the primary-hospital care continuum: using the multi-level framework in explaining care coordination. BMC Health Serv Res. 2013;13:296.
9. Bernabei R, Landi F, Gambassi G, Sgadari A, Zuccala G, Mor V, et al. Randomised trial of impact of model of integrated care and case management for older people living in the community. BMJ. 1998;316(7141):1348–51.
10. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.
11. Romoren TI, Torjesen DO, Landmark B. Promoting coordination in Norwegian health care. Int J Integr Care. 2011;11(Spec 10th Anniversary Ed):e127.
12. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.
13. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q. 2004;82(4):581–629.
14. May CR, Mair F, Finch T, MacFarlane A, Dowrick C, Treweek S, et al. Development of a theory of implementation and integration: Normalization Process Theory. Implement Sci. 2009;4:29.
15. Ferlie EB, Shortell SM. Improving the quality of health care in the United Kingdom and the United States: a framework for change. Milbank Q. 2001;79(2):281–315.
16. Grol R, Wensing M. What drives change? Barriers to and incentives for achieving evidence-based practice. Med J Aust. 2004;180(6 Suppl):S57–60.
17. May C, Finch T. Implementing, Embedding, and Integration Practices: An Outline of Normalization Process Theory. Sociology. 2009;43(3):535–54.
18. Normalization Process Theory On-line Users' Manual and Toolkit [http://www.normalizationprocess.org/]
19. McEvoy R, Ballini L, Maltoni S, O'Donnell CA, Mair FS, Macfarlane A. A qualitative systematic review of studies using the normalization process theory to research implementation processes. Implement Sci. 2014;9:2.
20. May C, Finch T, Mair F, Ballini L, Dowrick C, Eccles M, et al. Understanding the implementation of complex interventions in health care: the normalization process model. BMC Health Serv Res. 2007;7:148.
21. Malterud K. Systematic text condensation: a strategy for qualitative analysis. Scand J Public Health. 2012;40(8):795–805.
22. Bamford C, Heaven B, May C, Moynihan P. Implementing nutrition guidelines for older people in residential care homes: a qualitative study using Normalization Process Theory. Implement Sci. 2012;7:106.
23. Lloyd A, Joseph-Williams N, Edwards A, Rix A, Elwyn G. Patchy 'coherence': using normalization process theory to evaluate a multi-faceted shared decision making implementation program (MAGIC). Implement Sci. 2013;8(1):102.
24. Gask L, Bower P, Lovell K, Escott D, Archer J, Gilbody S, et al. What work has to be done to implement collaborative care for depression? Process evaluation of a trial utilizing the Normalization Process Model. Implement Sci. 2010;5:15.
25. Murray E, Burns J, May C, Finch T, O'Donnell C, Wallace P, et al. Why is it difficult to implement e-health initiatives? A qualitative study. Implement Sci. 2011;6:6.
26. de Stampa M, Vedel I, Mauriat C, Bagaragaza E, Routelous C, Bergman H, et al. Diagnostic study, design and implementation of an integrated model of care in France: a bottom-up process with continuous leadership. Int J Integr Care. 2010;10:e034.
27. Duner A, Blomberg S, Hasson H. Implementing a continuum of care model for older people-results from a Swedish case study. Int J Integr Care. 2011;11:e136.
28. Rycroft-Malone J, Seers K, Crichton N, Chandler J, Hawkes CA, Allen C, et al. A pragmatic cluster randomised trial evaluating three implementation interventions. Implement Sci. 2012;7:80.
29. Kotter J. Leading change. Boston: Harvard Business Review Press; 2012. p. 121–36.
30. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. BMC Med. 2010;8:63.
31. Whittle C, Hewison A. Integrated care pathways: pathways to change in health care? J Health Organ Manag. 2007;21(3):297–306.
32. Lewin S, Glenton C, Oxman AD. Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study. BMJ. 2009;339:b3496.

Paper III

Generic care pathway for elderly patients in need of home care services after discharge from hospital: a cluster randomised controlled trial

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Abstract

Background

Improved discharge arrangements and targeted post-discharge follow-up can reduce the risk of adverse events after hospital discharge for elderly patients. Although more care is to shift from specialist to primary care, there are few studies on post-discharge interventions run by primary care. A generic care pathway, **Pa**tient **T**rajectory for **H**ome-dwelling elders (PaTH) including discharge arrangements and follow-up by primary care, was developed and introduced in Central Norway Region in 2009, applying checklists at defined stages in the patient trajectory. In a previous paper, we found that PaTH had potential of improving follow-up in primary care. The aim of this study was to establish the effect of PaTH – compared to usual care – for elderly in need of home care services after discharge from hospital.

Methods

We did an unblinded, cluster randomised controlled trial with 12 home care clusters. Outcomes were measured at the patient level during a 12 months follow-up period for the individual patient and analysed applying linear and logistic mixed models. Primary outcomes were readmissions within 30 days and functional level assessed by Nottingham extended ADL scale. Secondary outcomes were number and length of inpatient hospital care and nursing home care, days at home, consultations with the general practitioners (GPs), and health related quality of life (SF-36).

Results

163 patients were included in the PaTH group (six clusters) and 141 patients received care as usual (six clusters). We found no statistically significant differences between the groups for primary and secondary outcomes except for more consultations with the GPs in PaTH group

(p = 0.04). Adherence to the intervention was insufficient as only 36 % of the patients in the intervention group were assessed by at least three of the four main checklists in PaTH, but this improved over time.

Conclusions

Lack of adherence to PaTH rendered the study inconclusive regarding the elderly's functional level, number of readmissions after hospital discharge, and health care utilisation except for more consultations with the GPs. A targeted exploration of prerequisites for implementation is recommended in the pre-trial phase of complex intervention studies.

Trial registration: Clinical Trials.gov NCT01107119, registered 2010.04.18.

Background

For elderly patients characterised by multimorbidity, functional decline and complex medical regimens, the transition between general hospitals and primary care is associated with a risk of adverse events; especially concerning medication discrepancies [1, 2], insufficient information transfer [2, 3], and inadequate follow-up in primary care [2]. Three systematic reviews from 2012-2014 [4-6] found that several types of interventions may improve transition across care settings; multicomponent interventions incorporating both pre-discharge and post-discharge interventions seems to be most effective in reducing post-discharge adverse events [5]. Although there is broad consensus that more care must shift from hospital to primary care [7, 8], only few of the papers included in the reviews were studies of post-discharge intervention performed by primary care. However, two Scandinavian studies have shown that post-discharge interventions run by primary care can reduce readmissions [9, 10] , dependence on municipal care [10] and mortality [11].

The care pathway, ′**Pa**tient **T**rajectory for **H**ome-dwelling elders′ (PaTH) was developed [12] and introduced [13] in Central Norway region in 2009 to ensure adequate pre-discharge planning and coordination between general hospitals and primary care for elderly patients in need of home care services after hospital discharge. Furthermore, post-discharge follow-up by home care professionals and general practitioners (GPs) was structured to ensure adequate care of medical conditions, prevent functional decline and ensure sufficient social support by introducing checklists at defined stages in the patient trajectory (Table 1). PaTH was developed by health care professionals from six municipalities and three hospitals who decided on a generic care pathway – suitable for patients with most diagnoses– in contrast to care pathways developed and used in hospitals targeting a defined group of patients with a specific medical condition [14].

Table 1 Main activities of PaTH

Time / responsible	Procedure(s) / main themes on checklists
Discharge call from hospital to home care services at the day of discharge. (Checklist 1)	Predefined information was transferred to home care services with emphasis on immediate follow-up needs and medication.
Post-discharge assessments by a home care nurse within three days. (Checklist 2)	Structured assessment with emphasis on health issues, preventive measures, self-care and safety issues.
Post-discharge examination by the general practitioner (GP) within two weeks. (Checklist 3)	Structured exchange of information between home care services and GPs before and after GP consultation. Emphasis on observations passed on by the home care professionals, review of medical situation and medication by the GP, and plan for further follow up in collaboration between GP and home care services.
Post-discharge assessment by a home care professional within four weeks. (Checklist 4)	Structured assessment with emphasis on physical / cognitive functional ability, health issues, safety issues, Social situation, and self-care. Evaluation of whether care matches the needs of the care recipients.

During a qualitative process evaluation of the implementation of PaTH [13], home care professionals expressed that they were better prepared before discharge and experienced improved collaboration and exchange of information with the GPs. They also reported that the systematised observations and measures provided by using PaTH resulted in services of higher quality. The home care leaders also valued PaTH as a management tool that served to facilitate change in coordination and provision of health care. These effects on the process level became gradually more apparent with time in the municipalities where the home care professionals found a way to incorporate PaTH into daily working routines.

The aim of this study was to establish the effect of PaTH on patient level – compared to usual care – for elderly patients in need of home care services after discharge from a general hospital, regarding primarily the patients' functional level and readmissions, secondarily use of health care services, mortality and quality of life.

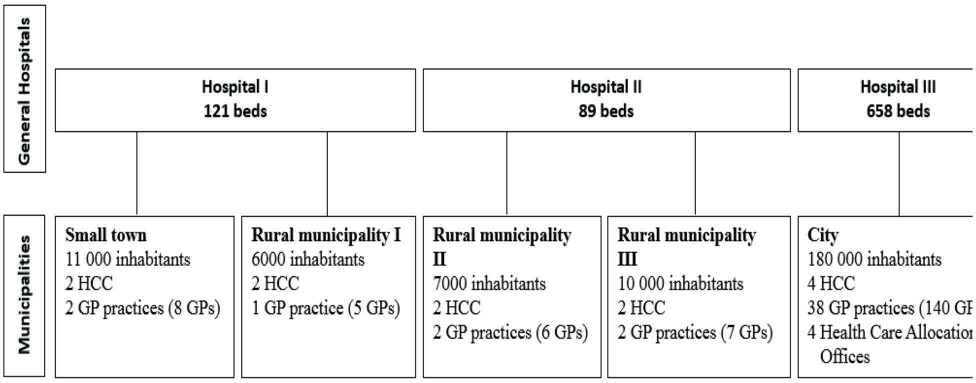
Methods

This study of the effect of the recently developed PaTH [12], had an unblinded, cluster randomised controlled trial (cRCT) design and enrolled patients consecutively in the period October 2009 – March 2011. It was registered in Clinical Trials.gov (NCT01107119).

Ethics and eligibility

The Regional Committee for Medical and Health Research Ethics in Central Norway (REK 4.2009.670) and the Norwegian Social Science Data Services (NSD 215289) approved the study. The six municipalities that were involved in developing PaTH [12] were eligible to participate in this trial, and five of the local municipal authorities agreed to participate. The home care units in those five municipalities formed all together 12 home care clusters, two to four in each municipality (Figure 1).

Figure 1 Organisation of health care services participating in PaTH



HCC = home care cluster GP = general practitioner.
All hospitals serve as general hospitals to the participating municipalities. Hospital III also has regional and university functions.
Every municipality has one or more home care units with nurses and nursing assistants providing health and social care to inhabitants with reduced functional level. One home care cluster included one to three home care units in the same municipality.
GPs usually work in group practices and operate independently of the home care services. Every inhabitant has a right of free choice of a regular GP, which implies that the GP may have patients in common with all home care services in the municipality.
Larger municipalities have health care allocation offices with case managers who do a broad assessment of patients in need of municipal health and social care services other than private physiotherapy and GP services. They have a purchaser role deciding on what kind of services to be provided.

Patients eligible for study inclusion had to be 70 years or older and served by one of the included clusters, or scheduled to receive home care services after discharge from hospital – either directly to their own homes, or via an intermediate stay (anticipated duration ≤ four weeks) at a local rehabilitation facility or nursing home. They also had to be able to understand and sign a written consent form, and could not participate in other studies.

Randomisation and recruitment

A randomisation procedure was designed for intervention (PaTH) - and control clusters (equal numbers) from each of the participating municipalities, and an independent organisation (the

Ministry of Health) performed the randomisation by drawing lots. Patients were enrolled within the randomised clusters, either by municipal case managers (Figure 1) in discharge meetings at the hospital (city only), or by nurses in the home care services immediately after they came home. When municipal case managers recruited patients, they informed the home care professionals about the inclusion through annotations in the electronic health record.

Intervention

At defined stages in the patient trajectory, PaTH introduced checklists (Table 1, Additional file), to ensure closer follow-up of the patients' medical condition and functional ability by reminding health personnel to assess, communicate and act upon relevant issues. The checklists were to be used mainly within the home care services. The hospitals followed usual procedure when contacting PaTH and control clusters before discharge, but the PaTH clusters required more comprehensive information, which was defined in the checklists. Control clusters followed their usual procedures regarding information exchange and focused on supporting the patients' everyday needs. Observations and assessments in the control clusters were dependent on the judgement of the individual health care professionals, and there were no regular procedures of follow-up by the GPs post-discharge.

There was a three months' pilot period running from October 2009 involving one of the intervention clusters, resulting in improvements of some details on the checklists. PaTH was gradually introduced in the other municipalities from January to March 2010.

Outcomes and data collection

Primary outcomes were number of readmissions, defined as acute unplanned admissions for any diagnosis within 30 days, and functional level measured by Nottingham extended ADL scale (NEADL) at baseline, six and 12 months [15]. NEADL was chosen for assessment of functional ability as this is a validated tool used in several studies, in Norway and internationally, evaluating treatment of stroke [16], hip fractures [17, 18] and rehabilitation of elderly [19].

Secondary outcomes were number and length of inpatient hospital and nursing home stays, days at home, consultations (including home visits) with the GPs, use of home care services, deaths at six and 12 months, and health-related quality of life (SF-36) [20].

Outcomes were assessed at the level of the individual home care recipient and data were collected during a 12-month observation period for each person. All data were collected from registries and electronic health records except for NEADL and SF-36, which were completed by the patients themselves, by health personnel in the home care services or by a research assistant (city) in dialogue with the patients. The first author extracted demographics, diagnoses, patient outcomes and consumption of health care services from electronic health records of the home care services, the GPs and the hospitals.

The degree of compliance with PaTH was measured by recording all documented use of the four main checklists (Table 1, Additional file 1) in the electronic health records of the home care services.

Sample size estimation and statistical analyses

We did not have data on normal changes in NEADL (primary outcome) in an unselected home care population during a 12 months period. We therefore estimated sample size based on a proxy, using mobility data in the IPLOS register. IPLOS is an individual based, standardised national registration system that describes patient disability and impairment based on WHO's classification of disabilities [21]. It has been mandatory to use for all individuals receiving public nursing home care or home care services in Norway for several years [22]. We did a survey of IPLOS data of 2300 home care recipients in the city of Trondheim during a 12 months period, previous to the present study, and found a mean mobility level at baseline of 2.3 points (on a 1–5 scale), a standard deviation of 0.80, and a decline in mobility of 11.5 %. To identify a difference in mobility level of at least 0.3, the required sample size was estimated to be 151 patients per group (with a t-test) – under the assumption that the PaTH and control groups were independent samples of equal size with equal standard deviation of 0.8, power of 0.90 and α of 0.05. Cluster randomisation was not taken into account.

For analysis of the effect of PaTH, we used linear mixed models (NEADL and SF-36) and logistic mixed models (health care utilisation). With linear mixed models, site and patient-id were used as random factors. Multiple imputations were not done as this has been found to be unnecessary when performing mixed model analyses on longitudinal data [23]. With logistic mixed models, functional level at baseline, number of chronic diseases and 'living alone' were used as fixed factors. Site (cluster) and patient-id were set as random factors, and days at risk were accounted for, except in analyses of health care utilisation at six and 12 months, which did not include patient-id and days at risk.

The results are presented as an intention-to-treat analysis. Three subgroup analyses were performed; the first subgroup analysis excluded patients who died before discharge, remained in nursing home > 4 weeks after discharge, did not receive home care services, or for whom no checklists in PaTH were used; in the second analysis, patients were exposed to at least two checklists and in the third analysis at least three of the four checklists.

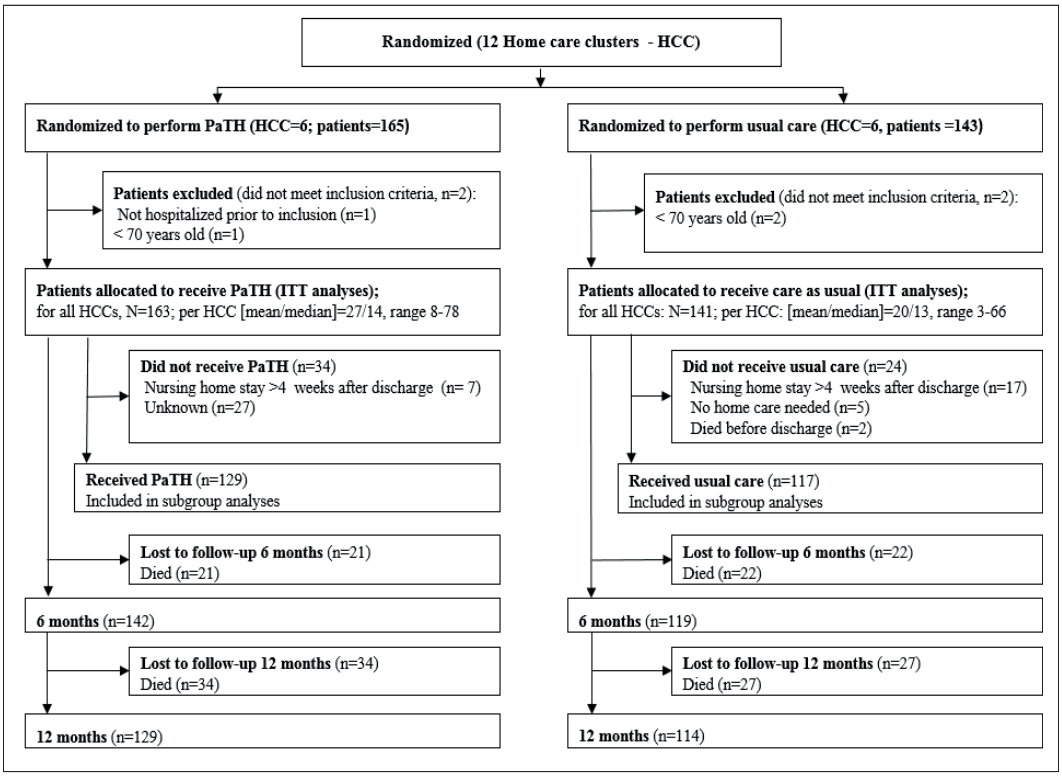
SPSS (version 21) was used for descriptive analyses, and R (version 2.13.1) [24] was used for mixed models analyses.

The 2010 CONSORT checklist [25] has been guiding the presentation.

Results

12 home care clusters from five Norwegian municipalities included a total of 304 patients (Figure 2). The intervention (PaTH group) - and control group were comparable with respect to baseline characteristics for the patients, apart from lower functional level in the PaTH group ($p < 0.002$) (Table 2).

Figure 2 Flow of clusters and participants



There were no dropouts except for deaths during the trial. Register data from hospitals and municipal care systems were complete. Printouts from GPs' electronic health records were missing for six patients in the PaTH group and five patients in the control group. The response rate was similar in the groups ranging from 99 % to 80 % for NEADL questionnaires and 59 % to 76 % for the SF-36 questionnaires (Table 3).

Table 2 - Baseline characteristics of participants

Characteristics	**PaTH group** (N=163)	**Control group** (N=141)
Female sex, n (%)	101 (62.0 %)	83 (58.9 %)
Age, mean (SD), range	83.1 (5.7) 71-96	82.4 (5.7) 70-96
Living alone, n (%)	107 (65.6 %)	97 (68.8 %)
Chronic conditions[1], mean, SD)	3.5 (2.0)	3.8 (1.8)
Primary diagnoses at index hospital stay, n (%)		
Cardiac / vascular	53 (32.5 %)	38 (27.0 %)
Infections	31 (19.0 %)	24 (17.0 %)
Fractures / contusions	28 (17.2 %)	21 (14.9 %)
Cancers	13 (8.0 %)	16 (11.3 %)
Pulmonary disease	5 (3.1 %)	4 (2.8 %)
Neurological disease	1 (0.6 %)	8 (5.7 %)
Other diseases	32 (19.6 %)	30 (21.3 %)
Functional level (IPLOS score)[2] , mean (SD)	2.06 (0.47)	1.89 (0.46)

[1] Chronic diseases include established diseases like e.g. stroke, but not risk factors such as hypertension or hypercholesterolemia

[2] IPLOS data [22] consisting of 17 variables on activities of daily living, both instrumental (e.g. prepare food) and non-instrumental (e.g. personal hygiene). Lower scores imply greater independence.

All PaTH clusters used the PaTH checklists, but to varying degree (Table 4); 79 % (129 patients) of the patients were assessed by at least one; 63 % (103 patients) by at least two and 36 % (59 patients) by at least three checklists. Use of checklists improved over time; 52 % of the first half of included patients in the intervention group and 75 % of the last half were assessed by at least two checklists.

The PaTH and control groups did not differ with respect to the primary outcomes: functional level (Table 3) and readmissions (Table 5), or the secondary outcomes: quality of life (Table 3), mortality and health care utilisation, apart from more GP consultations ($p = 0.04$) in the PaTH group (Table 5). Moreover, there were no differences between the groups in the subgroup analyses.

Table 3 Functional level (NEADL) and health related quality of life (SF-36)

Variable	Observed mean (SD) PaTH group / control group			Estimated mean difference (95% CI) / p-value PaTH group vs control group	
	Baseline	**6 months**	**12 months**	**6 months**	**12 months**
NEADL					
Response rate[1]	99 % / 99 %	83 % / 90 %	80 % / 82 %		
Sum score	33.3 (15.3) / 34.0 (16.0)	36.1 (17.0) / 34.9 (15.8)	35.5 (17.1) / 32.1 (16.2)	1.4 (-2.1 to 5.0) / 0.43	2.4 (-1.3 to 6.2) / 0.21
Mobility	7.4 (5.9) / 8.0 (6.1)	8.9 (6.2 / 8.4 (6.1)	8.5 (6.2) / 7.3 (6.4)	0.8 (-0.6 to 2.1) / 0.26	1.1 (-0.4 to 2.5) / 0.15
Kitchen activities	10.7 (4.5) / 10.9 (4.4)	11.4 (4.6) / 11.2 (4.6)	11.0 (4.6) / 10.8 (4.9)	0.1 (-0.9 to 1.2) / 0.79	0.01 (-1.1 to 1.2) / 0.94
Domestic activities	7.1 (4.7) / 7.2 (4.9)	7.4 (5.1) / 7.4 (4.5)	7.3 (4.9) / 6.7 (4.7)	-0.1 (-1.2 to 1.0) / 0.87	0.1 (-1.1 to 1.3) / 0.87
Leisure activities	8.2 (3.3) / 8.0 (3.7)	8.4 (4.0) / 7.9 (3.7)	8.6 (4.0) /7.5 (3.4)	0.5 (-0.4 to 1.3) / 0.26	0.6 (-0.3 to 1.5) / 0.18
SF-36					
Response rate[1]	59 % / 61 %		76 % / 72 %		
PCS	30.7 (7.2) / 29.1 (8.2)		37.3 (9.6) /34.8 (10.1)		1.3 (-1.6 to 4.3) / 0.38
MCS	38.6 (9.9) / 38.0 (11.6)		46.7 (10.9) / 46.1 (12.5)		1.1 (-2.6 to 4.8) / 0.56

PaTH: **Pa**tient **T**rajectory for **H**ome–dwelling elders

NEADL: Nottingham extended ADL scale. The score ranges from zero to 66. Higher score imply increased independence.

SF-36: Health related quality of life, **S**hort **F**orm **36**. Higher score imply higher quality of life.

PCS: Physical component summary

MCS: Mental summary component

[1] Response rates of NEADL and SF-36 in percent of patients alive

Table 4 Number of patients (%) with documented use of checklists at the PaTH sites

	Small town	Rural municipalities			City		Total
	HCC I (n=17)	HCC II (n=11)	HCC III (n=8)	HCC IV (n=8)	HCC V (n=78)	HCC VI (n=41)	(n=163)
Adherence to PaTH							
No checklist used	0	0	0	3 (38 %)	21 (27 %)	10 (17 %)	34 (21 %)
1 checklist used	7 (41 %)	0	0	2 (25 %)	12 (15 %)	5 (12 %)	26 (16 %)
2 checklists used	7 (41 %)	2 (18 %)	1 (13 %)	1 (13 %)	20 (26 %)	13 (32 %)	44 (27 %)
3-4 checklists used	3 (18 %)	9 (82 %)	7 (88 %)	2 (25 %)	25 (32 %)	13 (32 %)	59 (36 %)
Checklist used							
Discharge call	2 (18 %)	8 (73 %)	*	*	16 (21 %)	23 (56 %)	50* (31 %)
HCS assessment 3 days	17 (100 %)	11 (100 %)	8 (100 %)	5 (63 %)	53 (68 %)	28 (68 %)	122 (75 %)
GP assessment 2 weeks	5 (29 %)	8 (73 %)	8 (100 %)	3 (38 %)	38 (49 %)	16 (39 %)	78 (48 %)
HCS assessment 4 weeks	6 (35 %)	6 (55 %)	7 (88 %)	2 (25 %)	29 (37 %)	9 (22 %)	5 (36 %)

*Missing data. In rural area II and III, discharge calls were registered on paper and were not any longer available when data was collected from the electronic health records.

HCC: home care cluster

HCS home care services

GP: general practitioner

Table 5 Health care utilisation and care situation, PaTH group vs control group

Time	**Variable**	**PaTH (N=163)**	**Control (N=141)**	**Odds ratio [2] (95 %CI)**	**P-value**
During 30 days	Readmissions n (%)	27 (16.6 %)	25 (17.7 %)	0.8 (0.4-1.7)	0.65
At 6 months	No care, n (%)	33 (20.2 %)	22 (15.6 %)	1.6 (0.8-3.2)	0.17
	Home care, n (%)	103 (63.2 %)	90 (63.8 %)	1.1 (0.7-1.8)	0.62
	Permanent nursing home stay, n (%)	6 (3.7 %)	7 (5.0 %)	0.4 (0.1-1.4)	0.10
	Dead, n (%)	21 (12.9 %)	22 (15.6 %)	0.7 (0.4-1.5)	0.38
At 12 months	No care, n (%)	30 (18.4 %)	24 (17.0 %)	1.0 (0.5-1.9)	0.95
	Home care, n (%)	86 (52.8 %)	78 (55.3 %)	1.1 (0.7-1.8)	0.60
	Permanent nursing home stay, n (%)	13 (8.0 %)	12 (8.5 %)	0.7 (0.3-1.7)	0.47
	Dead, n (%)	34 (20.9 %)	27 (19.1 %)	0.8 (0.4-1.6)	0.40
During 12 months	Hospital admissions (n) / patients (n)	244 (106)	230 (96)	1.0 (0.2-1.3)	0.77
	Days in hospital, mean (SD)	10.3 (15.0)	11.0 (15.7)	0.8 (0. 5-1.4)	0.43
	Nursing home admissions (n)[1] / patients (n)	175 (94)	147 (85)	0.9 (0.7-1.3)	0.62
	Days in nursing homes[2], mean (SD)	41.4 (76.8)	45.9 (76.9)	0.7 (0.2-2.2)	0.55
	Days at home, mean (SD)	267.5 (123.7)	260.9 (127.6)	1.8 (0.9-3.4)	0.08
	GP encounters, mean (SD)[3]	5.1 (5.0)	4.4 (4.47)	1.4 (1.0-1.8)	0.04

[1] Include both permanent and short term stays in nursing homes / rehabilitation facilities

[2] All variables are adjusted for IPLOS, number of chronic conditions and living alone. Variables measured during 12 months are accounted for days at risk.

[3] Available data from GPs' electronic health records: PaTH group /control group: 157 patients (96 %) / 136 patients (97 %) while data on all patients were available from hospital and municipal care records.

Discussion

Lack of adherence to PaTH rendered the study inconclusive regarding the elderly's functional level and the number of readmissions after hospital discharge. The effect of intended PaTH use could not be adequately tested because most patients (64 %) were assessed by either none of the main PaTH checklists (21 %) or only one or two (44 %) of them (Table 4). Furthermore, we had to base the sample size estimation on a proxy as we only had access to normal decrease in ADL in the target population from the Norwegian IPLOS scoring system. The sample size estimation was not adjusted for the cluster design, which generally requires more participants than individual-controlled trials [26]. However, no cluster effects were found in this study – except for a statistical non-significant cluster effect on deaths – thus minimising this limitation.

The cluster design represented a strength of the study. This was chosen because PaTH implied a new way – involving all home care staff – to provide and organise the daily services of home care in the post-discharge period. An individual randomised design would have implied a substantial risk of contamination of the control patients, reducing the possibility of detecting effect of the intervention [27]. Other strengths are high response rate to NEADL, and completeness of registry data (from hospitals and municipal care) on health care utilisation. The real-life multicentre setting is a strength, as we could test feasibility of the intervention in several locations in a city as well as in larger and smaller rural communities. However, multicentre settings increase the complexity and can reduce the possibilities of detecting effect in a trial [28].

A promising finding in our study was a higher number of GP consultations in the PaTH group than in the control group. In two Scandinavian studies with documented effect of post-discharge interventions performed by primary care [9-11], the physicians took a more active part in the medical follow-up in the early post-discharge period than in our study. The PaTH procedures implied that home care staff performed the main follow-up and initiated the GP consultations, leaving the GPs in a more passive role. GPs and home care nurses, working within different organisations in geographically separated offices, performed separate assessments, and communicated mainly by fax or electronically. In light of these findings, we believe that more active involvement of GPs and closer integration of follow-up by home care services and GPs in the early post-discharge phase is important to improve outcomes for this frail patient group.

Even if it was not possible to document other effects of PaTH on patient level in this cRCT, our former study of the implementation process [13] indicated positive effect of PaTH on the process level. Several studies have documented that care pathways can have an effect, both on the quality of health care provision and on patient level outcomes, but the effect is dependent on how the implementation process is carried out [29, 30]. A systematic review from 2012 by Smith et al. on interventions in primary care, concluded that multicomponent complex organisational interventions, such as changes in delivery of care, seem less effective on patient level outcomes than interventions directed primarily at the patients, e.g. training directed on improving activities in daily living [31]. One reason can be that implementation of complex interventions, requiring behavioural changes for the health personnel involved, takes time and require targeted efforts before the intervention is settled in the organisation [32]. This became evident in our previous implementation study [13] where we found that enthusiasm and positive attitude to the intervention was not sufficient for a successful implementation. Considerable efforts were needed to make the home care professionals understand their responsibilities in PaTH and how to assess the patients by using the

checklists. A strong managerial focus on creating commitments and engagement to PaTH and practical facilitation of work processes further characterised the implementation process in the municipalities that succeeded in integrating PaTH into daily working processes.
In our cRCT, the implementation challenges were underestimated as the home care professionals had been sitting in the driver's seat during the development process [12], and the care pathway was developed according to their own needs of information transfer and structured follow-up [12]. Furthermore, there were no indications of implementation challenges during the pilot period. A more targeted exploration in the pre-trial phase would have been necessary to disclose these challenges. We used the implementation theory 'Normalisation process theory' (NPT) [33] when exploring the implementation process [13] and see, in retrospect, that NPT could have been useful in the pilot period as well for more targeted testing of the prerequisites for implementation.

For future studies of complex interventions we suggest, in line with the UK Medical Research council [26], a prolonged pilot period for testing of acceptability and understanding of the intervention and, furthermore, to explore the potential for implementation into daily working practices by applying an implementation theory. We further suggest that adherence to the intervention is closely recorded before preceding to the main trial to ensure that full effect can be observed within the study period.

In some of the municipalities participating in the cRCT, PATH is now in common use. Further studies are needed to evaluate the long term sustainability as well as exploration of potential adverse events to service provision and patients.

Conclusions

Lack of adherence to PaTH rendered the study inconclusive regarding the elderly's functional level, number of readmissions after hospital discharge and health care utilisation except for more consultations with the GPs. A targeted exploration of prerequisites for implementation, supported by relevant implementation theories, is recommended in the pre-trial phase of complex intervention studies.

Abbreviations

CI: Confidence interval

cRCT: Cluster randomised controlled trial

GP: General practitioner

HCC: Home care cluster

HCS: Home care service

IPLOS: Individbasert pleie- og omsorgs statistikk (Individualised care statistics)

NEADL: Nottingham extended ADL scale

OR: Odds ratio

PaTH: **Pa**tient **t**rajectory for **h**ome-dwelling elders

SF-36: Health-related quality of life, **s**hort **f**orm **36**

Competing interest

The authors declare that they have no competing interests.

Authors' contributions

HG designed the RCT. TR collected data for the RCT and drafted the manuscript. TR and ØS performed the statistical analyses. HG, AS AG. ØS and OS provided input on the manuscript, read, and approved the final version.

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References

1. Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. Adverse drug events occurring following hospital discharge. J Gen Intern Med. 2005; 20(4):317-323.
2. Mesteig M, Helbostad JL, Sletvold O, Rosstad T, Saltvedt I. Unwanted incidents during transition of geriatric patients from hospital to home: a prospective observational study. BMC Health Serv Res. 2010; 10:1.
3. Kripalani S, LeFevre F, Phillips CO, Williams MV, Basaviah P, Baker DW. Deficits in communication and information transfer between hospital-based and primary care physicians: implications for patient safety and continuity of care. JAMA. 2007; 297(8):831-841.
4. Hesselink G, Schoonhoven L, Barach P, Spijker A, Gademan P, Kalkman C, Liefers J, Vernooij-Dassen M, Wollersheim H. Improving patient handovers from hospital to primary care: a systematic review. Ann Intern Med. 2012; 157(6):417-428.
5. Rennke S, Nguyen OK, Shoeb MH, Magan Y, Wachter RM, Ranji SR. Hospital-initiated transitional care interventions as a patient safety strategy: a systematic review. Ann Intern Med. 2013; 158(5 Pt 2):433-440.
6. Leppin AL, Gionfriddo MR, Kessler M, Brito JP, Mair FS, Gallacher K, Wang Z, Erwin PJ, Sylvester T, Boehmer K et al. Preventing 30-day hospital readmissions: a systematic review and meta-analysis of randomized trials. JAMA Intern Med. 2014; 174(7):1095-1107.
7. Munton T, Martin A, Marrero I, Llewellyn A, Gibson K, Gomersall A. Getting out of hospital. London: Matrix Evidence; 2011.
8. The coordination reform. Proper treatment - at the right place and right time. Report to the Storting no 47. Oslo: Norwegian Ministry of health and care services; 2008-2009.
9. Rytter L, Jakobsen HN, Ronholt F, Hammer AV, Andreasen AH, Nissen A, Kjellberg J. Comprehensive discharge follow-up in patients' homes by GPs and district nurses of elderly patients. A randomized controlled trial. Scand J Prim Health Care. 2010; 28(3):146-153.
10. Garåsen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomized controlled trial. BMC Public Health. 2007; 7:68.
11. Garåsen H, Windspoll R, Johnsen R: Long-term patients' outcomes after intermediate care at a community hospital for elderly patients. 12-month follow-up of a randomized controlled trial. Scand J Public Health. 2008; 36(197).
12. Rosstad T, Garasen H, Steinsbekk A, Sletvold O, Grimsmo A. Development of a patient-centred care pathway across healthcare providers: a qualitative study. BMC Health Serv Res. 2013; 13(121).
13. Rosstad T, Garasen H, Steinsbekk A, Haland E, Kristoffersen L, Grimsmo A. Implementing a care pathway for elderly patients, a comparative qualitative process evaluation in primary care. BMC Health Serv Res. 2015; 15:86.
14. Campbell H, Hotchkiss R, Bradshaw N, Porteous M. Integrated care pathways. BMJ. 1998; 316(7125):133-137.
15. Lindman A, Damgaard K, Tjomsland O, Helgeland.J. [Readmissions of elderly patients in Norway] Oslo: Nasjonalt kunnskapssenter for helsetjenesten (The Norwegian Knowledge Centre for the Health Services); 2012: 35.
16. Wu CY, Chuang LL, Lin KC, Lee SD, Hong WH. Responsiveness, minimal detectable change, and minimal clinically important difference of the Nottingham

Extended Activities of Daily Living Scale in patients with improved performance after stroke rehabilitation. Arch Phys Med Rehabil. 2011; 92(8):1281-1287.

17. Sylliaas H, Brovold T, Wyller TB, Bergland A. Prolonged strength training in older patients after hip fracture: a randomised controlled trial. Age Ageing. 2012, 41(2):206-212.
18. Prestmo A, Hagen G, Sletvold O, Helbostad JL, Thingstad P, Taraldsen K, Lydersen S, Halsteinli V, Saltnes T, Lamb SE et al. Comprehensive geriatric care for patients with hip fractures: a prospective, randomised, controlled trial. Lancet. 2015; doi: 10.1016/s0140-6736(14)62409-0
19. Parker SG, Oliver P, Pennington M, Bond J, Jagger C, Enderby P, Curless R, Vanoli A, Fryer K, Julious S et al. Rehabilitation of older patients: day hospital compared with rehabilitation at home. Clinical outcomes. Age Ageing. 2011; 40(5):557-562.
20. Ware JE, Jr. SF-36 health survey update. Spine. 2000; 25(24):3130-3139.
21. WHO: International classification of impairments, disabilities and handicaps: A manual of classification relating to the concequences of disease. Switzerland: 1980.
22. About IPLOS – a register for statistics on municipal health and care services. Norwegian Directorate of Health.[http://helsedirektoratet.no/kvalitet-planlegging/iplos-registeret/about-iplos/Sider/default.aspx]. Accessed 3 May 2014
23. Twisk J, de Boer M, de Vente W, Heymans M. Multiple imputation of missing values was not necessary before performing a longitudinal mixed-model analysis. J Clin Epidemiol. 2013; 66(9):1022-1028.
24. R: A language and environment for statistical computing. [http://www.gbif.org/resource/81287] Accessed 2 May 2015
25. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012; 345:e5661.
26. Rutterford C, Copas A, Eldridge S. Methods for sample size determination in cluster randomized trials. Int J Epidemiol. 2015; 44(3):1051-1067.
27. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008,;337:a1655.
28. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: new guidance. Medical Research Council; 2008.
29. Allen D, Gillen E, Rixson L: Systematic review of the effectiveness of integrated care pathways: what works, for whom, in which circumstances? Int J Evid Based Healthc. 2009; 7(2):61-74.
30. Whittle C, Hewison A: Integrated care pathways: pathways to change in health care? J Health Organ Manag. 2007; 21(3):297-306.
31. Smith SM, Soubhi H, Fortin M, Hudon C, O'Dowd T. Managing patients with multimorbidity: systematic review of interventions in primary care and community settings. BMJ. 2012; 345:e5205.
32. May C, Finch T, Mair F, Ballini L, Dowrick C, Eccles M, Gask L, MacFarlane A, Murray E, Rapley T et al. Understanding the implementation of complex interventions in health care: the normalization process model. BMC Health Serv Res. 2007; 7:148.
33. May C, Finch T. Implementing, Embedding, and Integration Practices: An Outline of Normalization Process Theory. Sociology. 2009;43(3):535-554.