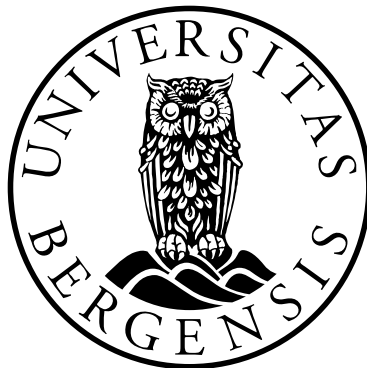# Bridging the Gap between Primary Care and Specialized Mental Health Care

A mixed method study of the quality of referral information and the referral letters' potential impact on quality of care

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Scientific environment

My main supervisor has been Aslak Aslaksen (Director of the Department of Radiology at Haukeland University Hospital and Associate Professor in the Department of Global Public Health and Primary Care). Co-supervisors were Kjell Haug (Professor of the Department of Global Public Health and Primary Care) and Kris Vanhaecht (Professor of the School of Public Health, University of Leuven/Department of Quality Management, University Hospitals Leuven/Leuven Institute for Healthcare Policy, Leuven, Belgium).

In addition to the research group of the Research Network on Integrated Health Care in Western Norway (lead by Dr Eva Biringer), I am also a member of the research group on Social Epidemiology and Health Service Research (lead by Professor Sturla Gjesdal) of the Department of Global Public Health and Primary Care at the University of Bergen in Norway.

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Particularly, I would like to acknowledge my main supervisor, Aslak Aslaksen, for his patience, wisdom and courage to guide me in preparing and conducting a study that to some degree challenges traditional medical research. Together with co-supervisors Kjell Haug and Kris Vanhaecht, these mentors have formed my "scientific anchor". Kris Vanhaecht also introduced me to a large international research network (European Pathway Association) that has been of great help and inspiration. Mostly valuable has also been the contribution of Eva Biringer as my local mentor. With her knowledge and interest in my work and ideas, she has been a role model for senior researchers.

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Contents

Abstract

Background

A major cause of adverse events in health care is insufficient information transference between health professionals. Despite the cardinal role of referral letters as the means of communication between primary care and specialized mental health care, earlier studies have shown that these letters often lack essential information. The impact of this lack of communication on patient care is unknown. The present study primarily aims to explore what information referral letters from primary health care professionals to specialized mental health care services for adults ideally should include. Secondly, an instrument to measure the quality of these letters will be developed and tested. Finally, indicators to measure the impact of referral letters on the quality of specialised mental health care will be created.

Design and methods

Using a mixed method design, we employed qualitative group interview methods, literature reviews and quantitative rating technics. In addition to health professionals we involved patient representatives and managers in all steps of the study. We adapted the RAND/UCLA Appropriateness Method to develop indicators of specialised mental health care quality. The study was conducted in western Norway.

Results

Nineteen information items were regarded as essential in referral letters from primary care providers to specialized mental health care professionals, including personal information, case history and social situation, present state and results, somatic health, treatment efforts and involved professional network, as well as the patient's own goals and preferences. The instrument developed to measure the quality of the referral letters was found to be both valid and reliable. For assessing the impact of the referral letters, we found appropriateness of priority decisions and delays to be essential factors of mental health care quality. Thus, we recommend four indicators: correctness of priority between patients, delay in assessing referral, delay to onset of care, and appropriateness of referral.

Discussion

The present study recommends a greater emphasis on information to facilitate coordination of care interventions and services and on patient involvement than existing standards for referral letters to specialised mental health care. The developed indicators on potential impact of referral letter quality are in accordance with the existing literature on quality of the referral process. However, our results only include process indicators, not outcome indicators. Limitations in the generalizability of the selection of the most essential information items and indicators are possible.

Conclusion

Based on the international definition of quality in health care and on reported challenges to health care regarding coordination, cooperation and timely access, our study indicates that sufficient referral communication is a key factor that enhances high quality health care. Compliance to the recommended 19 information items is expected to improve timely access and decrease delays in the process of care. The developed measurements enable both exploration of the referral information's impact on mental health care quality and provision of valid data for systematic improvement to practice. However, the challenges we experienced in defining valid indicators highlight the importance of thorough preparation of measurements and process evaluation as recommended by new guidelines for research into complex health service interventions. Further research is needed to explore a) the strength of the association between referral information, our recommended process indicators, and patient outcome; b) the effects of systematic interventions to improve the content of referral letters; and c) to what degree our results are valid to other contexts and for other patient groups than those explored in the present study.

List of publications

Paper 1:

Hartveit M, Thorsen O, Biringer E, Vanhaecht K, Carlsen B, Aslaksen A. Recommended content of referral letters from general practitioners to specialised mental health care: a qualitative multiperspective study. BMC Health Service Research 2013, 13:329

Paper 2:

Hartveit M, Aslaksen A, Vanhaecht K, Thorsen O, Hove O, Haug K, Assmus J, Biringer E. Development and testing of an instrument in Western Norway to measure the quality of referral information from primary care to specialised mental health care. International Journal of Care Coordination 2015. DOI: 10.1177/2053434515589012.

Paper 3:

Hartveit M, Thorsen O, Biringer E, Haug K, Vanhaecht K, Aslaksen A. Quality indicators for the referral process from primary to specialised mental health care: an explorative study in accordance with the RAND appropriateness method. Submitted BMC Health Service Research

Paper 4:

Hartveit M, Biringer E, Vanhaecht K, Haug K, Aslaksen A. The Western Norwegian mental health interface study: a controlled intervention trial on referral letters between primary care and specialist mental health care. BMC Psychiatry 2011, 11:177

1. Introduction

1.1 The prevalence and importance of mental health problems.

Mental and substance use disorders are the leading cause of disability worldwide [1]. Globally, they are the leading cause of "years lived with disability" (YLDs), accounting for 22.9% in 2010 [2]. While existing reports suggest that these disorders contribute to early death only to a limited degree [2], a Norwegian study by Nome et al. revealed that people with severe mental illness can expect up to a 25-year reduced life expectancy compared to the general population [3]. Mental diseases have a large impact on the patients' family as well. The risk of developing a mental disorder later in life is twice as large among children of parents with mental illness compared to the general population [4]. In the Norwegian context, approximately 37% of children live with a parent who has experienced a mental health disorder in the last year, whereas approximately 10% live with a parent with a severe mental illness [4]. Further, mental problems are a challenge to society, being a major cause of sickness absence from work and disability pension [5]. Despite the large impact of mental diseases on individuals and society and also the potential for recovery, persons with mental problems are at risk of not receiving sufficient health care for several reasons. First, mental health services experience similar challenges as other health services regarding the gap between recommended and existing care [6-8]. Second, mental health care is often provided in cooperation between health services at different levels by a wide range of professionals [7, 9]. This implies many handover situations where the risk of adverse events is high [10]. Third, mental health systems are in general characterized by greater obstacles to patient-centred care mainly because clinicians tend to underestimate the patients' ability to make their own decisions and for some patients' reduced ability to ensure that they receive sufficient care [7]. Fourth, at a system level, mental health care has less developed quality measurements and infrastructures for improvement efforts than somatic health care systems [7].

1.2   Mental health care

1.2.1 Quality of mental health care

The quality of health care is defined by the degree that it is safe, effective, patient-centred, timely, efficient and equitable [6]. There are three valid perspectives used to define and assess the quality of health care: the professional perspective, which represents health professionals' competence within evidence based medicine and care, the patient perspective, which represents the experiences and competence of patients as receivers of care, and the organizational and political perspective, which represents management competence and the public's preferences and expectations [11, 12]. Each perspective embodies a knowledge or insight that complements each other. The level of quality of health care is determined by the gap between existing performance and best practice as defined in a consensus between the three perspectives.

The gap between existing performance and best practice is caused by underuse, overuse and/or misuse [6]. Underuse, or not performing the recommended interventions, is the main source of low quality. Patients receive approximately 50% of the recommended care, with a large variation between patient groups [8]. People with alcohol dependence were found to be the patient group that experienced the largest underuse, receiving only 10% of the recommended care, while persons with depression received almost 60% in a large study by McGlynn et al. [8]. The risk of underuse is expected to be particularly high within mental health care because of its stigma or the services' inability to meet the needs as experienced by the patients [7]. Overuse, or implementing interventions that do not add any value or may even harm the patient, can be caused by insufficient information transference between services. Examples are duplication of diagnostic tests and other interventions during the process of care [13, 14]. Misuse is when interventions are not performed in the recommended way, such as providing an intervention for another condition than the intervention is recommended for. A lack of information in referral letters may cause misuse due to a misunderstanding of the patient's needs [15].

1.2.2 Mental health services in Norway

As in many countries, the Norwegian health service is organised into two levels: primary care and specialised health care. Primary care is organised by the municipality, whereas specialised health care is governmental. Health care is dominated by public health care. Only one per cent of the full-time equivalents (FTEs) in specialised health care are private [16]. Primary mental health care is constituted by general practitioners (GPs), mental health nurses and, in some municipalities, psychologists in addition to regular primary care services as homecare. All citizens are entitled to a defined GP who is responsible for their primary medical care. Specialised mental health care services are organised with both local mental hospitals (Distrikts psykiatriske sentre, DPS) and specialised mental hospitals. There are approximately three FTEs per 1000 inhabitants within the public specialised mental health care system for adults [16]. However, even when specialised substance use care is included, mental health services constitute only 19% of the FTEs in Norwegian specialist health care [16]. In addition to the health professionals who offer mental health services, a large amount of other services provide care to people with mental disorders, such as employment services, social services and voluntary organisations.

Access to specialised health care is regulated by priority-regulations that consider the impact on survival and quality of life, the availability of effective treatment and the cost-effectiveness as criteria for deciding if and when specialised health care should be provided [17]. This situation is assessed firstly by a medical doctor in primary care (usually the GP). If the GP decides to refer the patient, a psychiatrist or clinical psychologist examines the referral and determines if the patient is given first priority (a legal right to receive the care within the timeframe set as a medically acceptable waiting time), second priority or if the referral is rejected (i.e. the patient will not receive specialised mental health care).

A reform to improve mental health care was launched in Norway in 1997 [18]; a separate reform to increase the cooperation and coordination between primary care and specialised health care was launched in 2012 [19]. Both initiatives aim to provide a

more decentralised model with a larger responsibility for mental health care on primary care providers. Most care for mental problems is now provided by primary care professionals. Since these reforms, the number of patients receiving mental health care from a GP has increased and now includes approximately 13% of the population (650,000 persons per year) [20]. Approximately 4% receive specialised mental health care [20]. The large amount of patients receiving mental health care from primary care highlights the GPs' important role as gatekeepers for specialised mental health care [20].

1.3 The gap between services

1.3.1 Care coordination and clinical handovers

Sufficient coordination across patient conditions and services and over time is perceived as one of the six challenges to health care as defined by the Institute of Medicine (IOM) [6]. However, health care is becoming increasingly specialised with a large number of services and health professionals involved in each episode of care [21]. The level of integration in health services can be defined by the means of cooperation on a continuum from full segregation to full integration [21]. The optimal degree of integration is determined by a balance that enhances a sufficient specialised and yet also a "seamless" care process [21]. There are three types of continuity: relational, management and informational [22]. Relational continuity regards the ongoing therapeutic relationship between the patient and the caregiver, management continuity means a consistent and complementary delivery of care, whereas informational continuity implies the sharing of essential patient information between involved health professionals [22]. As in many other countries, the Norwegian health care system is based on the lowest level of integration where cooperation between primary and specialised health care is mainly done using a referral system. The GP has the coordinating and gatekeeper role between primary and specialised health care.

"Clinical handover" refers to the transference of the responsibility for care between persons or systems within a process of care [10]. It can be defined as "the process of

transferring primary authority and responsibility for providing clinical care to a patient from one departing caregiver to one oncoming caregiver" [23]. The discontinuity in handover-situations represents an increased risk to patient safety [24, 25]. Retrospectively, limitations in communication are found to be the most frequent factor that precipitates adverse events [24]. The need for research to establish valid measures and explore the impact of effective handover on patient safety and coordination is therefore highlighted [24].

1.4 Communication at the interface: the referral letters

1.4.1 The referral process and referral letters' role

The referral process consists of activities to coordinate health care between primary and specialised care and to ensure timely access to specialised health care. GPs can request a cognitive consultation, procedural consultation or co-management of care from specialised health care [26]. At this interface, information is communicated between services found to have diverging expectations to their roles in the care process [27-29]. The involved services' separate legislation, diagnostic manuals, management system and other factors that influence the performance of care imply that communication is demanding. Further, communication must be tailored to the needs of a large set of professionals due to increasing specialisation in health services [30]. A recent literature review by the King's Fund in Great Britain concluded that there is "frequently no shared understanding of the purpose of the referral among the GPs, the patients and the consultant" [31]. The severe limitations in written communication between primary and specialised health services for facilitating a shared understanding found in a recent Swedish study may explain some of the lack of common understanding [25].

The existing literature indicates that the referral process is seen as an important factor to health care quality in most Western countries, e.g. the Nordic countries [25, 32-35], Great Britain [31, 36], the United States [37], Canada [13, 38] and Australia [39], as well as in Sri Lanka [40] and Saudi Arabia [41]. Many countries are challenged to

comply with the increasing demand for specialised health care and have introduced mechanisms to regulate access to specialised health care including waiting lists for patients [34, 42]. Also in countries with no defined referral system, such as Sri Lanka, the quality of the communication between GPs and hospitals is seen as essential to bridge the gap between primary care and hospitals [40].

The appropriateness of referrals can be assessed using three dimensions; "necessity" regarding the correctness of the decision *whether* the patient should be referred, "destination" regarding *where* the patient should be referred, and "quality /process" [43]. Among other aspects, "quality/process" is defined by the degree to which necessary tests have been performed, whether the referral letter includes required information, and to what extent the patient has been involved in the referral decision [43]. Among these, the content of referral letters is seen as a key factor in the referral process [31]. Information transfer, shared understanding and working atmosphere have been found to predict handover quality, and information transfer is seen as the most important [24, 44].

Referral letters are the main means for information transference between primary care and specialized health care when a person is referred to hospital [26, 45, 46]. They are expected to serve an essential role for coordination across the two levels of health care, to ensure timely access to specialized health care and to facilitate safe, effective and patient-centred care when primary health care is insufficient [6, 26].

1.4.2 Quality of existing referral letters

The information provided in the referral letters is not in compliance with what is regarded as necessary information by the receiving hospital specialists within mental health care as well as in somatic health care [14, 38]. Mental health care referral letters usually include administrative information [38]. However, information that adequately described the situation and also the need for specialized mental health care, such as the patient's mental status, psychiatric history and past treatments, were presented in less

than half of the referral letters included in a recent literature review [38]. Information on involved mental health services was contained in less than every fifth referral letter, while only every tenth letter included information on the patient's risk concerns [38]. Within a Norwegian context, referral letters are also found to be insufficient. A main conclusion of a national revision of mental health care services for adults by the Office of the Auditor General of Norway ("Riksrevisjonen") was that referral letters do not include sufficient information [47]. This finding was expected to have a negative impact on timely access and horizontal equity [47]. However, the existing literature is based on different standards for what information referral letters should include [38]. A "good referral letter" is related to the perspective of the ones who define the construct. Not all standards are developed in cooperation between consultants and GPs, even though the literature reveals the importance of a common cognitive picture of their cooperation and the process of care [44, 48, 49]. Further, according to definition of quality in health care, patients and managers also represent experiences and knowledge important for defining the full scope of this communication modality [11, 12]. Another limitation to the existing literature on the quality of referral letter is that most studies have been based on instruments that remain invalidated or do not even report the reliability of the instrument used, introducing an uncertainty regarding the reliability of the results.

1.4.3 Quality improvement of the referral process and referral letters

Efforts to improve aspects of the referral process within different contexts have been introduced worldwide [14, 31, 37, 38]. Interventions to reduce referral rates and to improve the content of referral letters have been emphasized [31, 36]. However, factors other than the patient's need for specialised health care have been found to influence the referral rates, such as the GP's gender and experience and geographical proximity to specialised care institutions [20, 31, 50]. Interventions including educational activities as peer review discussions and feedback among GPs have been found to reduce the variation in referral rates and improve the content of referral letters

[14, 36]. Improving the content of the referral letters within cancer care are found to affect specialists' confidence that they made the right decisions regarding patient urgency positively [39]. Further, less time was spent assessing referral letters sent to a medical ward when the letters were improved by the use of electronic templates compared to those that were not [51]. Within mental health care, the results of different interventions to improve referral communication are diverging, even leading to less complete information being sent [38]. Studies do indicate, however, that high-quality information exchange between primary care physicians and specialists within mental health care has a significant impact on the effect of interactive communication on patient outcome [52]. It has even been suggested that such interactive communication "offers an equal if not better return on investments than many clinical interventions" [52].

1.5 Exploring the referral process

1.5.1 The importance of valid measurements

Valid measurements or indicators serve an essential role within quality improvement efforts as well as for health service research [53, 54]. Indicators should be valid, reliable, sensitive, feasible and easy to communicate [53]. Measurements that do not or may not meet these criteria introduce the risk of drawing the wrong conclusion during all phases in quality improvement: selecting the most important improvement area, detecting in more detail the type and degree of low quality, defining intervention, exploring if the intervention improves the quality, deciding if a satisfying level of quality has been reached and ensuring the sustainability of the results [53]. The validity of indicators can be described in terms of construct validity, which refers to the degree that the indicator addresses a real, coherent and meaningful entity and performs as predicted on different criteria [55, 56]. We lack an agreement upon definition of the construct "high-quality referral information". Further, the existing suggestions do not represent all perspectives necessary for a valid defintion [56]. A standard definition of high quality referral information should be compiled by representatives of relevant services, patients and managers/politicians [11, 12].

1.5.2 Process indicators and mechanisms

According to Donabedian, the outcome of health care is a result of structures and processes [57]. To change the outcome, we must alter the structures (such as competence, electronic support systems and number of health professionals) and/or the processes; the latter is seen as having the most potential to improve outcome [58, 59]. A large amount of indicators of patient outcome has been published, such as mortality and quality of life [60, 61]. However, to improve these outcomes, we need to understand the processes and the determinants for improved outcome within different contexts [59, 62]. Mediating factors are determinants that are themselves affected by a change in the process and thereby influence the outcome [53]. Detection of such factors is recommended for several reasons. First, an understanding of the mediating factors positively affecting the quality of care will enable the development of interventions tailored to support the mechanism that influences the outcome [53]. Second, mediating factors tend to be related with more than one outcome [53]. Consequently, the detection of such key mediating factors facilitates the effective improvement of a set of outcomes [63]. Third, the use of process indicators to measure the mediating factors enables the identification of improvement potential and also the evaluation of improvement efforts because these indicators are more sensitive to change than are outcome measures [64]. Further, process indicators serve an essential role in revealing variations in health care that might not lead to significant differences in health outcomes but are nevertheless integral to the quality of care as perceived by patients [64]. To detect if and how referral letters affect patient outcome, it is therefore necessary to explore the referral process to a) reveal the impact of referral information on potential mediating factors and b) explore how and to what degree these mediating factors influence the outcome of health care.

An emphasis on exploring the processes to gain insight into how the outcome is achieved is supported by critics who have spoken out against the traditional, positivistic research design [63, 65, 66]. Health services are complex systems characterized by several interacting components and a large number and variety of potential outcomes in which contextual factors have an impact (i.e. "complex

intervention" as defined by the UK Medical Research Council) [67-69]. Studies reporting limited or diverging results of interventions to improve health care have been criticized for not complying with the complexity of the intervention and its potential outcomes and for not adapting the intervention to the context [66, 70]. In these cases, process evaluation is therefore recommended [71]. Within the social sciences, causation as causal mechanisms is suggested as an alternative to the reductionists' understanding of causality [72, 73]. Mechanism refers to "the entities of a causal process that produces the effect of interest" [72]. Mechanisms serve an essential function to understand how the results are obtained [73]. The theory of mechanism-based explanation has clear similarity to the theory of Donabedian where outcome is seen as a product of the structures and the processes within a context [57]. Pawson and Tilley have developed a relativistic framework for research on complex systems such as health care. In this framework, "Realistic Evaluation", the outcome (O) is seen as a product of the underlying mechanisms (M) within a context (C) [74]. The CMO-model ("context + mechanisms = outcome") [74] is argued to provide a deeper understanding of how and under what circumstances an intervention affects the outcome [75]. However, the existing literature contains a surprising lack of studies that have explored the complexity of the referral process. Establishing valid measurements and exploring their related mechanisms is seen as a priority of future research within handover communication to determine causal effects and identify best practices and effective interventions to improve communication between health professionals [24, 26].

By understanding these processes or mechanisms, we can define theory ("reason-giving") [76]. Theory is essential to a) designing tailored interventions to support underlying mechanisms, b) detecting potential effects of a well-designed intervention and c) enabling generalization so that others can develop their own tailored interventions based on the theory [76, 77]. However, regarding the referral process and its potential impact on quality of care, we lack knowledge on both what we should do (what information to include in the referral letter) and how and to what degree the quality of health care is affected by improved referral communication. We also have little insight into the mechanisms and impact of contextual factors of this complex

process. Therefore, we need to define best practice (i.e. what information the letters should include) and gain insight into the process of referral to detect valid indicators for the quality of referral information and the referral process.

In summary, sufficient coordination and cooperation is one main challenge to health care in general and for mental health in particular. With the integration model used in many western countries' health care systems, the referral letter holds an important function to ensure the coordination and cooperation between the involved services and health professionals. To improve the quality of referral letters within mental health care, we need a definition of best practice against which to measure the quality of existing referral letters. We also need to explore if, how and to what degree the quality of referral letters has an impact on important outcomes. This process will require an adapted research design appropriate for the complexity in health service interventions in which the development of valid measurements plays an important role.

The literature review that formed the basis for the study was completed in December 2010. Additional, more specific literature scrutiny was further conducted for Study 1 and Study 3 (completed June 2012).

1.6 The aims of this study

The main aim of the present study is to explore and define determinants and outcomes of the potential causal chain between the referral information and the quality of mental health care. The object is to define valid measurements for these determinants and outcomes to enable exploration of if and to what degree the referral information can be improved and identify the potential improvement's impact on central elements of the quality of mental health care. The present study aims at achieving the following:

a)   Exploring what information referral letters to specialized mental health care services for adults ideally should include according to the three perspectives of quality in health care.

b)   Developing an instrument to measure the quality of referral information to specialised mental health care services and exploring its psychometric properties.

c)   Exploring how mental health care can be affected by the quality of referral information and developing valid indicators to assess these areas.

1.7 The research questions

To enable an exploration of if or to what degree the quality of referral letters to specialised mental health care services for adults have an impact on patient, professional and organisational outcomes, we raised the following research questions:

1) What information is seen as most important and should be included in referral letters from primary care to specialised mental health care services to facilitate prioritisation and planning of patient treatment and follow-up?

2) What items should a valid instrument that measures the quality of referral information to specialised mental health care include, and to what degree are the data provided by the instrument reliable?

3) What quality indicators are relevant and valid in the assessment of the potential impact of improved referral information on specialised mental health care for adults?

2. Methods

The present study constitutes the first steps in the planned interventions study described in Paper 4. The intervention study, named "The Western Norway Mental Health Interface Study", is designed in accordance with the (UK) Medical Research Council's guideline on evaluating complex interventions, including a thorough preparation of measurements [68]. It aims at exploring to what degree the quality of referral letters within mental health care can be improved and the potential improvement's impact on patient, professional and organizational outcomes [78]. During this process, valid measurements to quantify the quality of referral letters and their potential impact are needed, as illustrated in Figure 1 [78].
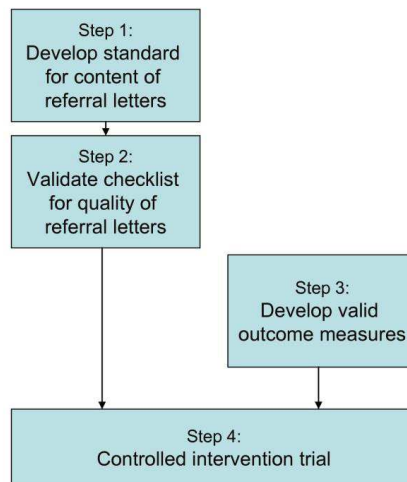
Step 1:
Develop standard
for content of
referral letters

Step 2:
Validate checklist
for quality of
referral letters

Step 3:
Develop valid
outcome measures

Step 4:
Controlled intervention trial

Figure 1: Illustration of the stepwise progression in "The Western Norway Mental Health Interface Study" [78].

The study presented in this thesis constitutes steps 1–3 in The Western Norway Mental Health Interface Study.

2.1 Mixed methods design

Our study consists of three steps that were performed with a mixed method design to answer the research questions posed. Mixed methods can be defined as the combined

use of qualitative and quantitative methods and have been specified by some as being one complete method plus a different simultaneous and sequential supplemental method [79]. Our three steps, denoted Studies 1, 2 and 3, constitute a stepwise progression to define valid measurements for exploring the referral information's potential impact on the quality of care. In Study 1, we identified the recommended content of referral letters as seen by the stakeholders. This formed the basis for an instrument to measure the quality of this communication, which was developed and assessed in Study 2. In Study 3, indicators to measure how and to what degree quality of care is affected by the quality of referral information were defined. The design was developed in accordance with recommendations for exploring causality involving complex interventions and systems: It emphasises thorough development and selection of valid indicators to study the process and detect potential mediating factors [68, 75, 80, 81].
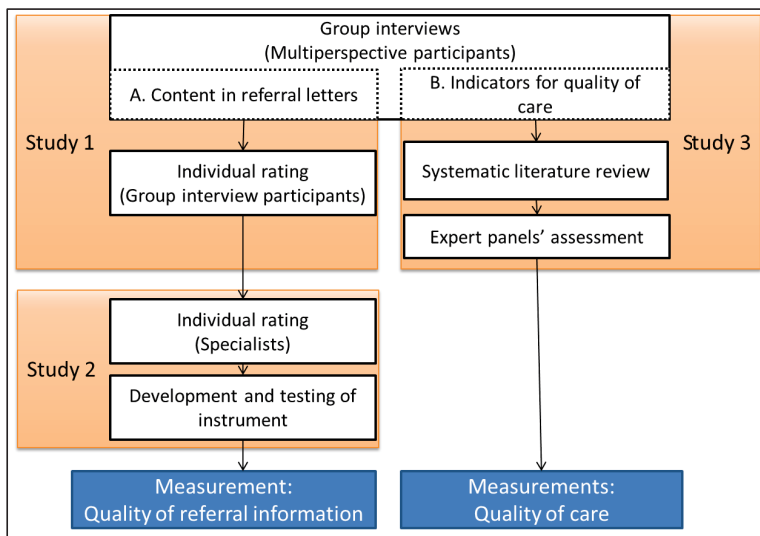

Figure 2: Illustration of the steps conducted in the present study, where Steps 1 and 2 produce a measurement of the referral information and Step 3 is designed to reveal indicators of the quality of care.

2.2 Setting

Our study was conducted in Western Norway with participants representing specialists, managers and researchers in specialized mental health care, GPs and mental health nurses in primary care and patient representatives within mental health. The Norwegian health care system is predominately public and is largely free (the maximum patient charge per year is approximately 2000 NOK/230 Euro). It is organized with two levels, where the 428 municipalities are responsible for primary care and specialized health care services are organized by health authorities owned by the state. Each local health authority is responsible for providing sufficient specialized health care for the population in a defined geographical area. All citizens have a designated GP who is responsible for their primary medical care. GPs are paid by the public and serve both a coordinating role for the patient and a "gatekeeping" role for specialized services. This gatekeeper role and also the priority given to different patients in regards to accessing specialized health care have received increased attention in Norway in recent years because of an exponential increase in health expenditures within specialised health care services.

2.3 Methods and materials

2.3.1 Study 1: Developing recommended content in referral letters

Group interviews and a postal questionnaire constituted a consensus development process [82] that aimed to detect information characterizing good referral letters and to select the most important information items. In the first phase, four group interviews were conducted with mixed groups containing patient representatives, health professionals (both primary and specialised health care) and managers. They responded to the question, "What information should referral letters contain to give specialised mental health care providers the necessary information to correctly and sufficiently prioritize between and plan treatment and follow-up of the patients?" The interviews were structured using the nominal group technique [83] and involved developing an affinity diagram [84] followed by a semi-structured focus group

interview [82]. The nominal group technique includes written brainstorming where the participants write their suggestions on post-it notes that will be collected by the facilitator [83]. During the affinity diagram development process, the notes are analysed by the group, which reviews the notes to ensure common understanding of their content, exclude overlapping notes and group the suggestions into thematic units with a nominal heading [53, 84]. Between two sessions of the nominal group technique and the affinity diagram development, a semi-structured focus group interview was conducted to gain a deeper insight and generate new ideas [82]. The interview was led by a senior mental health researcher (EB), while the categorising of themes was carried out by the group itself and observed by a researcher (MH).

In the second phase, the participants received a postal questionnaire consisting the suggested information items from all the groups, and they were asked to individually rate each item's importance on a scale from 0 (= "not important/irrelevant") to 5 (= "extremely important/cardinal"). With the occurrence of a perceived overlap of items, the participants were to place a "0" by the redundant item and mark it with the number of the item that should replace it. The analyses were conducted by first excluding the items that the most participants considered replaceable. Second, we used a predefined cut-off limit to include only the items rated as highly important (4 or 5 on the scale) by 75% or more of the participants, as did Deneckere and colleagues [85].

The study was conducted within the Western Norway Regional Health Authority (population: 1 million). The participants were selected by purposive sampling [82] to represent the defined valid perspectives of quality in health care: professional, patient and management/political perspective [11, 12]. To stimulate the discussion and gain insight into the subject from different perspectives, each focus group included representatives from each perspective. The four groups contained 19 participants, and 12 were men. Nine of the participants were health professionals within primary or specialized mental health care, four were patient representatives, and six were managers. Of the 15 participants representing the professional and management perspective, 9 were medical doctors (two general practitioners), 4 were psychologists and 2 were nurses. Twelve of these were specialists. They were all experienced;

almost half of the professionals and three of the four patient representatives had more than 15 years of experience in their present position. Participants were enrolled by their organisations (institution or patient organisation) based on their experience and interest in the subject.

2.3.2 Study 2: Developing and exploring an instrument

With the purpose of developing a valid instrument to measure the quality of referral information, Study 2 included methods to select the most essential information found in Study 1 and to explore the validity and reliability of the instrument [56], as illustrated in Figure 3.
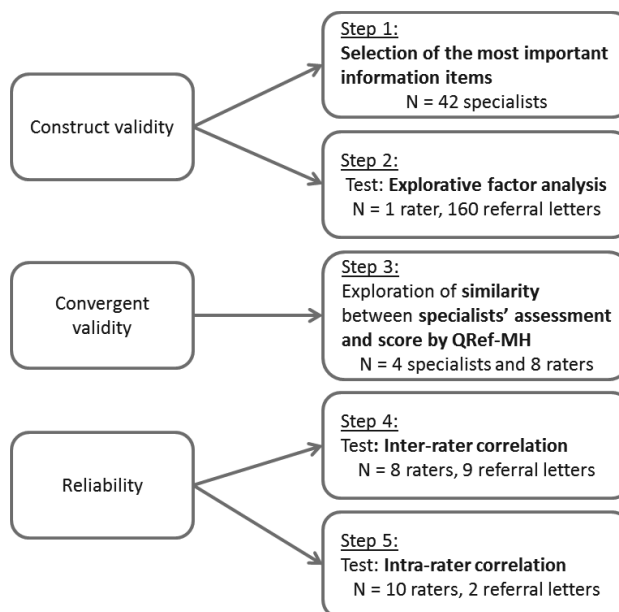

Figure 3: Illustration of how the validity and reliability of QRef-MH data were explored by the steps in Study 2.

Construct validity

To select the most essential items constituting the core elements of high quality referral letters, the specialists responsible for assessing referral letters sent to public specialist mental health care providers in the region of Western Norway (population: 1 million) were invited to rate the recommended items from the former steps (Study 1). The participants were selected for their central competence at using the information provided in the referral letters to a wide range of specialised mental health care services. Similar to the former rating-process, the specialists were asked to rate the items by importance (from 0 (= "not important/irrelevant") to 5 (= "extremely important/cardinal")). The specialists were also asked to mark the information items they thought should be mandatory in all referral letters to specialised mental health care professionals. The items that were significantly more important or marked as "should be mandatory" by significantly more specialists than other items formed the content of the alpha-version of the instrument. In addition, we ensured representation of all main themes recommended by the multi-perspective focus groups. Each item was formed as a dichotomous variable (includes/does not explicitly include the information) and the instrument was named the Quality of Referral Information-Mental Health (QRef-MH). An explorative factor analysis was conducted to identify potential underlying dimensions and describe if and how the items should be grouped together [82]. For this, a random sample of 160 referral letters written by GPs to public specialised mental health care providers was rated by one researcher. The number of referral letters included was based on the "rule of thumb" of ten times the number of items [82, 86]. Because of client confidentiality, the three items regarding personal identification were not included in the analysis.

Convergent validity

The existing literature lacks validated instruments to enable an exploration of the convergent validity of our instrument. The specialists assessing referral letters at one local mental hospital were therefore asked to prospectively select nine referral letters representing the range of quality in received referral letters as perceived by their clinical expertise (three low-, three medium- and three high-quality letters). Consistency in the assessment between specialists was examined by comparing the

group's assessment with the assessment by a specialist with corresponding responsibility at another local mental hospital. The specialists' assessments of the nine letters were compared descriptively with the assessment using the QRef-MH. The QRef-MHs were scored by eight raters who were blinded to the specialists' assessment of the letters' quality. These raters represented the central stakeholders for the instrument: researchers, GPs, specialists and quality facilitators at mental hospitals.

Reliability

The alpha version of the tool was tested on the psychometric properties in terms of their inter-rater reliability and test-retest reliability. The reliability tests were carried out on the same nine referral letters as the convergent validity exploration. The number of raters and letters examined by the instrument was determined by an estimation using a 95% confidence interval (CI) and an expected interclass correlation (ICC) = 0.7, as reported in a study by François [13].

2.3.3 Study 3: Development of indicators for the quality of health care

The RAND/UCLA Appropriateness Method [81] is a systematic method of combining expert opinion and evidence widely used to develop indicators in areas where scientific evidence is limited [54]. In our study, this method was adapted to develop indicators to measure the quality of mental health care expected to be sensitive to changes in the quality of referral letters. In addition to the literature review and expert panels included in the method, we also conducted group interviews to supplement the results of the literature review. Table 1 describes the steps in our study in relation to the steps in the RAND Appropriateness Method:

The steps in the RAND/UCLA appropriateness method [54, 81]	The steps in the present study
	Focus group interviews including patient representatives, managers and health professionals
Systematic literature review	Systematic literature review
Generate preliminary indicators	Preliminary indicators generated from both focus group interviews and literature review
Selection of expert panel	Selection of experienced specialists and researchers in specialised mental health care
Presentation of existing evidence and individual rating (postal)	Panel meeting with oral presentation of existing evidence with opportunity for individual reflections before discussion and assessment of the preliminary indicators
Panel meeting with presentation of the first rating, discussion and assessment of the preliminary indicators	
Analysis of final rating	The groups' assessments and categorising of the indicators were analysed by two researchers individually
Development of recommended indicators	Development of a ranked list of indicators

Table 1: The steps in our study in relation to the steps in the RAND/UCLA Appropriateness Method [54, 81].

Group interviews

Structured focus group interviews with the same participants who took part in the interviews of Study 1 were conducted. The participants responded to the question, "If the referral letters were improved in the way you suggest, how do you think this would affect the process of care?" The interviews were moderated by a researcher (EB) and observed by a second researcher (MH). The suggested ideas (written by the participants on post-it notes) and the audiotaped discussions were individually analysed by two researchers (MH and OT) and were guided by the steps of systematic text condensation by Giorgi, as described by Malterud [87]. The results from the individual analyses were discussed by the two researchers, and a consensus about the categories and preliminary indicators was reached.

Literature review

The literature search was conducted using PsycINFO, Embase and PubMed for a period of 10 years (2002–week 26 in 2012). Because of the scarcity of existing literature, wide inclusion criteria were employed. All papers revealing, suggesting or discussing a potential causal chain between the contents of the referral letters and aspects of quality of care were included. However, articles suggesting indicators clearly relevant for only one mental health diagnosis were excluded as "diagnosis-specific". The three databases were searched for articles where the phrase "referral letter(s)" occurred in the title or in the abstract, and the included studies were limited to adult patients. Based on the abstracts, articles were selected for full text reading, and relevant preliminary indicators were identified.

By consensus, two researchers (MH and OT) combined the results from the interviews and literature review.

Expert panels

Three expert panels were set up, and they included three, three and two participants to assess the qualities of the indicators suggested in the interviews and literature. The participants were all experienced psychiatrists or trained psychologists, and four were also experienced researchers. They were asked to assess each indicator using the criteria for good indicators regarding validity, reliability, sensitivity to change, acceptability, feasibility, simplicity and communicability [26, 53, 54]. Using an individual assessment followed by a group discussion, the expert panels were asked to place the indicators into one of three groups: bad/unacceptable, acceptable/needs adjustment or good/recommended. "Bad/unacceptable" was defined as an indicator that lacked relevance to mental health care or for other reasons seen as unuseful. To be "good/recommended", the indicators needed to be mostly in line with the criteria as defined above and also to recommend further testing. The mid-category "acceptable/in need of adjustment" includes indicators that are seen as interesting but in need of major revision to the definition of numerator and denominator. The participants were encouraged to suggest improvements to the indicators.

2.4 Statistical analyses

A set of statistical analyses was conducted to explore the validity and the psychometric properties of the QRef-MH in Study 2. Descriptive statistics (mean, max/min and confidence interval) were calculated for the specialists' score on the suggested information items' importance and also for whether they specified that the items should be mandatory. Wilcoxon Signed Rank test with a significance level of $p < .05$ was used to reveal the items rated as significantly more important or suggested as being mandatory significantly more often. The non-parametric test was chosen because we did not expect a normal distribution as the items had been selected for high importance [88]. For each item, we compared the rank of difference to the median between the raters' score on one item with the mean score on all other items per rater.

Explorative factor analyses were conducted to explore the correlations between variables to reveal potential underlying constructs ("factors") and grouping of items [86]. A potential factor was defined by an Eigenvalue exceeding 1.0.

Different analyses were carried out to explore the QRef-MH's reliability. For inter-rater correlation in the total score, which is a linear scale, inter-class correlation (ICC) was applied. To control for systematic differences between raters, the exploration was based on ICC consistency. Inter-rater correlation for each item (dichotomous variable) was analysed by Fleiss κ to include multidimensional factors (due to several raters and different referral letters). An alpha level of 0.05 was used. For the test-retest, Cohen's κ was used as it explores only one dimension and compares scores of two points in time.

The analyses were conducted using the Statistical Package for the Social Sciences (SPSS), ver. 20.0, or Matlab R2010a.

2.5 Context

The study was conducted in Norway where the absolute majority of specialist health care is provided by public primary and specialist health care professionals. Mental

health care is constituted by primary care organised by municipalities (428 as of January 2015) and local and specialised mental hospitals organised by local health authorities, which are divided into larger regional health authorities owned by the government. In addition, amenities other than health services are often involved in the care of people with mental illness. In the Norwegian health care system, all citizens are entitled to a primary medical doctor. In addition to providing medical care at the primary care level, this GP also serves as a "gatekeeper" to specialised health care by deciding if a patient should be referred to a specialist. GPs are also given a central position in the care to ensure coordinated and coherent care. The two-level health service with a referral system is similar to that of most industrial countries [14, 26, 31, 38].

Access to specialised health care is regulated by a law defining three dimensions that determine the degree of need for specialist health care: severity, the expected effect and availability of effective interventions, and cost-effectiveness [17]. The decision of whether a patient should receive specialised health care is made by a specialist based on the information provided in the referral letter. The patients are given either first priority, meaning that they have a legal right to receive the care within a period seen as medically acceptable, second priority, when the care will be provided without a time limit, or the referral request may also be rejected [17].

2.6 Ethical consideration

Participation in the focus group and expert panel conformed to written informed consent standards. All referral letters were scrutinized by professionals at local hospitals to eliminate all information that could be used to identify patients before they were used in this study. The Regional Committees for Medical and Health Research Ethics (2010-01255) and the Norwegian Social Science Data Service (ref. no. 24340) approved the study. The study is registered at ClinicalTrials.gov (NCT01374035).

3. Results

Using the present studies, we have revealed a recommendation for the content of referral information to specialised mental health care (Study 1) and developed and tested an instrument to measure to quality of such information (Study 2). Further, we have explored how the quality of care can be affected by the quality of the referral information and developed a set of recommended indicators to explore this phenomenon (Study 3). Together, these studies' results constitute recommended definitions of both dependent and independent variables in the expected causal relationship between referral letters and quality of mental health care. In the following section, the main findings are summarized. Further details on the results are provided in the papers (see appendix).

3.1 Recommended content of the referral information

The four interview groups suggested 174 information items as being relevant to include in referral letters for specialised mental health care services for adults. After excluding inter-group duplicates and items assessed as replaceable, 71 items were left. Of these, 40 were assessed as more important than the others by the group interview participants. In addition to information usually suggested for inclusion in referral letters, our study recommends that referral letters to specialised mental health care services should include the overall plan for care, the involved services and interventions and the patient's preferences and goals. An introductory section with check-off points about essential information, such as the patient's risk of harm to him or herself or others and responsibility for children, was also recommended.

The groups suggested from five to eleven headings. Seven headings were found to adequately cover the four sets of headings: personal information and contact information, important introductory information (check-off points), case history and social situation, present state and results, past and on-going treatment efforts and involved professional network, the patient's assessment, and the reason for the referral.

3.2 Quality of Referral information–Mental Health (QRef-MH)

The second study developed an instrument to measure the quality of referral letters using the results of Study 1 as the basis. Nineteen items were found to constitute a valid definition of high-quality referral letters with regard to construct and convergent validity. The instrument, called the QRef-MH, was found to be reliable with regard to inter-rater and test-retest correlation.

Construct validity

By excluding items representing headings for other items, 46 items were found to constitute the essence of the 71 suggested information items from Study 1. On a 0–5 point scale measuring the importance of the suggested items by the specialists (N=42), the mean scores for the 46 items were 4.31 (mean for the item with the lowest score: 2.93 (SD: 1.18), mean for the item with the highest score: 4.95 (SD: 0.23)). Using the Wilcoxon Signed Ranked test, 18 items were found to be rated significantly higher than all other items. At mean, 11 raters ticked "should be mandatory" (min: 0, max: 38) across the 46 items. Ten items were marked as "should be mandatory" by significantly more raters than the mean of the other items. These ten items were among the set of 18 items seen as significantly more important. Notably, the specialists' scores excluded all items regarding patient involvement. However, the research team decided to include one item that summed up the patient involvement items (Item 19: The patient's goals, desires and motivation) as patient involvement was defined as a main group of items recommended by the multiperspective groups. The 18 items selected by the specialists and the one item regarding patient involvement formed the basis for the QRef-MH instrument.

Recommended content for referral letters to Specialized Mental Health Care (adults):

- *Personal information that ensures correct identity and contact information, inclusive of phone numbers of relatives.*
- *Patient data: Social security number, place of residence.*
- *Information about the referring doctor, and contact information: phone number, where to reach him/her.*

- *Is the patient suicidal?*   ☐ *Yes*   ☐ *No*
- *Is the patient a threat to others?*   ☐ *Yes*   ☐ *No*
- *Is there an emergency situation?*   ☐ *Yes*   ☐ *No*
- *Is the patient responsible for the care of children?* ☐ *Yes*   ☐ *No*
- *Do you suspect severe illness/psychosis?*   ☐ *Yes*   ☐ *No*
- *Does the patient have a drug problem or addiction?* ☐ *Yes*   ☐ *No*

- *Concrete information on previous suicide risk*
- *Somatic health and diseases relevant for this referral.*
- *Present problem, present mental status*
- *Level of function: present level, loss and duration of the loss*
- *Present state of symptoms and duration of symptoms*
- *Updated medication record*
- *Tested interventions with assessment of the effect, what has the referring doctor tried so far?*
- *Existing interventions/involved services with assessment of the effect.*

- *The patient's goals, desires and motivation*
- *"Order"/goal for the referral, what the referring doctor is asking of the specialist health care provider.*

Figure 4: The information items recommended for inclusion in referral letters to specialized mental health care professionals for adults in Studies 1 and 2 [89, 90].

An exploratory factor analysis (EFA) based on a score of 160 referral letters produced seven factors with an Eigenvalue > 1.0. However, the five researchers were not individually or by consensus able to define any theoretically or clinically supported

constructs underlying these factors. There were minor correlations between the items, varying from –0.148 to 0.429. A clear majority of the items correlated at the level of "slight" ($\kappa = 0.00–0.20$) or "poor" ($\kappa < 0.00$) [82]. The dataset was found to redeem the criteria for this analysis (KMO > 0.6 and Bartlett's test was significant). No items were excluded based on the factor analysis.

Convergent validity

When compared descriptively, the scores of the QRef-MH reflected mainly the same pattern as the group of specialists' assessment; letters assessed as being of high quality were given a higher score on the QRef-MH than ones of medium or low quality. However, there was some discrepancy between the eight raters' scores. In particular, the score for referral letter 4 varied greatly; interestingly, this was the letter the specialists also disagreed on the quality of.

Reliability

Inter-rater correlation for the sum score showed a moderate correlation (ICC = 0.58 [95% CI 0.32, 0.86; $p < .001$]). There were differences in the inter-rater correlation between the three groups of referral letters assessed by experience as low-, medium- or high-quality letters. The highest correlation (ICC = 0.67 [95% CI: 0.26, 0.91; $p < .05$]) was found for the medium quality referral letters. The inter-rater correlation for 13 of the 16 items was significant (Fleiss κ, $p < .05$). However, the inter-rater correlations per item varied; for item 5, regarding information about whether the referred person is a threat to others, the correlation was poor (Fleiss $\kappa = –0.02$, 95% CI: –0.23, 0.20). Most items had fair agreement (0.2–0.4). Only the item regarding whether a medication list is defined had substantial agreement (0.73, 95% CI 0.52, 0.95).

Using Cohen's κ, we found a substantial test–retest correlation (κ between 0.60 and 0.80) for five of the ten raters. For three raters, the correlation was almost perfect with $\kappa > 0.8$. These eight correlations were all significant at a p level of < .05. However, the intra-rater correlation for the last two raters was moderate ($\kappa=0.48$, CI –0.05, 1.01) or fair ($\kappa= 0.29$, CI: –0.43, 1.01).

3.3 Potential impact of the referral information

Within a RAND Appropriateness Methodology including focus groups, a literature
review and expert panels, the third study revealed a large set of potential areas of
health care that are expected to be affected by the quality of referral information.
However, defining indicators for redeeming the criteria for high quality indicators was
challenging. Only four suggested indicators were recommended, and another five were
seen as acceptable if adjustments were made.

Focus group interviews
After excluding intergroup duplicates, the four groups suggested 128 indicators or
areas expected to be affected by improved referral information. During the analyses,
three categories of suggestions emerged: co-operation, timely access and
organisation/logistics. "Co-operation" included suggestions such as a common
understanding of and respect for the distribution of responsibility between primary
care and specialised health care, avoiding duplication of interventions and improved
co-ordination between the involved services to provide a coherent process of care.
"Timely access" comprised performance measures for the decision making to ensure
that the patients assessed as (medically) most in need receive specialised mental health
care first. Most suggestions within "organisation/logistics" concern delays and waste
in the process of care and have focused on the optimal use of scarce specialised health
care resources, such as the specialists' time. Ten preliminary indicators emerged from
the three categories. Of these 10 indicators, four where in the category of "co-
operation", three were in "timely access" and three were in "organisation/logistics".

Literature review
The literature search resulted in a total of 253 hits (PubMed: 88, PsycINFO: 24 and
Embase: 141). After applying the inclusion criteria, 30 articles were included, whereas
only 3 were from the database for mental health, PsycINFO. During the analyses, five
categories evolved defining potential areas expected to be affected by the quality of
referral information: timeliness and delay, attendance/drop-out, unnecessary
consultations and investigations, appropriateness of the referral, and correctness of

prioritisation of patients. Fifteen preliminary indicators were derived from the abstract of these five categories. These were fully supported by the areas suggested by the focus group interviews. In addition, the focus group participants proposed measuring the degree of common understanding of the treatment plan among the involved services and health professionals.

Expert panels

The expert panels' assessment of the indicators' appropriateness resulted in the recommendation of 4 of the 16 suggested indicators measuring timely access, delay, waiting time and appropriateness of referral. The indicator "timely access" assesses whether the specialist's assessment of urgency (maximum acceptable waiting time) based on information given in the referral letter correlates with their corresponding assessment from a clinical evaluation. The second indicator measures whether the receiver of the referral was immediately able to determine the priority of the patient or whether he/she had to request further information to prioritise the patient correctly. The third indicator concerned waiting time for specialised health care treatment for patients with severe conditions or less severe conditions, respectively. Severity is defined by "severity factors" [89] regarding the risk of harming oneself or others, substance abuse, psychosis and caring for children. The fourth recommended indicator is the appropriateness of a referral. It measures whether the hospital specialist perceives the referral to be timely and to describe a situation where referral is recommended.

In all expert panels, participants spontaneously expressed that they considered the quality of referral information to be an important factor in the quality of health care. However, they were also explicit about the difficulties observed when defining good indicators according to the set criteria [26, 53, 54]. The inter-panel agreement on the assessment of the suggested indicators was high. Seven of the 16 presented indicators were assessed as unacceptable. The panellists saw the suggested causal chain as clearly weak or questionable to mental health care because of expected confounding factors that influenced these seven indicators. Further, limited feasibility was given as a counterargument for some of the indicators. Five indicators were seen as acceptable

but in need of improvements. The participants expressed that they expected these indicators to represent existing causal chains but were in doubt as to the strength of the causal chains, strength of confounding factors and/or reliability. An overview of the 16 indicators is presented here (for more details, see paper 3):

Indicator	Short description	Assesses as
1. **Timely access**	The correlation in priority given to the patient between the assessment of the referral letter and an equal assessment based on a clinical assessment.	Recommended
2. **Delay in process of assessing the referral**	The amount of referrals delayed because of additional gathering of information by the specialized mental health care.	Recommended
3. **Waiting time for high priority patients**	Measuring if the patients with the greatest need have the shortest waiting time. "Need" is defined by "severity factors": severe mental illness/psychosis, risk of suicide, risk to others, in care of children, substance abuse and younger than 23 years.	Recommended
4. **Appropriateness of referral**	Agreement between the referring GP and the receiving specialist on if the referral is appropriate.	Recommended
5. Rejected referrals	The amount of referrals rejected. By using high quality referral letters, specialists can be more confident that rejection is appropriate.	Acceptable/ in need of adjustments
6. Aborted episodes of care	Amount of aborted episodes of care defined as terminated by the service after ≤ 3 consultations because of incorrect access to specialised mental health care.	Acceptable/ in need of adjustments
7. Severity in high priority patient group (severity factors)	Amount of patients in a high priority group that have three or more of the severity factors (as defined in Indicator 3).	Acceptable/ in need of adjustments
8. Realism in expectations toward specialised mental health care	Amount of referrals including a realistic expectation toward specialized mental health care, as assessed by the specialist receiving the referral letter.	Acceptable/ in need of adjustments
9. Supportive information gathering	The number of extra activities conducted to gather sufficient information to assess the referral.	Acceptable/ in need of adjustments
10. Severity in the high priority patient group (diagnosis)	Amount of patients in the high priority group with a high degree of severity measures by diagnosis.	Unacceptable
11. Common understanding of the coordinated care plan	The degree of common understanding among involved professionals on what interventions they think are involved in each patient's care plan.	Unacceptable
12. Adequate specialist response (referring	The amount of referrals were responded to adequately as assessed by the referring GP.	Unacceptable

GP)		
13. Adequate specialist response (patient)	Amount of referrals responded to in accordance with the referral request, as assessed by the patient.	Unacceptable
14. Time to decide priority	Time used by the specialist to assess a referral letter, including time for gathering extra information.	Unacceptable
15. Attendance to first consultation	Amount of patients attending their first consultation.	Unacceptable
16. Attendance to consultations in the first 3 months	Amount of "drop-outs" within the first three months.	Unacceptable

Table 2: Overview of the 16 suggested indicators. (For more information, see paper 3)

The focus group interviews and expert panels revealed local factors that may affect the indicators' validity and reliability for benchmarking, such as how the assessment of referral letters is organised and the capacity of the various specialised mental health units. Further, diagnosis is not appropriate to define the degree of patients' needs or severity of condition and should be replaced by "severity factors", as suggested in a previous study [89]. For all indicators, including those recommended, the expert panels emphasised the need for testing by exploring which factors should be controlled for and testing these factors.

The areas expected to be affected in the referral process as found in our study is illustrated in Figure 5 by the appropriateness of decisions and potential delays:
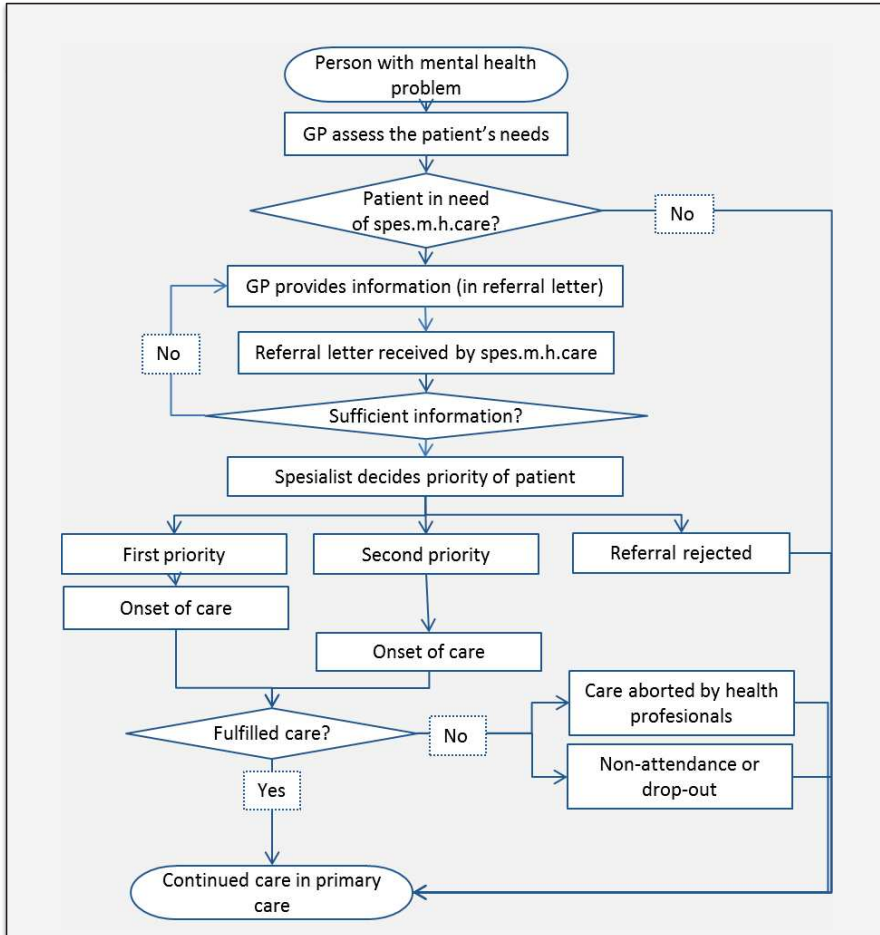
Figure 5: Illustration of the referral process with decisions and potential delays that can be measured by the suggested indicators in Study 3 [91] .

4. Discussion

4.1 Main findings

Using on a mixed methods design, we identified 19 information items that were highly recommended in referral letters to specialised mental health care services for adults. In addition to information usually found in such standards, we recommend that information regarding the involved professional network and patient involvement also should be included. An instrument constituted by dichotomous variables (does the referral letter include the information, or not) of the 19 items was found to be both valid and reliable for measuring the quality of referral letters. To explore the impact of the referral letters on health care, we identified several areas that were expected to be relevant. These were represented by 16 indicators, whereas only 4 were recommended for measuring the correctness of priority between patients, delays and appropriateness of referral. Another five indicators were seen as relevant but in need of adjustments before they could be accepted. In the following chapter, I will discuss these findings with regard to the validity and generalizability of our results in accordance with existing knowledge and the appropriateness of the design and methods employed. At the end, I will relate our study to the planned Western Norway Mental Health Interface Study, which our study constitutes the first three steps of.

4.2 Validity of the results and conclusions

Our study produced the definitions of "high-quality referral letters to specialized mental health care for adults" and "high-quality mental health care in relation to the referral process" and also the operationalization of these constructs. The existing literature reveals a set of definitions and sub-definitions of validity [54, 56, 82]. In the present study, for validity, we used the definitions by Trochim et al. where construct validity is defined as "the degree to which inferences can legitimately be made from the operationalisations in your study to the theoretical constructs on which those

operationalization are based" [55]. Figure 6 illustrates the operationalization of the constructs in our study inspired by Trochim's "The idea of construct validity":
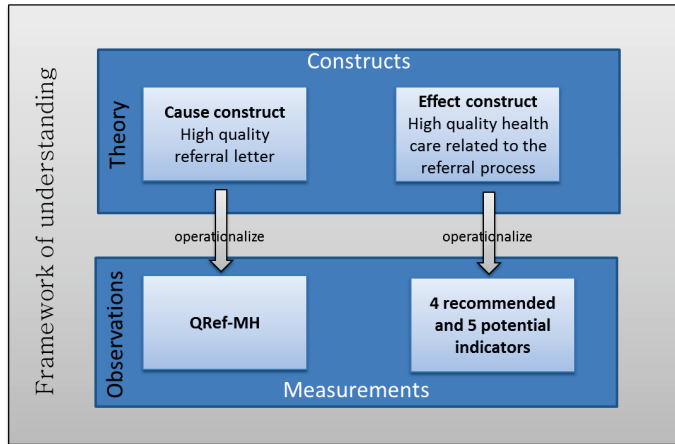

Figure 6: Illustration of the operationalization of the constructs defined in our study ("High-quality referral letter" and "High-quality health care related to the referral process") to measurements ("QRef-MH" and a set of indicators) based on Trochim's model [55]

This development and operationalizing is carried out within the framework of health service and quality improvement science within mental health services. In the following section, I will first discuss the validity of our definition of the recommended content of referral letters and its operationalization and then the areas and indicators of health care that are expected to be affected by referral letters.

4.2.1 The construct of "high-quality referral letter" (Study 1)

High-quality referral letters should be formulated in a way that clearly defines the destination of the request to assess the urgency of the patient's need and suggest the appropriate care for the patient [31, 92]. Important aspects of the referral letter's quality are organization, completeness and accuracy [93]. Our study (Study 1) recommends organizing the information in a traditional way, with one exception; pertinent information that is highly relevant for assessing the urgency of the referral

should be outlined using items that can be checked off. These types of items are in accordance with many electronic referral systems and force the referring doctor to include necessary information [51, 94]. For referral letters to be "complete", we recommend inclusion of the following information in accordance with existing suggested standards: information to correctly identify the patient and the referring doctor, clinical details as diagnosis, status and investigations, a medication list, reasons for the referral and any information that has been given to the patient [38, 95]. Recent literature has proposed including information regarding the reason for referring, which is in accordance with our results [38, 40, 95]. This suggestion is also supported by the discordancy found between the referring family physician, psychiatrist and patient/family in how they perceive the reason for consultation, what to expect of the process of care and who will implement the recommendations within mental health care [31, 48]. An explicit statement of the reason for the referral can clarify the GP's expectations and enable the patient and specialized health care provider to detect any discrepancy between this and their own expectation.

The participants in our study also emphasised information on related professional networks, patient involvement and parenthood. Interestingly, these types of information have not or have only partly been highlighted in existing standards. They are, however, supported by known challenges to health care and its associated services.

Information on on-going treatment efforts and related professional networks were recommended in our study to enable specialized health care providers to see their role in the overall treatment plan. In a literature review by Durbin and colleagues, only a minority of the included studies recommended information on cooperating partners in integrated or shared care, and these were limited to services within mental health [38]. This is in contrast to Pincus et al.'s analysis of challenges to mental health care, which stated that "disconnected care delivery arrangements require multiple provider "handoffs" of patients for different services and the transmission of information to and joint planning by all of these providers, organizations, and agencies." [7]. Care for people with mental health diseases usually requires interventions from different

supportive organisations, such as social and employment services in addition to different primary and specialized health care, to be effective [9, 96]. To assess the expected effect of potential specialist health care interventions and their cost-effectiveness and thereby determine if a patient should be prioritized for specialized mental health care, information on existing and planned care and support is therefore essential. Our findings may represent one result of the overall Norwegian national reform to improve coordination across health services [19], but they could also be seen as the outcome of including all relevant stakeholders when defining the information items. However, these findings might also represent a worldwide shift in health care in response to an increasing specialization and multi-professionalism within health care [21], where referral letters are seen as means to ensure continuity across services. A recently developed referral form from Australia for early intervention teams supports our findings by requiring information on the referring doctor's role after specialised mental health care interventions and including check-off points for other professionals involved in the patient's care [92].

Our study's emphasis on patient involvement by recommending information on the patient's aims, preferences and recovery efforts is not supported by the existing literature [38, 95, 97]. Increased patient-centred care and involvement has been called for worldwide for the last 20 years [6, 98]. Within the Norwegian context, patient involvement has been a legal right for the last 15 years [99]. However, a recent Norwegian study indicated that this emphasis on patient involvement at a macro system level has only to a limited degree been adapted to the clinical environment and the health professionals' quality improvement efforts [100]. The patient's values and preferences are essential when choosing between treatment options and determining what types and degrees of risks are acceptable to the patient [101]. Research within personal recovery reveals the significance of patient involvement for their wellbeing [102]. Nevertheless, existing standards for referral content only include information regarding what information the patient is given [38, 95]. A Danish study found that information on the patient's expectations towards the care was included in only 7% of the referral letters to a medical unit [35]. Further, poor patient-centred documentation

was found in all handover records between primary and specialist health services for patients with chronic diseases in a small Swedish study [25]. The specialists' ratings in our study (Study 2) also excluded the patient involvement items. However, involving the patient in decisions about his or her own treatment (shared decision making) requires skills that health professionals may not possess, or they could have had past negative experiences with such involvement [103]. Therefore, we do not know if the exclusion of patient involvement items is because of previous negative experiences where patients were involved in decision making, if these specialists view patient involvement as less important in general or if information regarding the patient's preferences is seen as not so important in referral letters. The items were positively ranked, but they were not found among the items selected as significantly most important, lending support to the idea that patient involvement is considered relevant.

Information regarding whether the referred patient is a caregiver of children is seen as essential information by our study. Most standards for referral letters include an item for social factors and/or family, but no item has been specified to detect if any children are affected by the patient's illness [38]. Children of parents with severe mental health problems are found to be at particular risk of developing mental illness themselves in addition to the risk of receiving insufficient care during periods when the parent is ill [4, 104]. Within the Norwegian specialized health service, there is a large focus on parents as patients and their potential need for support to manage their responsibility as caregivers [105]. This may have influenced our results that indicate the need for information about the patient's role in caring for children.

4.2.2 The operationalization of "high-quality referral letter" (Study 2)

We identified 19 items representing the most essential elements when measuring the construct quality of referral letters. This number is less than many standards revealed in the existing literature [38, 92, 95]. An essential question is whether these 19 items comprise the scope of the construct of a "high-quality referral letter" in a sufficient

way. Based on the existing literature, it is difficult to determine if 19 is a suitable number of items. However, according to the literature on effective communication in handover situations, accuracy and organization of the content are essential to reduce the risk of pertinent information becoming lost or overshadowed by less important information [93, 106]. Reducing the number of information items to only the most essential is therefore recommended [38, 106]. Our explorative factor analysis revealed limited correlations between items, lending support to the importance of each of the 19 items. However, further research is needed to explore each item's relevance for important outcomes of the referral process, such as those recommended in our third study. By exploring to what degree each item can predict the outcome, we can promote further understanding of the relevance of each item and the instrument's ability to predict outcome (predictive validity) [56]. The existing literature lacks studies exploring this concept [38].

When comparing the QRef-MH score with specialists' clinical judgement of the referral letter, we found a clear pattern where referral letters assessed as having a high quality by the specialists were scored higher on the QRef-MH than those of medium and low quality, supporting the convergent validity of the instrument. However, we have limited knowledge on the validity and reliability of specialists' assessment. In a recent qualitative study, Thorsen and colleagues found that consultants have specific ideas about what they see as relevant referral information [107]. However, we do not know how they rate the general quality of a referral letter. The specialists' score is based on the perceived overall quality of the letters, while our instrument measures the existence of defined information items as dichotomous variables. The specialist's assessment may also include dimensions other than the existence of relevant information, such as the degree of completeness of the information or whether it is correct and clearly defined [107]. This distinction may offer a reason why the convergence between the QRef-MH score and the specialists' assessment was not complete. Another explanation may be the divergent perspectives represented by the QRef-MH and the specialists. The QRef-MH is based on a set of stakeholders'

perspectives on what constitutes a high-quality referral letter, while the specialists only represent one perspective.

4.2.3 The construct and operationalization of "high-quality mental health care related to the referral process" (Study 3)

In our third study, we explored how the quality of referral letters can affect the quality of care by defining the theoretical construct of "quality in health care related to the referral information" and operationalizing the construct to indicators. Even though many studies have revealed limitations of these letters, no existing research has included a systematic exploration of the potential effect of low-quality referral letters [108]. Therefore, we do not know to what degree our 16 indicators measure the full scope of the impact of referral information on mental health care. However, the indicators identified by our study are in line with the Speciality Referral Process model suggested by Guevara and colleagues [26]. In this model, the quality of the referral process is defined by the resources used and the quality of the process leading to patient-reported and clinical outcomes, including mortality and unintended consequences [26].

Resource use as a waste of time was highlighted in our study for exploring the referral information's impact on quality of care. The amount of time used to gather additional referral information and the provision of services not suited for the patient's situation that cause patients to drop out and health professionals to abandon processes of care constitute a waste of scarce resources; our study recommends that these resources be measured. A considerable amount of time is used to assess referral letters [107]. When referral letters within medicine are improved, the amount of time specialists spend handling these referral letters can be reduced by more than 30% [51]. Non-attendance also constitutes a major waste in specialized mental health care. As many as every fourth patient does not show up for scheduled care appointments [49].

The majority of the indicators revealed by our study are in regards to aspects of "quality" in Guevara's model, including appropriateness, effectiveness, efficiency,

patient-centeredness, safety, equity and timeliness [26]. Reported improvement efforts use a reduced referral rate as a central indicator [36]. However, obstacles experienced by mental health patients for seeking professional help [7] argue for more specific measurements to identify if the patients most in need of specialised health care are being prioritized. Our results suggest that a central element of the construct of high-quality care related to the referral process is whether correct decisions are made when selecting patients most in need and if providers plan for appropriate care for these patients. This element is also supported by Jiwa and colleagues, who reported an increased confidence among consultants when the referral letters were improved that they had made the right decision regarding when cancer patients should come to the clinic [39]. A lack of essential referral information is expected to prevent reliable decisions regarding risk assessment, resource allocation and destination for the referral [31]. Another central element of our findings is the emphasis on the timeliness of specialised health care interventions to ensure prompt, safe, effective and appropriate care. Appropriateness of referral is highlighted by the increased amount of referrals to specialized health care services in many countries [31, 36, 109]. In a study by Evans and colleagues, 28% of referrals to specialized mental health care were assessed as inappropriate by consultants [49]. However, among consultants in this same study, the judgement of appropriateness was found to be inconsistent [49]. According to our results, common understanding and cooperation between GPs, consultants and patients are expected to improve when the referral information improves. A shared understanding among involved parties and sufficient information are two of the three factors found to predict handoff quality within somatic health care [44]. A lack of sufficient referral information is perceived by consultants as an important barrier to cooperation with GPs [46]. Our study suggested that patient involvement be measured by the degree the received care is perceived by the patient as being in accordance with the referral letter and to what degree there is a common understanding of the coordinated care plan among involved professionals and the patient. The existing literature has revealed that patients often do not know what to expect from the process of care, which supports the relevance of involving patients to a larger degree in the referral process [48].

The performance measures suggested by Guevara and colleagues are in accordance with Donabedian's structure, process and outcome indicators [26, 57]. Our study did not, however, reveal the same outcome measures suggested by Guevara et al. (i.e. patient-reported outcome, clinical outcome, mortality and unintended consequences). The large risk of confounding factors is the main reason given by our participants for this discrepancy and is supported by the literature on strength and limitations in the process and outcome indicators [64]. Outcome indicators are recommended only when health is expected to be affected significantly [64]. The quality of health care is only one determinant of patient outcome [64], and the referral process is only one part of the health care process. The probability of health being significantly affected by the referral letters' quality is therefore unknown. Further, it is essential that measurements are sufficiently sensitive and targeted to detect changes and also to reveal information in the areas viewed as (clinically) most important for patient outcome [110]. Process indicators enable an exploration of potential mediating factors relevant for the outcome [75]. The indicators recommended by our study can provide important insight into the underlying mechanisms affecting the outcome and also illuminate which elements in the process must be changed to improve patient outcome [58, 111]. However, a limitation to our recommended indicators is that we do not know to what degree they in fact have an important impact on outcome. Our results represent the first step to enable "outcome-validated process indicators" [58].

4.3 Reliability of our findings

The reliability of our findings regards the consistency of the rating used to select the most important items in the referral letters. Our selection is based on ratings by both the participants in the multi-perspective group interviews and specialists. We have not explored the psychometric properties of the scales used to assess the importance of the items. However, all guidelines for the content of referral letters are based on the assumption that a general interpretation of "high-quality referral information" exists among specialists. Assuming this, the high inter-rater correlation between the 42 specialists supported the reliability of our result. Further, the specialists' score

revealed mainly the same pattern as the group interview participants' score. The items rated as among the most important by the specialists were all included in the items assessed as highly important by the other participants. Uncertainty regarding the reliability of the scores implies an uncertainty for the number of items selected and whether they represent the optimal selection. However, based on the discussion on validity and the following methodological considerations, I assess this risk to be of less interest to the trustworthiness of our results.

4.4 Methodological considerations

Existing recommendations for the content of referral letters are most often based on small-scale consensus decisions among medical doctors [39, 51, 112], and the instruments used to measure the letters' qualities are usually not validated [26]. The literature does not provide information on validation processes for indicators to explore the impact of referral letters on quality of care. Methodological consideration for the design, sample and methods constituting our study is therefore of interest from both a scientific and an improvement perspective. In the following section, I will offer some consideration regarding the appropriateness of mixed methods-design, the multi-perspective samples and how we structured the exploration of the constructs and indicators.

4.4.1 Mixed methods

Traditionally, the answers to research questions have been sought using either qualitative or quantitative methods [82]. The main focus within medical research has been on revealing the effect of an intervention, with (quantitative) randomised controlled trials as the golden standard [77]. The reductionist approach where elements of health care are explored and isolated seems to also be the general rule for the limited research into the impact of referral letters [38]. Our study on the recommended content of a referral letter is based on an exploratory mixed methods design where a qualitative method is followed by a quantitative method [113]. To explore areas of

health care that are expected to be affected by the quality of referral letters we conducted group interviews and a systematic literature review (i.e. a convergent mixed method design [113]), followed by an expert panel rating. The qualitative methods facilitated a more open-minded exploration of the referral letters' recommended content and their potential consequences. The generalizability of the results from such methods is, however, to a large degree unknown. By conducting a quantitative questionnaire to reveal which item is seen as the most important, we were able to draw conclusions from a larger panel [113]. However, the divergence in the basic scientific understanding represented by the different methods can be challenging for researchers who use a mixed methods design [86]. Therefore, the risk of not fully understanding the threats to the validity of the results for both qualitative and quantitative studies exists. Further, mixed methods are both time and resource consuming [86]. Nevertheless, when exploring complex processes like the referral process, combining methods is recommended [67] and is necessary to gain insight into the mechanisms and contextual factors relevant for exploring how patient and organizational outcomes can be affected [74].

4.4.2 Samples

The inclusion criteria for the different samples used in the present study are based on the theory of relevant perspectives in health care and of communication and processes. Contrary to existing standards for referral letters, which have been defined by health professionals, we included central stakeholders in the referral process: health professionals from both primary and specialised health care and patient representatives and managers (i.e. the valid perspectives in health care [11, 12]). The inclusion of representatives from both primary and specialist health care services is supported by a discrepancy in what is seen as a good referral letter and the lack of shared understanding of the purpose of the referral found between GPs and consultants [31, 48, 114]. Further, the two services can have a diverging understanding of the role of specialised mental health care [115]. The inclusion of professions other than just

medical doctors is in accordance with the increasing level of specialisation in health care [21]. Patient representation is highlighted in the IOM's definition of high-quality health care, as patients hold an essential expertise based upon their experience as receivers of care [6, 11, 98]. Including managers in the sample is essential; the referral letter forms an application for specialised health care in which organisational aspects and political set priorities are relevant for ensuring timely access for those prioritized. We expect our multi-perspective approach to enrich the discussion and to provide a more valid definition of "high-quality referral information" than if it included only health professionals.

Our second and third samples included specialists within specialised mental health care only. Their selection of the most essential information items in referral letters and appropriate indicators for quality of care was based on the suggestions made by the multi-perspective groups. There are several arguments for altering the sample in this part of the study. First, according to theories on processes and communication, specialists hold an essential position as receivers of referral information [84]. It is essential that this information is tailored to the receiver's needs. Second, the large panel of specialists included in the second sample represented the range of (public) specialised mental health care professionals for adults in a larger region than the group interview members. Consequently, their selection of information items is expected to be tailored to the needs of the majority of the receivers of the information. However, switching to a mono-perspective sample may have altered the definition of significant information in referral letters at the expense of the patient and also from a management perspective. Care was taken by ensuring that all major information areas as defined by the multi-perspective groups were represented in the final definition of the recommended referral content. To my knowledge, our sample of 19 multi-perspective participants and 42 specialists constitutes one of the largest samples systematically set up to define recommended content in referral letters in the existing literature. The third sample was constituted by specialists, but some of them were also researchers. Their competence with regard to mental health services and the validity of measurements is

expected to contribute positively in defining valid indicators to explore the potential impact of referral letters' qualities.

When using delphi-methods, the rating is usually conducted by the same panel twice to reveal a consensus [53]. Our moderated Delphi-method, where the multi-perspective panel's rating was followed by the specialists' rating, does not allow for reconsideration of the rating after seeing other ratings as traditional Delphi-methods [53, 85]. One the other hand, it utilizes both types of expertise and gives weight to the perspectives of those who receive the letters. An alternative to the Delphi-method is consensus meetings, where the participants meet face-to-face [82]. This is, however, more time-consuming for the participants, may be more challenging to analyse, is often more expensive and does not provide sufficient data for statistical analyses [53, 82].

4.4.3 Structured group interviews

Our group interviews were structured in accordance with a nominal group technique and affinity diagram, which is a method used to reveal and systemize ideas in response to a defined question [83, 84]. The structure intends to facilitate the group process for ensuring sufficient inclusion of all participants. This is particularly important in groups where there is a risk of dominance by one or a few participants, such as our groups with specialists and patient representatives [53]. On the other hand, structure may be a barrier for creativity [82]. Therefore, we supported structured brainstorming with an oral discussion in accordance with focus group interviews [82] in between two sessions of brainstorming. Alternative methods include only oral methods as individual interviews and focus group interviews. However, a major challenge to such methods lies in making sense of a large amount of data [116]. A main threat to the validity of analysing qualitative data is the potential bias introduced by the researchers' interpretation [82]. In the nominal group technique, the participants conduct the first step of the analyses (i.e. interpreting and grouping the results [87]). However, results of analyses led by the group itself may reflect only a minority of the

participants [82]. We observed that some participants took a more active role than others during the analyses. The later individual rating of suggested items did, however, ensure equal representation of all participants. The nominal group technique and affinity diagram are widely used within quality improvement to enhance ideas and provide a deeper understanding of a practical challenge. Based on the concrete nature of our research question, I expect the method used in this study to contribute positively to provide a valid response to the question. However, I do not expect the method to be appropriate to facilitate the exploration of more abstract areas within health service research.

4.4.4 Exploration of a new measurement

In the second phase of our study, we developed and tested the psychometric properties of a measurement intended to measure the quality of referral letters according to the amount of information given. Surprisingly, the existing literature does not, or only partly, reveal the exploration of instruments to measure the quality of referral letters, even though many studies have reported the quality of these letters [26, 38]. Considerations to how we defined items and explored psychometric properties is therefore of interest.

Defining items

The items in our instrument to measure referral information were defined as dichotomous variables (information is/is not explicitly provided in the referral letter). Instead of dichotomous variables, we could have chosen ordinal or continuous ones to measure the degree to which the information is given. This process would provide more sensitive data than our dichotomous variables. Further, it is in line with the nature of quality that is usually assessed with a continuous scale. However, these alternatives bring in an element of completeness and accuracy of information, requiring that the rater possesses information available only to those knowing the patient's situation.

The formulation of items within the instrument is to a large degree authentic as defined by the group interview participants. A refinement of the formulations may positively affect the reliability by reducing the risk of diverging interpretation among raters. However, in this balance between emphasizing validity of the construct as defined by the valid perspectives and degree of inter-rater reliability, we chose to mostly retain the original formulations.

Exploring psychometric properties

The alpha version of the instrument was tested for inter- and intra-rater reliability as previously recommended [56]. For feasibility reasons, we included only the number of raters and referral letters expected to be sufficient according to calculations based on the limited knowledge on expected reliability [13]. According to Prince et al., 50–100 participants are usually included in these tests [56]. Our sample of eight raters scoring nine referral letters was within the lower limit of the recommended numbers. However, adding more referral letters would not have affected our conclusion as we reported a significant correlation for most tests. More referral letters would only affect the correlation coefficients positively, if at all, because of reduced variation. Including more raters would enable exploration of the properties for the subgroups of raters (GPs, specialists and quality facilitators). However, we did not see the importance of this to justify the time used for this.

Explorative factor analysis has been recommended to explore potential subscales [56]. Studying the correlations between the data for each item and suggested factors (Eigenvalue > 1) can reveal indications for overlap between items and potential underlying constructs [82]. Excluding overlap is recommended to increase the feasibility of the instrument and the guideline for the content of referral letters. However, there is also the risk of eliminating statistical (but not conceptual) overlapping items. Therefore, three researchers individually assessed whether the factors represented theoretically supported underlying constructs. Confirmatory factor analysis was seen as inappropriate as the seven headings suggested in Study 1were developed to organize the items, not to represent an underlying construct.

A set of statistical tests was conducted to examine the QRef-MH's psychometric properties. We used the Wilcoxon signed rank test to select the items seen as most important by the specialists. Excluding items on the basis of a given significance level carries the risk of excluding items seen as clinically significant. To limit this risk, we ensured that all major areas as suggested by the group interviews were represented among the included items. The Wilcoxon signed rank test compares the median score for two sets of data. To compare one item to the rest of the items, we calculated the mean for the other items. This process can be criticized for limiting variation in the dataset. However, alternatives as parametric t-tests assume a normal distribution, which we did not expect within this sample. Interclass correlation (ICC) was conducted to explore inter-rater correlation for the sum score. ICC consistency enables a comparison between raters adjusted for individual differences on their exploitation of the scale and their degree of strictness. The inter-rater correlations per items were explored using the Fleiss kappa. However, the kappa is sensitive to the prevalence index [117]. Even though the referral letters used for these tests were selected to represent the variety of quality, the prevalence of a score of "0" across raters and letters for some items was clearly high. If we had constructed referral letters to ensure representation of all required information, the kappa would have been positively affected. On the other hand, constructing letters would introduce potential limitations to the generalizability of our results to the "real world".

4.4.5 The adapted RAND/UCLA Appropriateness Method (RAM)

In the original protocol (Paper 4), the adapted RAND/UCLA Appropriateness Method (RAM) was not included. However, as the existing literature was found to be even weaker than expected, we decided to strengthen our study with the RAM. The consensus-methods RAM emphasises combining scientific evidence with expert clinical opinion [54]. Our adaption of the RAM included qualitative group interviews to supplement the existing literature. The group interviews were tailored to our research question with regard to the type of health service and context. Further, these

participants defined the expected impact of a construct (referral information) that they had a common definition for within a context familiar to all the participants. Therefore, we expect our adaption to constitute an improvement to the method for achieving valid results in situations where existing evidence is clearly weak and contextual factors are expected to be of importance. Further, RAM has been criticized for not conveying the users' perspective [53, 54]. Existing literature is almost solely based on the professional perspective (e.g. [92, 118, 119]). By supplementing this existing literature with group interviews that include patient representatives, we expect to utilize the competence of patients to a larger degree. However, conducting group interviews is time-consuming. Further, the interviews do not typically provide evidence for causality and can therefore upset the balance between scientific evidence and clinical expert opinion in the original RAM.

The literature and group interviews suggested a range of areas expected to be affected by the quality of the referral letters. It did not, however, reveal clearly defined indicators for all suggested areas. When in doubt, we discussed possible indicator definitions in the research group and with experienced specialists to determine the most appropriate definitions. Scientifically, I see this part as the weakest link in the method. The transparency is limited, making the assessment of the results' validity more difficult. Further, important areas may not be represented among the recommended indicators because of inappropriate or insufficient definitions. For these reasons, we report not only the indicators but also all areas expected to be affected. The expert panels also offered valuable contributions by providing adjustments to the suggested indicators, showing the strength of a stepwise process that makes use of both existing knowledge and clinical expertise of the RAM for exploring areas with a weak evidence base.

4.5 Generalizability

External validity refers to the degree that our results and conclusions can be generalized to a wider population of interest [82]. Generalizability can be explored by similarities to other places, settings, peoples and times [55]. We argue that our results

are expected to be valid for health services with a similar organization as the Norwegian system, including primary and secondary health care, and GPs as gatekeepers for specialized health care. In the following section, I will discuss this concept further with regard to the degree we can expect our results to be valid to a) other countries where services are organized somewhat differently than our Norwegian services, b) other patient groups and c) future referral communication.

4.5.1 Generalizability to place and setting

Regardless of the referral system, all health services with divided primary and specialized health care services face challenges in the handover situations [10]. Further, most standards for referral letters to specialized mental care services include information items grounded in medical science (e.g. information on the patient's somatic health and a list of medications) and practical items (e.g. identification of the patient and the referring doctor). Other items can be explained by the need to clarify elements of the cooperation, such as if investigations or interventions are conducted by the referring doctor and the reason for the referral. These items are expected to be less affected by contextual factors as they are grounded in science or have practical purposes valid across political and organizational systems. However, the weighting of information and the new information items we identified in our study can result from a political process to increase cooperation between services and legal rights for patients [19, 99]. The Norwegian definition of "high-priority patients" and the effort to offer these patients a legal right to care with less waiting can be seen as a central factor for recommending information regarding involved services. Further, introducing these legal rights may place a larger emphasis on the priority aspect of the referral process than can be found in other health systems. In contrast, there is international agreement on the challenge to ensure timely access to health care and to coordinate care across health services [7]. Therefore, I expect the items recommended by our study to be relevant for mental health care in general, but the selection of the most essential

information items among the set of suggested items may vary to some degree between contexts.

The 16 indicators recommended in our third study for exploring to what degree the quality of health care is affected by the quality of referral information are partly based on existing international literature. Further, they are clearly related to internationally recognized challenges to health care defined by the IOM [6]. The suggested areas expected to be relevant for health care are characterized by a two-level health system where the demand for specialized health care is larger than can be provided and access is controlled with a referral system. For instance, delays in the process from the referral decision to different health care interventions is also emphasised within other Nordic countries [34]. However, there may be limitations to the generalizability of the definitions of indicators. Even though the areas the indicators are set out to measure are seen as valid, the definitions may not be the most appropriate within another context. Quality indicators developed by the RAM in the USA are found to have clear similarities with the UK indicators, but an adaption of the indicator definitions to the UK context is seen as necessary [120]. The assessment of validity and reliability of the defined indicators are expected to be highly affected by contextual factors. We do not know if the same four indicators recommended by our study would be selected by other health service organizations.

4.5.2 Generalizability to other patient groups and potential subgroups

The existing literature reveals a variety of standards for referral letters, whereas the majority is defined for a specific patient group [38, 39]. In Norway, a general standard across all patient groups has been suggested [121]. However, the reviewed guidelines recently suggested a few specifications for some larger diagnosis groups, such as mental disorders, in addition to the general information [95]. To achieve a balance between being specific enough and also feasible for GPs, a minimum set of information items for mental health services should be identified [38], as we did in our

study. Some of the information we recommend regards the symptoms or situations typical of mental health referrals (e.g. risk of self-harm and signs of psychosis), whereas others include diagnosis-unspecific information, such as identification of the patient and a list of medications. The latter is recommended across patient groups and support generalization of these results to other patient groups. Our study also recommends items regarding patient involvement and information on related professional networks. Many patients referred for specialized mental health care suffer from severe mental illnesses known to have a large impact on everyday living and therefore have a great need for coordinated care over a long period of time [9]. These characteristics can also be valid for other patient groups, such as those suffering from chronic obstructive pulmonary disease, paralysations and the elderly with multiple diseases [122]. It is reasonable that information regarding involved services and patient involvement is therefore also essential for these patient groups, indicating the potential for the generalization of these findings to other patient groups.

On the other hand, the existing literature reveals standards developed for subgroups of patients within mental health, which have been divided by diagnosis or by the type of service [38, 92]. Not all patients referred to specialized mental health providers are in need of long-term care involving several services, and our definition of "high-quality referral information" may only be partly valid for this minority of patients. Further, the areas expected to be affected by the quality of referral letters, as found in the third study, may not be as essential to the definition of high-quality care for these patients as for the larger population of patients within specialized mental health. However, as the participants in the different steps of the studies are selected to represent knowledge to the wide range of mental health diseases, we expect our results to be valid for the great majority of the adult patient referred to specialized mental health.

4.5.3 Generalizability to the future health care system

The referral letter has two main aims: applying for specialised health care and providing sufficient information for the assessment of needs and planning of care [92,

107]. In Norway, as in many countries, primary care and specialized health care have separate electronic patient record (EPR) systems, implying a need for transferring information between the systems when a patient is referred. New integrated systems to ease the sharing of information are being developed [94], and within a few years we may have access to the same patient information across health services. Nevertheless, if GPs are to retain the role of gatekeepers, the referral letter will be necessary to notify the specialised health care provider about the potential need for such care. Further, it will still be necessary to select the most essential information as the basis for the decision regarding if, when and how a patient should receive specialized health care, in accordance with effective handover communication [10, 106]. Even if the gatekeeper role of GPs were eliminated, the list of essential referral information can constitute an important support for self-referring patients. I will therefore argue that the necessity of our definition of essential referral information is only limited threatened by these potential future changes.

The validity over time of the suggested indicators of quality in health care (Study 3) is unknown. They were developed to explore to what degree the quality of health care is affected by the quality of referral letters. Future research may refute the causality underlying some of the suggested indicators.

4.6 Our study as the first steps in the Western Norway Mental Health Interface Study

The present study constitutes the first steps in a planned study to explore the quality of referral information, if and to what degree the quality of these referral letters can be improved and the potential improvement's impact on defined patient, professional and organisational outcomes, as described in Paper 4. The Western Norway Mental Health Interface Study is planned in accordance with the (UK) MRC's revised guidelines (from 2008) for evaluating complex interventions, which emphasise thorough development of measurements for the intervention and outcome [68]. Contrary to the early version of the guideline (from 2000), the revised version recognises the value of understanding the processes that contribute to the improved outcome [68, 69].

However, when our study was planned, guidance on to how the process evaluation should be prepared and conducted was not yet deliberated. This year, the (UK) MRC published guidelines for the process evaluation of complex interventions supporting our emphasise on exploring the processes [71]. These guidelines recommend investigations into the three key components of a process evaluation: implementation, mechanisms of impact and context [71]. The implementing component regards what is being implemented and how. In our case, we defined the guidelines for the content of referral letters (Study 1) and have described how they will be implemented in Paper 4. Perceiving the intervention as being one part professional knowledge and the other part improvement knowledge has, to my knowledge, not been mentioned in the literature before. However, it is in accordance with Batalden and Stoltz's model of linkage between knowledge required for continual improvement [122]. The second component, mechanisms, includes defining mediators, as we did in the third study, and is emphasised to enable the development of a hypothesis about causal pathways [71]. One of our objects was to reveal measurements for "patient, professional and organisational outcomes" (page 1, Paper 4). Even though we specified the goal of "valid outcome measures that are sensitive to changes in Specialised Mental Health Care following improved referral letters" (page 4, Paper 4), we did not fully foresee the clear emphasis on mediating factors as made by our panels. Our results highlight the importance of process measurements in understanding how the communication in the referral process can affect the outcome. We recommend measuring only mediating factors that are expected to predict the outcome of health care, e.g. improved referral letters can imply the correct priority among patients as seen by specialists which is essential for timely access and therefore safe and effective care. However, the indicators we suggest are not outcome-validated (i.e. explored to determine if they in fact predict the outcome) [64]. In our protocol, we planned to test the predictive value of referral information to each of the suggested (process) indicators, but we did not assess these indicators' impact on outcome. Steps to explore the indicators' relevance for outcome should therefore be included in a revised protocol of the Western Norway Mental Health Interface Study, as recommended by the new guidelines [71].

In the protocol (Paper 4), we described that indicators for outcome are to be developed by literature review and interview groups followed by a test of the correlation with the quality of the referral information. Because of the scarcity in existing literature, we planned interviews. However, due to the insight provided by the group interviews on the complexity of the referral process (i.e. the large amount of health care areas potentially affected by referral information and difficulties with defining valid indicators), we decided to adapt the RAM [81]. The extra step of holding expert panels that included participants familiar with the contextual factors and criteria for indicators offered insight into potential causal pathways and risks of confounding factors. It also revealed potential limitations to the outcome measures suggested in the protocol, especially "length of stay". Although time consuming, the revision of the protocol to adapt the RAND appropriateness method is essential for the validity of our finding and interpretation. It also gave insight into the third domain in process evaluation: contextual factors relevant for the implementation of a complex intervention.

Complex intervention, as represented by communication and coordination activities across health services, is affected by contextual factors, and the context may act as a barrier to or facilitator of the intervention's implementation and its effect on outcome [71]. In contrast to the positivistic research design's emphasis on standardisation and generalizability, the context is seen as an active element in mechanism-based explanations [72, 74]. Within a mechanism-based explanation, and according to the MRC's guidelines, it is essential to define the pre-conditions and outcomes within the same context [67, 68]. To our knowledge, our study is among the first to explore and define the construct and its operationalization for both high-quality referral information and quality of care related to the referral process within the same system. We also ensured a common understanding of the preconditions among the participants for defining and assessing indicators of health care by selecting participants from similar contexts and by asking them as a group to define high-quality referral letters before suggesting impacts.

The qualitative methods employed in the present study allow insight into how referral information can affect the provision of mental health service. When knowledge on the

causality within a defined context is first revealed, the next step should be to explore its generalizability to other contexts. The insight gained by the mechanism-based exploration method used in our study enables a larger degree of the standardization of interventions by their function rather than by their concrete activity [70]. Defining the intervention by the mechanisms they are meant to support makes it possible to define replicable interventions that are adapted to the context [70]. In this way, we can reveal the predictive value of tailored interventions defined by the generalizable mechanisms they support with a (positivistic) RCT-design.

Causality exists only when there is a linear relationship between cause and effect; the cause must occur before the effect [56]. However, our study indicates a relationship between the quality of referral information and quality of care, as the quality of care may affect the quality of referral information. For instance, one of the recommended indicators of care quality is related with the appropriateness of the referral. The necessity of the referral is also defined as a characteristic of a high-quality referral [43]. It is reasonable to believe that improvements to the other indicators of health care quality can also impact the quality of referral information. This "spiral" where input affects output and improved output then positively affects the input is in accordance with Øvretveit's model of the "Soulful spiral" [123]. Further, it is in accordance with systems theory, which states that a change in one element of the system affects the other parts of the system [84, 123]. Within a social system where communication takes place, the response of the receiver of the letters may affect the sender's motivation for providing sufficient information. Flink and colleagues found no differences in the primary care follow-up of a hospital stay when comparing patients where the hospital sent a request for follow-up with those where no such handover information was given [25]. A similar lack of appropriate response is also experienced by GPs who send referral requests [124]. In such situations, we may expect a negative spiral where low-quality referral information produces an inappropriate response, resulting in even less effort to write good referral letters among GPs. With the thorough development of instruments that measure input and output, employ both qualitative and quantitative methods and emphasise the detection of potential mechanisms, such a spiral can be

detected. In contrast, a positivistic exploration of the effect on a defined output will not reveal such correlations. The potential mutual effect between input and output is, however, not discussed in the MRC's guidelines [68].

The MRC's guidelines for evaluating complex interventions, which formed the basis for our study, have many similarities with the CMO-model by Pawson and Tilley [68, 74, 111]. It can be seen as a compromise between positivism and realism by suggesting an RCT-design supported by the exploration of the potential underlying mechanisms and contextual factors [71]. A scientific framework from social science, including the theory of mechanism-based explanations and the CMO-model, provides valuable insight on how and why outcomes can be improved [71]. I see the combination of methods from both scientific paradigms as necessary in developing research designs and revealing knowledge within the field of health service research and implementation science. However, our study constitutes only the first step in the development of an evaluation of a complex intervention as recommended by the MRC. The next steps of exploring the effect of referral information and an intervention to implement guidelines for the content of referral letters, will reveal the strengths and limitations of the scientific framework defining the research design.

4.7 Implications and recommendations for further research

Insufficient information in handover situations is found to be a main reason for adverse events in health care, causing a large amount of harm, disability and death [10]. The results of the first step in our study form a checklist that can help the referring GPs to include sufficient information in the referral letters. The use of a checklist has been found to imply significant improvements within surgery [125] and may have similar positive effects in the transition between primary and specialised mental health care. By representing the recommendation of the major stakeholders, it could also facilitate communication that is better suited to enhance quality as assessed by all the relevant perspectives. Objective measurements, as developed in the second and third steps of our study, can provide feedback on performance to enable benchmarking and to evaluate continuous quality improvement efforts.

Using the QRef-MH and the indicators developed to measure aspects of quality of health care, we can investigate the impact of referral information on important areas of health care. Further, we can explore each information item's predictive value for quality of care and also these items' relevance for the construct of "high-quality referral letters". An evidence-based standard for the content of referral letters, including only items found to have an important impact on outcome, will then be possible. However, this reductionist's understanding may fail within the complex referral system where factors other than the existence of a particular piece of information may also be relevant [93]. Therefore, further research to reveal the predictive value of each item is recommended to be conducted within a mixed method design exploring not only the effect of each item but also any potential mechanisms and potential interrelations between items. It is also essential to test to what degree the suggested indicators on quality of care are in fact affected by the quality of referral information in clinical settings. Such exploration should control for factors such as the patient's gender, age, diagnosis and function to reveal if there are subgroups of patients where some information is more essential than for others. Finally, these process indicators should be explored by their relevance for mortality, quality of life and similar outcome indicators to detect "outcome-validated process measures".

The implications of our study within other contexts are to some degree unknown and should continue to be explored. Further research should also investigate the validity of our findings for other patient groups and contexts to possibly detect valid referral standards across diagnosis groups and health care systems. This process will increase the feasibility for GPs to comply with the spectra of referral letter standards.

A deeper understanding of how quality of care can be improved is possible through a focus on the underlying mechanisms of communication between involved services. At the same time, it enables an examination within the positivistic tradition, (i.e. to detect the predictive value of sufficient referral information on different mediating factors for the quality of care). Exploring mediating factors can reveal mechanisms that enable systematic improvement efforts that affect these factors or mechanisms and thereby improve the outcome [67]. Further, detecting key mediating factors that affect a range

of outcomes facilitates cost-effective interventions. By revealing health service elements that affect the outcome and developing valid and reliable measurements for these elements, future audits and national indicators can emphasise system performance to a larger degree than the present focus.

5. Conclusion

In handover situations where the responsibility of patient care is transferred and the risk to patient safety is expected to be particularly high, sufficient information is the main means to reduce this risk. Nevertheless, the literature indicates insufficiency in the information provided in the referral process. Based on a mixed method design, including structured group interviews, sequential rating within a Delphi-model, a systematic literature review and expert panel, we have attempted to answer research questions regarding the ideal content of referral letters to specialized mental health care services for adults, the validity and reliability of an instrument to measure the quality of such referral information, and how the referral information may impact the quality of care. A large set of information items considered relevant in referral letters was suggested, and 19 items were selected as the most essential. In addition to the information usually recommended by suggested standards, such as information to identify the patient and the referring medical doctor, clinical details, list of medications and the reason for the referral, our study emphasised information on commenced interventions and the involved services for the specialized health care to determine their role in the overall care plan, and patient involvement. The instrument to measure the quality of referral information, which was named the Quality of Referral information–Mental Health (QRef-MH), was found valid and reliable within our Norwegian context. In response to the research question regarding the potential impact of the quality of referral letters, it was revealed that several areas of health care are expected to be affected (e.g. timely access, organization/logistics, cooperation and waste of resources). However, defining appropriate indicators for the areas redeeming the quality criteria for indicators (valid, reliable, feasible, sensitive and easy to communicate) was challenging. Only 4 of the 16 suggested indicators were recommended. These 4 measure the correctness of priority between patients, a delay in the process of assessing the referral letter, a delay to the onset of care, and the appropriateness of the referral.

We expect the recommendation for referral information and the areas potentially affected by the quality of referral letters to be relevant in most health care systems with a two-level health service in which specialized health care is a scarce resource and access is given by first a medical doctor representing primary care and second by a hospital specialist. The selection of the most essential information may, however, be affected by politically set priorities. The assessment of the indicators for quality of care is expected to be highly influenced by local factors. It is not recommended to adopt the selection of the four indicators to other contexts before further exploration is conducted. There may be undetected limitations to the validity and reliability of the QRef-MH. Large-scale tests and explorations of its properties within other contexts and for potential subgroups of patients are recommended.

Using the developed recommendation for the content of referral letters to specialized mental health care, we have defined guidelines for GPs that can be used as a checklist to ensure that the necessary information is gathered and included in the referral letter. Compliance with these guidelines is expected to have a positive impact on timely access and coordination between services. Contrary to most existing standards for referral letters, we have included the perspectives of service users and managers in addition to health professionals from both primary and specialized health care. This choice is expected to provide a fuller picture of the essential information to ensure a safe and coordinated handover. Further, our employment of a large panel of specialists (representing the care for a wide range of mental disorders) enabled the development of a valid yet feasible set of guidelines. The present study also contributes to health service research. The measurements we have developed are necessary for a systematic exploration of to what degree and how referral information affects the quality of mental health care. Through this process, greater insight into how the quality of health care can be improved is possible.

A deeper understanding of how qualities of care are affected (i.e. revealing mediating factors) is essential to enable systematic and effective improvements. Our study is conducted within a positivistic scientific framework focusing on objective measurements of observations in combination with elements of relativism, including

both qualitative and quantitative methods. The relativistic paradigm, which emphasises revealing and explaining causality through mechanisms, forms a central grounding for the present study. The indicators we recommend represent expected mediating factors (i.e. potential mechanisms for the outcome of health care). By revealing mechanisms, we can facilitate systematic improvement efforts by supporting the mechanisms that cause the outcome. Further, our instrument and indicators enable objective measurements for quality improvement efforts. The increasing evidence for system errors causing unnecessary harm, disability and death, and the potential of improvement efforts, opens the door for a larger focus on quality improvement and patient safety research in the future. Our study is an example of such research to facilitate systematic improvements to patient outcome by optimizing the systems.

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Recommended content of referral letters from general practitioners to specialised mental health care: a qualitative multi-perspective study

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Abstract

Background: In most Western countries, the referral letter forms the basis for establishing the priority of patients for specialised health care and for the coordination of care between the services. To be able to define the quality of referral letters, the potential impact of the quality on the organisation of care, and to improve the quality of the letters, we need a multidimensional definition of the ideal content. The study's aim was to explore what information is seen as most important and should be included in referral letters from primary care to specialised mental health care to facilitate prioritisation and planning of treatment and follow-up of the patients.

Methods: Based on purposive sampling, four mixed discussion groups, which included general practitioners, mental health nurses from primary health care, psychiatrists and psychologists from specialised mental health care, managers and patient representatives, were formed; they were asked to identify the information they considered important in a mental health referral letter. In line with the Delphi technique, the importance of the themes was later individually rated by the participants. The study was conducted within The Western Norway Regional Health Authority.

Results: The four groups identified 174 information themes. After excluding themes that were assessed as duplicates, replaceable or less important, 40 themes were suggested, organised in seven units. A set of check-off points of essential information is recommended as an introduction in the referral letter.

Conclusion: Compared with general guidelines and guidelines for somatic care, the results of this study suggest that the referral letter to specialised mental health care should have a larger emphasis on the overall treatment plan, on the specific role of specialised health care in the continuum of care, and on patient involvement. Further research should evaluate the validity of these findings for other patient groups in need of integrated care and investigate how the quality of referral letters affects patient-related and organisational outcomes.

Trial Registration: Trial Registration number: NCT01374035

Keywords: Referral and consultation, Mental health, Health services, General practice, Group interview

Background

Patients suffering from mental disorders are one of the largest patient groups worldwide and constitute a significant contribution to the global burden of disease [1]. Provision of equal healthcare to those with equal needs (horizontal equity) and sufficient accessibility to specialised mental health care is therefore important not only to the individual patients and their relatives, but also to the society [1,2]. Within a health care system where specialist health care is a limited recourse, it is of great importance that the patients most in need are prioritised. In Norway, as in many Western countries, the prioritisation is conducted in two steps: first, a General Practitioner (GP) decides if a patient should be referred; and second, a specialist decides if and when the patient should receive specialist health care. For both steps, the GP needs to know what information the referral letter should include [3]. However, studies on the

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content of referral letters suggest that they lack important information [4-6]. The consequences of low quality referral letters are to a large degree unknown, but a positive correlation has been found between the content of referral letters and the specialists' confidence that they have enough information to make the correct priority for patients receiving cancer care [7]. A recent study by Holman et al. revealed a fair inter-rater reliability between specialists prioritisation of patients based on referral letters within mental health care [8], indicating a risk of low horizontal equity. Both studies suggest defining guidelines for the content of referral letters as one strategy to improve the process of prioritisation [7,8].

During recent decades, suggestions as to what information referral letters ideally should include have been put forward, but variable quality of referral letters seems to be persistent [5,6]. According to Øvretveit's definition, quality in healthcare involves three perspectives: professional, patient, and management [9]. Guidelines, for instance for the ideal content of referral letters, should be defined by consensus of representative health professionals, patients, and managers. Studies revealing a discrepancy within the professional perspective regarding the appropriate content of referral letters indicate that both GPs and hospital specialists should be represented [10-12]. However, existing studies on the quality of referral letters are often based on a standard determined and defined by health personnel alone or only by hospital specialists [4,6]. Another barrier for improving the content of referral letters could be the extent and numbers of different guidelines that GPs are expected to comply with, if all specialities define their own local guidelines. By contrast, using scientific methods to define one standard of the most important information by consensus between the involved parties is in accordance with effective quality improvement [9,13,14].

By legislation, the prioritisation of patients in Norway is based on an assessment of (i) the condition and its influence on quality of life, (ii) the expected effect of recommended interventions (utility), and (iii) the cost-effectiveness of suggested intervention [15,16]. "The good referral letter" is a Norwegian recommended guideline for the content of referral letters [17]. It is a general form for both somatic and psychiatric care, and includes the patient's personal information, information on the referring doctor, special information (allergy), diagnosis, expected treatment, relevant information on the patient's situation and condition, the level of pain or problems, and the degree of urgency [17]. It does not focus on patient experiences as suggested in mental health referral letters [18].

To be able to explore the consequences of the quality of referral letters and to improve the quality of referral letters, we need a valid definition of the most important information it must include [13,19]. The study is an example of a procedure for the first two steps in quality improvement: select the target area and define recommended practice (see Table 1 "The first two steps in quality improvement"). The aim of the present study was to identify what a referral letter to specialised mental health care should include to provide the necessary information to correctly and sufficiently prioritise and plan treatment and follow-up of patients, as perceived by patients, health professionals and managers.

Methods
The study consisted of two steps. First, structured group interviews [20] with mixed groups representing patients, health professionals and managers were conducted. Second, the Delphi method (a postal questionnaire method where suggested items are reviewed by the same participants for a second rating) [20] was used to prioritise the suggested themes from the group interviews. The study was conducted within the Western Norway Regional Health Authority (population: 1 million). We used purposive sampling [20] based on Øvretveit's defined perspectives of quality in health care [9]. Health professionals from both primary health care (GPs and mental health nurses) and specialised mental health care (psychiatrists and trained psychologists) represented the professional perspective. Participants were enrolled by persons or organisations external to the study based on their experience and interest in the subject. Patient representatives and GPs were enrolled by their local organisations, while managers, mental health nurses in primary care and specialists were suggested by their managers. Participation was based on written informed consent according to the Helsinki Declaration [21]. The study was presented and accepted by the Norwegian Social Science Data Service and the National Committee for Medical and Health Research Ethics.

Step 1: group interviews
The group interviews were conducted as consensus development panels, as defined by Bowling [20]. Four groups were formed and interviewed once in a nearby health care centre. There were 19 participants, whereas twelve were men. Nine of the participants were health professionals within primary or specialized mental health care, four patient representatives and six were managers. In addition to their professional titles, many had experience in several areas, e.g. managers or patient representatives that also have a health professional background. They were all experienced; almost half had more than 15 years of experience in their present position. The timeframe for an interview was predefined to last two to three hours. The interviews started with a short presentation of the participants, the study, and the purpose of referral letters. By brainstorming, participants wrote ideas

Table 1 The first two steps in quality improvement

Theory based steps	In this case
1. Select target area	
Frequency	Large patient population [1], referral letters used whenever need for specialised health care.
Importance	Large suffering, large impact on society [1]
Complexity	Many stakeholders, inter-organisational
Insufficiently effective, efficient, accessible, acceptable/patient-centred, equitable, and/or safe care [28]	Risk of incorrect prioritisation of patients and inappropriate care [7,8]
Expected improvement potential [13]	Studies reveal that referral letters in general and within mental health care lack important information [4-6]
2. Determine/define recommended practice	
Explore existing knowledge [13]	Literature review revealed no evidence-based recommended standard for content of referral letters to specialised mental health care
If not sufficient knowledge: Define recommended practice	Structured group interview using the method Language Processing [20]
A. Involve valid perspectives [9]:	Including:
Professional	Health professionals from primary care (GPs and mental health nurses) and from specialist mental health care (psychiatrist and trained psychologists)
Patient/client	Patient representatives from Mental Health Patient Organisation
Organisational	Operating managers within specialist mental health care.
B. Make feasible [13]	Delphi process to determine the most important content. Exclusion of themes where less than 75% of participants have rated them as highly important [22].

The theoretical framework for the method employed in this study.

on post-it notes to the question "What information do you think is important that the specialised mental health care receive in a referral letter?". The ideas (information themes) were collected and reviewed in the group to ensure a common understanding of each theme. The participants were then encouraged to take part in open discussion on issues relevant to good referral letters and were given the opportunity to write down additional themes. At the end, the groups analysed their themes by grouping them and creating a heading for each group of themes. The interview was led by a senior mental health researcher (E.B.); while the categorising of themes was led by the group itself and was observed by a researcher (M.H.). One week after the second interview, the participants in the first two groups were phoned by a researcher and asked if they had additional themes. This part of the process did not result in any new themes and was discontinued. The input from the four groups was combined and analysed together by two researchers (M.H. and O.T.). First, inter-group duplicates were removed. Then, themes with equivalent meanings were made into single themes. Finally, by consensus, new common headings were developed based on the groups' headings with the associated themes by two internal researchers (A.A. and M.H.) and one external researcher (O.H.). These headings were reviewed and approved by the researcher leading the group interviews (E.B.).

Step 2: individual rating
Within the Delphi technique, the suggested information requirements that had been analysed and organised into

the new headings and themes were sent to the participants [20]. They were asked to individually rate each theme's importance on a scale from 0 (= "not important/ irrelevant") to 5 (= "extremely important/cardinal"). With the occurrence of a perceived overlap of themes, the participants were to place a "0" by the redundant theme and mark it with the number of the theme that should replace it. We started the analysis of the individual ratings by excluding the theme that the most participants considered replaceable and marking the theme that replaced it. We then excluded the theme that was seen as second most replaceable by the participants, and so on. Themes that were marked as "replacers" were not excluded. Those assessed as replaceable by only one or two participants were not excluded. Finally, we used a predefined cut-off limit of 75% or more of the participants scoring the themes at 4 or 5, as did Deneckere and colleagues [22]. Only the themes rated as most important or second most important by 75% or more of the participants were included.

Results
Four group interviews were conducted with a total of 19 participants Seventeen completed the individual ratings using the questionnaire. The four groups suggested 174 themes. After excluding inter group duplicates and themes assessed as replaceable, 71 themes were left. Once we excluded themes that less than 75% of the respondents had rated as important (4 or 5 on the scale), we had a list of 40 themes that the participants considered as

the most important information in a referral letter to specialised mental health care. The process is illustrated in Figure 1 "The reduction process". The groups suggested from five to eleven headings. The four sets of headings with the suggested themes were analysed by three individual researchers. By consensus, seven headings were found to adequately cover the four sets:

- ➢ Personal information and contact information.
- ➢ Important introductory information (check-off points).
- ➢ Case history and social situation.
- ➢ Present state and results.
- ➢ Past and on-going treatment efforts, involved professional network.
- ➢ The patient's assessment.
- ➢ Reason for the referral.

The main findings are that referral letters to specialised mental health care should include the overall plan for care, the involved services and interventions, and the patient's preferences and goals as well as the regular information usually found in referral letters. An introductory section to the referral letter with check-off points about essential information was also suggested. The recommended information for a referral letter to specialised mental health care for adults, including the check-off points, is shown in Figure 2 "Suggested content of referral letters to Specialised Mental Health Care".

Figure 1 The reduction process.

Discussion

The findings of the study identify referral letter information seen as important when referring a patient to specialised mental health care. The recommendations from the multi-perspective groups suggests a stronger emphasis on information about the planned integrated care, the specialist health care provider's role in it, and on the patient's involvement compared with "standard" referral letter forms. An introduction with seven check-off points on essential information also evolved during this study.

In contrast to many other efforts to define a standard for content of referral letters, we chose to invite the patients, the management and the professionals to give their perspective into the referral letter evaluation process. Since the referral letter is a communication means mainly between GPs and specialists, it can be argued that doctors are the only ones who are able to discern the type of information it should contain. However, there is increased focus on the importance of the patient perspective to aid in understanding and improving the quality of health care [9,23]. Another important aspect is health care management including knowledge about economic and legal opportunities and boundaries. Studies showing disagreement on appropriateness of referrals and the content of referral letters between stakeholders in the referral process support a comprehensive sampling [11,12]. We argue that the inclusion of all three perspectives gives a fuller description of the health care process and as such increases the validity of the results.

The groups were mixed to increase the richness of the data. Yet, there is the risk that the asymmetrical distribution of power that can be found within health care services could be maintained in the groups. To offset this possible asymmetry, and based on advice from patient representatives, we aimed at including at least two patient representatives in each group, but because of mitigating circumstances, achieved this in only two of the four groups. However, the large amount of input from the patient representatives gives us reason to believe that the effort to create a balance of power in the groups was successful. The definition of quality in health care, which forms the basis for the sampling method, is valid for all health care and therefore strengthens the generalisability of the findings. However, legislation, tradition and culture can affect which information is seen as important in a referral letter. The participants in this study were selected for their extensive experience and interest in the subject, and though this gave indepth insight into the topic, it can also at times be a barrier to innovative ideas and criticism within the topic. Another limitation in the study can be the type of services and professions represented in the sample. Other services such as unemployment agencies or social services may have information that could alter the results regarding
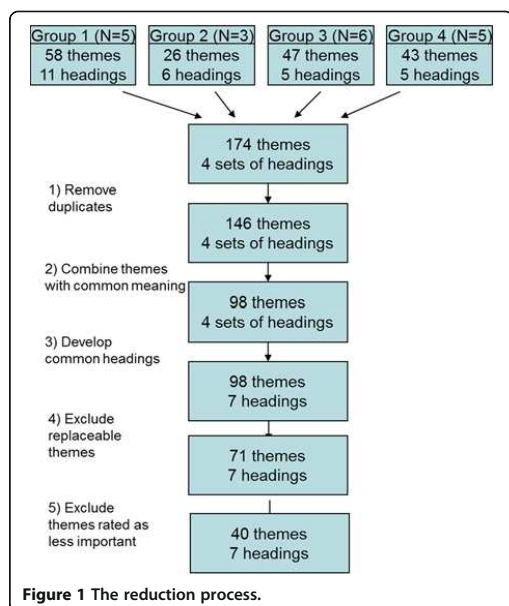
Personal information and contact information

- Personal information that ensures correct identity and contact information, inclusive of phone numbers to relatives
- Patient data: Social security number, place of residence
- Information on the referring doctor, and contact information: phone number, where to reach him/her.
- If the referring doctor is not the patient's GP/family doctor, who is?

Important introductory information (check-off points)

- Is there an imminent danger for the need of compulsory care? ☐ Yes ☐ No
- Is the patient suicidal? ☐ Yes ☐ No
- Is the patient a threat to others? ☐ Yes ☐ No
- Is there an emergency situation? ☐ Yes ☐ No
- Is the patient responsible for the care of children? ☐ Yes ☐ No
- Do you suspect severe illness/psychosis? ☐ Yes ☐ No
- Does the patient have a drug problem or addiction? ☐ Yes ☐ No

Case history and social situation

- Case history. Focus on changes, e.g., worsening
- Development of psychiatric symptoms over time
- Duration of condition/chronic state
- Concrete information on any episodes of violence
- Concrete information on former suicidal risk
- Psychosocial situation (economics, employment, residence, social network, activities)

Present state and results

A. Function, symptoms and limitations
- Present problem, present mental status
- Level of function: present level, loss and duration of the loss
- Present state of symptoms and duration of the symptoms
B. Somatic health
- Somatic health and diseases
- Other important conditions – comorbidity
C. Test results
- When symptoms of depression: MADRS (Montgomery–Åsberg Depression Rating Scale)
D. Medications
- Updated medication record
- Side effects experienced from medications

Past and on-going treatment efforts, involved professional network

A. Tested interventions with assessment of the effect
- What has the referring doctor tried so far?
B. Existing interventions/involved services with assessment of the effect
- Other supportive services that the patient or the family uses
C. Existing plans

The patient's assessment

- The patient's experience of the situation/problems
- The patient's desire for and motivation for treatment
- The patient's thoughts or attitude towards the treatment intervention
- Has the patient induced self-treatment or complimentary medicine?

Reason for the referral

- «Order»/goal for the referral, what the referring doctor is asking of the specialist health care provider
- Reason for referral at this time

Figure 2 Suggested content of referral letters to specialised mental health care.

assessment of important referral letter content. We argue that the results of this study are generalisable to health care systems similar to that of Norway. The method that we used to define the recommended content of referral letters, however, we argue is generalisable to health care in general.

There are many similarities between our findings, the Norwegian guideline "The good referral letter" [17], and international suggested standards within somatic care [5,24]. However, our study suggests more emphasis on the professional network, in which specialised health care is only one element. For instance, our informants thought information about services and interventions that the patient receives and about the overall care plan are important health care elements to convey when referring a patient to specialised mental health care. "The good referral letter" and other existing referral letter forms within somatic care do lend weak support also for our results concerning patient involvement [4,24], though some include information on the patient's experience with the disease [6]. In contrast, the study on referral letters within mental health by Shaw and colleagues supports our patient focus findings [18]. The specific need for information regarding integrated care and patient involvement for patients with mental disorders highlights the need for a separate guideline for the content of referral letters within mental health care. However, it is noteworthy that similar information requirements have been found in other groups of patients who require shared or integrated care, such as the elderly [4]. Thorsen and colleagues defined three types of referral letters: a request for a specific assessment or treatment, an invitation to have a second opinion, and a request for mutual responsibility for the care of a patient [25]. Care for people that are referred to specialist mental health care usually requires cooperation between this service and primary health care [2]. Referral letters for these patients are therefore often a request for mutual responsibility for a period of time. Further research should explore if our results are valid for patients that are in need of integrated or shared care regardless of the diagnosis.

Optimal prioritisation of patients to ensure sufficient accessibility to specialised mental health care is important to patient safety. However, the structures and processes involved to support this are complex [26]. The present study focuses on one part expected to be relevant; the need for sufficient information to prioritise among patients. It suggests that there is some information seen as important when referring a patient to mental health care not emphasised in a general referral letter form. However, factors other than the content of referral letters can affect the setting of priorities, such as acquaintance with the referring GP [27]. Recognising that there may be many factors affecting the accessibility of specialised mental health care, the present study should be seen as one step in exploring best practices for one of the factors. Future research should emphasise exploration of the referral process in the following areas: (a) if or to what degree the content of referral letters have an impact on the quality of care [28] for patients with mental diseases; (b) the generalisability of our findings to other patient groups and context; and (c) if or to what degree other factors than the content of referral letters are relevant for the outcome of the referral process and the subsequent care for the patient.

Conclusion

In this study, we have explored the information that a referral letter to specialised mental health should include. We have revealed some important elements of patient information and care that are not aspects of general referral letter forms. Our findings recommend a stronger focus on the on-going and planned care, so that specialised mental health care has a greater understanding of its role, and more emphasis on the patient's assessment and preferences. Beyond that, a general form, like "The good referral letter", can serve as a guideline. The recommended set of introductory check-off points can serve as a checklist for GPs when writing a referral letter and can outline essential information for specialists. However, it is important to evaluate if or to what degree high quality referral letters, according to the results of this study, improve the outcomes for patients and the organisation, and if they have a positive impact on the accessibility of specialised health care for the patients most in need.

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IV

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STUDY PROTOCOL   **Open Access**

The Western Norway mental health interface study: a controlled intervention trial on referral letters between primary care and specialist mental health care

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Abstract

Background: Referral letters are the main communication means between Primary and Specialised Mental Health Care. However, studies of referral letters reveal that they lack important information, and how this lack of information affects the care for patients is unknown. This study aims to explore if and to what degree the quality of referral letters within Mental Health Care for adults can be improved and the potential improvement's impact on defined patient, professional and organisational related outcomes.

Methods and design: A controlled study with pre and post test will be prepared and accomplished to explore the correlation between the content of referral letters and outcomes of the care for the referred patients. The study is performed in accordance with the guideline of the Medical Research Council on development and evaluation of complex interventions. Using a mixed method design, a stepwise model will be conducted: Firstly, process and outcome measures will be developed and tested. Secondly, by these measures, the results from an intervention group of General Practitioners (GPs) who receive a complex quality improvement intervention will be compared with results from a control group who perform "care as usual". Compliance to the introduced guideline will be measured as a mediator.

Discussion: The Western Norway Mental Health Interface Study is among the first trials to evaluate the impact of the quality of referral letters on the organization of care. This study will provide information that will be usable for healthcare managers and clinicians in both Primary and Specialised Care settings.

Trial Registration: ClinicalTrials.gov: NCT01374035

Background

The prevalence of mental disease is high. Depression is ranked as the leading cause of disability and affects around 120 million people worldwide [1]. As in most countries, Norwegian mental health care is organized using a decentralized model with Primary Health Care often being the first service the patient contacts before being referred to Specialized Mental Health Services. The present decentralisation, sub-specialization and organisation where health professionals, to some degree, independently make

decisions regarding the treatment of the patients increases fragmentation in health care [2]. Therefore, the communication and coordination between the various services is essential. It is particularly important in mental health care for three reasons: Firstly, it is composed of multiple providers and services [3], secondly, it consists of interventions that are mutually dependent for achieving a positive outcome for the patient [3] and thirdly, the patients who use mental health care services often have low level of functioning and lack the ability to ensure that they receive the interventions they need [4].

Research shows that the risk of adverse advents is highest during the transition between two links in the process. This is the moment where responsibility for a

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patient transfers from one service to the next [4,5]. Referral and discharge letters are the most common, and often the only, communication between Primary Care and hospitals [6-8]. However, national and international studies of the quality of this written communication reveal that the quality is poor with regard to the various types of information they cover [7,9-12]. Even though there is no standard for the content of mental health referral letters in Norway, studies imply that there is a potential for improvement also within Mental Health Care [13]. Research has shown that referral letters lack information on assessment of suicidality [13,14], medical and treatment history [15] and planning for integrated care [13].

Quality in Health Services is defined by Øvretveit as "fully meeting the needs of those who need the service most, at the lowest cost to the organisation, within limits and directives set by higher authorities." [16]. It implies that three dimensions are involved: client-quality, professional quality and management quality [16]. When assessing and improving quality, all three dimensions are relevant. "Care Pathways", also known as "Critical Pathways" or "Clinical Pathways", is a complex intervention used to improve the three dimensions in quality of care [17]. Research shows promising results on the effects on patient care and the organization of the care in surgical and medical care when Care Pathways are applied [17-19]. Though there is little research that can demonstrate positive effect of Care Pathways in Mental Health Care [20,21] and in the continuum of care including Primary Care [22,23], the concept is seen as an important contribution toward improving future health care [2,24]. Challenges within research methodology can be argued to be a reason for the limited knowledge on the method's potential and problems [25]. The emphasis on facilitation of communication and coordination in the Care Pathways model implies it has potential to improve the quality of the referral process and letters [26].

A complex intervention is recognized by the high number of interacting components it has. It is made up of a set of components that may interact and cause a synergy effect, which makes it difficult to define the "active ingredients" of the intervention [25,27]. Intervention in the process of coordination and communication between the involved services in a referral process meets the criteria for a complex intervention. The state of the art framework to develop and evaluate complex interventions is described by the Medical Research Council [27,28].

Given the extensive and sole use of referral letters as a link from Primary to Specialised Mental Health Care, it is surprising that their potential for improvement and impact on the service has not been explored to a larger degree. Based on the theoretical and empirical background defined above, there is support for conducting research on these documents' content, the effect they have on the organisation of Specialised Care and the effect of the interventions aimed at improving their content. The increasing use of electronic patient records and electronic transmission of referral and discharge letters is an opportunity for the implementation of research-based interventions that effectively improve and standardise this vital interface [29].

Methods and design
Objectives
The main object is to study the function of referral letters as a means to coordinate the care process for adults when referred from Primary Care to Specialised Mental Health Care. The study will explore if and to what degree the quality of these referral letters can be improved and the potential improvement's impact on defined patient, professional and organisational related outcomes.

Research questions
The main research question is to what degree a defined quality improvement intervention geared toward improving the content of referral letters has an impact on patient, professional and organisational related outcomes in the Specialised Mental Health Care. To be able to answer this question we need to ask two underlying questions: Firstly, does a defined quality improvement intervention improve the compliance to the key characteristics of good referral letters? Secondly, what is the correlation between the compliance to the key characteristics of good referral letters and patient, professional and organisational outcomes within the Specialised Mental Health Care? (Figure 1)

There are two premises that are required in order to answer the posed research questions. The first premise is to define the necessary characteristics of a good referral letter to Specialised Mental Health Care and to translate these characteristics into a valid instrument to measure the quality of these letters. The second premise is to define a set of valid outcome measures that are sensitive to the possible impact of the intervention.

Design
The study includes the two first phases in Medical Research Council's revised framework for developing and evaluating complex interventions: 1) the "Development" phase and 2) "Feasibility and piloting" phase [28]. Our study consists of four steps performed with a mixed method design that combines qualitative and quantitative approaches in order to answer the research questions. Because of the stepwise progression of the study, each step is planned based on how it will be conducted, but the amount of tests and participants will be decided consecutively based on power analysis and other considerations. Step 1 gives input for development of the characteristics

1. Does the quality improvement intervention give significant improvements to patient, organisational and professional related outcomes?

   a) Does the intervention improve the content of referral letter?

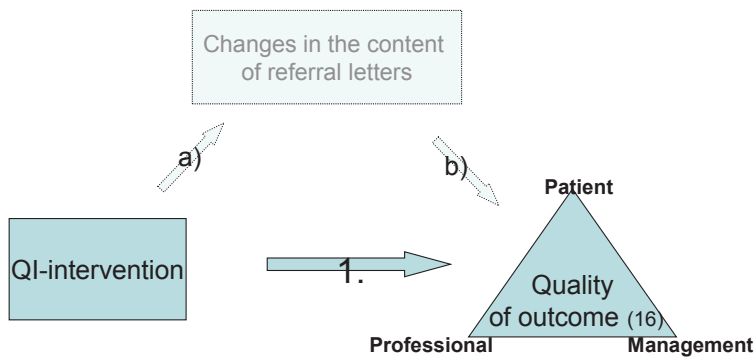   b) Do improved referral letters have an impact on patient, organisational and professional related outcomes?

Changes in the content of referral letters

a)

b)

Patient

QI-intervention

1.

Quality of outcome (16)

Professional

Management

Figure 1 The main research questions in the study.

checklist for good referral letters. In step 2, the checklist's validity as an instrument for assessing the quality of referral letters will be tested. During step 3, the set of outcome measures will be developed and tested to strengthen the causal chain [28]. Step 4 consists of a quasi-experimental study with a pre-post test design using an intervention and a control group (Figure 2).

Step 1: A qualitative study with the aim of detecting the characteristics of good referral letters and outcomes that could be affected by improved referral letters will be performed. Interview by nominal group technique [30] in groups with representatives of the patient, professional (mental health nurses and GPs in Primary Health Care and psychiatrists and psychologist in Specialised Mental Health Care) and management perspectives will be conducted. The groups will be asked questions regarding the two premises: A) Information referral letters should contain to give the Specialised Mental Health Care the necessary information to correctly and sufficiently prioritize, plan treatment and follow-up the patients and B) The possible impact improved referral letters could have on Specialized Mental Health Care.

Step 2: The main aim in step 2 is to use the results from step 1 and premise A together with the results from a literature search to develop a valid tool to assess the
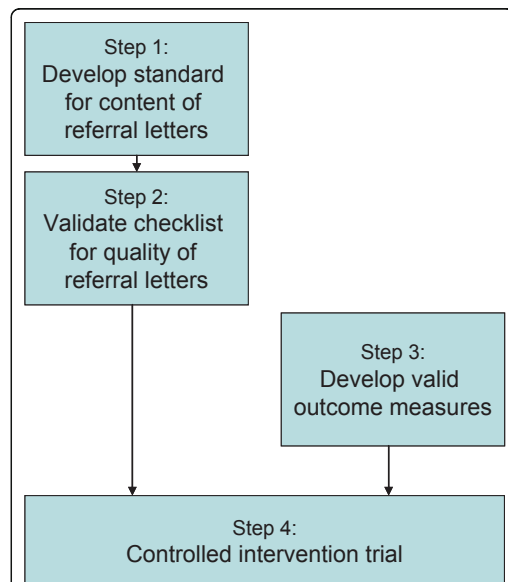
Step 1:
Develop standard for content of referral letters

Step 2:
Validate checklist for quality of referral letters

Step 3:
Develop valid outcome measures

Step 4:
Controlled intervention trial

Figure 2 Illustration of the stepwise progression of the study.

quality of referral letters. A Delphi-technique [30] will be used to rank the characteristics defined in step 1 and defined in the literature on content of referral letters. Both the participants in all the interview groups and specialists from Specialised Mental Health Care and general practitioners (GPs) will be included in this study phase. The alpha version of the tool will be tested on psychometric properties in terms of their interrater reliability, test-retest reliability and correlation between checklist score and receivers' assessment of the referral letter's usefulness. The reliability tests are to be performed on referral letters drawn from a retrospective sample of patient records from Helse Fonna local health trust, Division for Mental Health Care. The number of documents examined by the checklists will be determined by a power analysis after the checklist is developed and pilot testing (N = 10) is completed.

Step 3: The main aim in step 3 is to develop a set of valid outcome measures that are sensitive to changes in Specialised Mental Health Care following improved referral letters. The development of measures will be based on a triangulation of methods [31]. A set of possible measures will be developed based on the interview groups' suggested measures and a literature review on process and outcome measures relevant for Specialised Mental Health Care. These measures will be tested one by one on their correlation with the quality of the referral letter. A number of referral letters will be drawn from the Electronic Patient Record System, depersonalized and scored on the developed referral letter checklist. For each referral letter, data on the suggested outcome measures will also be collected. The correlation between quality of referral letters and outcome measures will then be tested. The outcome measures that are found to have the strongest theoretical and empirical support for their correlation with the quality of referral letters will be used during the intervention study in step 4.

Step 4: The aim of step 4 is to study, firstly, if and to what degree a Care Pathway-inspired intervention for GPs improves the compliance to the guideline developed in step 1 and 2 and, secondly, what the impact is of the intervention and improved referral letters on patient, organisational and professional related outcomes. A controlled quasi-experimental design with pre and post test will be conducted.

Setting and Sample

The study will be conducted within the region of Helse Fonna Local Health Authority on the Western coast of Norway. This health authority is responsible for the Specialised Health Care of 18 municipalities and has a total population of 165,000. Four public local mental hospitals and two public specialised mental health hospitals constitute most of the Specialised Mental Health Care for the population. Mental Health Services in Helse Fonna

receives approximately 300 referral letters per month. There are 144 GPs within the region. To reduce the risk for contamination of the data, GPs within a health centre or office will be seen as a cluster in the inclusion process. All GP offices will be divided into two groups: one will be invited to participate and the second will serve as a control group. GPs in an invited centre who volunteer to participate constitute the intervention group. Data from GPs who do not choose to participate, but are working with participants in the intervention group, will be excluded (Figure 3).

Units of analysis

To answer the research question regarding the impact of the intervention on the quality of the referral letters, the units of analysis will be each GP. When studying the intervention's impact on the outcome, each referral letter will form the unit of analysis. Only referral letters for elective examination or treatment will be included.

Description of the intervention

The intervention includes several components to enhance the mutual understanding of the referral process by making the different activities, roles and goals explicit [32]. It meets the criteria for a complex intervention and constitutes a set of intervention elements adapted into the context of the organization [27,28,33] to facilitate the phases in the process of change defined by Grol and Wensing [30]. The intervention includes development of process and outcome measures defined in step 1-3. Firstly, GPs in the intervention group, in cooperation with representatives from Primary Mental Health Care, Specialist Mental Health Care, patient representatives and managers, will be involved in defining the key characteristics of a high quality referral letter to Specialised Mental Health Care Secondly, the participants in the intervention group will be presented the characteristics of a good referral letter, data on compliance to these characteristics in existing referral letters and the outcomes following the referral letters. Thirdly, they will participate in an individual interview focusing on ability and motivation for change. This is mainly seen as a part of the data collection, but can also serve as an active ingredient. And finally, they will receive consecutive feedback on their performance when they send a referral letter, both on the compliance to the guidelines and the outcome for the patient.

Description of the measures

Following the MRCs guidelines for complex interventions, this study will make use of both qualitative and quantitative data to answer the research questions. Within step 1 and 2, a validated checklist to assess the quality of referral letters will be developed as a process measure. Outcome measures will be developed in step 3. In addition, data on the process of implementing a change and the context will be collected both by
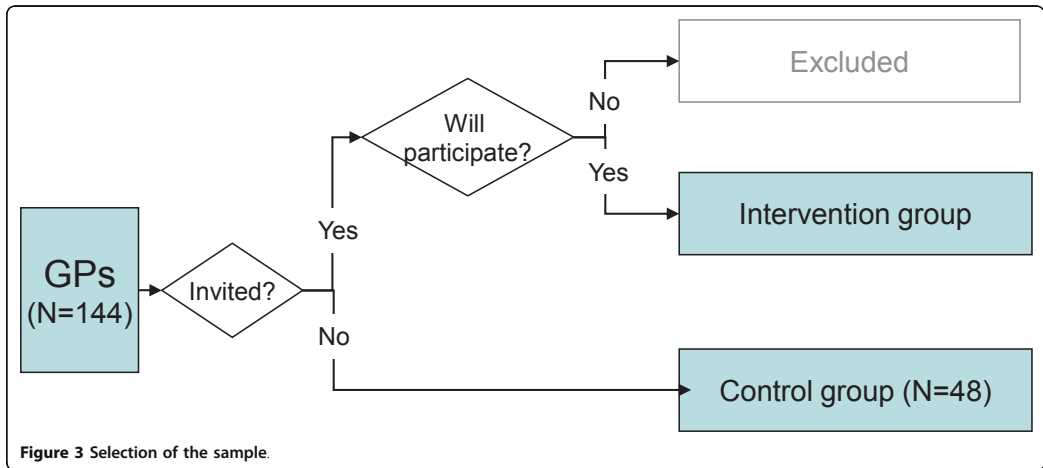
Figure 3 Selection of the sample.

questionnaire and individual interviews. The data collection consists of the following:

Structure measures Before the intervention:

- Questionnaire to the GPs in the intervention group on background variables (age, experience as GP, approximate number of patients with moderate or severe mental health problems, etc.).
- Individual interview with the GPs in the intervention group about their experience with structured quality improvement efforts and referrals to Specialised Mental Health Care, their motivation for changing and their plan to implement the new guideline.

After the intervention:

- Individual interview with the GPs in the intervention group about their experience with the intervention and motivators for continuous improvement.

Process measures • Quality of referral letters measured by the validated checklist from step 1 and 2.

Outcome measurement • Quality of care measured by the indicators from step 3.

- Length of stay. Measurement is from date of admission or onset of out-patient treatment until date of discharge (documented in Electronic Patient Record as end of treatment period), assessed up to six months after admission.
- Response time for referral letters in Specialised Mental Health Care. Referral letters will be followed for the duration of the assessment and prioritization process until response letter is sent, an expected average of 10 days.
- Usefulness of the information in the referral letters. Based on the specialist's assessment, the usefulness and accuracy of the information given in the referral letters will be scored after the first consultation with the patient.

The data collection will mainly be prospective. However, since the development of the process measures a part of the intervention, the pre test of compliance to the characteristics of high quality referral letters will be retrospective using referral letters from the Patient Record System (Figure 4).

Registration and Ethical approval
Step 1 and 2 are approved by the Norwegian Social Science Data Service (register number 24340) and the National Committee for Medical and Health Research Ethics. The application for approval for steps 3 and 4 depends on steps 1 and 2, and will be applied for after step 2 is complete. The study is registered at Clinical-Trials.gov registration number NCT01374035.

Participation will be based on written informed consent. All data from the Patient Record System, including referral letters, will be depersonalized by health professionals who already have access to the information before it is delivered to the researchers.

Discussion
Cooperation and coordination is necessary for ensuring that the patients in Mental Health Care receive a sufficient continuum of care when referred from Primary to

Figure 4 The development of the process and outcome measures.
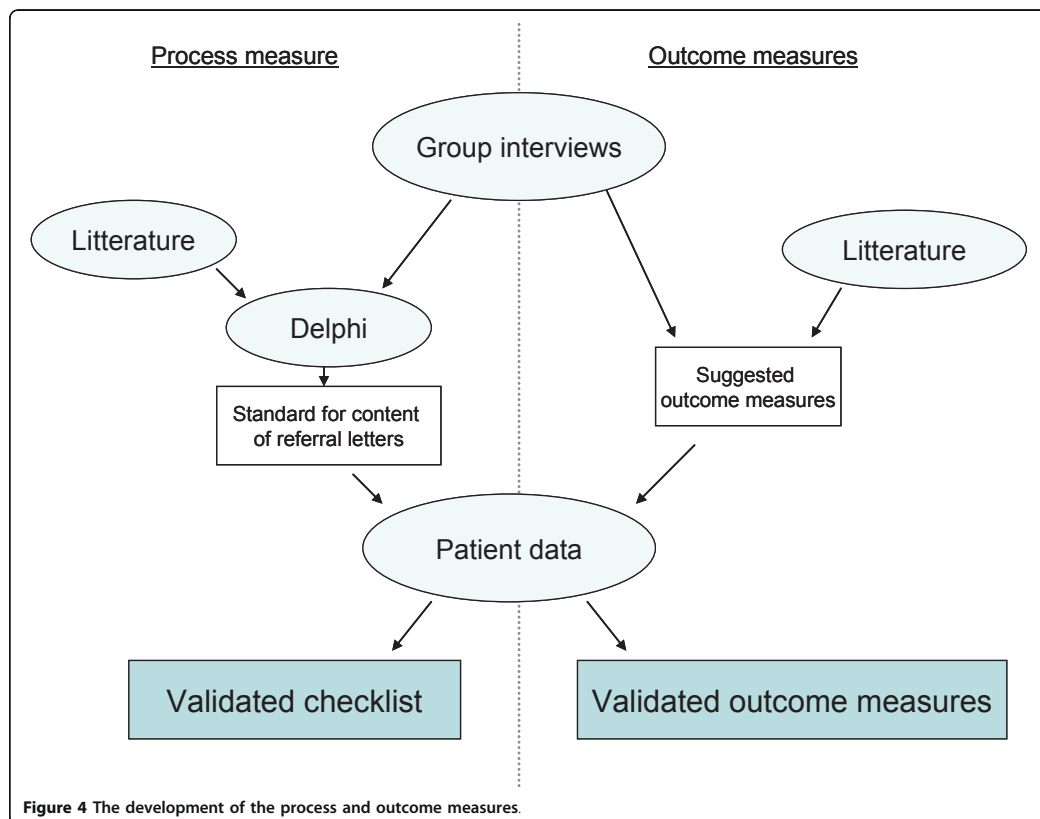
Specialist Health Care. However, our knowledge about the degree to which the main means for this - the referral letter - affects the specialised care is limited. Because of this, we do not know whether we should place emphasis on improving the referral letters. The main object of this study is to investigate the impact of an intervention aimed at improving the quality of referral letters on patient, professional and organisational related outcomes. The intervention is a complex intervention. The implementation of such a complex intervention, according to the MRCs definition, requires careful planning and development of measurements that can detect important causal chains. The study employs a stepwise development of valid process and outcome measures.

Triangulation is recommended to enhance the validity of the findings to compensate for the methods' various weaknesses [31]. We combine three research methods by making use of data from group interviews, examining existing literature and testing existing data from patient records to develop process and outcome measures. From

these procedures, we will be able to perform a controlled intervention study in Mental Health Care for adults. Since the strong focus on referral letters as important means for care coordination can be argued to be based mainly on expectations and beliefs rather than evidence, this study will contribute important information about referral letters even if we find no correlation between improved referral letters and quality of care.

There are several possible obstacles to effective cooperation between Primary Care Services and Specialist Mental Health Services [34]. There may not be agreement between the services about which information is essential and correct in referral letters. This study will, therefore, use a guideline for content of referral letters that will be collaboratively developed by representatives from both Primary and Specialist Health Care. We will also test the correlation between the quality of a referral letter defined by the guideline to the quality defined by the specialist's assessment after the first consultation with the patient.

In this study we will be able to compare the intervention group's pre results with the post results as well as compare the results of the intervention group with the control group. The intervention group consists of GPs who are willing to participate and the control group is expected to be a natural sample of GPs. We do not expect them as group to differ in the way they write referral letters before the intervention. But we expect that the intervention group could be more motivated for change than the control group as defined in Prochaska's model for stages of readiness to change [30]. Since we compare content of referral letters, not willingness to change, we argue that the groups are comparable. However, we emphasise that the intervention is tested on a group expected to be at the "contemplation" or a later phase in Prochaska's model. The effect of the intervention can only be generalized to groups that are at the same level of readiness, not to the general population.

A lot of effort is put into improving the coordination between health services. The referral letters are seen as an important means for this coordination, and they have been found to lack important information. However, we do not know if and how the quality of these letters affects the outcome for the patients and the services. This study will explore the correlation between the quality of referral letters and outcome measures based on the state-of-the-art framework of the Medical Research Council. To our knowledge, this is the first trial about the impact of referral letters on Specialised Mental Health Care and is an important aspect of building knowledge about a complex process of coordination and possible improvement potential within Health Care.

List of abbreviations
MRC: Medical Research Council; QI: Quality improvement; GPs: General Practitioners (medical doctors in Primary Health Care)

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