UiT
THE ARCTIC UNIVERSITY OF NORWAY

Faculty of Health Sciences – Department of Community Medicine

Practical health co-operation – a cluster randomised study

The impact of referral templates on quality of care and health care co-operation between primary and secondary care

—

Henrik Wåhlberg

A dissertation for the degree of Philosophiae Doctor – May 2019

Table of contents

Acknowledgements

The research described in this thesis was conducted at University Hospital of North Norway Harstad and at the Department of Community Medicine, Faculty of Health Sciences, University of Tromsø The Arctic University of Norway. This research was performed from August 2011 to February 2015 and was sponsored by a research grant from Northern Norway Regional Health Authority (Helse Nord RHF).

This research was proposed by the excellent clinician and tutor, Dr. Per Christian Valle. I am very grateful for the opportunity to take his idea and develop it into a full PhD project. Dr. Valle also co-supervised this PhD project and continually contributed with great interest, especially by adding a wider clinical perspective when I became too narrowly interested in methodological concepts.

I am very grateful for the continual and knowledgeable support of my main supervisor, Dr. Ann Ragnhild Broderstad. Her ever-persistent positive attitude and encouragement have been invaluable when progress was slow. Without her help navigating the unfamiliar terrain of research, I would not have been able to complete this PhD project.

In addition, I am very grateful for the precise and clear feedback and support of my co-supervisor, Dr. Med Siri Malm. Her experience with and knowledge of succinctness and clarity in research have been very useful when my words exceeded the scientific content.

Statistical advice from Associate Professor Tonje Braaten made the third article possible and helped demystify some of the more dimly-lit areas of statistics.

My office co-workers, Maria Serafia Fjellstad, Siri Martinsen, and Florian Prael, also deserve great gratitude for their everlasting patience with my papers, binders, clutter, and research frustration.

Without the work and interest of general practitioners, this PhD project could not have taken place, and their unpaid assistance is greatly appreciated. I also want to thank the consultants who aided with the quality criteria scoring, as well as Øyvind Isaksen, Astrid Lunde Gjervold, and Silje Lehne Michalsen for scoring the referrals within this PhD project.

My thanks also go out to the staff of the Medical Department of the University Hospital of North Norway Harstad, including doctors, nurses, and support staff, for their enduring patience and support. My time working in the endoscopy unit, and the staff and patients in that unit, allowed me to relax and focus on things other than the tedious tasks that often accompany PhD work. Unni Isaksen and Herdis Helland deserve a special mention for practical and technical assistance.

I am also grateful for the participation of all the patients who allowed me to access and use their information, without which this PhD project would not have been possible.

Finally, I want the express my admiration for and gratitude toward my wife Sandra and my children Selma and Karin for their everlasting support and normality.

Summary

High-quality services and evidence-based care are vital components of a well-functioning health care system. Currently, the focus on high-quality health care has led to the routine measurement of national quality criteria and, in Norway, a national patient safety programme. However, parts of the health care system are based more on traditions that have developed over the years than on scientific reasoning. For example, the process of referral from general practitioners (GPs), i.e., primary care to hospital doctors, i.e., secondary care has remained unchanged for many years, although the introduction of electronic communication has improved the more administrative aspects. Moreover, the clinical content of referral documents continues to be debated, with hospital doctors emphasising that the lack of important information makes it difficult for them to deliver high-quality care and prioritise those with the highest need.

The present intervention study looked to facilitate a better transfer from primary to secondary care in the Norwegian health care system by implementing referral templates (available as laminated paper and electronic documents) which were designed for four diagnostic groups (1) patients with dyspepsia, (2) patients with suspected colorectal malignancy, (3) patients with chest pain, and (4) patients with chronic obstructive pulmonary disease. Using a clustered approach, the fourteen GP surgeries located in the geographical area served by the University Hospital of North Norway Harstad were randomised to an intervention or control group, with seven surgeries in each.

In total, 500 patients were included in the analysis, 281 in the intervention and 219 in the control group. There were no significant baseline differences between GPs or patients in the intervention and control groups, but there were more referrals sent from female GPs and GP specialists in the intervention than the control group. The referral template was used for about half of the new referrals in the intervention group, which was less than hoped for.

The main hypothesis in the current project was that the implementation of a referral template would lead to a measurable increase in the quality of hospital care.

Paper I showed that the content of referral documents in the intervention group was significantly better than that in the control group, when measured against the referral template. After adjustment for whether the GP was board certified or not, centred GP list

size, GP hospital experience (in years), and categorised GP surgery size, the effect of the referral intervention was estimated at 18% (95% confidence interval 11, 25 $p<0.001$). In addition, the analysis showed that board certified GPs produced referral documents of higher quality, whereas, surprisingly, longer GP hospital experience reduced the quality of referral documents.

To examine the effect of the increase in quality of referral documents on patients' experience of the treatment process, self-administered questionnaires were developed. As presented in Paper II, a total of 410 (82.0%) patients returned a completed questionnaire. In general, patients were very satisfied with their care, but areas with most dissatisfaction concerned patient interaction, involvement, and information. There were no significant differences between the responses in the intervention and control groups. Analyses were done on a single-question basis, but to further assess the effect of clustering, a multilevel model was built after multiple imputation using chained equations with predictive means matching to account for missing data in the questionnaires. The effect of clustering was low, as assessed when using the imputed data in a multilevel regression model.

The main outcome measure of the study was the quality of the care process for each individual patient, based on quality indicators developed from previous publications and guidelines. In addition, each care pathway was given a subjective quality score (scale 1-10) by medical specialists who were unaware of the intervention status of the patient. As shown in Paper III, we observed no significant effect of the referral template on quality indicator score (1.80%; 95% confidence interval -1.46, 5.06, $p=0.280$) or the subjective quality score. The prioritisation of patients in the intervention group was no better than that in the control group.

The current study showed significant improvement in the quality of referral documents following the referral intervention, but no significant change in patient experience or quality of care. The results may have been influenced by the relatively low usage of the referral template (approximately 50% of referrals in the intervention group were done using the referral template) and the wide variation in scoring from the specialists. Based on this study, broad-scale implementation of referral guidance cannot be

recommended before a more stringent assessment has shown it to be useful in clinical practice.

Sammendrag

Kunnskapsbaserte tiltak og behandling av høy kvalitet er grunnleggende komponenter i en velfungerende helsetjeneste. Fokuset på høy behandlingskvalitet har ført til at det nå foregår rutinemessige målinger av nasjonale kvalitetskriterier og det er startet et nasjonalt pasientsikkerhetsprogram. Selv om dette pågår er det fremdeles deler av behandlingskjeden som er mer basert på tradisjoner utviklet over mange år enn forskningsbasert kunnskap. Prosessen med henvisning fra allmennlegen til sykehuset har ikke endret seg på mange år, selv om introduksjonen av elektronisk kommunikasjon har forbedret noen av de mer administrative aspektene av henvisningen. Det kliniske innholdet i henvisningene debatteres fremdeles. Sykehuslegene mener ofte at mangelen på viktig informasjon gjør det vanskeligere å skape helsetjenester av høy kvalitet og prioritere de som trenger tjenesten mest.

Konseptet til denne intervensjonsstudien var å skape bedre samhandling mellom nivåene i helsetjenesten ved å implementere en intervensjon på henvisningene fra fastlege til sykehus. I intervensjonsgruppen ble det tatt i bruk henvisningsmaler ved henvisning av pasienter tilhørende fire ulike pasientgrupper. Disse fire gruppene var pasienter med (1) dyspepsi, (2) mistanke om kreft i tykktarmen, (3) brystsmerter eller (4) kronisk obstruktiv lungesykdom (KOLS). De fjorten legekontorene i området som sokner til Universitetssykehuset Nord-Norge (UNN) Harstad ble grupperandomisert til en intervensjon eller kontroll gruppe, med totalt 7 legekontor i hver.

500 pasienter deltok i prosjektet frem til analyse og av disse var 281 i intervensjonsgruppen og 219 i kontrollgruppen. Det var ingen signifikante demografiske forskjeller mellom pasientene eller allmennlegene i de to gruppene. Derimot var flere av henvisningene sent fra kvinnelige allmennleger og allmennlegespesialister i intervensjonsgruppen enn i kontrollgruppen. Intervensjonen ble tatt i bruk i cirka halvparten av de nye henvisningssituasjonene i intervensjonsgruppen, noe som er mindre enn vi opprinnelig ønsket.

Hovedhypotesen i dette prosjektet var at en forbedring i henvisning fra fastlege til sykehuset skulle gi en målbar forbedring i kvaliteten på sykehusbehandlingen.

Artikkel I viser at henvisningene i intervensjonsgruppen var signifikant bedre enn de i kontrollgruppen, når de ble målt opp i mot henvisningsmalene. Korrigert for allmennlegens spesialiststatus, sentrert pasientlistestørrelse, allmennlegens sykehuserfaring (i år) og kategorisert legekontorstørrelse ble effekten av intervensjonen estimert til 18% (95% CI 11, 25 p<0.001). I tillegg viste analysen at spesialister i allmennmedisin skrev henvisninger av bedre kvalitet og at, overraskende nok, lengre sykehuserfaring hadde sammenheng med henvisninger av lavere kvalitet.

For å undersøke effekten av den økte henvisningskvaliteten på pasienterfaringene med behandlingsprosessen utviklet prosjektet spørreskjemaer. Artikkel II viser at etter utsendelse av en påminnelse svarte totalt 410 pasienter (82,0%). Generelt var pasientene meget fornøyd med sin behandling, men var minst fornøyd med informasjonen fra behandlerne og egen involvering i beslutningsprosessene. Det var ingen større forskjeller mellom pasienter i intervensjons- og kontrollgruppen. For videre å undersøke effekten av grupperandomisering ble dataene analysert med regresjonsteknikk etter at statistisk korreksjon for manglende svar i skjemaene var utført. Effekten av grupperandomsering på pasienterfaringene var liten.

Hovedutfallsmålet i studien var effekten av intervensjonen på behandlingskvalitet for hver enkelt pasient. For å måle kvaliteten i behandlingskjeden utviklet prosjektet kvalitetsindikatorer basert på tidligere publiserte indikatorer og behandlingsretningslinjer. I tillegg ble hvert behandlingsforløp scoret på en subjektiv skala (1-10). Scoring ble gjort av spesialister uten kjennskap til om pasienten var i intervensjons- eller kontrollgruppen. Artikkel III viser at det ikke var noen signifikant forskjell mellom de to gruppene, hverken på kvalitetsindikatormålet (1,80 %; 95% CI -1,46, 5,06, p=0,280) eller den subjektive kvalitetsscoren. I tillegg ble ikke prioriteringen av pasientene mer presis i intervensjonsgruppen enn i kontrollgruppen.

Denne studien viste dermed ingen forbedring i pasientopplevelse eller behandlingskvalitet, til tross for klar forbedring av henvisningskvalitet. Resultatene kan ha blitt påvirket av relativt lav aktiv bruk av intervensjonen og stor variasjon i kvalitetsscoring gjort av spesialistene. Ut fra denne studien kan en ikke anbefale stor utbredning av henvisningsmaler før tydelige effekter er blitt vist i praksisnær forskning.

List of papers

This thesis is based on the following papers, hereafter referred to as Papers I, II, and III.

Paper I: Wåhlberg H, Valle PC, Malm S, Broderstad AR: **Impact of referral templates on the quality of referrals from primary to secondary care: a cluster randomised trial.** *BMC Health Services Research* 2015, **15**:353

Paper II: Wåhlberg H, Braaten T, Broderstad AR: **Impact of referral templates on patient experience of the referral and care process: a cluster randomised trial.** *BMJ Open* 2016, **6**:e011651.

Paper III: Wåhlberg H, Valle PC, Malm S, Hovde Ø, Broderstad AR: **The effect of referral templates on out-patient quality of care in a hospital setting: a cluster randomized controlled trial.** *BMC Health Services Research* 2017, **17**:177

Abbreviations

GP	General practitioner
UNN	University Hospital of North Norway
COPD	Chronic obstructive pulmonary disease
EHR	Electronic health record
ICD-10	International Classification of Diseases tenth revision
Deff	Design effect
ICC	Intra-cluster correlation coefficient
CI	Confidence interval

1.0 Introduction

Health care is commonly organised into levels, with the sharpest divide between out-of-hospital primary care and hospital-based secondary care. However, individual patients often receive care at multiple levels, both physically in the community and in the hospital, and across different health care professions. Hence, health care coordination and communication are important aspects in any health care system.

In Norway, general practitioners (GPs) represent primary care and act as gatekeepers to hospital doctors at the secondary care level. Health care in Norway is governed by two main laws: the act relating to specialised health services[1] and the act relating to municipal health services[2], but the act relating to patients' rights[3] and to health personnel[4] are also of interest. All these acts share the common, explicitly stated purpose of safeguarding equal access to high-quality health services for all, but they are also meant to ensure the appropriate use of resources. At the time of the present study, the act relating to patients' rights gave patients a legal right to health care, provided the patient could be expected to benefit from that care and that the costs were in concordance with the effect of the care[3]. In practice, the application of this right for secondary care was determined by the hospital consultant, based on communication from the GP, usually in the form of a referral document.

Traditionally, the referral document has been the standard form of communication and transfer of responsibility from primary to secondary care. Although the content and quality of referral documents have been debated for some time[5,6], there has been limited research on the clinical benefit of improving this quality[7]. In addition, there has been surprisingly little research on the referral process, as indicated in a relatively recent editorial from the United States[8]. However, in Norway, research focusing on referral rates[9,10], referral interventions[11,12], and cost analyses[13], is starting to emerge.

The demand for out-patient secondary care in Norway is steadily rising, with a 7% increase in out-patient hospital appointments observed between 2008 and 2012[14]. It has been estimated that if every single GP referred one additional patient to secondary care every day, it would increase the number of referrals by one million per year[15]. Given the current number of appointments[14], this would increase the workload by approximately

20%, and would, under the current health care structure, be unsustainable. The demand for quality care is also increasing, both in Norway and internationally[16,17]. In the everyday clinical setting, these increasing demands, coupled with a perceived lack of information in the referral documents received, make it difficult to prioritise individuals referred from a GP to the hospital according to their needs.

With this background in mind, the main aim of the present thesis was to investigate whether improving the quality of referrals could lead to improved delivery of high-quality care to each individual patient without any specific increase in capacity or funding.

2.0 Background

2.1 Focus on quality and safety in health care

Internationally, the focus on prevention of medical errors and improving quality of medical care is increasing[16-19]. There are journals[1] dedicated to the publication of papers on quality, quality improvement, and quality measurement, as well as large international conferences devoted to the topic. Nationally, the Norwegian Patient Safety Programme: 'In Safe Hands', was launched in 2014 and aims to reduce preventable patient harm, establish lasting structures for patient safety, and improve patient safety culture[20]. This focus has taken many forms, from the publication of a multitude of management guidelines [21-23], to introducing car production methodology into the efficient management of patient care pathways [24-26]. However, much of the work being done focuses on separate and specific health care processes, either at the primary or secondary care level, rather than trying to assess the entire health care process. In addition, a recent editorial pointed out that care must be taken to ensure that quality, and not just quality measurement, remains the purpose of any given quality improvement process[27].

2.2 The role of the referral in transitions of care

Transitional care has been defined as "a set of actions designed to ensure coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location"[28]. Although key roles for both the sending and receiving care team have been identified, key information about the patient may not be adequately communicated[29]. In Norway, the Health Sector Coordination Reform, which started in January 2012, aims to improve health care cooperation to ensure effective preventive care and to ensure that health care is delivered at the right level[30].

When referrals are made from GPs to hospital doctors, the major exchange of information is done through the written text of the referral document[31,32]. Problems with this communication can lead to difficulties in finding a correct diagnosis or repeat testing and initiation of treatment that has already proven ineffective[33]. Thus it is clear that the referral document is an important communicative tool between primary and secondary care

[1] E.g., BMJ Quality & Safety, International Journal for Quality in Healthcare, BMC Health Services Research, American Journal of Medical Quality

providers. However, as a Norwegian study from 2007 amongst elderly patients demonstrated, both referral and discharge documents are often missing vital information, even “to such an extent that it might represent a health hazard to older patients”[32]. A Finnish quality assessment of referral documents for patients with asthma concluded that 45% of these documents were of poor or unacceptable quality, when evaluated against criteria developed by GPs and hospital respiratory specialists[34]. A recent Canadian survey showed that the main problem specialists identified in referral documents was that they lacked a reason for referral[35]. Others have also reported varying quality and content of referral documents in different clinical settings[36-43].

The quality of the referral document is not always perceived as relevant to the referral process. However, there seems to be good agreement between GPs and hospital doctors as to what a referral document should contain [5]. In the United States, the National Quality Forum has published preferred practices for care coordination, including transitions of care[44]. In Norway, there are agreements and guidelines that govern the content of electronic referral and discharge documents [45,46], but they are mainly limited to headings and content categories, without specifying the precise information needed in each clinical scenario. In a recent Norwegian study, it is this lack of information, rather than the structure of the referral document itself, the hospital doctors perceived as a barrier to care cooperation[47].

The present, steadily rising referral rates[48] and demand for out-patient medical services[49] are creating a strain on medical departments, with an increasing need to be able to prioritise patients. Others have shown high variation in referral rates [10], which may be related to a GP’s gender and speciality status[9]. In addition, factors other than the perceived risk of serious disease may affect the decision to refer, such as patient reassurance, medico-legal risk reduction, handing over of care, or simply to get a second opinion[50]. Given this wide variation in referral rates, referral quality, and referral reasons, the work that hospital doctors must do to identify referred patients with the highest need for health services is becoming more difficult.

2.3 Previous interventions applied to the referral process

In 1964, Kunkle described the communication breakdown in patient referrals as a "disorder of medical practice (which) is largely curable"[33]. Since then, many studies have aimed to improve the quality of referrals from GPs to hospital doctors, with mixed results. In Scotland, a complex intervention combined the dissemination of referral guidelines with open access to an investigation service for lower urinary tract symptoms or microscopic haematuria, which led to reduced wait times and fewer out-patient appointments[51]. In another study amongst patients with dyspepsia, the dissemination of referral guidelines alone was compared with the combination of the dissemination of referral guidelines and educational outreach. They concluded that the combined approach may be better than the dissemination of referral guidelines alone, but the intervention did not change the diagnostic yield at gastroscopy[52]. For patients with lower bowel symptoms, Jiwa *et al* compared interactive electronic referral alone to a combination of interactive electronic referral and educational outreach or no intervention. The interventions did increase the amount of information in referral documents, but it did not increase the proportion of organic pathology amongst those referred[53]. However, the uptake of the intervention was poor. In a systematic review by Faulkner *et al* on interventions in primary care and their effect on referral quality, the authors concluded that such assessment is difficult[54], as end-points and targets are not clearly defined in the literature. Does improving quality mean a simple reduction in referral numbers, more appropriate referral content, or more relevant care of higher quality?

Drawing on some of the studies discussed above, a Cochrane review on interventions to improve referrals from primary to secondary care concluded that few interventions on the referral system have been rigorously evaluated[7]. The review further concluded that structured referral sheets and local educational interventions have an impact on referral rates. However, few studies have been able to present findings on several aspects of the referral process simultaneously. The review recommended further studies, both to validate current findings and highlight others factors of the referral process, such as referral numbers, referral quality, secondary care management, flow of patients through the referral process, patient outcome and satisfaction, and resource use.

2.4 Quality of care

In the evaluation of any health care intervention, the assessment of the effect on the quality of care delivered to patients is paramount. Quality of health care is defined by the American Institute of Medicine as: “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge”[55]. On a more operative level, it has been suggested to define quality of care as “the degree to which health services achieve a level of care deemed adequate by evidence-based quality measures of the structure, process and outcomes of care”[56].

Health services evaluation and the measurement of quality of care is a complex field. Much of the perceived global quality measurements are done to measure adherence to specific actions and for accreditation or reimbursement purposes[57,58]. However, this measurement is thought to be useful in documenting quality of care, making comparisons, prioritising, and improving quality of care and accountability[59,60]. The area of quality measurement is still under development, and new areas, including patient feedback, are continually evaluated, even via Facebook[61].

Quality measures are usually classified into structural, process, or outcome measures, as suggested by Donabedian[62]. Structural measures are often easy to evaluate, such as equipment, facilities, and staffing numbers. However, structural measures are often only weakly associated with outcomes[63]. Process measures consider components of the encounter between the patient and the health care professional, such as tests ordered or treatment initiated[60]. Outcome measures use specific health outcomes as quality measures and directly measure survival, complications, and quality of life [63]. However, the assessment of outcome measures is often hampered by the infrequency of events (e.g., mortality) and the length of time between an intervention and the possible outcome[64]. If a structural or process measure is used, it should already be shown to be associated with better outcomes[64]. Today the use of quality criteria range from system- or national-level measurements for reimbursement and quality efforts[65,66] via disease-specific areas[67,68], to quality criteria for subparts of management of individual conditions[69] and procedures[70].

However, quality indicators are only tools to support quality improvement; they are not necessarily direct measures of quality[71]. Others have raised the issue of whether the measurement of smaller aspects of care may shift the focus from other unmeasured, but equally important, aspects of care[57,72]. A review of performance indicators in the speciality referral process identified multiple indicators[73], but most of these focused on the structural components of the referral process, and as such, may not holistically depict the quality of the entire treatment process. As we recognise the difficulties of quality measurement, the current thesis aimed to holistically depict the quality of the entire patient care pathway across several of the domains of quality indicated by the Institute of Medicine in the landmark 2001 report *Crossing the Quality Chasm*; safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity[55].

2.5 The four diagnostic groups

In this PhD project, the intervention and subsequent quality measurement focused on four diagnostic groups, i.e., patients referred within four common diagnostic scenarios in the hospital ambulatory care setting. The scenarios were chosen to represent several specialties across the medical spectrum. In addition, they represent clinical situations with some diagnostic difficulty in primary care, encompass symptoms with which patients commonly present in GP practice, and are adept for relatively simple referral guidelines. They are also scenarios in which differential diagnoses are potentially very serious, but where many patients have more mundane explanations for their symptoms.

2.5.1 Dyspepsia

Dyspepsia usually refers to recurrent pain or discomfort in the upper abdomen[74]. In the Roma III classification of functional gastrointestinal disorders, functional dyspepsia includes one or more of the following symptoms: (a) bothersome postprandial fullness, (b) early satiation, (c) epigastric pain, and (d) epigastric burning. For the Roma III criteria to be fulfilled there also has to be no evidence of structural disease (including at upper endoscopy) that is likely to explain the symptoms[75]. However, dyspepsia is a term which has had many interpretations by different physicians[75], and the diagnosis of functional dyspepsia can only be applied after investigation. In the primary care setting, the term ‘uninvestigated dyspepsia’ is often used[74], as it is difficult to clinically differentiate between dyspepsia

and, for instance, gastroesophageal reflux disease[76]. The current PhD project considered referrals from primary care, and as such a wider definition of dyspepsia was used: all patients referred with uninvestigated upper gastrointestinal symptoms were included. This included patients with upper abdominal pain/discomfort, upper abdominal burning, reflux symptoms, early satiety and so forth.

Approximately 20-30% of people in Western societies report dyspeptic symptoms[77,78]. Dyspepsia represents about 2-5% of all medical consultations, in European populations[79]. Of these, approximately 25% have an underlying organic cause at gastroscopy[80]. In the United Kingdom, the cost of dyspepsia from a health services perspective was estimated at £500 million in 2002[81]. This figure is probably lower today, in light of cheaper medication, but dyspepsia still represents major financial burden, in addition to the burden of symptoms borne by patients.

Others have tried to use symptoms to differentiate significant from more mundane underlying disease[82], and to prioritise between patients with upper gastrointestinal symptoms[83]. There is an internationally accepted set of 'alarm features' (Table 1) specifically aimed at identifying underlying malignancy[84]. In this PhD project, these features were included in the construction of the referral template, although not all of them were prioritised in the final version.

Table 1 – Alarm features in a patient with dyspepsia

Age >55 years with new-onset dyspepsia
Family history of upper gastrointestinal cancer
Unintended weight loss
Gastrointestinal bleeding
Progressive dysphagia
Odynophagia
Unexplained iron deficiency anaemia
Persistent vomiting
Palpable mass or lymphadenopathy
Jaundice

2.5.2 Suspected colorectal malignancy

Colorectal cancer is a major malignancy. In 2012, the age-standardised incidence rate of colon cancer in Norway was 24.1/100,000 for women and 26.7/100,000 for men, making it the second most common cancer amongst women and third most common amongst men[85]. Colon cancer ranked third in terms of cancer mortality in Norway 2012 for both men and women[85]. Cancers of the rectum and anus are also potentially serious conditions.

Common symptoms of colorectal cancer include occult blood in stool, rectal bleeding, change in bowel habits, abdominal pain, weight loss, fatigue, and diarrhoea[86]. However, no single, clear symptom can currently identify patients with colorectal cancer in primary care, although a combination of symptoms can alert a GP as to the possible diagnosis[87-89]. Referral prioritisation systems, like the 2-week wait in the United Kingdom, have struggled to improve diagnostic certainty[90]. Some countries have screening programmes in place for colorectal cancer, but the Norwegian programme is still in a pilot phase[91]. Hence, the early identification of patients with this potentially serious disease remains difficult.

2.5.3 Chest pain

Coronary artery disease remains an important, albeit decreasing, cause of mortality; ischaemic heart disease was responsible for 11.6% of deaths in Norway in 2012[92]. Chest pain is the symptom most classically associated with coronary artery disease, but non-life-threatening aetiologies are much more common explanations for chest pain in general practice[93]. Causes of chest pain other than coronary artery disease include acute diseases such as pulmonary embolus, aortic dissection, and perforated gastric ulcer, together with more benign, less acute diseases, such as musculoskeletal chest pain, gastroesophageal reflux disease, pneumonia, pleuritis, stress, panic disorder, and other psychogenic diseases[94].

Earlier epidemiological work in the United Kingdom suggests that 14% of men report chest pain suggestive of coronary artery disease and a further 24% report atypical chest pain[95]. Patients with chest pain represent approximately 1% of the GP caseload[96,97]. However, only about 10% of patients end up with a diagnosis of stable coronary artery disease, and about 1-4% with acute coronary syndrome[97,98]. Much of the diagnostic

work-up and consideration is focused on the identification of those 10% of patients with coronary artery disease. The patients referred by the GP to the hospital for chest pain evaluation represent an important, and sometimes challenging, proportion of medical out-patients. Hence, the current project included patients referred for chest pain evaluation or evaluation of suspected coronary artery disease.

2.5.4 Chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease (COPD) is an airway disease with persistent, and usually progressive, airflow limitation, coupled with an enhanced chronic inflammatory response[99]. It is often associated with acute exacerbations and comorbidities[99]. In many countries, the prevalence of COPD is directly related to tobacco smoking; however indoor and outdoor pollution may also be contributing factors, especially in developing countries[100].

It has been estimated that between 250,000 and 300,000 suffer from COPD in Norway[101], with a yearly incidence of about 1% of the population[102]. For approximately 1% of the population, the disease is serious enough to warrant regular review by primary and/or secondary care[101]. In 2009, almost 1% of the Norwegian health expenditure was estimated to be attributable to COPD[103]. More than 2000 people die from COPD every year in Norway, which is almost equal to the number of people who die from lung cancer[92]. It is also clear that many of those affected are unaware that they have the disease, as only 43% of incident cases in a Norwegian population study had a prior diagnosis of asthma, bronchitis, emphysema, and/or COPD[102], suggesting a clear phenomenon of underdiagnosis.

2.6 The Norwegian health care system

The Norwegian health care system is relatively uniform throughout the country. In 2013, 98.8% of the population had a regular GP, and at the end of 2013 there were 4387 GPs with an average list size of 1150 patients[104]. Specialist health care is delivered through government-owned regional health authorities, mainly via public hospitals. However, the regional health authorities do outsource some out-patient care to privately operating specialists. GP services are organised through the 426 municipalities. GPs either work privately, with capitation payment and fee-for-service reimbursement, or as municipal

employees. There are no financial incentives related to the referral process. GPs represent primary care and act as gatekeepers to secondary care, including hospital doctors and private specialists. In the study area, access to specialist care is practically impossible without referral from a GP, whereas in more urban areas, some access may be possible.

In Norway, the use of electronic health records (EHR) and electronic referrals is almost ubiquitous. In 2008, 98% of the GP surgeries surveyed reported using EHR[105], and in 2010, 96% of the GPs surveyed reported that they always used EHR for their daily clinical work[106].

2.7 Current referral practice

Referrals to the University Hospital of North Norway (UNN) Harstad are nearly all electronic, but some paper referrals are still in use, mainly from smaller GP surgeries and temporary GPs. Paper referrals are scanned by hospital support staff and included in the hospital EHR. The demographic data in referrals are automatically extracted from the GP's EHR, whereas the clinical content is based on free text and may be very short or very long, depending on the GP's preference.

3.0 Aims of the thesis

The increasing focus on quality in health care, together with the obvious shortcomings in the transition of care and the rising need for services within confined financial boundaries, inspired this PhD project.

The main aim of the thesis was to document the need for good communication between providers when referring patients from primary to secondary care. Indeed, the referral is the "key" which unlocks access to the large and expensive secondary care system. In the trial that constituted this PhD project, we postulated that improvement of the referral document would lead to a measurable increase in the quality of health care delivered.

Primary hypothesis:

- The use of a referral template in the communication between GPs and secondary care will lead to a measurable increase in the quality of health care delivered (Paper III)

Secondary hypotheses:

- The use of a referral template in the communication between GPs and secondary care will lead to a measurable improvement in referral quality (Paper I)
- The use of a referral template in the communication between GPs and secondary care will lead to improved patient experience (Paper II)
- The use of a referral template in the communication between GPs and secondary care will lead to more appropriate prioritisation of patients, as measured by final diagnosis (Paper III)
- The use of a referral template in the communication between GPs and secondary care will lead to an increase in the 'appropriateness' of referrals (Paper III)

Hence, we hope to enlighten the debate regarding health care cooperation in the area of referral quality and its effect on the subsequent health services care pathway of each individual patient.

4.0 Material and methods

4.1 Study design

This PhD project is based upon a cluster randomised study, in which GP surgery was used as the clustering unit. Local GP surgeries were randomised to use either referral templates (intervention group) or standard referral practice (control group).

4.2 Study population

The GP surgeries in the area served by the Medical Department at the UNN Harstad were randomised, and study participants were recruited from out-patient clinics at the UNN Harstad. The UNN Harstad is a general medical hospital located in Northern Norway. It serves an area with a small town and the surrounding, less densely populated countryside (Figure 1). At the time of the study, the UNN Harstad had general medical admissions and out-patient clinics with specialists in cardiology, gastroenterology, haematology, nephrology, rheumatology, neurology, and pulmonary medicine. Except for one private cardiology specialist, no other specialist medical services were available locally. At the time of the study, the UNN Harstad handled approximately 3000 admissions each year, and approximately 5500 patients were seen in the out-patient clinics for a total of about 9000 consultations (own data). The nearest tertiary referral centre is located in Tromsø, approximately 300 km away.

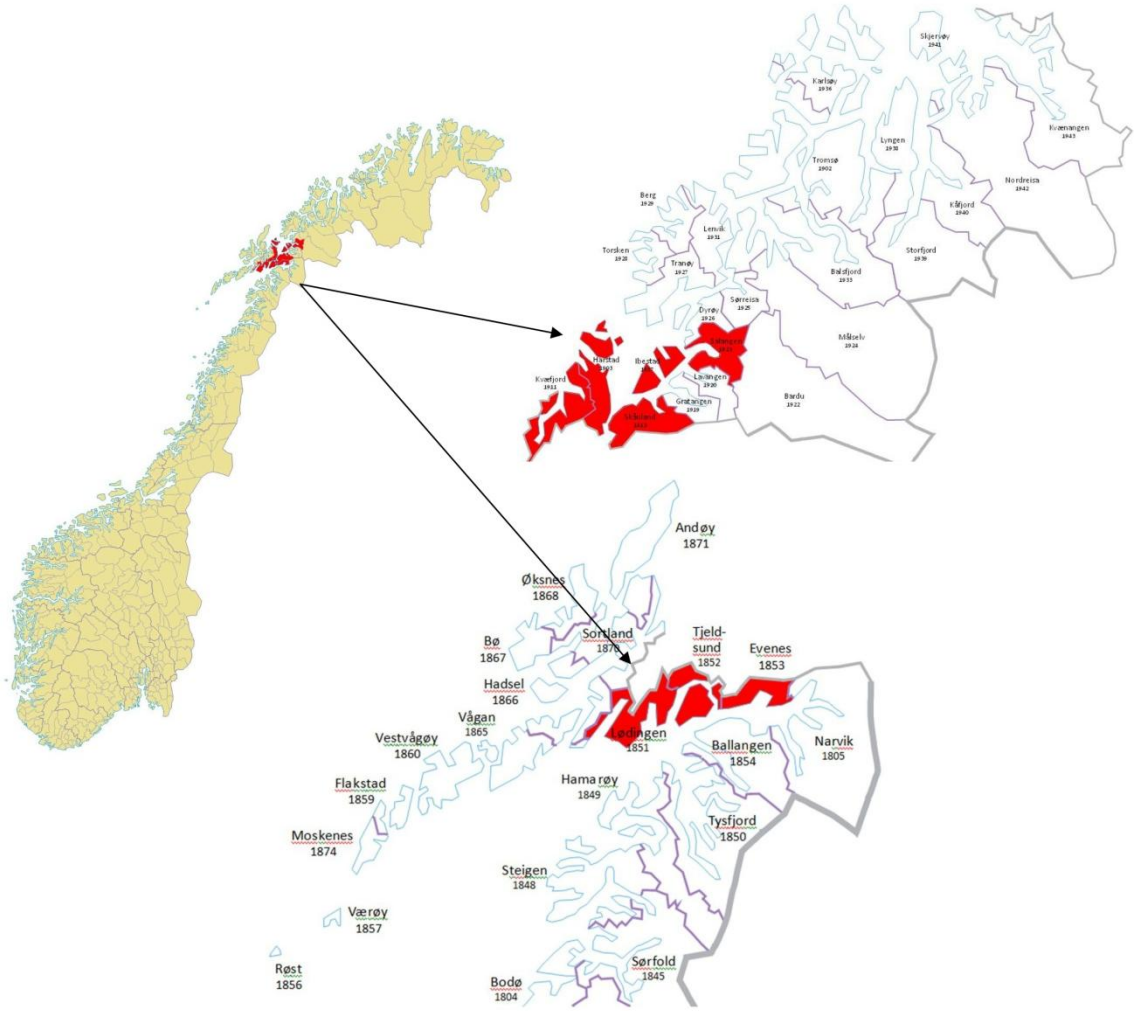

Figure 1 - Map of area served by the UNN Harstad. Source: Kartverket (The Norwegian Mapping Authority)

4.2.1 GP surgeries

14 community GP surgeries were included in the randomization process. These 14 GP surgeries had an average of 4.2 doctors. On average each GP had a list size of 848 patients. Of these GP surgeries five were larger, town-based centres whereas nine were smaller, more rural centres.

4.2.2 Study participants

The study population consists of patients referred from a GP for elective appointments at the Medical Department UNN Harstad. Only patients initiating a new period of contact were asked to participate. Patients referred from a hospital doctor or who attended for a scheduled follow up appointment were not included. Children (<18 years of

age) and patients with reduced capacity to consent were excluded from participation in the study.

4.3 Randomisation

To ensure that intervention and control groups were comparable in terms of number and socio-demographic characteristics, GP surgeries were randomised after stratification by location (town-based vs. rural surgery). This was done because, as previously mentioned, the area served by the UNN Harstad has one town and several surrounding municipalities of much smaller size. As an example, as of 1 January 2011, Harstad had 23,423 inhabitants and Ibestad had 1419, with an average age of 39.91 and 48.54 years, respectively[107]. The location of the GP surgery was not expected to influence the outcome variables in the study. Others have shown variation in referral rates based on hospital proximity[108], but the outcomes in this PhD project were designed to assess the individual patient/doctor contact episode for each patient, not referral rates. When approached, two GP surgeries declined the invitation to be part of the intervention group; therefore they were used as part of the control group, and two additional GP surgeries were randomly selected to the intervention group (Figure 2).

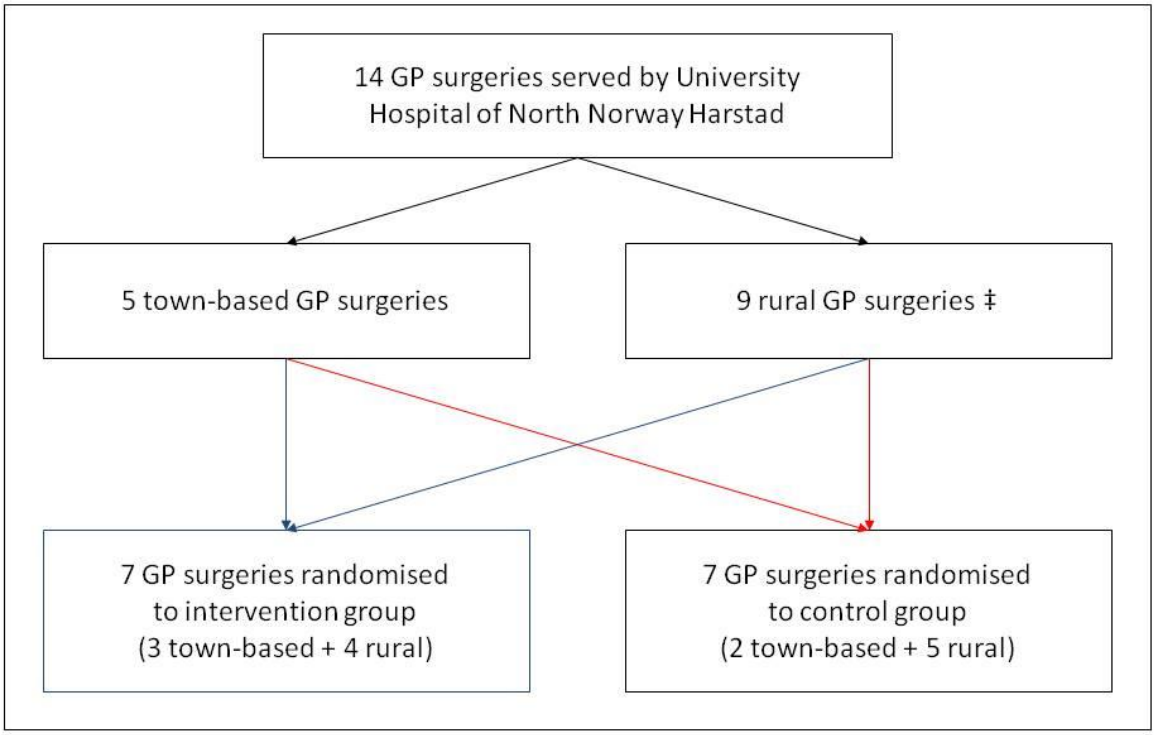

Figure 2 - **Flow chart of the randomisation process.** ‡ From the four rural GP surgeries initially randomised to the intervention group, two refused. Therefore, they were used as part of the control group, and two additional GP surgeries initially randomised to the control group were randomised to, and consented to take part in, the intervention group.

4.4 Recruitment

The study population consists of patients within the four diagnostic groups described in Chapter 2.5 (patients referred with dyspepsia, suspected colorectal malignancy, chest pain, and COPD or suspected COPD), who were referred by a GP to the Medical Department of the UNN Harstad for elective appointments. In total, these diagnostic groups represented a substantial number of the new referrals to the Medical Department of the UNN Harstad (own data, 2008) and, as such, enabled our clinical research to be conducted in a small hospital. Only patients initiating a new period of contact were considered eligible for inclusion in the study.

Eligible patients received written information about the present study, a consent form, and a prepaid return envelope along with their hospital appointment letter. These were sent out by a hospital nurse unaware of the intervention status of the GP surgery that referred the patient. At the hospital appointment, doctors asked eligible patients to participate in the study and, if needed, gave them a new consent form and prepaid return

envelope. The study organisers regularly reminded hospital doctors to recruit eligible patients. If hospital doctors forgot to ask patients to participate at their appointment, but subsequently remembered, a new information letter and consent form was sent to the patient. This procedure was followed in the intervention and control groups.

The referral documents sent by GP surgeries in the intervention group were sent electronically to a separate inbox at the UNN Harstad, as described below. This enabled study organisers to send information letters and consent forms to intervention patients who were not recruited at their hospital visit. A similar procedure could not be followed for the control group, as it would have required reviewing all referrals and appointments, which was outside the ethical approval of the project.

4.5 Intervention

The intervention consisted of the implementation of referral templates for the four diagnostic groups to be used at the initiation of a referral to the UNN Harstad. The PhD candidate was unable to locate existing referral guidelines in the literature that were appropriate for the current study. Therefore the referral templates for the four diagnostic groups were developed by the PhD candidate in collaboration with local specialists, based on national prioritisation guidelines and international literature[109-116]. No formal theory of development was employed. Specific informational bullet points were collected by the candidate and local specialists based on the literature and subject knowledge. These informational bullet points were then ranked by other specialists across Northern Norway on a scale of 1-5, and the specialists were given the option to add further bullet points. Earlier studies have had problems with the uptake of referral interventions[7,53]. To reduce this problem, only informational bullet points considered imperative (i.e., with a ranking of 5) by the consulted specialists were kept in the final referral template, to keep the number of items as low as possible. Local GPs were invited to the take part in the development of the referral templates at a meeting, but no formal feedback was elicited. The intervention was piloted by GPs at two GP surgeries before implementation. The items in the referral template for suspected colorectal malignancy are presented in Table 2, with the all four templates available in the Appendix.

Table 2 – Items in the referral template for suspected colorectal malignancy

Item no	Item text
1	Change in bowel habits
2	Blood in stool
3	Weight loss
4	Family history of colorectal cancer
5	Previous medical history of bowel disease or results from previous bowel investigations
6	Results of digital rectal examination
7	Iron deficiency anaemia
8	Clinical findings at abdominal examination
9	Results of faecal occult blood test
10	GP's clinical suspicion

Referral templates were provided to GP surgeries in the intervention group as laminated paper copies and as electronic templates in the EHR. The electronic referral templates did not function as a required electronic check list, but as bullet points that could be used in the referral text if the GP so wished. Referrals from GP surgeries in the intervention group were sent electronically to a separate inbox at the UNN Harstad, which could only be accessed by two secretaries and the PhD candidate. These referrals were then immediately sent to the inbox of the appropriate clinical speciality for assessment, thereby entering the normal electronic referral pathway. This setup was chosen to enable the estimation of referral template uptake, as discussed later in this thesis. The study team did not consider this setup to be part of the intervention, as it did not change GP behaviour when referring, but the fact that referrals from GP surgeries in the intervention group were sent to a separate inbox did serve as a reminder to GPs. No evaluation and care processes after referral receipt in the separate inbox were altered, compared with standard referral practice. No referral templates were provided to the GP surgeries in the control group. The referral pathway is represented in Figure 3.

During the study period, each GP surgery in the intervention group received regular lunch time visits, mail reminders, and updates regarding the progress of the project. No such visits or reminders were provided to the GP surgeries in the control group, nor was information about the project easily publically available.

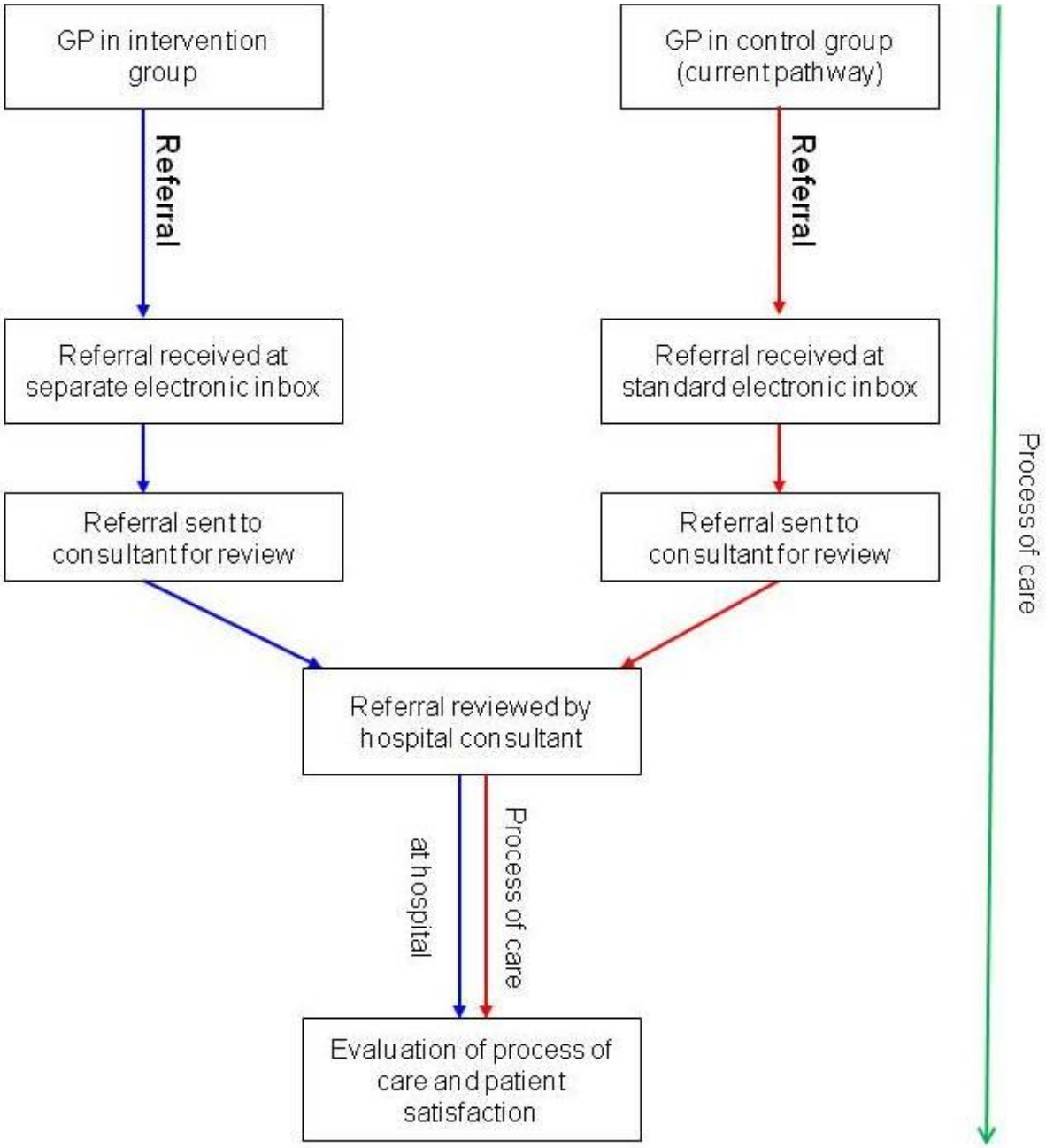

Figure 3 - **Referral pathway**. Flow of referral and process of care in the intervention (blue arrows) and control group (red arrows)

4.6 Expected change process

In this project, the development of the referral intervention was empiric, with no formal evaluation of the expected change process. The intervention consisted of two separate parts: (1) the four referral templates and (2) visits and follow-up by study personnel. The expected change process for the individual participants at each level in the health care chain is presented in Figure 4. It is worth noting that the intervention did not change hospital out-patient scheduling, the sending or content of hospital appointment letters, or any other aspect of health care logistics surrounding the intervention. The intervention was developed with feedback from local stakeholders (GPs, hospital consultants, and information technology staff), but no formal, in-depth interviews were carried out regarding the expected change process outlined in Figure 4.

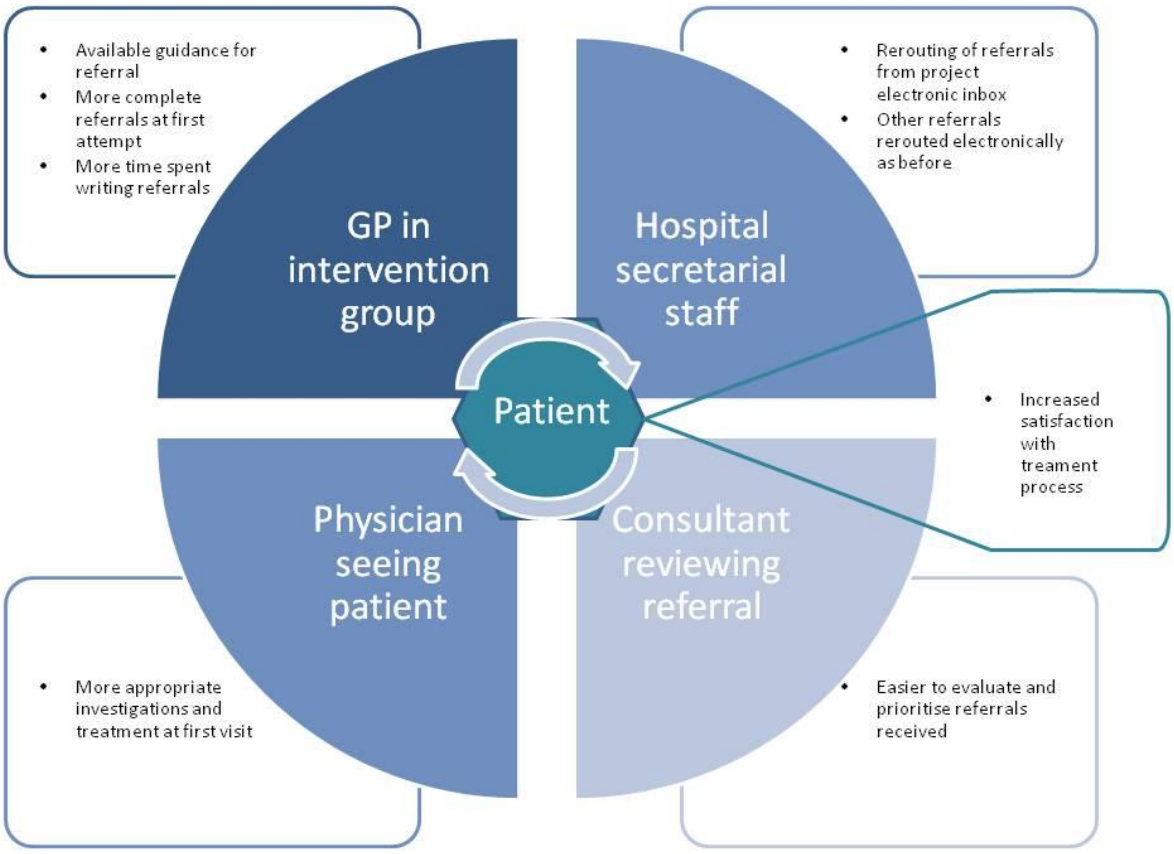

Figure 4 - Graphical representation of expected change process at each health care level

4.7 Primary outcomes

4.7.1 Quality of care

This study aimed to assess the impact of increased referral quality on quality of care. To assess quality of care, quality indicators were developed for each of the diagnostic groups. The indicators were generated from previous, international quality assessment tools, in addition to national and international guidelines. Where necessary, adaptations were made to correspond to locally accepted practice. The necessity of such adaptations has been previously demonstrated when quality indicators are to be used in a new context[117]. As an example, the quality indicators for dyspepsia were developed using guidelines from the American Gastroenterological Association, the National Institute of Clinical Excellence (United Kingdom), the Swedish Gastroenterological Association, international articles, and UpToDate[23,83,118-126]. The full set of quality indicators and references are available in the Appendix.

Each patient care pathway was scored by medical specialists (scoring panel), blinded to the intervention status of the patient. The total quality score used in the final analysis was calculated as adherence scores, that is, the number of criteria met divided by number of applicable criteria, expressed in percentages, as illustrated by Ashton[127]. If a criterion was deemed applicable, but no information was found in the clinical notes, it was recorded as 'not met' (applicable, but not answerable); in essence a conservative approach[128]. It was decided not to apply weighting based on clinical importance. Although it would seem tempting to give items specific criteria weights according to their importance, this practice also adds complexity without adding much to the clinical findings, as discussed by Lyons and Payne in 1975[129].

4.8 Secondary outcomes

4.8.1 Referral quality

The aim of the implementation of the referral template was to increase the quality of referrals and then to assess whether this translated into improved care. Hence, a measure of referral quality was paramount to the completion of this study. The scoring system was based on the referral template used, with one point awarded for each clinical detail

requested in the referral template that was present in the received referral. This is similar to scoring systems used in other referral evaluations[34,38]. No weighting was applied.

Referrals were scored by three raters, blinded to the intervention status of the patient. However, when the electronic template was used the intervention status was sometimes obvious. Twenty percent of the referrals were scored independently by two raters, no referral was scored by all three raters, and the three rater-pairs shared at least 25 referrals each.

4.8.2 Patient experience

Patient experience is an ever more important aspect in the evaluation of health care interventions, and the evaluation of patient experience can help drive improvements in quality of care[130]. Better patient experiences are associated with safety and clinical effectiveness[131]. Multiple tools exist to measure various aspects of care coordination[132] and patient experience. However, after a thorough search, no relevant questionnaire was found in Norwegian. Therefore, a patient experience questionnaire was developed for the current project; it aimed to measure patient experience with the care coordination and treatment process. The questionnaire included all questions from the full version of the Generic Short Patient Experience Questionnaire[133,134] and the two questions about health interaction from the Commonwealth Fund Survey 2010[135]. Further questions were added to assess (1) who referred the patient, (2) if the referral was seen as appropriate, and (3) an overall assessment of the hospital (Table 3). The full questionnaire is included in the Appendix. The questionnaire was piloted with local health professionals and patients to evaluate the content, face validity, and acceptability[136,137]; however, no further formal evaluation of the questionnaire was done.

Table 3 – Questionnaire details

Question no	Item text
1	Did the clinicians[a] talk to you in a way that was easy to understand?
2	Do you have confidence in the clinicians' professional skills?

3	Did you get sufficient information about how examinations and tests were to be performed?
4	Did you get sufficient information about your diagnosis/conditions?
5	Did you perceive the treatment to be adapted to you situation?
6	Were you involved in decisions regarding your treatment?
7	Did you perceive the institution work practices as well organised?
8	Did you perceive the equipment at the institution to be in good working order?
9	Overall, was the help and treatment you received at the institution satisfactory?
10	Do you believe that you were in any way given incorrect treatment (according to your own judgement)?
11	Did you have to wait before you were given an appointment at the institution?
12	Overall, what benefit have you had from the care at the institution?
13	Did the hospital specialist lack basic medical information from your GP about the reason for your visit or test results?
14	After your saw the hospital specialist, did your GP lack important information about the care you got from the specialist?
15	Was the referral to the out-patient department necessary (according to your own judgement)?
16a	Were you referred by your GP for the out-patient appointment?
16b	If no in question 16a; who referred you?
17	If you take an overview of your entire treatment process, how would you evaluate the institution?

[a] 'Clinicians' refers to those who had the main treatment responsibility. This is linguistically clearer in the Norwegian wording.

The questionnaire was mailed to study participants after their hospital appointment. To increase the response rate, pre-paid envelopes were provided, addresses were hand-written, the questionnaire was kept as short as possible, and association with the research body was clearly indicated[138]. For initial non-responders, a mail reminder was sent approximately 1 month after the first questionnaire was sent out.

4.8.3 Health process outcomes

To further assess the effect of the referral template on the care pathway, information on other health process outcomes was retrieved through a manual review of EHR:

- wait time from date of referral to date of first hospital appointment in days
- time from referral to initiation of treatment in days
- number of hospital appointments before a diagnosis was made
- outcome of referral – hospital appointment/return information/referral rejected
- application of 'right to health care'

'Right to health care' is a legal term in Norwegian health care[3]. Every referral received is evaluated by a hospital doctor, who determines whether that individual patient, in that care pathway, has the right to prioritised health care. The 'right to health care' is applied only if the patient can be expected to benefit from the health care process and if the cost is in accordance with the expected benefit. Patients to whom this legal right is applied are then assigned a maximum wait time in accordance with prioritisation guidelines[110,139,140].

In addition, the positive predictive value was calculated as it was for glue ear referrals in otolaryngology by Bennett *et al*[141]. When adapting this concept to a hospital medical out-patient department, we defined positive predictive value as the proportion of referrals that led to a histological diagnosis, diagnostic clarification, or change in medical management. This was scored by the scoring panel on the same scoring sheets as the quality of care criteria, though under a separate heading.

The scoring panel also applied a subjective assessment of the care pathway. This was done in two ways. Firstly, a quality rating of the treatment process was given on an ordinal scale of 1-10. Secondly, the scorers assessed whether the treatment process was appropriate with a binary yes/no response.

To evaluate the correlation between seriousness of diagnosis and initial prioritisation, the variable 'wait time' was correlated with severity of final diagnosis. Wait time was defined as the time from the referral was received at the hospital until the first out-patient appointment, measured in days. To differentiate between the seriousness of the various

illnesses, the possible outcome diagnoses were grouped into two, three, or four severity levels. The four-level structure was used for the analysis in Paper III. The categorisation was done by the PhD candidate based on the International Classification of Diseases tenth revision (ICD-10) diagnostic codes, and it was reviewed by specialists in the relevant field. If more than one diagnosis was located for an individual patient, the ICD-10 code associated with the highest severity grouping was used in further analyses.

4.9 Blinding

As per protocol, the referring GP could not be blinded in the trial, since the intervention was to be actively used by the GP. The patient was not aware of the intervention, but no active effort was made to keep the patients blinded. Hospital doctors who recruited the patients were not aware of the intervention status of the referring GP surgery. Further down the care pathway in the hospital, intervention and control patients were mixed into the general caseload for each hospital doctor. However, complete blinding was not always possible, as a small number of GPs used the referral template electronically; thus the use of the referral template was graphically visible in the hospital EHR. However, the majority of the time, the hospital doctor was blinded to the intervention status of the patient. In addition, the hospital doctors were not informed of which outcomes were recorded to assess the treatment process. The quality scorers were blinded to the intervention status of the patient.

4.10 Statistical methods

Detailed descriptions of statistical methods are provided within each paper. In general terms, all baseline characteristics and outcome data were compared between the intervention and control groups using appropriate statistical tests. P-value of <0.05 was set as the significance level, although in regression modelling a p-value of 0.10 was used for interactions in Paper I. The rational for this is discussed in the paper.

The PhD project was designed with a two-level data structure, with the intervention aimed at the level of the GP surgery and the outcomes measured at the level of the individual patient. A further division into three levels, as detailed in Figure 5, could be argued for, but no statistical benefit was found for introducing a third level in the analysis.

Moreover, adding a third level to an analysis also increases the complexity of modelling. Multilevel analyses were employed throughout the project, when appropriate.

In addition, a significant number of returned questionnaires in Paper II had missing data. The primary analysis was done on a single-question basis, but to further examine and verify the findings, imputation was performed. There was deemed to no clear pattern of missingness, and multiple imputations using chained equations with predictive means matching was employed.

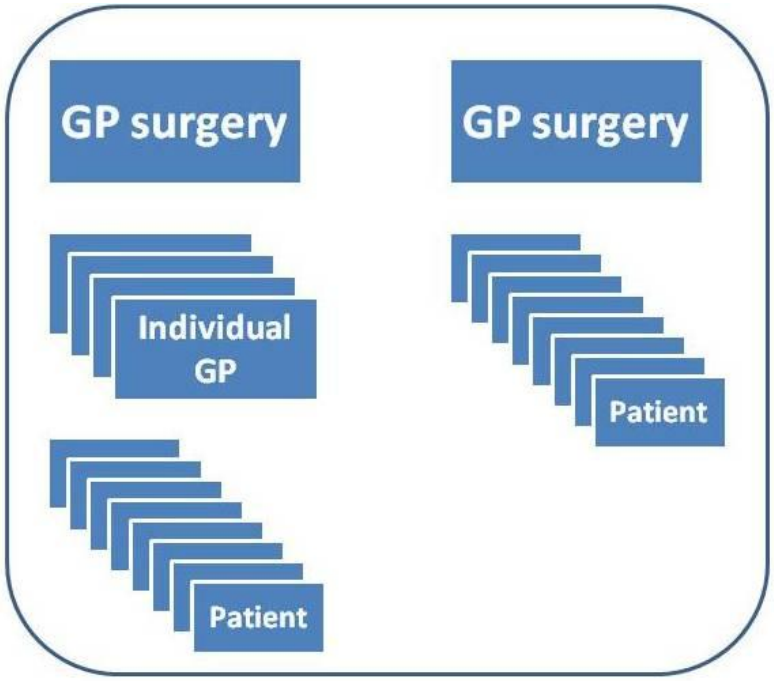

Figure 5 - Multilevel structure of data represented - on the left a three-level structure and on the right a two-level structure, as employed in this thesis.

4.11 Sample size

Sample size calculation is presented in the methods paper, which was published prior to the start of this PhD project [142], with additional discussion in Paper III and Chapter 6.1.1 of the current thesis. The calculations were based on the primary outcome; a change of 10% in the quality score was determined to be clinically interesting. Setting a significance level of 0.05 and using PASS 2008 (NCSS, LLC, Kaysville, Utah, USA), a sample size of 855 patients in the intervention and 855 patients in the control group was needed for an 80% power to detect a 10% difference between the groups. Using intra-cluster correlation coefficient (ICC) values from different primary care-based interventions[143-145], the design effect (Deff)

would increase the sample size by between 1.15 and 12.9, depending on the ICC. This sample size was used for planning, but later analysis showed that this included a mathematical error. For further discussion please refer to Chapter 6.1.1.

4.12 Study registration and accordance with the CONSORT statement

Before inclusion began, the study was registered at www.clinicaltrials.gov with the registration number NCT01470963. During statistical analysis and article writing, every effort was made to follow the CONSORT statement for the reporting of cluster randomised trials[146].

4.13 Ethics

The study followed the directions of the Helsinki Declaration. Before inclusion started, the project was presented to the Regional Ethical Committee for Medical Research in North-Norway, who determined that it was not within the scope of the Health Research Act (REK NORD 2010/2259). As such, it did not require further evaluation in the ethical committee. The project has been approved by the Data Protection Official for Research. All participants provided written informed consent.

5.0 Summary of results in Papers I-III

5.1 Paper I: Impact of referral templates on the quality of referrals from primary to secondary care: a cluster randomised trial

Paper I presents the results of the referral intervention on the quality of referral documents received. Referrals were scored by three raters, blinded to the intervention status of the patient. The scoring system was devised from the referral templates, hence it measured how much of the information deemed important by the specialists was actually available.

A total of 500 patients (281 patients in the intervention group and 219 patients in the control group) were included in Paper I, after the exclusion of 38 patients who did not fulfil the inclusion criteria. There were no significant baseline differences between the patients or GPs in the intervention and control group. There were more referrals sent from female GPs and GP specialists in the intervention than the control group. About 50% of referrals in the intervention group were sent to the designated electronic address. The interrater reliability was very good with Kappa = 0.90 ($p<0.0001$).

Average referral quality, not corrected for clustering, was significantly higher in the intervention group for all diagnostic groups, except COPD. Using a multilevel regression model with the GP surgery as the clustering unit, a 20% difference was seen between the intervention and control groups. The ICC was calculated to be 0.14 (95% confidence interval [CI] 0.02, 0.25). The final model was adjusted for whether the GP was board certified, centred GP list size, GP hospital experience (in years), and categorised GP surgery size. Taking these variables into account, the effect estimate was reduced to 18% (95% CI 11, 25; $p<0.001$). The model also suggested that board certified GPs produced referrals more in line with the referral template (9%; 95% CI 4, 14; $p<0.001$), whereas longer hospital experience predicted slightly less complete referrals, with a point estimate of -2% per year of hospital experience (95% CI -1, -3; $p<0.001$).

Paper I showed a clear effect of the referral intervention on referral quality. This effect was of a large enough magnitude to seem clinically interesting. The increase observed was in line with effects noted in other studies. However, several limitations must be noted. Firstly, as the scoring system measured the completeness of information, it is likely that

some of the effect size noted was due to conscientious GPs who took a special interest in the study. In addition, the inclusion rate of patients from the Medical Department at the UNN Harstad is not known, nor is the proportion of GPs who actively used the intervention. However, a non-protocol analysis (data not shown) showed that, when considering only referrals sent from GP surgeries in the intervention group, a difference in referral quality as large as the intervention effect was seen the comparison was made between GPs in the intervention group who sent their referrals to the designated electronic address and those who did not.

This paper also highlights the difficulties of implementing change in ongoing medical practice. Future studies should aim to use simple referral guidance, collaboratively developed by primary and secondary care providers, and preferably embedded in the EHR.

5.2 Paper II: Impact of referral templates on patient experience of the referral and care process: a cluster randomised trial

This paper presents patient experience of the referral intervention. Evaluation of patient experience is widespread in the health care field. Such evaluations can help drive quality improvement and are associated with safety and effectiveness.

A patient questionnaire was developed, based on previously validated questionnaires, to assess patient experience with the care coordination and treatment process. The resulting questionnaire was piloted with health professionals and patients, but no further validation took place. Questionnaires were sent to all patients who consented to take part in the referral project, with a new questionnaire sent to non-responders after approximately 1 month.

The response rate after the mailing of the first questionnaire was 69.4%, but after reminders were sent to non-responders, this increased to 82.0%. Non-responders were younger than responders, but there were no significant differences between the non-responders in the intervention and control groups. Results are presented on a single-question basis, but to further assess the effect of clustering, a multilevel model was built after multiple imputation using chained equations with predictive means matching was employed to account for missing data in the questionnaires. Due to a high level of ‘not applicable’ answers, one question was left out of the imputed analysis.

Four hundred ten questionnaires were returned; 236 (57.6%) from the intervention group and 174 (42.4%) from the control group, which reflected the difference between these groups in the whole study population. When looking at individual questions, overall satisfaction was very high, with only minor differences between the intervention and control groups. Interestingly, the most negative responses in both groups concerned questions on patient interaction and information. When looking at a multilevel regression model using imputed data, the effect of clustering was low.

In total, this indicates no clear effect of the implementation of referral templates on the patient experience, in a setting of generally high patient satisfaction. The negative feedback concerning patient interaction, involvement, and information could be of use to the UNN Harstad for improvement of the patient experience.

5.3 Paper III: The effect of referral templates on out-patient quality of care in a hospital setting: a cluster randomized controlled trial

This paper presents the main outcome of the study, the quality of the hospital-based care and health care process following the referral intervention. The measurement of quality is becoming increasingly important in modern medicine, partly for quality improvement, but also for prioritisation, accountability and comparison purposes. The measurement of quality of care is challenging as it is mainly a subjective and intangible concept.

To measure quality of care, the current study developed process quality indicators based on previously published indicators, treatment guidelines, and international literature for each of the four diagnostic groups. The criteria were adapted to fit locally acceptable practices. Scoring was done by external specialists from other Norwegian hospitals, blinded to the intervention status of the patient. The scoring panel also provided a subjective quality assessment (scale 1-10) and assessed the positive predictive value of a referral. The adequacy of prioritisation in the intervention and control groups was also assessed by comparing the seriousness of the final diagnosis against the wait time from referral to hospital appointment. There was wide variation in the scoring across members of the scoring panel, but there was no indication of bias in the scoring between the intervention and control groups.

The study sample consisted of the same 500 patients presented in Paper I (281 in the intervention and 219 in the control group). In addition to the baseline characteristics described in Paper I, there was no difference between the patients in the intervention and control groups with regard to who they saw at the hospital (specialists vs junior doctor in training) or whether 'right to health care' was applied in their case.

The results showed no significant effect of the intervention on the measured quality indicator score, the subjective quality score, or the positive predictive value of referral. The prioritisation in the intervention group was not significantly different from that in the control group. A reworking of the sample size calculation showed that, given the ICC and the study estimates for average score and standard deviation, the study was adequately powered to detect the 10% difference deemed clinically relevant in the methods paper.

Hence, Paper III showed no clear impact of the referral intervention on quality of care. However, these results are hampered by low intervention uptake and wide scoring variation. Although the current assessment proved negative, it still seems reasonable to assume that more referral information will improve patient management, but more stringent research is needed before any broad scale implementation is contemplated.

6.0 Discussion

6.1 Methodological considerations

6.1.1 Cluster randomised trial – rational and statistical considerations

The study was planned as a cluster randomised trial. In essence this means randomising groups of individuals rather than individuals themselves[147]. However, the unit of observation remains the individual within these groups. Hence, randomisation is carried out at an overarching level, whereas measurement happens at the individual level (Figure 6).

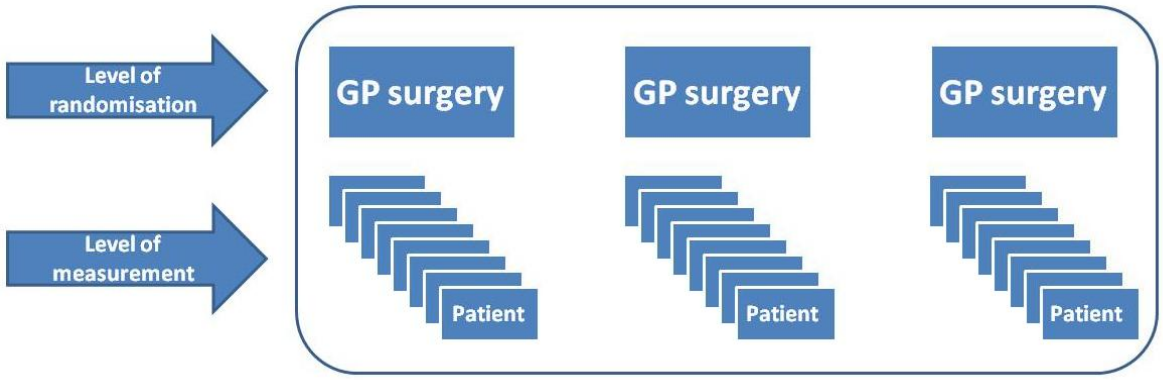

Figure 6 – Graphical representation of the two levels in the current cluster randomised study

The cluster randomised design was chosen due to its suitability for interventions implemented at the level of the health care organisational unit[148]. The present project could not be carried out at the level of the individual patient, or even at the level the individual GP, due to the risk of contamination between either subsequent referral situations for each individual GP or contamination between different GPs at the same surgery[149]. Such contamination would likely reduce the point estimate of the intervention effect and introduce more uncertainty in the final results. In addition, as future interventions are likely to be EHR-based, the relevance of the study would be reduced if individual GPs were randomised, as the EHR is usually the same for all GPs in a single surgery.

However, the choice of cluster randomisation carries several concerns, mainly in the areas of power and analytical techniques. Firstly, the power of a cluster randomised study is not as high as that of an individually randomised study, given a fixed number of potential participants[150]. Standard statistical techniques, such as the t-test, assume independence

of observations[151]. However, as the name suggests, in cluster randomised trials, members of the same cluster are more likely to have similar outcomes than randomly selected individuals from the general population[147]. This similarity will also depend on the outcome measured. Therefore, in the current study, a higher clustering effect was expected on the measurement of referral quality (mainly GP surgery-dependent) than on the measurement of quality of care (mainly hospital-dependent). Clustering increases the variance, as less information is gained from each observation, and hence it also increases CIs, compared to individual randomisation[152]. This non-independence of outcomes must be accounted for in the sample size calculation to give appropriate power to any study[152]. Some previous publications have used only one cluster in the intervention and control groups, which, in essence, is the same as having one patient in each group. This comes about as there is no way to mathematically correct for the variation between clusters, and therefore any difference observed can be a between-cluster difference instead of a true intervention effect[153].

The Deff is often used to correct sample size for the clustered design, by multiplying the sample size needed in an individually randomised trial with an otherwise identical design with the Deff[154]. This is given as Deff = $1 + \rho(m-1)$, where ρ is the ICC and m is the size of each cluster. Increases in both ICC and cluster size lead to more statistically inefficient designs. Hence, any cluster randomised study benefits more, in terms of power, by increasing the number of clusters[155]. Calculation using the Deff requires equal cluster sizes and an identical ICC in the intervention and control groups[147].

For the current PhD project, the number of clusters could not be increased above the 14 GP surgeries in the area served by the UNN Harstad. In addition, no precise ICC for similar interventions at the referral interface could be found in the literature. After reviewing other primary care interventions, it was determined that an ICC ranging from 0.001 to 0.08 was plausible[143-145]. This gave a design effect of 1.15 to 12.9. For a power of 80%, and setting the limit for a clinically interesting difference between the intervention and control group of 10%, a sample size requirement of between 1964 and 22,093 was estimated in the methods paper[142]. This sample size was used as the basis for study planning, but in addition to assuming equal cluster size and varying amount of clusters, it also included a mathematical error in the basic calculation. Using the correct baseline data (with Power and Precision V4),

a sample size range from 84 to 180 was revealed to be more correct. In a relatively recent publication, Hemming *et al* showed[156] how to calculate sample size when the cluster number is fixed. Using this formula, the study was feasible under the given conditions, but it quickly became unfeasible if the ICC increased above the given range. The uncertainty of ICC from the literature and its impact on sample size calculations is further discussed by Donner, who recommends sensitivity analyses using a range of ICC in the planning of any study[157].

In reality, the ICC for the main outcome was 0.02 (95% CI 0.00, 0.06) and the sample size range of 84 to 124 presented in Paper III seems appropriate. Therefore, in retrospect, the effort to achieve adequate sample size to avoid a type II error was unnecessary. Indeed, with the sample size of 500, the study was, in fact, powered to detect much smaller differences than the arbitrarily set, clinically important difference of 10% for the main outcome.

The choice of analytical method in cluster randomised trials is paramount. As noted above, the correlation between individuals within the same cluster leads to estimation of CIs that are too narrow, and hence an increase in type 1 error, if standard analytical techniques are applied[147]. Although it is paramount to use correct analytical techniques when performing and reporting on cluster randomised trials[146], it is also important to note that the effect of clustering is usually small where the outcomes relate to individual participants' health or behaviour[147,158], as opposed to more cluster-specific outcomes. This is clearly identified in the current study, as the estimated ICC for referral quality was 0.14 (95% CI 0.02, 0.25), whereas the estimated ICC for the main outcome was 0.02 (95% CI 0.00, 0.06). Hence the clustering of data was stronger with regard to referral quality and almost negligent with regard to the main outcome. This is illustrated in Figure 7, in which data generated for the purpose of example only was used, with three GP surgeries, 30 patients, and two outcomes. In Figure 7, the outcome 'Referral quality score' is more influenced by the GP surgery level, and the 'Quality of care score' is measured purely at the patient level. Regardless of the actual level of correlation in the data, it remains good practice to analyse data in a manner that is appropriate to the study design. The current study applied appropriate analytical methods as indicated in the published methods paper[142].

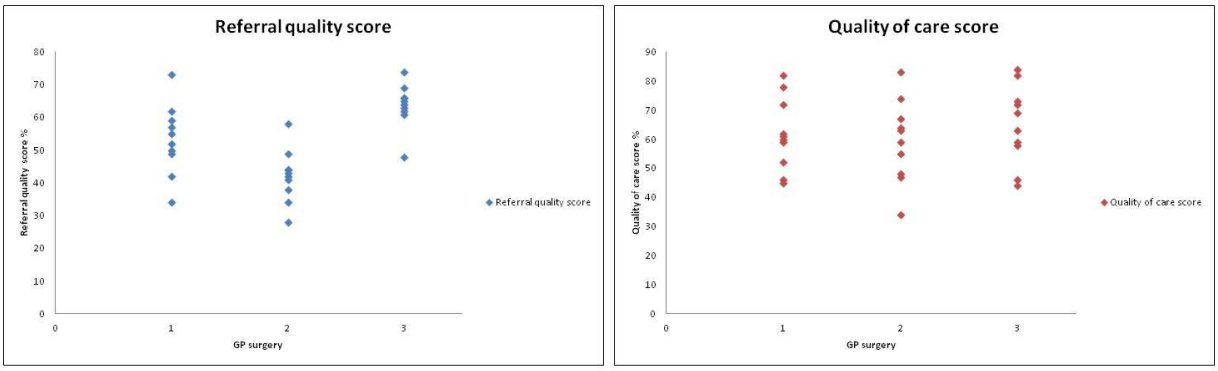

Figure 7 – Graphical representation of clustering with the Referral quality score data showing more clustering on the level of the GP surgery than the Quality of care score data.

In general, appropriate analysis of cluster randomised trials can be done either at the cluster level or at the patient level[149]. In the cluster-level analysis, data are aggregated for each cluster (using cluster mean, cluster proportion, or other summary data), and one data point is provided from each cluster. This enables the use of standard analytical techniques, as the data points are now considered independent. However, this does not allow for the correction of covariates at the individual level[149]. In addition, this analytical technique is less efficient when there is substantial variation in cluster size[152]. At the patient level, more advanced techniques, such as multilevel modelling, must be employed, which allows for the inclusion of covariates measured at the patient level. In this thesis, the inclusion of covariates was paramount to understanding the relationship between the intervention and its outcome; consequently, patient-level analysis was employed throughout, with the exception of the questionnaire data. The design of the questionnaire necessitated analysis based on the summarised data from each question. For further assessment of the results, regression models were also employed, but this was only done to further investigate the data and assess the effect of clustering.

Individual-level analysis provides more precise estimates than cluster-based analysis, especially when clusters vary in size[147], as in the current study. However, the number of clusters in this PhD project was small (seven both in the intervention and control groups), and in these settings, the use of advanced analytical techniques may be inappropriate[152]. Textbooks suggest that at least 10 clusters are necessary for a multilevel/mixed-model approach, which was applied in this study[147]. With few clusters there is a higher need for model assumptions to be met, and few clusters allows for fewer covariates at the cluster

level[147]. In this PhD project, the covariates used were almost exclusively at the level of the individual GP or individual patient, but care was taken to include only appropriate covariates, while explaining the relationship between the intervention and outcomes as precisely as possible.

In essence, the clustered nature of the study design put constrains on the statistical strength and analytical possibilities of this study. However, it also allowed the results to be more applicable to a standard health care setting. This applicability was a clear goal from the outset of the project, and as such necessitated the more complex, clustered design.

6.1.2 Randomisation

This trial has been presented as a cluster randomised trial. The clusters in the study were contacted and consented to participate *after* the initial randomisation had taken place. This is not recommended practice[147]; pre-randomisation consent for all available clusters (in this case, GP surgeries) is preferred. In addition, two GP surgeries declined to participate as part of the intervention group and were subsequently placed in the control group, meaning that a further two surgeries had to be randomised to the intervention group (see Chapter 4.3).

At the time of the study, the area served by the UNN Harstad had 14 GP surgeries (see Chapter 4.2.1). To achieve an adequate sample size, the study needed to recruit individual patients from all these GP surgeries. As discussed in Chapter 6.1.1 increasing cluster numbers is preferred over increasing cluster size. Extending the study area to include other hospitals was also considered at length, but was abandoned due to the complexities of running a multisite study. In addition, it was postulated that using relatively stable GP surgeries that were closely related to a small hospital would make the intervention more acceptable and uptake more complete. During the design phase, the PhD candidate and the study team envisaged an objective and quantifiable measurement, akin to a classical randomised drug trial. However, during the trial, the PhD candidate gradually came to understand that, in reality, the implementation was more like a pragmatic trial: it aimed to include all clusters and relevant patients with a significant degree of intervention flexibility, usual-care comparators, and clinically significant outcomes measured under normal

conditions[159]. This intention of clinically relevant, patient-oriented research probably led the drive to use all available data and a suboptimal randomised procedure.

In a sense, this form of inclusion of clusters increased the external validity of the trial, in that all potential individual participants were included. On the other hand, this reversal of randomisation could have led to selection bias at the cluster level, as more interested GPs consented to join the study. Given the lack of consent from some of the GP surgeries, it is possible that the entire design of the study should have been changed.

The research project in this thesis is presented as a randomised trial, with the limitations discussed above. Papers I-III would have benefitted from a deeper discussion of the randomisation process, and support and advice from experienced research institutions could have been sought earlier in the PhD project. However, the conclusions presented and the implications for further research remain, in the view of the PhD candidate, valid.

6.1.3 Complex interventions in a real life clinical setting

In a recent Norwegian study, only 38% of newly diagnosed lung cancer patients were referred to a specialised service for assessment of whether their lung cancer could have been caused by occupational exposure, even when frequent reminders were sent[160]. In a study by Jiwa *et al*, colorectal referrals were sent using a newly developed, interactive, electronic pro forma, but the uptake of the intervention was only 18%[53]. Both of these studies were performed with educational outreach and follow-up, yet the intervention uptake was very limited. This highlights the difficulties of research in a 'real life' clinical setting. Not only can interventions be complex, but complexity already exists at the level of the health care system[161]. In a health care setting, a complex intervention is defined as being "built up from a number of components, which may act independently and inter-dependently"[162]. A complex system, on the other hand, is one that "is adaptive to changes in its local environment, is composed of other complex systems, and behaves in a non-linear fashion"[161], with examples such as primary care, hospitals, and schools. Hence, the effect of any given intervention must be interpreted not only in the context of its own complexity, but also in light of its effects on the entire system. It is therefore not surprising that uptake may be low and performance difficult when applying interventions at the GP/hospital interface, where many other factors than the ongoing study impact clinical decisions.

A classic example of a complex intervention in the medical field is the stroke unit. In any trial assessing the impact of stroke units on morbidity and mortality after a stroke, it is hard to define the specific active component (e.g., various health professionals, drugs, guidelines, discharge routines), and hence replicating the results is more challenging[162]. The current project introduced a referral template at the GP/hospital interface coupled with educational follow-up, a seemingly straightforward and simple intervention. However, given the complexities of the health care system and the interaction between the system and the intervention, it would be unwise to assume that all of the observed effect was purely based on the referral template itself, and that the study had envisaged all the potential effects of the intervention.

Although the complexities of the intervention and systems make the interpretation of intervention effects difficult, it more than likely improves generalisability. The implementation of an acceptable and feasible intervention using a clustered study technique in normal clinical practice likely mirrors the effect in other settings, and follows guidelines set out for the evaluation of complex interventions[162]. However, further evaluation, especially quantitatively, would probably cast further light on the factors that affected the referral process.

6.1.4 Expected change process

The current project was not designed or prepared as a complex intervention. The basic research concept was primarily to design a simple intervention, implementable in everyday clinical practice with limited unintended consequences. Much effort was expended to identify measurable, relevant outcome measures to evaluate the intervention. In the design of the project, the PhD candidate somewhat underestimated the complexity of what was intended as a simple intervention. A good theoretical understanding of how the intervention causes change has been said to be paramount in designing and evaluating complex interventions[163]. This was not formally outlined prior to the implementation of referral templates, but in hindsight, many of the aspects regarding a more formal process were discussed. In this Chapter, a short description of the thought processes and expected effects of the intervention during the planning phase is provided along the framework provided by the Medical Research Council[164].

6.1.4.1 Development of the intervention and evaluation process

As presented in Chapter 2.3, two systematic reviews were found on the topic of referral improvement[7,54]. These reviews suggested that structured referral guidance and local educational outreach can achieve the intended effects on referral rates. No further major studies were found, and no further formal review paper was produced. Therefore, the research group concluded that referral improvement was possible. Underpinning the aim of referral improvement in the literature is the belief that improved referrals would lead to improvements in both service delivery and care. The cost of change in the current project would mainly be incurred at the level of the GP, with a potential increase in the time spent on each referral. Therefore, this PhD project was not designed to evaluate if referrals could be improved, but if improved referrals could lead to a measurable change in the care delivered to each patient, and hence justify the increased workload for GPs.

GP uptake and use of the intervention was recognised early as an important potential limitation (see Chapter 6.2). The use of obligatory electronic pop-up solutions were considered, but rejected based on the time necessary to develop this application, the cost, and the lack of flexibility it would provide to the referring GP.

Considering the intervention as a whole, the research team expected a measurable change in the outcome measures described in Chapters 4.7 and 4.8, but no large effect on referral numbers or other organisational factors. No appropriate prior assessment tools could be identified, and considerable time was spent researching and discussing different evaluation options. Given the expected change highlighted above, outcome evaluation was envisaged at several levels (Figure 4), as described in Chapters 4.7 and 4.8. With the aim of taking patient assessment into account, self-administered questionnaires were used. Although the intervention itself was not aimed directly at patients, the questionnaire was intended to measure the expected positive change in the experience of a more appropriate care pathway of higher quality.

6.1.4.2 Piloting of the intervention

The literature on both cluster randomised trials[147] and complex interventions[164] recommends piloting an intervention for feasibility, usage, and recruitment. No formal

feasibility or pilot study took place in the current PhD project. Instead, the intervention was piloted at local GP surgeries, and the patient questionnaire was piloted with health care personnel and patients. A formal feasibility study may have provided clues on how to improve the uptake of the intervention and improve sample size estimation. A pilot study could have highlighted the potential effect of the intervention on the outcome measures. This is especially interesting in a trial were the outcome measures have not been previously documented, as was the case in this trial.

6.1.4.3 Evaluation

A good theoretical understanding of the intervention has been described as the key to suitable outcome measures[164]. As shown in the current project, the assessment of health care interventions can be less straightforward than expected, and the effects difficult to assess accurately. In addition to the potential benefits of a pilot study, the discussion regarding a continuous, qualitative process of evaluation in Chapter 6.5.3 is pertinent in helping plan the evaluation of an intervention.

6.1.5 Blinding

Blinding is an important concept in modern medical research; ideally treatment allocation should not be known to the patient, investigators, or assessors[165]. It has been shown that intervention effects can be overrated if randomisation concealment is not carried out in a satisfactory manner[166]. Non-blinding of participants, organisers, or evaluators in any given study may give rise to bias in the form of differential treatment during the study process, differential drop out, or differential outcome assessment (information bias). However, as with the current study, full blinding may be unattainable with complex interventions[146,162,167]. In the design of the present study, efforts were made to ensure that patients and outcomes assessors remained blinded to the intervention status of all patients. It was especially important to also keep patients blinded, as patient experience was included as an outcome. However, because the referral template was included in an electronic form in the GPs EHR, it was sometimes evident when it had been used for referral. This was noted beforehand as a possible breach of both carer and assessor blinding, but very few of the GPs used the electronic referral template, instead referring to the laminated paper template.

As noted above, the lack of blinding in a study generally tends to increase the effect of the intervention. In the current project the intervention showed no clear effect on the main outcome, and no clear indication that bias has affected the patient treatment or outcome assessment.

6.1.6 Development of referral criteria

Transition of care and referrals have been part of the health care system for a long time, and the frustration amongst doctors with regard to these aspects is probably just as long-standing[168]. Therefore, it may come as a surprise that these processes seem excessively varied and idiosyncratic[9,169-171]. Guidelines and content advice exists from several sources across several specialities[5,12,44,109,172], but locating relevant content information for the referrals was more difficult than expected. Most of the symptoms included in the referral templates for each diagnostic group[110,173,174] were present in national guidelines for prioritisation. A clear scientific basis existed for the inclusion of some of the symptoms[83], and for others there seemed to be some consensus[109], but some research has shown that symptoms which are considered important may actually be of little value in predicting serious disease[175]. Therefore, priority was given to validated symptoms and previously published consensus documentation, but also to local adaptation and support for the final versions of the referral template. Ideally, there would have been more input from patients and GPs, as this could have strengthened both the content and acceptability of the intervention[44,162].

6.1.7 Development of quality indicators

In his book *The Definition of Quality and Approaches to its Assessment* Avedis Donabedian presented some of the first clear ideas of the assessment of quality in health care. In his framework, he identified three areas from which information on quality can be obtained: structure, process, and outcome[176]. As presented in the methods paper[142] and Paper III, the current PhD project mainly employed process quality indicators. This entails assessing whether certain actions have taken place during a care pathway[60]. However, it is not necessarily easy to develop quality indicators. Baker and Fraser presented four criteria that characterise a good quality indicator (Table 4)[177]. Several methods for the development of scientifically valid quality criteria also exist, for instance the RAND/UCLA appropriateness method[178], which utilises panels of experts to combine

recommendations from clinical guidelines with health care providers' opinions. However other methods have also been described[179,180].

Table 4 – Characteristics of an ideal quality criterion

Based on research evidence
Prioritised according to strength of research and influence on outcome
Measurable – clear and precise
Appropriate to the clinical setting

Initially, the current PhD project aimed to utilise existing quality indicators in the measurement of the intervention effect. However, early in the planning phase it became clear that few relevant clinical process indicators existed. Much of the indicators have been developed for use in national programmes, and to measure things like, 'how many stroke patients at a given hospital receive thrombolytic treatment'[181]. In the current PhD project, the aim was to compare the effect of an intervention at the GP/hospital interface by measuring the quality of care delivered to each individual patient, and not at an over-arching hospital or county level. Notable differences from these holistic quality criteria were found in, for instance, performance measures in the speciality referral process[73] and COPD care measures[182]. However, it is the view of the PhD candidate that the available published measures were not sufficient to capture the subtle effects of the intervention in the current project, and it was therefore decided to develop a new set of criteria to assess the outcome. Although a formal RAND/UCLA approach would have been preferable, it was not achievable within the time frame. In addition, the quality criteria score was only one of several outcomes that were recorded. Using advice from several sources[59,179], quality criteria were developed from available national and international literature. Although no formal panel process took place, the feedback from specialists within each diagnostic group was invaluable to the shaping of the indicator sets; it ensured that the criteria were indeed prioritised, measurable, and appropriate.

The current indicator set was created to depict the entire treatment process, and not focus solely on small aspects of care. In addition, a multilevel analysis with single-unit indicators would have been challenging. Therefore, the decision was made to generate a

total score from the indicators themselves. Some have argued that it is important to state the relative importance of different quality indicators, based on the available evidence[177]. In the current PhD project, this could have been achieved by weighting the indicators before calculating the final score. However, after consideration, and as shown by Lyons and Payne in 1975[129], it was decided that the considerable extra effort needed to weight the indicators was unlikely to provide better estimates for the intervention effect.

6.1.8 Statistical considerations

The main statistical aspects are discussed in each paper, with important aspects regarding statistical strength in cluster randomised trials discussed in-depth in Chapter 6.1.1.

The analysis plan for the study and papers was outlined in the methods paper. The only major deviation from this plan was the non-protocol analyses reported in Paper I, which used only referrals sent directly to the study-specific electronic address. This was done to highlight the importance of participating GPs actually utilising the intervention, and care was taken to ensure that this deviation from strict "intention-to-treat" analyses was highlighted in the paper. In addition, the nature of the questionnaire necessitated an analysis based on single questions rather than a combined, total score.

To assess the adequacy of prioritisation, possible outcome diagnoses were grouped into two, three, or four severity levels (see Chapter 4.8.3). In the final analysis, the four-level structure was used, as it most closely resembled normal clinical thinking, and the numbers in each group were large enough to allow for such analyses.

6.2 Uptake of the intervention

Uptake of the intervention in this PhD project is discussed in both Papers I and III, but deserves further mention and discussion, as it is imperative to the assessment of the intervention effect and future research. Internationally, interventions at the referral level have always had difficulties with uptake. Examples include a study by Jiwa *et al*, which had an uptake as low as 18%[53]. A Cochrane review of referral interventions indicated that, at best, only half of structured referral sheets were complete at referral[7]. However, a recent Norwegian study utilising electronic optional guidelines in the referral process reported that 88% of the intervention GPs used the intervention "all the time"[12].

With the referral intervention presented in this PhD thesis, the research team hoped that the implementation of a complex intervention at the GP/hospital interface would be more achievable in a small group of GPs who are geographically and traditionally closely linked to hospital staff. As noted above, this PhD project cannot, due to privacy and ethical concerns, provide a completely accurate figure for intervention uptake, as this would have required reviewing the records of all patients with a new hospital appointment during the study period. However, as presented in Paper I, 49.5% of the referrals in the intervention group were sent to the project-specific electronic address (Figure 8). This number represents the absolute minimum use of the intervention, and it is reasonable to assume that it was used also for some of the referrals sent by intervention GP surgeries to the standard electronic address.

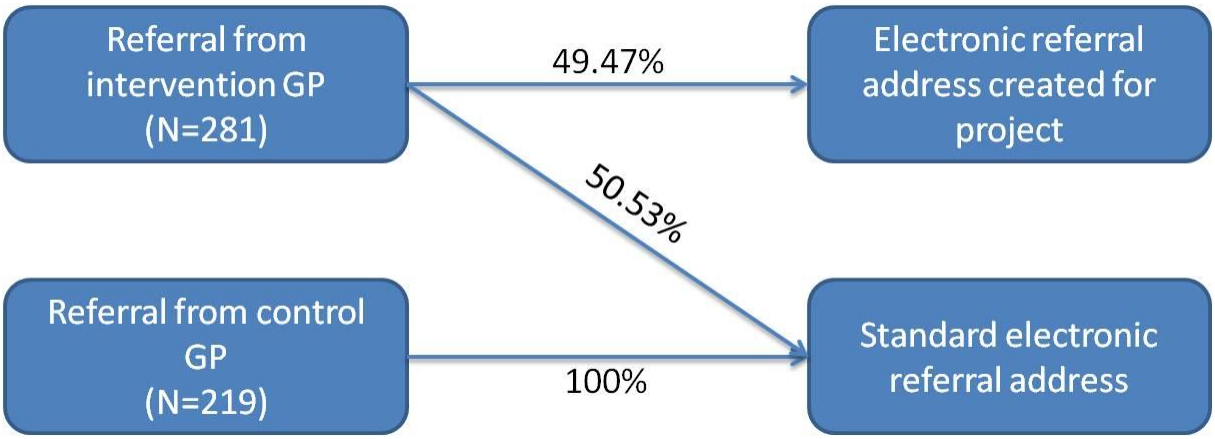

Figure 8 – Graphical representation of the use of the specific referral address created for the project

Given the relatively low intervention uptake observed in the present PhD project compared to the study by Rokstad *et al*, it seems prudent to advise that further research on referral interventions should be implemented in the EHR, and these interventions should be in a format that allows their use in normal clinical workflow.

6.3 Assessment of bias

6.3.1 General assessment of bias in the study

The assessment of bias in any given study is important to ensure there is no major threat to the validity of the results. In the first section aspects of bias relevant to the general design of the study are presented. Following this is a brief assessment of specific issues related to bias in the each of the papers that form the basis of this thesis.

Selection bias is present when individuals have different probabilities of being included in the study sample according to relevant study characteristics[183]. In clinical research today, the main reason for choosing a randomised design is to reduce selection bias[184] by ensuring the study groups are as similar as possible. Although randomisation can often reduce selection bias, the lack of concealment of randomisation may lead to exaggerated effect estimates[166]. Lack of concealment is of particular interest in cluster randomised trials, which usually involve randomisation at one level and recruitment at another level. Ideally all patients and clusters (in this study the GP surgeries) should be included before randomisation[147]. In the current study this was not feasible, as consecutive patients who presented to their GP for referral to secondary care were to be subsequently recruited at their hospital appointment. Hence the identity of eligible patients was not known prior to the randomisation process. In addition, the suboptimal randomisation procedure discussed in Chapter 6.1.2 may have contributed to bias. The study therefore contained a risk of selective recruitment in the two study groups, and as such there was a clear risk of selection bias.

To reduce this risk, GP surgeries were randomised by a person not connected to the study. We also intended to recruit all potential patients and kept the list of exclusion criteria as short as possible to avoid further selection bias at the patient level. In addition, patients were recruited by hospital doctors who were unaware of the intervention status of the referring GP, thus preserving allocation concealment at the patient level. In a small subset of cases, however, the intervention status was obvious to the recruiting hospital doctor, as the electronic form of the referral template had been used. The available data shows no clear indication of selection bias in the study; the baseline characteristics of the two patient groups and the two GP surgery groups were similar. In addition, there was similar patient distribution across the four diagnostic groups in both the control and intervention groups. However, more patients were recruited into the intervention than the control group. As discussed in Paper I, we have no clear explanation for this. It is possible that increased focus on the four diagnostic groups in the intervention GP surgeries led to increased referral rates, a finding that has been shown in other studies[54]. We were unable to calculate the referral rates to assess this possibility within the material collected. As suggested by authors of a different study with recruitment imbalance, we employed recruitment at the hospital, not at

the GP surgery[185]. This form of recruitment has also been suggested in situations where individual recruitment occurs after cluster randomisation[186]. We have no reason to believe that there was differential recruitment between the intervention and the control groups at the out-patient department. However, study personnel did follow up on referrals sent to the dedicated electronic address (see Figure 8) and sent new consent forms to patients who had been referred within the project but had not been asked to participate during their hospital appointment. This practice may also account for the somewhat higher inclusion in the intervention group, but the actual secondary patient recruitment through this system was no larger than 20 patients.

Selection bias can also exist on levels other that the patient level. Recruitment strategies in large studies often preclude participation of many of patients seen in everyday clinical practice, and as such renders them less applicable. In cluster randomised trials, a more diverse group of patients is often recruited than in pure randomised trials, and more complex interventions are often employed[147]. The diversity of the included patients often more closely resembles normal clinical practice, and as such, it can alleviate some of the criticisms of randomised trials, e.g., not being directly comparable or relevant to standard care pathways[187]. In the current study, we aimed to recruit all patients referred within the four diagnostic groups to most closely resemble normal clinical practice.

Performance bias refers to systematic differences between the care provided, or exposure to factors other than the intervention of interest[188]. Avoidance of performance bias is best achieved by blinding of the participants, study personnel, and outcome assessors[184]. Blinding may be more challenging in cluster randomised trials than in standard trials[147]. Blinding in the current trial is described in the methods paper[142] and in Chapters 4.9 and 6.1.5 of the current thesis. We have no reason to believe that the lack of blinding that did occur significantly affected the care provided.

Attrition bias is related to systematic differences in withdrawals/exclusions. For the current study, the number of exclusions was relatively low and did not differ between the intervention and control groups (9, 3.1% and 8, 3.5%, respectively). Only one patient withdrew from the study. For cluster randomised trials, attrition may also occur at the cluster level. In this study, all clusters randomised were included in the final analysis. In

addition, an intention-to-treat analysis was performed, both at the cluster and the patient level, further reducing the chance of attrition bias[189]. Therefore, it is unlikely that attrition bias affected our results.

Contamination bias can exist when intervention-like activities find their way into the control group[190]. Several authors, including the authors of the methods paper for the current thesis, claim that the clustered design can reduce the risk of contamination[147,152]. Others have argued that contamination may not be much of a statistical problem and can be corrected in ordinary randomised trials with a smaller increase in sample size than would be required by the clustered design[191]. It is not impossible that our intervention GPs communicated with control GPs about the intervention, but it is unlikely that large-scale contamination took place. This is also supported by the actual increase in measured referral quality seen in the intervention group. This result would have been biased towards the null if large-scale contamination had occurred.

6.3.2 Assessment of bias in Paper I

Paper I presented the effect of the intervention on referral quality. The unknown, but likely high variation in the use of the intervention at intervention GP surgeries represents a potential bias. It is likely that the referral guideline was used in at least 49.7% of referrals (Figure 8), which may indicate a potential non-use of about 50%. This non-uptake would have biased the intervention effect towards the null, and carries importance for future interventions, in which the uptake of any intervention will be paramount.

The Hawthorne effect is well known, and relates to changes in behaviour because an individual is under study, not because of the intervention itself[192]. In most trials, this effect increases response in both the control and intervention groups, as it is the application of research interest, follow-up, and so forth that causes the effect[192]. However, the Hawthorne effect likely had very little impact on referral quality in the control group, as no intervention was carried out in the control group, and little general information about the study was disseminated in the local community. In the intervention group, however, it is not improbable that some of the intervention effect was due to a Hawthorne-type effect. The non-protocol analysis discussed in Paper I and Chapter 6.5.2 shows that the intervention

effect was mainly seen in those who used the dedicated electronic address for this study and therefore could be assumed to have used the referral template. This suggests that most of the effect seen was due to the intervention itself, and not a Hawthorn effect.

6.3.3 Assessment of bias in Paper II

In addition to the issues raised above, any study that employs questionnaires will always have to consider *non-response bias*. This occurs when there are important differences in patient-reported outcomes between responders and non-responders. As presented in Paper II, non-responders were younger than responders, but no significant differences in the variables measured were found between the intervention and control groups. As discussed in Paper II, several authors have shown that non-response bias is relatively small in health research[193,194]. This, coupled with the high response rate in our study, suggests that the risk of non-response bias is probably low.

On the other hand, questionnaire replies can be affected by a range of psychosocial determinants, previously dubbed "social-psychological artefacts"[195]. In essence, this contains cognitive biases that influence patient responses based on, for instance, self-interest bias, ingratiating response bias, and gratitude. These lead to responses that may be skewed positively due to a patient perception of his/her interest in gaining good standing with health providers[195]. As a net result, patient satisfaction surveys often show high levels of satisfaction; some have argued that dissatisfaction rates may be more useful[196]. The study questionnaire aimed to measure patient satisfaction with the entire referral process. The intervention occurred at GP level and probably went unnoticed by most patients. It is therefore unlikely that these biases had a differential effect on the intervention and control groups, but they may have contributed to the high patient experience ratings seen in Paper II.

6.3.4 Assessment of bias in Paper III

Paper III presents the assessment of the patient care pathway. The main outcome, the quality criteria, measured mainly the quality of treatment at the hospital. As such, a Hawthorne effect is potentially present as the hospital doctors knew that a research project was taking place. Frequent oral and written reminders of the project were used to ensure that as many patients as possible from both groups were recruited by hospital doctors.

These reminders were done to reduce potential selection bias, but they may also have improved the care at the hospital. However, hospital doctors did not have access to the final quality criteria and thus did not know how the care they provided would be assessed. In addition, hospital doctors generally did not know whether a patient was referred from an intervention or control GP surgery, although with the limitations discussed above. It is therefore unlikely that any Hawthorne effect had a selective effect in the intervention or control group, but we cannot rule out that the general quality of care increased during the intervention period.

Scoring was done by a panel of independent scorers based on anonymised EHR documentation. This process carries a definite possibility of lack of information, and even a form of *information bias* in the final results. We used EHR documentation as the primary source of quality information. Quality criteria could therefore only be assessed if they were adequately documented, and the quality of medical documentation and of the EHR has been debated[197-199]. There is no reason to believe that the documentation at the UNN Harstad is better or worse than that in Norwegian health care in general, although we did not measure this in the current study. Additionally, there is no indication that the quality of documentation differed between the intervention and control groups, though this was not formally evaluated in the study. It is plausible to assume that the potential Hawthorne effect discussed above led to more detailed documentation during the study period. It is hence unlikely that there was significant information bias in the current study, but it is possible that quality criteria were fulfilled, but not documented, in the care process.

6.4 Harms and unintended effects

No harmful event for any one patient was noted during the trial, but several potential harms were considered in the planning phase of the trial. Increased focus on the four diagnostic groups could have led to an increased number of referrals and longer wait times for patients in general, but there is no clear indication that this took place (see Chapter 6.5.1). In addition, the increased focus on referral content could have caused prolonged wait times for intervention patients who were categorised by the hospital specialist as probably less seriously ill, based on the referral. Although this could have increased the wait time for some patients, the correct prioritisation of patients is a clearly stated goal of the Norwegian health care system[200]. In the final study, no clear effect on prioritisation was found.

6.5 Other methodological considerations

6.5.1 Wait time

During the design of the intervention and outcome measures, the research team debated how best to measure the effect of the intervention on the quality of care and hospital management of the patients. In addition to the main outcome, secondary outcomes were defined, including wait time (see Chapter 4.8). In Paper III, wait time was analysed against the severity of the outcome diagnoses in order to see if prioritisation was more appropriate in the intervention than the control group. Apart from the statistical issues regarding the ordinal analysis discussed in that paper, the issue of wait time deserves some discussion.

The UNN Harstad is, in international and national terms, a small hospital. About 5500 patients a year attend medical out-patient consultations, whereas national out-patient numbers in Norway were approximately 1,650,000 in 2013[49]. This relatively small hospital size is also reflected in number of staff at the UNN Harstad. During much of the PhD project, staffing at the gastroenterological division was very good, with short wait times (median wait for dyspepsia patients in the project was 33 days and for suspected colorectal cancer it was 32 days). At other times, the staffing situation was less adequate; according to data from the Free Hospital Choice Norway the wait time in December 2014 was 8 weeks for both gastroscopy and colonoscopy[201].

As presented in Paper III, patients with very serious diseases were given higher priority than other patients, but no significant difference existed between the intervention and control groups. It is quite possible that the relatively short wait time during the PhD project meant that any difference would have been difficult to measure, although the evidence given for this is, at best, circumstantial. On the other hand, it would be unethical to argue for longer wait times for potential seriously ill patients just to ease the evaluation of a referral intervention. It is possible that further implementation of similar interventions at larger units may have a greater impact on referral prioritisation.

6.5.2 Non-protocol analysis and related retrospective thoughts on outcome measures

Throughout the project analyses, the comparison of the intervention and control groups was done based on the originally assigned groups (intention-to-treat), as

recommended in the CONSORT statement for parallel group randomised trials[202]. These results formed the basis for the conclusions presented in this thesis and in the papers. However, for completeness, Paper I also presents an unplanned non-protocol analysis, which shows a difference in referral quality between intervention GPs who used the dedicated electronic address and intervention GPs who did not that was just as large as the difference observed between the intervention and control groups. During the preparation of Paper III, a similar analysis was carried out for the main outcome (quality score), with results which were not significantly different from those presented in the intention-to-treat analysis in Paper III.

These analyses serve to highlight an important point in the design of the PhD project, which has been touched upon earlier, but deserves more specific mention. The project aimed to assess whether more relevant clinical information in the referral at the GP/hospital interface would lead to better prioritisation and quality of care at the hospital[142]. The analysis from Paper I confirms that the referrals contained more relevant information, especially in the situations where the referral templates were actively utilised (as illustrated by the non-protocol analysis). The analysis in Paper III showed no effect of the intervention on quality of care, and the non-protocol analysis also indicated no effect, even when the analysis was restricted to cases in which the referral template had been utilised. This highlights the difficulties mentioned in Chapter 6.1.3 about the implementation of complex interventions in real clinical life. The quality assessment presented in Paper III mainly measured how the performance at the hospital related to internationally accepted standards of care. In retrospect, it seems unlikely that hospital doctors would provide inferior quality of care only because the patient was unlucky enough to be referred by a GP who wrote referrals of lesser quality. Therefore, maybe not surprisingly, there was no clear effect of the main intervention, even when it was very likely that the intervention had been used. Future research would need to broaden the assessment of the referral intervention in clinical practice.

6.5.3 Quantitative versus qualitative research

Traditionally, medical research has been based on empirical verification via biomedical methods[203], but qualitative methods have gained popularity and are now an integral part of medical research[204]. This is not surprising, as the complexities and

subjectivity of clinical practice are often not reflected in the scientific logic of refutation[203], as exemplified by the specialist's evaluation in the current trial. Qualitative research involves various ways of systematically collecting, organising, and interpreting information gained from talking to, or observing people[205]. In a further development, mixed methods research has emerged to combine quantitative and qualitative methods, hoping to draw on the strengths of both schools of thought to better understand complex research objectives[206].

This PhD project aimed to examine if a referral intervention would lead to a measurable increase in the quality of care delivered at the hospital, using a traditional biomedical model with a randomised design and statistical analysis[142]. As shown in Papers II and III, no measurable effect was noted. In a project assessing the effect of interactive referral guidance at Akershus University Hospital[207], no effect was seen on referral quality, but a qualitative assessment[208] showed that GPs had a largely positive attitude toward the intervention and wanted it to be expanded. In the early phase of planning, we hoped to have the current intervention assessed by qualitative as well as quantitative methods, but this was cancelled due to funding and practical constraints. In retrospect, it would have been very useful to more formally assess the impact of the intervention on the GPs, patients, and hospital doctors from a qualitative perspective. A mixed methods approach to such a complex intervention can be especially useful in health services research[206] and would be recommended for future referral intervention assessments.

6.6 Generalisability

Assessment of generalisability, or external validity, is important in any study to help clinicians decide whether the findings are applicable to a wider range of patients[187,202]. Lack of consideration of external validity is a frequent criticism of trials, reviews, and guidelines[187]. Although generalisability has been highlighted in the various papers constituting this PhD, its importance warrants a more concise debate about the applicability of the results.

The *setting of the trial* includes the health care system, country, and selection of participating centres and clinicians (see Chapter 2.6). The current results are likely relevant for patient care pathways in Norway, but also in other health care settings in which GPs have

a gatekeeper role. In the selection of participating GP surgeries, all potential participants were included, which should increase the generalisability of the final results. The hospital was a local secondary hospital, university affiliated, but not a tertiary referral centre. It is therefore likely that similar interventions at facilities with a different case-mix may lead to different results.

The *selection of patients* is an important determinant of external validity (see Chapter 4.2.2). The current study utilised few exclusion criteria and included a variety of patients from ordinary clinical practice. However, as discussed in Papers I and III, we have no conclusive indication of the percentage of the eligible patients that actually participated. The clear intent of the study to include all patients would ensure generalisability, at least within similar health care systems, but the unknown inclusion rate hampers the analysis to some extent.

Characteristics of the randomised patients also contribute to external validity. The baseline characteristics of patients in the current study did not differ significantly. However, this does not necessarily mean that they are representative of the general population referred to this, or any other hospital. The underlying pathology, severity of disease, and comorbidities may differ between the study population and the general population referred to a hospital for care within the four diagnostic groups[187]. The project scored patient care pathways, but did not register specific final diagnoses in detail. We did, however, record presence or absence of a diagnosis of incident cancer. In the group referred for suspected colorectal cancer, the overall cancer rate was 8.4%, and in the dyspepsia group it was 0.8%. This corresponds well with findings from colonoscopies in a screening programme in the United Kingdom[209] and with findings at gastroscopies of dyspeptic patients[80]. Of course, the population in a screening programme will not be entirely the same as ours, but those who underwent colonoscopy in the screening programme already had a positive faecal occult blood test, and hence were not that dissimilar from patients with suspected colorectal malignancy in the current study. There is no clear indication that our study population deviates significantly from the general population under care for similar conditions elsewhere in Norway or Western Europe.

Often in clinical trials there are differences between the trial protocol and routine practice, which may hamper the generalisability of results[187]. The current cluster randomised trial was designed to be as close to ordinary clinical practice as possible. Although a Hawthorn effect may have affected the results, a direct transfer of the methods applied would be possible within any health care system that utilises referrals sent from a gatekeeping GP to a hospital.

In relation to *outcome measures*, the current trial employed novel quality criteria, together with patient experience and health care process outcomes. It is evident that the variation in quality assessment highlights some of the difficulties in assessing quality of care at a practical, patient-centred level. This variation may very well be seen as a limitation to the generalisability of the outcome measures. However, the options do not provide an easy alternative (Paper III). Many common quality metrics are developed to measure specific actions at the hospital/GP surgery level, and do not necessarily highlight the care pathway of the individual patient[210], as envisaged in this project. The outcome measures related to prioritisation, subjective quality score, and positive predictive value of referral are likely more generalisable.

Overall, the current study design and implementation means the generalisability of the results is quite high, at least to other areas where access to specialist services is via a gatekeeping GP. The transfer of the results to other health care settings may be hampered, as the baseline quality of referral and hospital/GP communication in a small Northern Norwegian hospital may be higher than that in large health care systems.

7.0 Implications for future research

The implementation of simple tools in the health care system can, as this thesis shows, be much more difficult to perform and evaluate than face value suggests. Our referral intervention intended to improve health care cooperation between independent organisations, but it did not manage to create the change expected in the health care delivered to each patient. Given the increased focus on quality and prioritisation[16,211], it is important and relevant to further examine the effect of the referral on the patient care pathway. Based on the current thesis, multiple areas are essential for future research.

7.1 Intervention improvement

Future interventions on the referral in a gate-keeper based system with two separate, independent levels of care should be based around the principles of complex interventions. Lack of effect is often due to shortcomings of the intervention itself[147]. The current PhD project shows that both the intervention itself and its implementation need to be strengthened. The development of the intervention should be performed according to internationally recognised frameworks[163]. Because GPs have different working styles, a higher degree of GP participation is needed to ensure the intervention is acceptable and applicable across variations in clinical practice. Once updated, the Norwegian National prioritisation guidelines could serve as a basis for referral guidance. As shown by Rokstad, embedding these solutions in the GPs EHR seems necessary to ensure uptake and usability[12].

7.2 Outcome assessment improvement

The current outcome measurement tools did not show an effect of the intervention. In the future, it will be important to produce a sound pre-trial concept of how referral intervention produces change at the hospital and to assess the change across varying GP settings[212]. The concept of attempted quality measurement using the quality indicators from this trial is unlikely to show an effect of any referral intervention. Instead, assessment of prioritisation, doctor/patient satisfaction, and cost are more likely to quantify these effects. In addition, continuous qualitative assessment of the process and outcome measurement procedures is needed to help guide further development.

7.3 Piloting

As shown by Rokstad[12], embedding of referral guidance is possible and acceptable, but their study was limited to a single symptom area. The research into the relevant content of referral documentation is also progressing[213]. Future piloting of solutions should focus on outcome assessment and qualitative assessment of the referral process to clarify complex pathways, in addition to acceptability and relevance in GP practice.

7.4 Wider implementation

Following further evaluation, it would also be pertinent to implement referral guidance in several different hospital areas and clinical cultures. Norway, with its well-developed primary care sector and almost ubiquitous EHR coverage, is very well suited for wide-scale assessment of the impact of such guidance. The relative simplicity of the Norwegian health care system (mainly governmentally provided and well-funded) could allow pertinent conclusions to be drawn from well-designed research.

8.0 Implications for health services design

Given the increasing use of health resources and the focus on prioritisation of scarce resources, the introduction of changes to improve the health care process seems tempting. In a prioritisation report from a governmental committee lead by Norheim, the issue of referral guidelines and their implementation in the EHR is discussed[211]. In light of the evidence from this PhD project, it is not certain that widespread implementation of mandatory referral guidelines will provide an immediate effect on health care services delivered, although the referral quality is likely to increase. It would seem unwise to widely implement obligatory referral guidance at every GP surgery without prior rigorous assessment, given the time constraints and the wide variations in clinical practice across GP surgeries. Before implementation, more rigorous evaluation of barriers to change should also be evaluated, including available resources, incentivisation, technology, culture, and care philosophies[214].

9.0 Conclusion

The current thesis presents a cluster randomised intervention on the interface between GPs and hospital doctors. In Paper I, a clear increase in referral quality (18%; 95% CI 11, 25; $p<0.001$) was noted when measured by criteria that specialists saw as important in their field. This did not translate to the expected improvement in patient experience (Paper II) or quality of hospital care (Paper III). A finding of no result or limited effect is not uncommon in health services interventions[147]. Retrospectively, it does seem unlikely that hospital doctors would provide an inferior level of care to individual patients just because their referral was substandard. More disappointing was the lack of effect on secondary outcomes, such as appropriate prioritisation and the subjective quality score for the patient care pathway.

The study performance itself was based on a pragmatic approach to real-life clinical work. It is hampered by questions regarding the randomisation procedure, lack of uptake, and a wide variation in scoring.

It is very unlikely that the lack of results we observed is due to conceptual error. It seems counterintuitive that more appropriate information does not allow easier identification of sicker patients and hence more adequate care. However, this study underestimated the complexities of research into health service delivery and failed to identify appropriate outcome measures. Further research with scientifically sound referral guidance embedded in the GP's EHR seems pertinent before widespread changes are made to the referral process.

10.0 Erratum

Erratum I: In Paper I page 5 it is stated that “patients ranged from 17 to 90 years of age”. Re-examination of baseline data shows that one patient was indeed aged 17 years at the time of inclusion and should not have been included. At the time, children >16 were treated at the adult facility, so no undue harm was done to the individual. Rerunning of the models without data from this individual did not lead to any significant change in values or outcomes.

11.0 References

1. Spesialisthelsetjenesteloven (2001). Lov om spesialisthelsetjenesten m.m.. Available www.lovdata.no (accessed 17.10.2014)

2. Helse- og omsorgstjenesteloven (2011). Lov om kommunale helse- og omsorgstjenester m.m.. Available www.lovdata.no (accessed 17.10.2014)

3. Pasient- og brukerrettighetsloven (2001). Lov om pasient- og brukerrettigheter. Available www.lovdata.no (accessed 17.10.2014)

4. Helsepersonelloven (2001). Lov om helsepersonell m.v. Available www.lovdata.no (accessed 17.10.2014)

5. Newton J, Eccles M, Hutchinson A: Communication between general practitioners and consultants: what should their letters contain? *BMJ* 1992, 304: 821-824.

6. Long A, Atkins JB: Communications between general practitioners and consultants. *Br Med J* 1974, 4: 456-459.

7. Akbari A, Mayhew A, Al-Alawi MA, Grimshaw J, Winkens R, Glidewell E *et al*.: Interventions to improve outpatient referrals from primary care to secondary care. *Cochrane Database Syst Rev* 2008, 4.

8. Katz MH: How can we know so little about physician referrals? *Archives of Internal Medicine* 2012, 172: 100.

9. Ringberg U, Fleten N, Deraas T, Hasvold T, Forde O: High referral rates to secondary care by general practitioners in Norway are associated with GPs' gender and specialist qualifications in family medicine, a study of 4350 consultations. *BMC Health Services Research* 2013, 13: 147.

10. Forde OH, Breidablik HJ, Ogar P: [Do differences in referral rates threaten the goal of equity in health care?]. *Tidsskr Nor Laegeforen* 2011, 131: 1878-1881.

11. Hartveit M, Biringer E, Vanhaecht K, Haug K, Aslaksen A: The Western Norway mental health interface study: a controlled intervention trial on referral letters between Primary Care and Specialist Mental Health Care. *BMC Psychiatry* 2011, 11: 177.

12. Rokstad IS, Rokstad KS, Holmen S, Lehmann S, Assmus J: Electronic optional guidelines as a tool to improve the process of referring patients to specialized care: An intervention study. *Scand J Prim Health Care* 2013, 31: 166-171.

13. Augestad KM, Revhaug A, Johnsen R, Skrovseth SO, Lindsetmo RO: Implementation of an electronic surgical referral service. Collaboration, consensus and cost of the surgeon - general practitioner Delphi approach. *J Multidiscip Healthc* 2014, 7: 371-380.

14. Huseby BM, Gjøen IJ, Sundet IB, Mehus KH, Rønningen L, Pedersen M *et al*.. Samdata spesialisthelsetjenesten 2012. Oslo: The Norwegian Directorate of Health; 2013.

15. Kristoffersen JE: Forskriften sykehusene bør frykte. *Tidsskr Nor Laegeforen* 2012, 132: 126-127.

16. The Norwegian Directorate of Health: *... and it's going to get better! National Strategy for Quality Improvement in Health and Social Services (2005-2015)*. Oslo: The Norwegian Directorate of Health; 2005.

17. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

18. Varkey P, Reller MK, Resar RK: Basics of Quality Improvement in Health Care. *Mayo Clinic Proceedings* 2007, 82: 735-739.

19. Thomson R: Quality to the fore in health policy - at last. *BMJ* 1998, 317: 95-96.

20. The Norwegian Patient Safety Program. In Safe Hands. The Norwegian Directorate of Health. www.pasientsikkerhetsprogrammet.no (accessed 17.09.2014)

21. Fox K, Garcia MAA, Ardissino D, Buszman P, Camici PG, Crea F *et al*.: Guidelines on the management of stable angina pectoris: executive summary: The Task Force on the Management of Stable Angina Pectoris of the European Society of Cardiology. *European Heart Journal* 2006, 27: 1341-1381.

22. Marsh JCW, Ball SE, Cavenagh J, Darbyshire P, Dokal I, Gordon-Smith EC *et al*.. Guidelines for the diagnosis and management of aplastic anaemia. British Committee for Standards in Haematology; 2010.

23. Talley NJ, Vakil N: Guidelines for the management of dyspepsia. *Am J Gastroenterol* 2005, 100: 2324-2337.

24. Ng D, Vail G, Thomas S, Schmidt N: Applying the Lean principles of the Toyota Production System to reduce wait times in the emergency department. *CJEM* 2010, 12: 50-57.

25. Deckard GJ, Borkowski N, Diaz D, Sanchez C, Boisette SA: Improving timeliness and efficiency in the referral process for safety net providers: application of the Lean Six Sigma methodology. *J Ambul Care Manage* 2010, 33: 124-130.

26. Dickson EW, Singh S, Cheung DS, Wyatt CC, Nugent AS: Application of lean manufacturing techniques in the Emergency Department. *J Emerg Med* 2009, 37: 177-182.

27. Perera R, Moriarty H: If quality is the answer ... what is the question? *Int J Qual Health Care* 2013, 25: 107-109.

28. Coleman EA, Boult C: Improving the quality of transitional care for persons with complex care needs. *J Am Geriatr Soc* 2003, 51: 556-557.

29. Coleman EA: Aspen Transitional Care Conference Proceedings. 2002. http://www.uchsc.edu/hcpr/documents/AspenTransitionProceedings.pdf (accessed 10.06.10)

30. St.meld.nr.47 - Samhandlingsreformen. Rett behandling – på rett sted – til rett tid. Oslo: Det Kongelige Helse- og Omsorgsdepartement; 2009.

31. Piterman L, Koritsas S: Part II. General practitioner-specialist referral process. *Intern Med J* 2005, 35: 491-496.

32. Garasen H, Johnsen R: The quality of communication about older patients between hospital physicians and general practitioners: a panel study assessment. *BMC Health Serv Res* 2007, 7: 133.

33. Kunkle E: Communication breakdown in referral of the patient. *JAMA* 1964, 187: 663.

34. Tuomisto LE, Erhola M, Kaila M, Brander PE, Kauppinen R, Puolijoki H *et al*.: The Finnish national asthma programme: communication in asthma care--quality assessment of asthma referral letters. *J Eval Clin Pract* 2007, 13: 50-54.

35. Canadian Medical Association. National Survey: experiences with referrals from primary to specialty care. Canadian Medical Association; 2013.

36. Ong SP, Lim LT, Barnsley L, Read R: General practitioners' referral letters--Do they meet the expectations of gastroenterologists and rheumatologists? *Aust Fam Physician* 2006, 35: 920-922.

37. Dentith GE, Wilson KE, Dorman M, Girdler NM: An audit of patient referrals to the sedation department of Newcastle Dental Hospital. *Prim Dent Care* 2010, 17: 85-91.

38. Syed AA, Large DM: Quality of GPs' referral letters to diabetes secondary care. *Practical Diabetes International* 2003, 20: 165-169.

39. Newton J, Hutchinson A, Hayes V, McColl E, Mackee I, Holland C: Do Clinicians Tell Each Other Enough? An Analysis of Referral Communications in Two Specialties. *Fam Pract* 1994, 11: 15-20.

40. Shaw I, Smith KM, Middleton H, Woodward L: A letter of consequence: referral letters from general practitioners to secondary mental health services. *Qual Health Res* 2005, 15: 116-128.

41. Bodek S, Ghori K, Edelstein M, Reed A, MacFadyen RJ: Contemporary referral of patients from community care to cardiology lack diagnostic and clinical detail. *Int J Clin Pract* 2006, 60: 595-601.

42. Jacobs LG, Pringle MA: Referral letters and replies from orthopaedic departments: opportunities missed. *BMJ* 1990, 301: 470-473.

43. Jenkins RM: Quality of general practitioner referrals to outpatient departments: assessment by specialists and a general practitioner. *British Journal of General Practice* 1993, 43: 111-113.

44. National Quality Forum. Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination: A Consensus Report. Washington, DC: National Quality Forum; 2010.

45. Ree AO. Medisinsk faglig innhold i henvisninger. KITH 22/03. Trondheim: Norwegian Centre for Informatics in Health and Social Care; 2003.

46. Ree AO. Medisinsk faglig innhold i epikriser. KITH 32/02. Trondheim: Norwegian Centre for Informatics in Health and Social Care; 2002.

47. Martinussen PE: Referral quality and the cooperation between hospital physicians and general practice: The role of physician and primary care factors. *Scandinavian Journal of Public Health* 2013.

48. Barnett ML, Song Z, Landon BE: Trends in physician referrals in the united states, 1999-2009. *Archives of Internal Medicine* 2012, 172: 163-170.

49. Huseby BM, Kalseth B, Gjøen-Øyen IJ, Mehus KH, Rønningen L, Pedersen M *et al*.. Samdata spesialisthelsetjenesten 2013. IS-2194. Oslo: The Norwegian Directorate of Health; 2014.

50. Coulter A, Noone A, Goldacre M: General practitioners' referrals to specialist outpatient clinics. I. Why general practitioners refer patients to specialist outpatient clinics. *BMJ* 1989, 299: 304-306.

51. Thomas RE, Grimshaw JM, Mollison J, McClinton S, McIntosh E, Deans H *et al*.: Cluster randomized trial of a guideline-based open access urological investigation service. *Fam Pract* 2003, 20: 646-654.

52. Banait G, Sibbald B, Thompson D, Summerton C, Hann M, Talbot S: Modifying dyspepsia management in primary care: a cluster randomised controlled trial of educational outreach compared with passive guideline dissemination. *Br J Gen Pract* 2003, 53: 94-100.

53. Jiwa M, Skinner P, Coker AO, Shaw L, Campbell MJ, Thompson J: Implementing referral guidelines: lessons from a negative outcome cluster randomised factorial trial in general practice. *BMC Fam Pract* 2006, 7: 65.

54. Faulkner A, Mills N, Bainton D, Baxter K, Kinnersley P, Peters TJ *et al*.: A systematic review of the effect of primary care-based service innovations on quality and patterns of referral to specialist secondary care. *Br J Gen Pract* 2003, 53: 878-884.

55. Crossing the quality chasm: The IOM Health Care Quality Initiative. Institute of Medicine. Washington, D.C: National Academy Press; 2001.

56. Leonardi MJ, McGory ML, Ko CY: Quality of Care Issues in Colorectal Cancer. *Clinical Cancer Research* 2007, 13: 6897s-6902s.

57. Panzer RJ, Gitomer RS, Greene WH, Webster P, Landry KR, Riccobono CA: Increasing demands for quality measurement. *JAMA* 2013, 310: 1971-1980.

58. Chassin MR, Loeb JM, Schmaltz SP, Wachter RM: Accountability Measures -- Using Measurement to Promote Quality Improvement. *New England Journal of Medicine* 2010, 363: 683-688.

59. Mainz J: Developing evidence-based clinical indicators: a state of the art methods primer. *Int J Qual Health Care* 2003, 15: i5-11.

60. Brook RH, McGlynn EA, Cleary PD: Measuring Quality of Care. *New England Journal of Medicine* 1996, 335: 966-970.

61. Timian A, Rupcic S, Kachnowski S, Luisi P: Do Patients "Like" Good Care? Measuring Hospital Quality via Facebook. *American Journal of Medical Quality* 2013, 28: 374-382.

62. Donabedian A. Evaluating the quality of medical care. Milbank Mem Fund Q 44, 166-203. 1966.

63. Cooperberg MR, Birkmeyer JD, Litwin MS: Defining high quality health care. *Urologic Oncology: Seminars and Original Investigations* 2009, 27: 411-416.

64. Mainz J: Defining and classifying clinical indicators for quality improvement. *Int J Qual Health Care* 2003, 15: 523-530.

65. Agency for Healthcare Research and Quality. National Healthcare Quality Report. 14-0005. Rockville: U.S. Department of Health and Human Services; 2014.

66. Jencks SF, Huff ED, Cuerdon T: Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998-1999 to 2000-2001. *JAMA* 2003, 289: 305-312.

67. Lindenauer PK, Pekow P, Gao S, Crawford AS, Gutierrez B, Benjamin EM: Quality of Care for Patients Hospitalized for Acute Exacerbations of Chronic Obstructive Pulmonary Disease. *Annals of Internal Medicine* 2006, 144: 894-903.

68. Campbell SM, Roland MO, Shekelle PG, Cantrill JA, Buetow SA, Cragg DK: Development of review criteria for assessing the quality of management of stable angina, adult asthma, and non-insulin dependent diabetes mellitus in general practice. *Quality in Health Care* 1999, 8: 6-15.

69. Young JM, Masya LM, Solomon MJ, Shepherd HL: Identifying indicators of colorectal cancer care coordination: a Delphi study. *Colorectal Dis* 2014, 16: 17-25.

70. Enns R: Quality indicators in colonoscopy. *Can J Gastroenterol* 2007, 21: 277-279.

71. Thomson RG, McElroy H, Kazandjian VA: Maryland Hospital Quality Indicator Project in the United Kingdom: an approach for promoting continuous quality improvement. *Qual Health Care* 1997, 6: 49-55.

72. Casalino LP: The Unintended Consequences of Measuring Quality on the Quality of Medical Care. *New England Journal of Medicine* 1999, 341: 1147-1150.

73. Guevara J, Hsu D, Forrest C: Performance measures of the specialty referral process: a systematic review of the literature. *BMC Health Services Research* 2011, 11: 168.

74. Talley NJ: American Gastroenterological Association Medical Position Statement: Evaluation of Dyspepsia. *Gastroenterology* 2005, 129: 1753-1755.

75. Tack J, Talley NJ, Camilleri M, Holtmann G, Hu P, Malagelada JR *et al*.: Functional Gastroduodenal Disorders. *Gastroenterology* 2006, 130: 1466-1479.

76. Thomson ABR, Barkun AN, Armstrong D, Chiba N, White RJ, Daniels S *et al*.: The prevalence of clinically significant endoscopic findings in primary care patients with uninvestigated dyspepsia: the Canadian Adult Dyspepsia Empiric Treatment - Prompt Endoscopy (CADET-PE) study. *Alimentary Pharmacology & Therapeutics* 2003, 17: 1481-1491.

77. Talley NJ, Zinsmeister AR, Schleck CD, Melton LJ, III: Dyspepsia and dyspepsia subgroups: a population-based study. *Gastroenterology* 1992, 102: 1259-1268.

78. Agreus L, Svardsudd K, Nyren O, Tibblin G+: Irritable bowel syndrome and dyspepsia in the general population: Overlap and lack of stability over time. *Gastroenterology* 1995, 109: 671-680.

79. Bytzer P, Talley NJ: Dyspepsia. *Annals of Internal Medicine* 2001, 134: 815-822.

80. Ford AC, Marwaha A, Lim A, Moayyedi P: What Is the Prevalence of Clinically Significant Endoscopic Findings in Subjects With Dyspepsia? Systematic Review and Meta-analysis. *Clinical Gastroenterology and Hepatology* 2010, 8: 830-837.

81. Moayyedi P, Mason J: Clinical and economic consequences of dyspepsia in the community. *Gut* 2002, 50: iv10-iv12.

82. Hippisley-Cox J, Coupland C: Identifying patients with suspected gastro-oesophageal cancer in primary care: derivation and validation of an algorithm. *British Journal of General Practice* 2011, 61: e707-e714.

83. Valle PC, Breckan RK, Amin A, Kristiansen MG, Husebye E, Nordgard K *et al*.: "Test, score and scope": a selection strategy for safe reduction of upper gastrointestinal endoscopies in young dyspeptic patients referred from primary care. *Scand J Gastroenterol* 2006, 41: 161-169.

84. Talley NJ, Vakil NB, Moayyedi P: American Gastroenterological Association Technical Review on the Evaluation of Dyspepsia. *Gastroenterology* 129: 1756-1780.

85. Cancer Registry of Norway: *Cancer in Norway 2012 - Cancer incidence, mortality, survival and prevalence in Norway*. Oslo: Cancer Registry of Norway; 2014.

86. Majumdar SR, Fletcher RH, Evans AT: How does colorectal cancer present? Symptoms, duration, and clues to location. *Am J Gastroenterol* 1999, 94: 3039-3045.

87. Astin MGTNR: The diagnostic value of symptoms for colorectal cancer in primary care: a systematic review. *British Journal of General Practice* 2011, 61: e231-e243.

88. Thompson MR, Perera R, Senapati A, Dodds S: Predictive value of common symptom combinations in diagnosing colorectal cancer. *Br J Surg* 2007, 94: 1260-1265.

89. Hippisley-Cox J, Coupland C: Identifying patients with suspected colorectal cancer in primary care: derivation and validation of an algorithm. *British Journal of General Practice* 2012, 62: e29-e37.

90. Rai S, Kelly MJ: Prioritization of colorectal referrals: a review of the 2-week wait referral system. *Colorectal Dis* 2007, 9: 195-202.

91. Cancer Registry of Norway. Colorectal Cancer Screening. Oslo: Cancer Registry of Norway; 2014. https://www.kreftregisteret.no/en/screening/Screening-for-colorectal-cancer/ (accessed 17.11.2015)

92. Statistics Norway. Causes of death 2012. Oslo: Statistics Norway; 2013.

93. Cayley WE, Jr.: Diagnosing the cause of chest pain. *Am Fam Physician* 2005, 72: 2012-2021.

94. Meisel JL, Cottrell D: Differential diagnosis of chest pain in adults. In *UpToDate*. Edited by Aronsen MD. Waltham, MA: UptoDate; 2013.

95. Lampe FC, Whincup PH, Wannamethee SG, Ebrahim S, Walker M, Shaper AG: Chest pain on questionnaire and prediction of major ischaemic heart disease events in men. *European Heart Journal* 1998, 19: 63-73.

96. McConaghy JR, Oza RS: Outpatient diagnosis of acute chest pain in adults. *Am Fam Physician* 2013, 87: 177-182.

97. Bösner S, Becker A, Haasenritter J, Abu Hani M, Keller H, Sönnichsen AC *et al*.: Chest pain in primary care: Epidemiology and pre-work-up probabilities. *Eur J Gen Pract* 2009, 15: 141-146.

98. McConaghy JR, Oza RS: Outpatient diagnosis of acute chest pain in adults. *Am Fam Physician* 2013, 87: 177-182.

99. Global Strategy for Diagnosis, Management and Prevention of COPD. Global Initiative for Chronic Obstructive Lung Disease; 2014.

100. Salvi SS, Barnes PJ: Chronic obstructive pulmonary disease in non-smokers. *Lancet* 2009, 374: 733-743.

101. The Norwegian Directorate of Health. KOLS. Nasjonal faglig retningslinje og veileder for forebygging, diagnostisering og oppfølging. IS-2029. Oslo: The Norwegian Directorate of Health; 2012.

102. Johannessen A, Omenaas E, Bakke P, Gulsvik A: Incidence of GOLD-defined chronic obstructive pulmonary disease in a general adult population. *Int J Tuberc Lung Dis* 2005, 9: 926-932.

103. Nielsen R, Johannessen A, Benediktsdottir B, Gislason T, Buist AS, Gulsvik A *et al*.: Present and future costs of COPD in Iceland and Norway: results from the BOLD study. *European Respiratory Journal* 2009, 34: 850-857.

104. Gaardsrud PØ. Styringsdata for fastlegeordningen. Oslo: The Norwegian Directorate of Health; 2014.

105. Norsk Senter for Elektronisk Pasientjournal. EPJ Monitor - Årsrapport 2008. Trondheim: NTNU; 2009.

106. Norsk Senter for Elektronisk Pasientjournal. EPJ Monitor - Årsrapport 2010. Trondheim: NTNU; 2011.

107. StatBank. 2018. Statistics Norway. Available at www.ssb.no (accessed 24.09.2018)

108. Heiberg I. Vertskommunenes forbruk av sykehustjenester. Tromsø, Senter for klinisk dokumentasjon og evaluering Helse Nord; 2010.

109. Jiwa M, Mathers N, Walters S: Quality of information on referrals to colorectal surgeons: towards consensus. *Curr Med Res Opin* 2002, 18: 72-77.

110. Nygaard E, Kårikstad V: *Prioriteringsveileder - Hjertemedisinske sykdommer*. Oslo: The Norwegian Directorate of Health; 2009.

111. Nygaard E KV: *Prioriteringsveileder - Fordøyelsessykdommer*. Oslo: The Norwegian Directorate of Health; 2009.

112. Nygaard E KV: *Prioriteringsveileder - Lungesykdommer*. Oslo: The Norwegian Directorate of Health; 2008.

113. BTS statement on criteria for specialist referral, admission, discharge and follow-up for adults with respiratory disease. *Thorax* 2008, 63: i1-i16.

114. Snow V, Barry P, Fihn SD, Gibbons RJ, Owens DK, Williams SV *et al*.: Evaluation of Primary Care Patients with Chronic Stable Angina: Guidelines from the American College of Physicians. *Annals of Internal Medicine* 2004, 141: 57-64.

115. Malm S, Schirmer H. Hjertesak: Riktigere prioritering av pasienter! Fastlegenytt [2]. Tromsø: UNN; 2010.

116. Erhardt L, Herlitz J, Bossaert L, Halinen M, Keltai M, Koster R *et al*.: Task force on the management of chest pain. *Eur Heart J* 2002, 23: 1153-1176.

117. Marshall MN, Shekelle PG, McGlynn EA, Campbell S, Brook RH, Roland MO: Can health care quality indicators be transferred between countries? *Quality and Safety in Health Care* 2003, 12: 8-12.

118. North of England Dyspepsia Guideline Development Group. Dyspepsia: Managing Dyspepsia in Adults in Primary Care. Newcastle upon Tyne: Centre for Health Services Research; 2004.

119. American Gastroenterological Association Medical Position Statement: Evaluation of Dyspepsia. *Gastroenterology* 2005, 129: 1753-1756.

120. American Gastroenterological Association Medical Position Statement on the Management of Barrett's Esophagus. *Gastroenterology* 2011, 140: 1084-1091.

121. Longstreth GF: Approach to the patient with dyspepsia. In *UpToDate*. Edited by Basow DS. Waltham, MA: 2009.

122. Jones R, Hunt C, Stevens R, Dalrymple J, Driscoll R, Sleet S *et al*.: Management of common gastrointestinal disorders: quality criteria based on patients' views and practice guidelines. *Br J Gen Pract* 2009, 59: e199-e208.

123. Fisher L, Lee Krinsky M, Anderson MA, Appalaneni V, Banerjee S, Ben Menachem T *et al*.: The role of endoscopy in the management of obscure GI bleeding. *Gastrointestinal Endoscopy* 2010, 72: 471-479.

124. Bull-Henry K, Al Kawas FH: Evaluation of occult gastrointestinal bleeding. *Am Fam Physician* 2013, 87: 430-436.

125. Riktlinjer handläggning av gastroesofageal refluxsjukdom. Svensk Gastroenterologisk Förening; 2008.

126. Ciclitira PJ, Dewar DH, McLaughlin SD, Sanders DS. The Management of Adult with Coeliac Disease. British Society of Gastroenterology; 2010.

127. Ashton CM, Kuykendall DH, Johnson ML, Wray NP: An empirical assessment of the validity of explicit and implicit process-of-care criteria for quality assessment. *Med Care* 1999, 37: 798-808.

128. Ashton CM, Kuykendall DH, Johnson ML, Wun CC, Wray NP, Carr MJ *et al*.: A method of developing and weighting explicit process of care criteria for quality assessment. *Med Care* 1994, 32: 755-770.

129. Lyons TF, Payne BC: The use of item importance weights in assessing physician performance with predetermined criteria indices. *Med Care* 1975, 13: 432-439.

130. Ellins J: Great expectations? Reflections on the future of patient and public involvement in the NHS. *Clinical Medicine* 2011, 11: 544-547.

131. Doyle C, Lennox L, Bell D: A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open* 2013, 3.

132. Schultz E, Pineda N, Lonhart J, Davies S, McDonald K: A systematic review of the care coordination measurement landscape. *BMC Health Services Research* 2013, 13: 119.

133. Sjetne IS, Bjertnes OA, Iversen HH, Olsen RV. Pasienterfaringer i spesialisthelsetjenesten. Et generisk, kort spørreskjema. Oslo: Nasjonalt kunnskapssenter for helsetjenesten; 2009.

134. Sjetne I, Bjertnaes O, Olsen R, Iversen H, Bukholm G: The Generic Short Patient Experiences Questionnaire (GS-PEQ): identification of core items from a survey in Norway. *BMC Health Services Research* 2011, 11: 88.

135. Skudal KE, Bjernæs ØA, Holmboe O, Bukholm G, Røttingen JA. Commonwealth Fund-undersøkelsen 2010: Resultater fra en komparativ befolkningsundersøkelse i 12 land. Oslo: Nasjonalt kunnskapssenter for helsetjenesten; 2010.

136. Edwards P: Questionnaires in clinical trials: guidelines for optimal design and administration. *Trials* 2010, 11: 2.

137. Cappelleri JC, Zou KH, Bushmakin AG, Alvir JMJ, Alemayehu D, Symonds T: *Patient-Reported Outcomes - Measurement, Implementation and Interpretation*. Boca Raton: CRC Press; 2014.

138. Edwards PJ, Roberts I, Clarke MJ, DiGuiseppi C, Wentz R, Kwan I *et al.*: Methods to increase response to postal and electronic questionnaires. *Cochrane Database Syst Rev* 2009, MR000008.

139. Nygaard E KV: *Prioriteringsveileder - Fordøyelsessykdommer*. Oslo: The Norwegian Directorate of Health; 2009.

140. Nygaard E KV: *Prioriteringsveileder - Lungesykdommer*. Oslo: The Norwegian Directorate of Health; 2008.

141. Bennett K, Haggard M, Churchill R, Wood S: Improving referrals for glue ear from primary care: are multiple interventions better than one *alone? J Health Serv Res Policy 2001, 6: 139-144.*

142. Wåhlberg H, Valle PC, Malm S, Broderstad AR: Practical health co-operation - the impact of a referral template on quality of care and health care co-operation: study protocol for a cluster randomized controlled trial. *Trials* 2013, 14: 7.

143. Smeeth L, Ng ES-W: Intraclass correlation coefficients for cluster randomized trials in primary care: data from the MRC Trial of the Assessment and Management of Older People in the Community. *Controlled Clinical Trials* 2002, 23: 409-421.

144. Cosby RH, Howard M, Kaczorowski J, Willan AR, Sellors JW: Randomizing patients by family practice: sample size estimation, intracluster correlation and data analysis. *Fam Pract* 2003, 20: 77-82.

145. Adams G, Gulliford MC, Ukoumunne OC, Eldridge S, Chinn S, Campbell MJ: Patterns of intra-cluster correlation from primary care research to inform study design and analysis. *Journal of Clinical Epidemiology* 2004, 57: 785-794.

146. Campbell MK: Consort 2010 statement: extension to cluster randomised trials. *BMJ* 2012, 345.

147. Eldridge S, Kerry S: *A Practical Guide to Cluster Randomised Trials in Health Services Research*, 1 edn. Chichester: John Wiley & Sons, Ltd; 2012.

148. Ukoumunne OC, Gulliford MC, Chinn S, Sterne JA, Burney PG: Methods for evaluating area-wide and organisation-based interventions in health and health care: a systematic review. *Health Technol Assess* 1999, 3: iii-92.

149. Campbell MK, Mollison J, Steen N, Grimshaw JM, Eccles M: Analysis of cluster randomized trials in primary care: a practical approach. *Fam Pract* 2000, 17: 192-196.

150. Cornfield J: Randomisation by group: A formal analysis. *American Journal of Epidemiology* 1978, 108: 100-102.

151. Frigessi A, Moger TA, Scheel I, Skovlund E, Veierød MB: *Statiske metoder i medisin og helsefag*. Oslo: Gyldendal Forlag; 2006.

152. Hayes JH, Moulton LH: *Cluster Randomised Trials*. Boca Raton: Chapham & Hall/CRC; 2009.

153. Hayes RJ, Bennett S: Simple sample size calculation for cluster-randomized trials. *Int J Epidemiol* 1999, 28: 319-326.

154. Donner A, Birkett N, Buck C: Randomization by cluster: Sample size requirements and analysis. *American Journal of Epidemiology* 1981, 114: 906-914.

155. Flynn TN, Whitley E, Peters TJ: Recruitment strategies in a cluster randomized trial cost implications. *Statist Med* 2002, 21: 397-405.

156. Hemming K, Girling A, Sitch A, Marsh J, Lilford R: Sample size calculations for cluster randomised controlled trials with a fixed number of clusters. *BMC Medical Research Methodology* 2011, 11: 102.

157. Donner A, Klar N: Pitfalls of and controversies in cluster randomization trials. *Am J Public Health* 2004, 94: 416-422.

158. Campbell M, Grimshaw J, Steen N: Sample size calculations for cluster randomised trials. Changing Professional Practice in Europe Group (EU BIOMED II Concerted Action). *J Health Serv Res Policy* 2000, 5: 12-16.

159. Gaglio B, Phillips SM, Heurtin-Roberts S, Sanchez MA, Glasgow RE: How pragmatic is it? Lessons learned using PRECIS and RE-AIM for determining pragmatic characteristics of research. *Implement Sci* 2014, 9: 96.

160. Slåstad S, Leira HL, Aas O, Amundsen T, Sørhaug S, Sundstrøm S *et al*.: Arbeidsbetinget lungekreft i Sør-Trøndelag. *Tidskr Nor Lægeforen* 2014, 134: 1943-7.

161. Shiell A, Hawe P, Gold L: Complex interventions or complex systems? Implications for health economic evaluation. *BMJ* 2008, 336: 1281-1283.

162. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D *et al*.: Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000, 321: 694-696.

163. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M: Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008, 337: a1655.

164. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions. London: Medical Research Council; 2008

165. Schulz KF, Grimes DA: Blinding in randomised trials: hiding who got what. *Lancet* 2002, 359: 696-700.

166. Schulz KF, Chalmers I, Hayes RJ, Altman DG: Empirical evidence of bias: Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA* 1995, 273: 408-412.

167. Bhopal R: *Concepts of Epidemiology*, Second edition edn. Oxford: Oxford University Press; 2008.

168. Mehrotra A, Forrest CB, Lin CY: Dropping the Baton: Specialty Referrals in the United States. *Milbank Q* 2011, 89: 39-68.

169. Al-Habsi H, Lim JN, Chu CE, Hewison J: Factors influencing the referrals in primary care of asymptomatic patients with a family history of cancer. *Genet Med* 2008, 10: 751-757.

170. Reeder BM, Lyne ED, Patel DR, Cucos DR: Referral Patterns to a Pediatric Orthopedic Clinic: Implications for Education and Practice. *Pediatrics* 2004, 113: e163-e167.

171. Kinchen KS, Cooper LA, Levine D, Wang NY, Powe NR: Referral of Patients to Specialists: Factors Affecting Choice of Specialist by Primary Care Physicians. *Ann Fam Med* 2004, 2: 245-252.

172. Kim Y, Chen AH, Keith E, Yee HF, Jr., Kushel MB: Not perfect, but better: primary care providers' experiences with electronic referrals in a safety net health system. *J Gen Intern Med* 2009, 24: 614-619.

173. Nygaard E KV: *Prioriteringsveileder - Fordøyelsessykdommer*. Oslo: The Norwegian Directorate of Health; 2009.

174. Nygaard E KV: *Prioriteringsveileder - Lungesykdommer*. Oslo: The Norwegian Directorate of Health; 2008.

175. Jellema P, van der Windt DA, Bruinvels DJ, Mallen CD, van Weyenberg SJ, Mulder CJ *et al*.: Value of symptoms and additional diagnostic tests for colorectal cancer in primary care: systematic review and meta-analysis. *BMJ* 2010, 340: c1269.

176. Donabedian A.: *The definition of quality and approaches to its assessment*. Ann Arbor, Mich: Health Administration Press; 1980.

177. Baker R, Fraser RC: Development of review criteria: linking guidelines and assessment of quality. *BMJ* 1995, 311: 370-373.

178. Brook RH, Chassin MR, Fink A, Solomon DH, Kosecoff J, Park RE: A method for the detailed assessment of the appropriateness of medical technologies. *Int J Technol Assess Health Care* 1986, 2: 53-63.

179. Hutchinson A, McIntosh A, Anderson J, Gilbert C, Field R: Developing primary care review criteria from evidence-based guidelines: coronary heart disease as a model. *Br J Gen Pract* 2003, 53: 690-696.

180. Perera R, Dowell A, Crampton P: Painting by numbers: A guide for systematically developing indicators of performance at any level of health care. *Health Policy* 2012, 108: 49-59.

181. Kvalitetsindikatorer - behandling av sykdom og overlevelse. The Norwegian Directorate of Health. Available at https://helsenorge.no/Kvalitetsindikatorer/behandling-av-sykdom-og-overlevelse. (accessed 02.12.2014)

182. Kerr E.A.: Chronic Obstructive Pulmonary Disease. In *Quality of Care for Cardiopulmonary Conditions - A Review of the Literature and Quality Indicators*. Santa Monica, CA: RAND; 2000:91-115.

183. Szklo M, Nieto FJ: *Epidemiology: Beyond the Basics*. Sudbury: Jones and Bartlett; 2007.

184. Jadad R, Enkin MW: Bias in Randomized Controlled Trials. In *Randomized Controlled Trials*. Blackwell Publishing Ltd; 2007:29-47.

185. Farrin A, Russell I, Torgerson D, Underwood M: Differential recruitment in a cluster randomized trial in primary care: the experience of the UK Back pain, Exercise, Active management and Manipulation (UK BEAM) feasibility study. *Clinical Trials* 2005, 2: 119-124.

186. Puffer S, Torgerson D, Watson J: Evidence for risk of bias in cluster randomised trials: review of recent trials published in three general medical journals. *BMJ* 2003, 327: 785-789.

187. Rothwell PM: External validity of randomised controlled trials: "To whom do the results of this trial apply?" *Lancet* 2005, 365: 82-93.

188. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0. Higgings, J. P. T and Green, S. www.cochrane-handbook.org . The Cochrane Collaboration; 2011. (accessed 04.12.2014)

189. Giraudeau B, Ravaud P: Preventing Bias in Cluster Randomised Trials. *PLoS Med* 2009, 6: e1000065.

190. Delgado-Rodriguez M, Llorca J: Bias. *Journal of Epidemiology and Community Health* 2004, 58: 635-641.

191. Torgerson DJ: Contamination in trials: is cluster randomisation the answer? *BMJ* 2001, 322: 355-357.

192. McCarney R, Warner J, Iliffe S, van Haselen R, Griffin M, Fisher P: The Hawthorne Effect: a randomised, controlled trial. *BMC Med Res Methodol* 2007, 7: 30.

193. Lasek RJ, Barkley W, Harper DL, Rosenthal GE: An Evaluation of the Impact of Nonresponse Bias on Patient Satisfaction Surveys. *Medical Care* 1997, 35.

194. Perneger TV, Chamot E, Bovier PA: Nonresponse Bias in a Survey of Patient Perceptions of Hospital Care. *Medical Care* 2005, 43.

195. Sitzia J, Wood N: Patient satisfaction: A review of issues and concepts. *Social Science & Medicine* 1997, 45: 1829-1843.

196. Williams B, Coyle J, Healy D: The meaning of patient satisfaction: An explanation of high reported levels. *Social Science & Medicine* 1998, 47: 1351-1359.

197. Romm FJ, Putnam SM: The validity of the medical record. *Med Care* 1981, 19: 310-315.

198. Moran MT, Wiser TH, Nanda J, Gross H: Measuring medical residents' chart-documentation practices. *J Med Educ* 1988, 63: 859-865.

199. Weiskopf NG, Weng C: Methods and dimensions of electronic health record data quality assessment: enabling reuse for clinical research. *Journal of the American Medical Informatics Association* 2013, 20: 144-151.

200. Helse og omsorgsdepartementet. Prioriteringsforskriften (2018). Available www.lovdata.no (accessed 26.09.2018)

201. Fritt Sykehusvalg Norge (Free Hospital Choice Norway). The Norwegian Directorate of Health, 2014. Available at www.frittsykehusvalg.no (accessed 09.12.2014)

202. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ *et al*.: CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010, 340.

203. Malterud K: The art and science of clinical knowledge: evidence beyond measures and numbers. *Lancet* 2001, 358: 397-400.

204. Cohen DJ, Crabtree BF: Evaluative Criteria for Qualitative Research in Health Care: Controversies and Recommendations. *The Annals of Family Medicine* 2008, 6: 331-339.

205. Malterud K: Qualitative research: standards, challenges, and guidelines. *Lancet* 2001, 358: 483-488.

206. Wisdom JP, Cavaleri MA, Onwuegbuzie AJ, Green CA: Methodological Reporting in Qualitative, Quantitative, and Mixed Methods Health Services Research Articles. *Health Serv Res* 2012, 47: 721-745.

207. Sluttrapport Prosjekt Interaktive henvisninger. Lørenskog: Akershus universitetssykehus; 2011.

208. Heimly V. Erfaringsrapport fra innføring av Interaktiv Henvisning ved AHUS. Lørenskog: Akershus universitetssykehus; 2011.

209. Lee TJW, Clifford GM, Rajasekhar P, Rutter MD, Kometa S, Ritchie MC *et al*.: High yield of colorectal neoplasia detected by colonoscopy following a positive faecal occult blood test in the NHS Bowel Cancer Screening Programme. *Journal of Medical Screening* 2011, 18: 82-86.

210. Chassin MR, Loeb JM, Schmaltz SP, Wachter RM: Accountability Measures - Using Measurement to Promote Quality Improvement. *New England Journal of Medicine* 2010, 363: 683-688.

211. Norheim OF, Allgott B, Gjul GK, Kjellevold A, Moen A, Sjøli S *et al*.. Åpent og rettferdig - prioriteringer i helsetjenesten. Oslo: Norges Offentlige Utredninger; 2014: 12.

212. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W *et al*.: Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* 2015, 350.

213. Eskeland SL, Brunborg C, Seip B, Wiencke K, Hovde O, Owen T *et al*.: First quality score for referral letters in gastroenterology-a validation study. *BMJ Open* 2016, 6: e012835.

214. Lau R, Stevenson F, Ong BN, Dziedzic K, Treweek S, Eldridge S *et al*.: Achieving change in primary care -- causes of the evidence to practice gap: systematic reviews of reviews. *Implementation Science* 2016, 11: 40.

PAPER I

Wåhlberg H, Valle PC, Malm S, Broderstad AR**: Impact of referral templates on the quality of referrals from primary to secondary care: a cluster randomised trial.** *BMC Health Services Research* 2015, **15(1)**:353

Wåhlberg et al. BMC Health Services Research (2015) 15:353
DOI 10.1186/s12913-015-1017-7

BMC Health Services Research

RESEARCH ARTICLE Open Access

Impact of referral templates on the quality of referrals from primary to secondary care: a cluster randomised trial

Henrik Wåhlberg[1,2*], Per Christian Valle[2], Siri Malm[2,3] and Ann Ragnhild Broderstad[2,4]

Abstract

Background: The referral letter is an important document facilitating the transfer of care from a general practitioner (GP) to secondary care. Hospital doctors have often criticised the quality and content of referral letters, and the effectiveness of improvement efforts remains uncertain.

Methods: A cluster randomised trial was conducted using referral templates for patients in four diagnostic groups: dyspepsia, suspected colorectal cancer, chest pain and chronic obstructive pulmonary disease. The GP surgery was the unit of randomisation. Of the 14 surgeries served by the University Hospital of North Norway Harstad, seven were randomised to the intervention group. Intervention GPs used referral templates soliciting core clinical information when initiating a new referral in one of the four clinical areas. Intermittent surgery visits by study personnel were also carried out. A total of 500 patients were included, with 281 in the intervention and 219 in the control arm. Referral quality scoring was performed by three blinded raters. Data were analysed using multi-level regression modelling. All analyses were conducted on intention-to-treat basis.

Results: In the final multilevel model, referrals in the intervention group scored 18 % higher (95 % CI (11 %, 25 %), $p < 0.001$) on the referral quality score than the control group. The model also showed that board certified GPs and GPs in larger surgeries produced referrals of significantly higher quality.

Conclusion: In this study, the dissemination of referral templates coupled with intermittent surgery visits produced higher quality referrals.

Trial registration: This trial has been registered at ClinicalTrials.gov. The trial registration number is NCT01470963.

Background

A referral facilitates the transition of care from a general practitioner (GP) to secondary care to establish a diagnosis, to provide treatment including surgery, and to offer advice or reassurance. Hospital specialists frequently have complained about the perceived quality of referral letters. Several studies have highlighted the varying quality and content of referrals across a range of clinical specialities [1–12]. A recent Canadian survey of more than 3000 GPs and specialists found that, among the main problems specialists identified, 51 % of referral letters had an unclear reason for referral [13]. This variation in quality makes the evaluation and prioritisation of incoming referrals difficult, with one author stating that prioritisation cannot be performed based on referral letters alone [14].

A high quality referral process will generally involve referral letters containing all necessary information in a context of shared understanding between GPs, patients and hospital staff [15]. There have been previous definitions of what referral letters should contain [16]. In Norway, the Norwegian Centre for Informatics in Health and Social Care (KITH) has developed guidelines governing the content of electronic referral and discharge letters [17, 18]. However, these guidelines present headings and content categories, but do not specify the precise clinical information required for different clinical

* Correspondence: henrik.wahlberg@uit.no
[1]Department of Community Medicine, UiT The Arctic University of Norway, 9037 Tromsø, Norway
[2]University Hospital of North Norway Harstad, St. Olavsgate 70, 9480 Harstad, Norway
Full list of author information is available at the end of the article

areas. A recent Norwegian study has highlighted that it is the lack of information in the referrals, rather than the structure and categories of the referral, that hospital doctors perceive as a barrier to high quality cooperative care [19]. To measure referral quality, it therefore seems necessary to focus more on measuring the informational quality of referrals than on measuring their structure. This conclusion is echoed by other publications in the field [8, 12, 20]. Several of these studies developed scoring systems collaboratively between hospital doctors and GPs [12, 20].

The introduction of electronic health records and communication has, to some extent, eliminated some of the structural problems with referral letters, but further work is needed to elucidate the relationship between the quality of clinical information in referrals and high quality health care processes. This is important as healthcare costs are rising globally [21] and services are being delivered within a framework of increasingly limited resources. In this context, it is imperative to improve patient prioritisation based on referrals in order to aid swift diagnosis in those with more serious disease and to provide evidence based high quality care to each individual patient. Tools to improve referral quality are paramount.

This paper reports the effects of a referral intervention on the quality of referrals in a cluster randomised trial. We hypothesized that the referral intervention would improve informational quality in the referrals. We assess whether other GP-related factors, including patient list size and years of experience, affect the quality of referrals written. This paper is part of a larger study assessing the effect of a referral intervention on the quality of health care delivered to individual patients. Information about further assessments within the referral project is available in the published methods paper [22].

Methods

Study setting

The Norwegian health care system is relatively uniform throughout the country. Each person has a regular GP who acts as a gatekeeper to secondary care [23]. GPs work either privately, with capitation payment and fee-for-service reimbursement, or as municipality employees. Specialist health care is delivered through governmentally owned regional health authorities, mainly in public hospitals. Some specialist outpatient care is purchased by the regional health authorities from private specialists, but access to this is very limited in the geographical area of the current study. Electronic health records are almost ubiquitous and referrals are sent according to a national standard that automatically includes demographic information including address, contact details and GP details [17].

Study design

This study was designed as a cluster randomised trial with the general practitioner surgery as the clustering unit. All 14 community GP surgeries in the area served by the University Hospital of North Norway (UNN) Harstad were randomised to the intervention or control group. The cluster design was chosen to avoid contamination between GPs, which could have occurred if individual GPs at the same surgery were randomised to different groups.

The referring GP could not be blinded because the intervention was actively used by the GP. Patients, hospital doctors and outcome evaluators were blinded to the patient's intervention status. However, in some cases the referral letter revealed the intervention status. Further information about study methods are available in detail in the methods paper [22].

Intervention

The intervention consisted of the distribution of referral templates to the intervention surgeries. The templates were provided in paper and electronic forms. The templates were to be used when initiating a new referral to the medical outpatient clinic for patients within the four diagnostic areas specified below. These referral templates were developed based upon national and international literature [12, 24–31] and in collaboration with local specialists within each medical field. A clinical assessment process using specialists from other Northern Norwegian hospitals provided further insight into template contents. To ensure intervention implementation by keeping it as simple as possible, we reduced the number of items in the referral template to include only those that the specialists felt were imperative in a referral for that clinical area. The templates contained a heading soliciting further information in the referral about each item listed in the subsequent list of items. For example, the items in the referral template for patients with suspected colorectal cancer are shown in Table 1 (translated into English). The other templates are available in Additional file 1. The intervention offices were also provided with a separate electronic referral address at the hospital to enable study organisers to track the use of the intervention.

The templates were distributed by the corresponding author (HW) during educational and/or lunch meetings at the intervention surgeries. Prior to the distribution of templates, the project had been presented to the GPs at similar meetings. The intervention was in use for approximately 2 years, from September 2011 to November 2013.

Additional follow-up was provided in the form of lunchtime visits to the intervention surgeries approximately twice yearly and intermittent mail leaflets and reminders. The lunchtime visits were performed by HW and provided information about the progress of the

Table 1 Referral template for patients with suspected colorectal cancer

Item #	Item text
1	Change in bowel habit
2	Blood in stool
3	Weight loss
4	Family history of colorectal cancer
5	Previous medical history of bowel disease or results of previous bowel investigations
6	Results of digital rectal examination (DRE)
7	Iron deficiency anaemia
8	Clinical findings at abdominal examination
9	Result of faecal occult blood test (FOBT)
10	The general practitioners clinical suspicion

study, reminders to use the intervention templates and answers to questions about the project. In addition, personal letters to participating doctors were sent when it was evident that the intervention had not been used in a received referral.

In the control group, normal referral practice continued. No information about the study was provided to the control surgeries.

Four separate diagnostic groups were selected; these represent both important clinical areas and a substantial amount of outpatient appointments.

- patients referred with dyspepsia
- patients referred with suspected colorectal cancer (CRC)
- patients referred with chest pain
- patients referred with confirmed or suspected chronic obstructive pulmonary disease (COPD)

At UNN Harstad in 2008 these diagnostic areas accounted for approximately 26 % of all patients in the medical outpatient clinics (own data), although separating new referrals from control patients in this material was not possible. In addition, patients in these clinical areas often represent a diagnostic challenge in primary care [32] and are well suited for simple referral templates.

Participants

The 14 GP surgeries in the area primarily served by UNN Harstad were included in the randomisation process. In 2013, these surgeries had a total list size of 39,253 patients. Five surgeries were town-based and nine were rural. To ensure equal sociodemographic backgrounds between groups, the surgeries were randomised stratified by town or countryside location, although the location of the surgery itself was not expected to influence the main outcome variables. Two centres initially randomised to the intervention group declined to participate, one because of lack of interest and one because the GP was about to retire. Two further centres were therefore randomly selected. The final intervention group consisted of three urban and four rural surgeries, with two urban and five rural surgeries in the control group.

New patients referred to the UNN Harstad medical outpatient clinics in any of the four diagnostic groups received written information about the study and a participant consent form along with their appointment letter. Patients were orally reminded of the study by the hospital doctor at their hospital outpatient appointment and were given a new consent form if appropriate. Children (<18 years of age) and patients with reduced capacity to consent were excluded from the project. Further details about the GP surgeries and the recruitment process are published in the methods paper [22].

Recruitment

Recruitment ran for about 2.5 years, from September 2011 to February 2014, to ensure that patients referred during the project (the template was used until November 2014) had an outpatient appointment before inclusion closed. This timeframe was chosen because few patients at the hospital experience waiting times of >4 months from the time of their referral to the time of their hospital appointment. A total of 538 patients were included in the project. Thirty-eight patients were excluded because they did not fulfil the inclusion criteria, as depicted in Fig. 1. In total, 290 patients were included in the intervention arm and 227 patients in the control arm.

Ethics

The study followed the directions in the Helsinki Declaration. Before recruitment started, the study was presented to the Regional Ethical Committee for Medical Research in North-Norway, who determined it not to be within the scope of the Health Research Act (REK NORD 2010/2259). The study was approved by the Data Protection Official for Research. The study is registered at ClinicalTrials.gov. The trial registration number is NCT01470963. All patients provided written informed consent.

Sample size

For the overall study, sample size calculation was performed for the main outcome variable (a health care quality score), as shown in the methods paper [22]. No specific sample size calculation was performed for the referral quality outcome reported in this paper.

Referral scoring

The referrals were rated according to a scoring system derived directly from the referral templates used. These

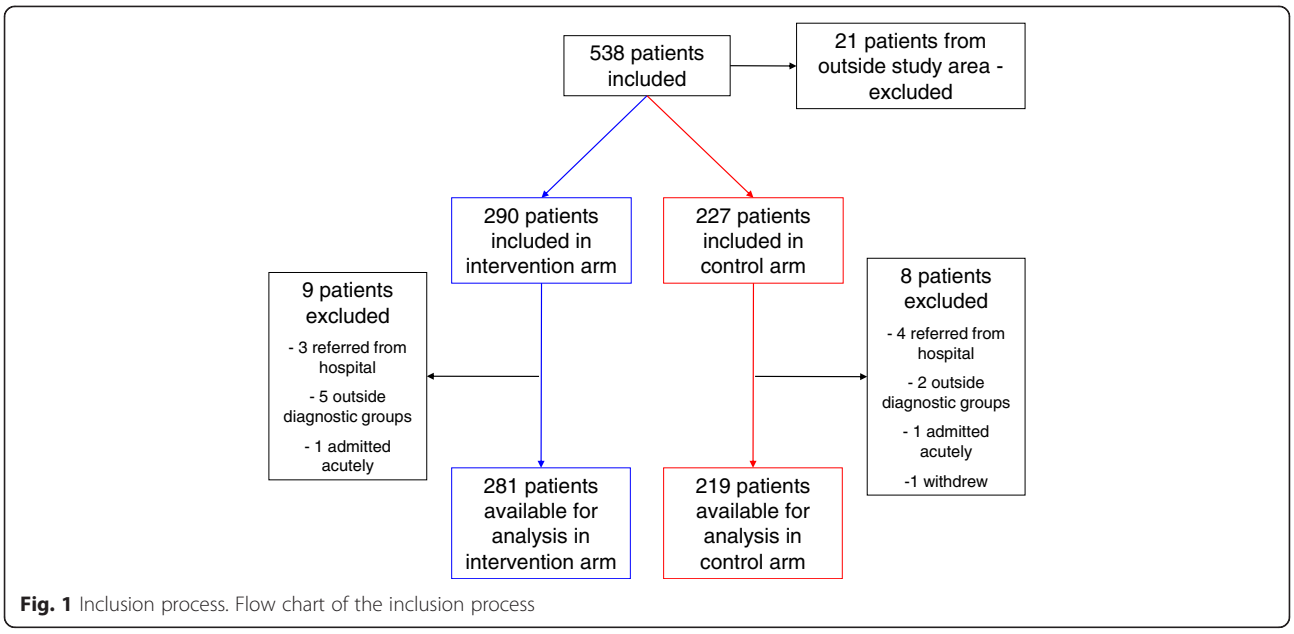

Fig. 1 Inclusion process. Flow chart of the inclusion process

templates specified the clinical information that specialists deemed most important in the referral, based on literature documented above. One point was awarded for the presence in the referral of each of the clinical details requested in the referral template. The maximum score possible for referrals for dyspepsia, suspected CRC, COPD and chest pain were 17, 10, 15 and 13 respectively. Other studies have also awarded points for the presence of core information including full contact details and legibility of referrals [33]. Because all but six referrals in this project were electronic, and such information is automatically included in the electronic referral, this information was not included in the scoring. The final referral score therefore represents how many of the information points in the template were actually articulated in the referral. Each score was then transformed to a percentage value.

Three raters scored the referrals. A sample of 100 out of the 500 referrals was scored independently by two raters. No referral was scored by all three raters, and all three rater pairs shared at least 25 referrals. The raters were blinded to the intervention status of the referring GP.

For further analysis, a small amount of data was imputed. For referrals initiated by interns, the list size was missing by default. Interns in Norway spend six months attached to a GP surgery where they do not have their own list of patients. Instead, they take part in the general workload of the surgery. For each referral initiated by an intern, the list size value in the dataset was set to the average list size value for the surgery the intern was attached to. This was believed to best represent the anticipated workload of each intern.

Speciality status was available for all referring GPs. Years of experience as a GP and in hospitals was available for 499 of 500 referrals, while data for the last case were imputed as mean values.

Statistical analysis

Analyses were stratified by intervention group and control group. To ensure rater consistency an interrater reliability analysis using the weighted Kappa statistic was performed, as developed by Cohen [34]. Referral scores were divided into centiles, and a weighted Kappa analysis was performed using quadratic weights. Additional analysis was carried out for each rater pair separately and with the data divided into quintiles to ensure consistency of analysis.

We chose to use standard weights (quadratic) to improve interpretability, in concordance with discussion on the appropriate use of Kappa analysis [35]. In this way, the weighted Kappa coefficient approximates the intraclass correlation coefficient [36]. The weighted Kappa coefficient increases with increasing numbers of categories, especially when using quadratic weights [37]. However, this increase seems more pronounced in the range of two to five categories.

The cluster randomised design necessitates an analysis that is suitable for clustering. In this project, multi-level regression modelling was used. A stepwise approach was used to build the multi-level model. Likelihood ratio tests were used to evaluate whether random regression coefficients should be considered. Continuous variables were centred to facilitate interpretation. Because the intervention was randomised at the level of the GP surgery, no slope could be added for the intervention effect. To assess the addition of confounders to level one of the model, a change in the magnitude of the regression coefficient for the intervention effect of more than 10 % was

considered indicative of a confound. In addition, the following variables were included based on prior subject knowledge: whether the referring GP was a specialist, the length of GP experience and GP list size. Effect modification was checked for relevant variables using $p < 0.10$ as the significance level. This level was chosen because the power to detect relevant interactions is often low, especially concerning cross-level interactions in multilevel studies [38]. Although increasing the type 1 error rate has been shown to be ineffective [39], it was judged to be better than missing important interactions. Analysis was done on an intention-to-treat basis, as recommended [40]. All referrals from intervention surgeries were therefore analysed as if they had used the referral intervention, even though it may have been evident that the intervention was not used. Stata version 13 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP) was used for all analysis.

Results

Baseline characteristics

Table 2 presents baseline characteristics of the study population. Patients ranged from 17 to 90 years of age. In both the intervention and control groups there were more women (59 and 58 %) than men (41 and 42 %). The majority of the referrals were in the dyspepsia group. Baseline characteristics for GP surgeries and referrals are available in Table 3. The groups appear similar, except that more referrals were initiated by male GPs in the control group than in the intervention group, which is probably caused by the slightly higher number of male GPs in the control group. Further, significantly more of the referrals in the intervention group than in the control group were made by GP specialists, thereby necessitating this as a covariate in the regression model. There were 37 referrals from interns, accounting for 7.4 % of the total number of referrals. A total of 139 of the 281 (49.5 %) intervention group referrals were sent to the designated electronic referral address created for the project; the rest were sent to the standard hospital electronic address.

Interrater reliability

The interrater reliability was found to be Kappa = 0.93 ($p < 0.0001$), 95 % CI (0.73, 1). Additional analysis with the data divided into quintiles showed Kappa = 0.90 ($p < 0.0001$), 95 % CI (0.71, 1). Analysis for each rater pair separately yielded Kappa values ranging from 0.85 to 0.93 (further details available upon request).

Primary outcome

The average referral quality in each of the four diagnostic groups, not corrected for clustering, was higher in the intervention than the control group (Fig. 2). Large variations in quality were seen across all four diagnostic areas, both in the intervention and control groups. Table 4 presents these findings, not corrected for clustering, showing highly significant improvements in referral quality scores in all clinical areas except COPD. However, the absolute number of COPD referrals was very low.

Baseline evaluation of the main outcome variable (referral quality) demonstrated that it was nearly normally distributed. Naïve analysis of data—that is, using a mixed models approach without adding the level of GP surgery into the analysis—was compared with a model including the GP surgery as clustering unit. Adding the random intercept to the model decreased the −2 log likelihood by 4529.25–4493.50 = 35.75. This is highly significant according to the Chi squared distribution with one degree of freedom. From the above analysis, the intraclass correlation coefficient (ICC) was calculated to be 0.14 (95 % CI (0.02, 0.25)). The final model corrected for whether the GP was a board certified specialist, centred mean GP patient list size, GP hospital experience (in years), and categorised GP surgery size. GP experience (in years) was removed from the model because

Table 2 Selected patient baseline characteristics by intervention status

	Intervention group	Control group	*p*-value
Patient demographics[1]			
Female/male, n (%)	166 (59.07)/115 (40.93)	127 (57.99)/92 (42.01)	$p = 0.807$
Age, years	59.21 ± 13.64	57.08 ± 15.26	$p = 0.101$
Urban/rural, n (%)	169 (60.14)/112 (39.86)	121 (55.25)/98 (44.75)	$p = 0.272$
Clinical group, n (%)			
- dyspepsia	144 (51.25)	120 (54.79)	
- suspected colonic malignancy	87 (30.96)	68 (31.05)	
- chest pain	46 (16.37)	27 (12.33)	
- chronic obstructive pulmonary disease	4 (1.42)	4 (1.83)	
Hospital appointment with senior house officer/specialist, n (%)	130 (46.26)/151 (53.74)	96 (43.84)/123 (56.16)	$p = 0.588$

[1]Data are presented as mean ± SD or number (%)

Table 3 Selected general practitioner (GP) baseline characteristics by intervention status[1]

	Intervention group	Control group	*p*-value
GP surgery variables[2]			
List size	830.79 ± 208.78	865.48 ± 100.69	$p = 0.475$
Female/male GP, n (%)	14 (58.33)/10 (41.67)	10 (43.48)/13 (56.52)	$p = 0.308$
Specialist yes/no, n (%)	18 (75)/6 (25)	11 (47.83)/12 (52.17)	$p = 0.055$
Years experience	16.02 ± 10.40	15.15 ± 11.15	$p = 0.784$
Years experience in hospital	2.81 ± 5.94	1.89 ± 3.06	$p = 0.510$
Number of GPs in surgery	4.33 ± 1.61	4.04 ± 1.58	$p = 0.536$
- median	5	5	
- mode	5	5	
GP referral variables per referral in dataset[2]			
Female/male referring GP, n (%)	182 (64.77)/99 (35.23)	93 (42.47)/126 (57.53)	$p < 0.00001$[4]
Number of GPs in surgery	4.43 ± 1.46	4.01 ± 1.62	$p = 0.003$[3]
Specialist yes/no n (%)	189 (67.26)/92 (32.74)	114 (52.05)/105(47.95)	$p = 0.000556$[4]
Years experience	16.21 ± 11.96	15.41 ± 11.70	$p = 0.456$
Years experience in hospital	1.54 ± 1.88	1.54 ± 2.46	$p = 0.994$
Other variables per referral in dataset[2]			
Electronic/paper referral n (%)	281 (100)/0 (0)	213 (97.26)/ 6 (2.74)	$p = 0.005$[3]

[1]Two GPs shared two lists at two separate surgeries, both in the intervention group. Weighted analysis taking this into account did not lead to significant change in the baseline characteristics
[2]Data are presented as mean ± SD or number (%)
[3]Significant at $p < 0.01$
[4]Significant at $p < 0.001$

it had no impact on the outcome of interest and had no clear association with referral quality. In addition, GP experience was clearly correlated with being a GP specialist, and its inclusion would thus reduce the power of the analysis without adding further insight.

Allowing the result to vary randomly at the level of the referring GP further decreased the −2 log likelihood of the baseline model to 4419.70 and reduced residual variance. The addition of a third level added complexity to the model and only changed the estimation of the intervention effect by 2 percentage points. It was therefore decided to keep the two level model proposed in the methods paper [22].

With this model, the multi-level regression analysis suggested a significant intervention effect with an approximately 20 % higher referral score in the intervention group. In the final model, adjustment reduced the effect estimate to 18 % (95 % CI (11, 25), $p < 0.001$) (Table 5). The model suggests that board certified GPs produced referrals that were closer to the referral template (9 %, 95 % CI (4, 14), $p < 0.001$), whereas longer hospital experience during a GP's career predicted slightly less complete referrals (−2 %, 95 % CI (−3, −1) $p < 0.001$). Larger GP surgeries also tended to produce higher quality referrals, but this association was not statistically significant. A Q-Q normality plot of residuals from the model showed no violation of normality assumptions.

Because only roughly 50 % of the intervention group referrals were sent to the intervention hospital electronic address, we performed a non-protocol multilevel model analysis comparing the quality of referrals between the intervention GPs who used the referral address and those intervention GPs who did not. We found a referral quality difference that was approximately as large as between the intervention and control group in the main analysis (21.9 %, 95 % CI (16.5, 26.2), $p < 0.001$).

Discussion

The current paper presents the impact of the dissemination of a referral template on referral quality. The intervention improved referral quality by 18 %, which is presumably clinically relevant. Our finding is consistent with reported increases in referral quality in similar intervention studies [41, 42], whereas another study reported a smaller effect size [43]. However, as discussed in a Cochrane review on the subject, there have been few studies aimed at improving the quality of referrals, and several have had methodological weaknesses [44].

The current study suggests that dissemination of referral templates combined with local follow-up measures can indeed improve referral quality in the communication between primary and specialist health care, which is consistent with the conclusions in the Cochrane report [44]. The data also suggest that being a board certified

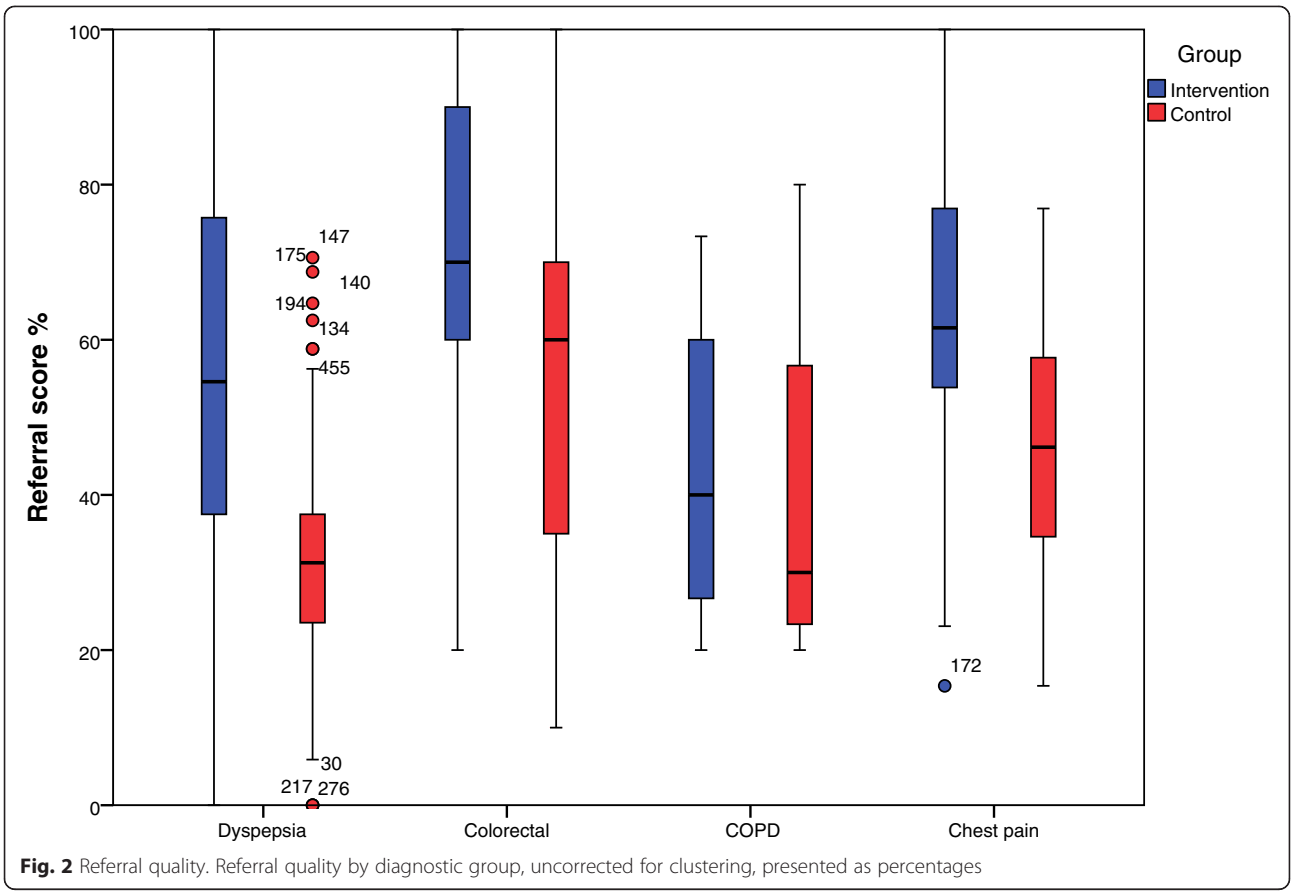

Fig. 2 Referral quality. Referral quality by diagnostic group, uncorrected for clustering, presented as percentages

GP improves the quality of written communication to specialist health services as measured by the referral scoring system. Surprisingly, a GP's experience as a hospital doctor does not appear to predict referrals that include more of the content requested by hospital consultants. Years of experience as a GP showed no association with the outcome of interest and was left out of the model entirely. This may suggest that it is the communication and collaboration between hospital-based specialists and dedicated GPs that can produce better referral quality, and not the experience of the GP or the presence of a referral template per se.

However, it is important to recognise that while a hospital physician will try to prioritise received referrals based on the risk of serious illness, many referrals are sent for reasons other than ruling out or diagnosing disease. These can include patient reassurance, reduction of medico-legal risk, handing over of care, or to obtain a second opinion [45]. Others have shown that factors including GP gender and GP speciality can affect referral rates and have discussed whether higher professional insecurity and/or higher responsiveness to patient demand may explain some of this variation [46]. It is conceivable that some of these factors also affect referral content, and that referrals are not purely based on the GP's perception of the patient's individual risk of serious disease.

Table 4 Average referral quality by diagnostic group, uncorrected for clustering[1]

	Intervention	Control	*p*-value
Dyspepsia	57.3 (53.0, 61.7)	31.4 (28.7, 34.1)	<0.001
Suspected colonic malignancy	70.1 (65.6, 74.6)	53.4 (48.5, 58.3)	<0.001
COPD	43.4 (7.1, 79.6)	40.0 (0, 83.3)	0.857
Chest pain	61.9 (56.2, 67.5)	45.3 (38.3, 52.3)	<0.001

[1]Presented as mean and 95 % CI

As shown above, in this study the quality of the referrals varied between the four clinical areas, with referrals for suspected colonic malignancy scoring highest (average 70.1 % in the intervention group and 53.4 % in the control group) and referrals for patients with COPD scoring lowest (43.3 vs. 40.0 %). We have found no comparable studies in which referrals for different clinical areas have been scored using the same scoring technique, and it is therefore hard to assess whether this quality difference is a general phenomenon. However, the referral template for colonic malignancy contained the fewest requested clinical data points, and the scientific basis for these points was better documented than those for the COPD or dyspepsia referrals. This may

Table 5 Intervention effect estimates

	Regression coefficient	95 % CI	*p*-value
Crude[1]	20.25	10.23, 30.27	$p < 0.001$
Adjusted[2]	18.00	11.03, 24.98	$p < 0.001$
- GP specialist yes/no	9.19	4.39, 13.99	$p < 0.001$
- GP list size (centred)	0.02	−0.01, 0.05	$p = 0.196$
- GP experience in hospital (in years)	−2.06	−3.08, −1.05	$p < 0.001$
- GP surgery size[3]	4.81	−2.73, 12.35	$p = 0.211$

[1]Baseline model with intervention effect with random intercept
[2]Adjusted for the variables listed below
[3]Categorised into binary variable 0–3 GPs and 3–6 GPs

suggest that for referral templates to be effective, simpler templates based on solid scientific research may be more acceptable and user-friendly in clinical practice than complicated templates.

The referral scores varied widely for each diagnostic area (Fig. 2). This confirms the pre-trial clinical suspicion of variation, which was one of the motivations for this study. Especially within the area of dyspepsia, wide variation was seen in both the intervention and control groups, with several outliers. This suggests that some GPs produce referrals of high quality, regardless of the referral intervention, and that some general practitioners in the intervention group took no interest in the intervention at all. This wide range in performance has also been noted when the referral rate has been assessed [46, 47]. Although uniformity does not necessarily equate to quality, it is intuitive that some degree of increased uniformity in referral quality would improve equity in the health care delivered to patients.

Adding interactions to the model showed a significant interaction between intervention status and being a board certified GP. This suggested a stronger intervention effect amongst those who were board certified. This was felt to be adequately represented in the model by the combination of the terms 'board certified GP' and 'hospital experience'.

The weighted Kappa analysis equates to 'almost perfect' agreement among raters (Kappa 0.81–1.00) according to Landis and Koch [48]. Even considering the increasing Kappa values with increasing categories discussed above, this shows not only excellent overall reliability, but also excellent agreement between all three rater pairs.

This study has several limitations. The referral templates used in the project were developed according to international literature and local practices. Referrals were scored based on how closely they followed this referral template. Conscientious GPs were therefore likely to score very high on the referral score, and this could bias the results in favour of the intervention. Nonetheless, the scoring system does equate with referral quality measurement scores used in other referral evaluation studies [2, 5]. In addition, further work in this project aimes to assess whether the presence of a greater quantity of relevant clinical information improves the quality of the health care process, and consequently this scoring system seemed appropriate. It is possible that some of the effect size noted above was caused by GPs who took a special interest in the study.

A further weakness is that the current project does not provide a clear indication of the proportion of the referring GPs who actively used the referral intervention. The referral templates were distributed and follow-up visits were arranged to ensure adherence to the study protocol. As presented above, only about 50 % of the referrals from intervention GPs were sent to the newly formed intervention electronic address. This suggests a fairly modest uptake of the intervention, and the non-protocol analysis showed a higher intervention effect amongst those GPs who actively utilised the electronic address. Because intention-to-treat analysis was used, this has probably attenuated the intervention effect. Similar difficulties have been seen in other projects, with an uptake as low as 18 % in a referral intervention study for patients with lower bowel symptoms [49]. However, a recent Norwegian project using referral guidance as an electronic pop-up reported that the 88 % of the intervention GPs used the intervention 'all the time' [20].

Many known barriers to changes of behaviour and application of clinical knowledge exist, including lack of knowledge/awareness, lack of applicability to the individual patient and organisational factors [50]. Feedback from the GPs in this project suggests that the intervention was used and appreciated, but also easily forgotten in hectic everyday clinical work. If wider application of referral guidelines is to be considered, careful assessment should be undertaken to identify barriers to their use and to indicate tailored interventions to overcome these barriers, as this has been shown to be more likely to improve professional practice [51].

Another limiting factor is that the rate of inclusion of relevant patients is unknown. During the inclusion phase, regular reviews took place to assess the rate of

inclusion at the hospital, which was estimated to be approximately 60 % of possible outpatient candidates. A completely accurate figure is not available, as this would require a manual search of the charts of every patient with an outpatient appointment, which is beyond the ethical approval of this project.

It is also clear that more patients were recruited from intervention GP surgeries than control GP surgeries. The total number of listed patients in the intervention and control group GP surgeries was very similar (19,347 vs. 19,906). The study did not have access to referral rates, and it is not clear whether these varied between the practices. There is no clear indication of major baseline differences between the GP surgeries and the study patients that can explain the difference in inclusion. One possible explanation is that the focus on the four diagnostic areas in the intervention offices caused more patients to be referred, but this cannot be demonstrated from the current data.

It is important to note that making referral information more in line with the hospital physicians' wishes does not automatically predict improved outcomes. It is conceivable that referrals that are more pleasing to the hospital consultant may give a false sense of precision in the evaluation and prioritisation of referrals. For colorectal cancer, a review of symptoms and diagnostic tests in primary care suggests that few symptoms and signs are sensitive and specific enough to be used to identify patients at higher risk. However, it does indicate that referral guidelines and symptom combinations may aid in this process [52]. Further research is necessary to identify the clinical symptoms, signs or tests that will allow a clear prediction of risk in order to guide the information included in referrals. As we wait for this guidance, we must use the tools currently available, including good communication and clear and informative referrals.

Healthcare costs are rising [21]. For healthcare managers and policymakers, it would be helpful if the implementation of referral guidelines can improve patient prioritisation, as suggested in a recent Norwegian report supporting the use of referral guidelines and their implementation in the electronic health record [53]. As discussed, caution must be exercised, because a more precise referral may not predict better quality of care. Further analysis within this project is currently underway to determine whether improved referral quality results in a meaningful change in patient prioritisation and quality of care.

Conclusion

This cluster randomised study assessing the impact of the dissemination of referral templates coupled with intermittent surgery visits by study personnel demonstrates a significant and substantial improvement in the measured quality of referrals in the intervention group. Further analysis is underway to determine whether this improvement in observed referral quality will predict an increase in the quality of care delivered to individual patients. For future studies, it appears prudent to utilise simple referral guidance, developed in collaboration between primary and secondary care. The referral guidance will need to be embedded in the patient record system to ensure its implementation.

Additional file

Additional file 1: Referral templates. (PDF 89 kb)

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

The study was conceived by PCV. All authors participated in the study concept and design. HW is the grant holder. ARB, PCV, SM and HW developed the referral templates and outcome measures. HW drafted the manuscript. All authors reviewed and approved the final version of the manuscript.

Acknowledgements

We thank Øyvind Isaksen, Astrid Gjervold Lunde and Silje Lehne Michalsen for scoring the referrals. The study is funded by the Northern Norway Regional Health Authority. The funding source did not have any role in designing the study or writing the manuscript.

Author details

[1]Department of Community Medicine, UiT The Arctic University of Norway, 9037 Tromsø, Norway. [2]University Hospital of North Norway Harstad, St. Olavsgate 70, 9480 Harstad, Norway. [3]Department of Clinical Medicine, UiT The Arctic University of Norway, 9037 Tromsø, Norway. [4]Centre for Sami Health Research, UiT The Arctic University of Norway, 9037 Tromsø, Norway.

Received: 21 October 2014 Accepted: 21 August 2015
Published online: 29 August 2015

References

1. Garasen H, Johnsen R. The quality of communication about older patients between hospital physicians and general practitioners: a panel study assessment. BMC Health Serv Res. 2007;7:133.
2. Tuomisto LE, Erhola M, Kaila M, Brander PE, Kauppinen R, Puolijoki H, et al. The Finnish national asthma programme: communication in asthma care–quality assessment of asthma referral letters. J Eval Clin Pract. 2007;13:50–4.
3. Ong SP, Lim LT, Barnsley L, Read R. General practitioners' referral letters–Do they meet the expectations of gastroenterologists and rheumatologists? Aust Fam Physician. 2006;35:920–2.
4. Dentith GE, Wilson KE, Dorman M, Girdler NM. An audit of patient referrals to the sedation department of Newcastle Dental Hospital. Prim Dent Care. 2010;17:85–91.
5. Syed AA, Large DM. Quality of GPs' referral letters to diabetes secondary care. Practical Diabetes International. 2003;20:165–9.
6. Newton J, Hutchinson A, Hayes V, Mccoll E, Mackee I, Holland C. Do clinicians tell each other enough? An analysis of referral communications in two specialties. Fam Pract. 1994;11:15–20.
7. Shaw I, Smith KM, Middleton H, Woodward L. A letter of consequence: referral letters from general practitioners to secondary mental health services. Qual Health Res. 2005;15:116–28.
8. Bodek S, Ghori K, Edelstein M, Reed A, MacFadyen RJ. Contemporary referral of patients from community care to cardiology lack diagnostic and clinical detail. Int J Clin Pract. 2006;60:595–601.
9. Grol R, Rooijackers-Lemmers N, van Kaathoven L, Wollersheim H, Mokkink H. Communication at the interface: do better referral letters produce better consultant replies? Br J Gen Pract. 2003;53:217–9.

10. Westerman RF, Hull FM, Bezemer PD, Gort G. A study of communication between general practitioners and specialists. Br J Gen Pract. 1990;40:445–9.
11. Cheng J, Beltran-Agullo L, Trope GE, Buys YM. Assessment of the quality of glaucoma referral letters based on a survey of glaucoma specialists and a glaucoma guideline. Ophthalmology. 2014;121:126–33.
12. Jiwa M, Coleman M, McKinley RK. Measuring the quality of referral letters about patients with upper gastrointestinal symptoms. Postgrad Med J. 2005;81:467–9.
13. Canadian Medical Association. National Survey: experiences with referrals from primary to specialty care. Ottawa, Ontario: Canadian Medical Association; 2013.
14. Patel NN, D'Souza J, Rocker M, Townsend E, Morris-Stiff G, Manimaran M, et al. Prioritisation of vascular outpatient appointments cannot be based on referral letters alone. Surgeon. 2008;6:140–3.
15. Goodwin N, Dixon A, Poole T, Raleigh V. Improving the quality of care in general practice. London: The King's Fund; 2011
16. Newton J, Eccles M, Hutchinson A. Communication between general practitioners and consultants: what should their letters contain? BMJ. 1992;304:821–4.
17. Ree AO: Medisinsk faglig innhold i henvisninger. Trondheim: The Norwegian Direcorate for Health; 2003.
18. Ree AO: Medisinsk faglig innhold i epikriser. Trondheim: The Norwegian Direcorate for Health; 2002.
19. Martinussen PE. Referral quality and the cooperation between hospital physicians and general practice: The role of physician and primary care factors. Scand J Public Health. 2013;41:874.
20. Rokstad IS, Rokstad KS, Holmen S, Lehmann S, Assmus J. Electronic optional guidelines as a tool to improve the process of referring patients to specialized care: an intervention study. Scand J Prim Health Care. 2013;31:166–71.
21. OECD. What Future for Health Spending? OECD Economics Department Policy Notes, No. 19 June 2013; 2013.
22. Wahlberg H, Valle PC, Malm S, Broderstad AR. Practical health co-operation - the impact of a referral template on quality of care and health care co-operation: study protocol for a cluster randomized controlled trial. Trials. 2013;14:7.
23. Carlsen B, Norheim OF. Changes in Norwegian physicians' perception of their gatekeeper role. Scand J Prim Health Care. 2003;21:209–13.
24. Jiwa M, Mathers N, Walters S. Quality of information on referrals to colorectal surgeons: towards consensus. Curr Med Res Opin. 2002;18:72–7.
25. Nygaard E, Kårikstad V. Prioriteringsveileder - Fordøyelsessykdommer. Oslo: Helsedirektoratet; 2009.
26. Nygaard E, Kårikstad V. Prioriteringsveileder - Lungesykdommer. Oslo: Helsedirektoratet; 2008.
27. Nygaard E, Kårikstad V. Prioriteringsveileder - Hjertemedisinske sykdommer. Oslo: Helsedirektoratet; 2009.
28. British Thoracic Society Standards of Care Committee. BTS statement on criteria for specialist referral, admission, discharge and follow-up for adults with respiratory disease. Thorax. 2008;63:i1–16.
29. Snow V, Barry P, Fihn SD, Gibbons RJ, Owens DK, Williams SV, et al. Evaluation of primary care patients with chronic stable Angina: guidelines from the American College of physicians. Ann Intern Med. 2004;141:57–64.
30. Malm S, Schirmer H. Hjertesak: Riktigere prioritering av pasienter! Fastlegenytt (2). 2010. UNN. 6-3-0012.
31. Erhardt L, Herlitz J, Bossaert L, Halinen M, Keltai M, Koster R, et al. Task force on the management of chest pain. Eur Heart J. 2002;23:1153–76.
32. Kostopoulou O, Delaney BC, Munro CW. Diagnostic difficulty and error in primary care–a systematic review. Fam Pract. 2008;25:400–13.
33. Murphy CL, Sheane B, Durcan I, O'Shea FD, Doran M, Cunnane G. Benefits of pre-referral preparation for rheumatology clinics. Ir Med J. 2013;106:275–7.
34. Cohen J. Weighted kappa: nominal scale agreement with provision for scaled disagreement or partial credit. Psychol Bull. 1968;70:213–20.
35. Maclure M, Willett WC. Misinterpretation and misuse of the kappa statistic. Am J Epidemiol. 1987;126:161–9.
36. Fleiss JL, Cohen J. The equivalence of weighted Kappa and the intraclass correlation coefficient as measures of reliability. Educ Psychol Meas. 1973;33:613–9.
37. Brenner H, Kliebsch U. Dependence of weighted kappa coefficients on the number of categories. Epidemiology. 1996;7:199–202.
38. Mathieu JE, Aguinis H, Culpepper SA, Chen G. Understanding and estimating the power to detect cross-level interaction effects in multilevel modeling. J Appl Psychol. 2012;97:951–66.
39. Marshall SW. Power for tests of interaction: effect of raising the type I error rate. Epidemiol Perspect Innov. 2007;4:4.
40. Eldridge S, Kerry S. A practical guide to cluster randomised trials in health services research. Chichester: John Wiley & Sons, Ltd; 2012.
41. Emslie C, Grimshaw J, Templeton A. Do clinical guidelines improve general practice management and referral of infertile couples? BMJ. 1993;306:1728–31.
42. Jiwa M, Walters S, Mathers N. Referral letters to colorectal surgeons: the impact of peer-mediated feedback. Br J Gen Pract. 2004;54:123–6.
43. Jillian M, Louise C, Sara T, Iain C, Jeremy G, Alastair L, et al. Pragmatic randomised controlled trial to evaluate guidelines for the management of infertility across the primary care-secondary care interface. BMJ. 2001;322:1282.
44. Akbari A, Mayhew A, Al-Alawi MA, Grimshaw J, Winkens R, Glidewell E, et al. Interventions to improve outpatient referrals from primary care to secondary care. Cochrane Database Syst Rev. 2008;4:CD005471.
45. Coulter A, Noone A, Goldacre M. General practitioners' referrals to specialist outpatient clinics. I. Why general practitioners refer patients to specialist outpatient clinics. BMJ. 1989;299:304–6.
46. Ringberg U, Fleten N, Deraas T, Hasvold T, Forde O. High referral rates to secondary care by general practitioners in Norway are associated with GPs' gender and specialist qualifications in family medicine, a study of 4350 consultations. BMC Health Serv Res. 2013;13:147.
47. Forde OH, Breidablik HJ, Ogar P. Do differences in referral rates threaten the goal of equity in health care? Tidsskr Nor Laegeforen. 2011;131:1878–81.
48. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics. 1977;33:159–74.
49. Jiwa M, Skinner P, Coker AO, Shaw L, Campbell MJ, Thompson J. Implementing referral guidelines: lessons from a negative outcome cluster randomised factorial trial in general practice. BMC Fam Pract. 2006;7:65.
50. Légaré F. Assessing barriers and facilitators to knowledge use. In: Straus S, Tetroe J, Graham ID, editors. Knowledge Translation in Health Care. Oxford: Blackwell Publishing Ltd; 2009.
51. Baker R, Camosso-Stefinovic J, Gillies C, Shaw EJ, Cheater F, Flottorp S, et al. Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2010;3:CD005470.
52. Jellema P, van der Windt DA, Bruinvels DJ, Mallen CD, van Weyenberg SJ, Mulder CJ, et al. Value of symptoms and additional diagnostic tests for colorectal cancer in primary care: systematic review and meta-analysis. BMJ. 2010;340:c1269.
53. Norheim OF, Allgott B, Gjul GK, Kjellevold A, Moen A, Sjøli S, et al. Åpent og rettferdig - prioriteringer i helsetjenesten (open and fair - priorities in the health care services). Oslo: Norwegian Ministry of Health and Care Services; 2014.

PAPER II

Wåhlberg H, Braaten T, Broderstad AR: **Impact of referral templates on patient experience of the referral and care process: a cluster randomised trial.** *BMJ Open* 2016;6:e011651.

BMJ Open

Impact of referral templates on patient experience of the referral and care process: a cluster randomised trial

Henrik Wåhlberg,[1,2] Tonje Braaten,[1] Ann Ragnhild Broderstad[2,3]

To cite: Wåhlberg H, Braaten T, Broderstad AR. Impact of referral templates on patient experience of the referral and care process: a cluster randomised trial. *BMJ Open* 2016;**6**:e011651. doi:10.1136/bmjopen-2016-011651

► Prepublication history for this paper is available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2016-011651).

Received 3 March 2016
Revised 13 September 2016
Accepted 30 September 2016

[1]Department of Community Medicine, UiT The Arctic University of Norway, Tromso, Norway
[2]University Hospital of North Norway, Harstad, Norway
[3]Centre for Sami Health Research, UiT The Arctic University of Norway, Tromso, Norway

Correspondence to
Dr Henrik Wåhlberg;
henrik.wahlberg@uit.no

ABSTRACT

Objectives: To evaluate if a referral intervention improves the patient experience of the referral and treatment process.

Setting: Interface between 14 primary care surgeries and a district general hospital.

Participants: The 14 general practitioner (GP) surgeries (7 intervention, 7 control) in the area around the University Hospital of North Norway Harstad were randomised and all completed the study. Consecutive individual patients were recruited at their hospital appointment. A total of 500 patients were recruited with 281 in the intervention and 219 in the control arm.

Interventions: Dissemination of referral templates for 4 diagnostic groups (dyspepsia, suspected colorectal cancer, chest pain and chronic obstructive pulmonary disease) coupled with intermittent surgery visits by study personnel. The control arm continued standard referral practice. The intervention was in use for 2.5 years.

Outcome: The main outcome was a quality indicator score. This paper reports a secondary outcome, the patient experience, as measured by self-report questionnaires. GPs in the intervention group could not be blinded. Patients were blinded to intervention status. Analysis was based on single-question comparison with a questionnaire subscore used to assess the effect of clustering.

Results: On the individual questions, overall satisfaction was very high with minor differences between the intervention and control group. Interestingly, the most negative responses, in both groups concerned questions relating to patient interaction and information. Very little evidence of clustering was found with an estimated intracluster correlations coefficient at $1.21e^{-11}$.

Conclusions: In total, this indicates no clear effect of the implementation of referral templates on the patient experience, in a setting of generally high patient satisfaction.

Trial registration number: NCT01470963; Results.

Strengths and limitations of this study

- Clinically relevant research in a regular district hospital setting.
- High response rate.
- Newly developed questionnaire hampers wider generalisation.

INTRODUCTION

Evaluation of patient experience and satisfaction is widespread with a wealth of literature concerning the development and use of questionnaires.[1–5] The evaluation of patient experience can help drive quality improvement,[6] and improved patient experience is associated with safety and clinical effectiveness.[7]

Care coordination is an important aspect of a well-functioning high-quality health service. It has been defined as 'the deliberate integration of patient care activities between two or more participants involved in a patient's care to facilitate the appropriate delivery of health care services'.[8] In the USA, the National Quality Forum (NQF) has published preferred practices for care coordination, including transitions of care.[9] This report includes clear recommendations for participation of the patient, or his/her designee, in the decision, planning and execution of a care transition. This is important, as exemplified by a recent Australian article, where patients with colorectal cancer perceived that poor information exchange led to suboptimal care.[10] Hence assessing patient experience of the referral process may be beneficial in assessing the effect of a referral intervention.

This article presents the patient experience aspect of a cluster randomised study evaluating the effect of the implementation of referral templates for four diagnostic groups—dyspepsia, suspected colorectal cancer, chest pain and chronic obstructive pulmonary disease (COPD)—in the patient referral pathway.[11] Previously, we have shown that the referral templates led to increased referral quality,[12] and the effect on the main outcome, quality of care at the hospital, is in

publication. This publication aims to assess whether the implementation of a referral template in the transition of care from the general practitioner (GP) to the hospital has affected the patient experience of the care process.

METHODS

Study setting

In Norway, the healthcare system is quite uniformly organised throughout the country. GPs act as gatekeepers to secondary care,[13] with specialist health services delivered by governmentally owned regional health authorities, mainly through public hospitals. Some specialist outpatient care is delivered by private specialists, but this is mainly purchased by the regional health authorities. The access to private specialists in the geographical area of the current study is very limited.

Study design

The study was designed as a cluster randomised study with the GP surgery as the clustering unit. A total of 14 surgeries were randomised, 7 to the intervention and 7 to the control group. The clustered design was chosen to avoid possible spill-over effect from the intervention to control GPs. Randomisation was performed by simple drawing by a person not connected to the research team, stratified by town versus countryside location of surgery.

As the intervention was to be actively used by the GPs, the referring GP could not be blinded. Patients, hospital doctors and outcome evaluators were blinded to the intervention status of the patients. Owing to the design of the intervention, the referral letter would sometimes reveal the intervention status, if the electronic template was used. No separate sample size calculation was performed for the patient experience outcome. The full study details are published in the methods paper.[11]

Intervention

The intervention consisted of the distribution of four separate referral templates to the intervention surgeries. These templates covered four clinical areas (dyspepsia, suspected colorectal malignancy, chest pain and COPD). The templates were to be used when initiating a new referral to the medical outpatient clinic at the University Hospital of North Norway, Harstad (UNN Harstad). The templates were distributed by the corresponding author (HW) during educational and/or lunch meetings and were provided as laminated reference sheets or in electronic form. In addition, follow-up visits were conducted regularly during the study period and intermittent mail leaflets and reminders were distributed to the intervention surgeries. Control offices continued standard referral practice.

Outcomes

The main outcome in the project was the quality of care delivered to each individual patient. In addition, health process indicators such as correct prioritisation were recorded and referral quality was also compared between the intervention and control group. The current paper presents the patient experience aspect of the study, as measured by self-report questionnaires.

Participants

The 14 GP surgeries primarily served by UNN Harstad were included in the randomisation process. In 2013, these surgeries had a total list size of 39 523 patients. The individual patients were recruited from consecutive new patients within one of the four clinical areas referred to, at the medical outpatient clinics at UNN Harstad. Study information and a consent form were sent to each individual patient together with their appointment letter. Further information, including a new consent form if appropriate, was provided at their hospital appointment. The individual patients were analysed as part of the intervention or control group depending on the intervention status of the GP surgery they were referred from. Children (<18 years of age) and patients with reduced capacity to consent were excluded from the study.

Recruitment

The study recruited patients for ~2.5 years and a total of 538 patients were included with 290 in the intervention arm and 227 in the control arm. The remaining 21 patients were referred from GP surgeries outside the regular area of UNN Harstad, and as such neither in the intervention nor the control group. These 21 were excluded, together with 17 patients who did not fill the inclusion criteria. In total, this left 281 patients in the intervention arm and 219 patients in the control arm (figure 1).

Questionnaire development

Multiple tools exist for measuring different aspects of care coordination[14] and patient experience; however, no complete questionnaire was located that covered the area in the current study completely. Therefore, a questionnaire was developed by combining validated questionnaires regarding patient experiences and care coordination. The questions used were the full version of the Generic Short Patient Experiences Questionnaire (GS-PEQ),[15] together with two further questions used in patient experience questionnaires in the Norwegian healthcare system (questions 11 and 12)[16] and the two questions about health interaction from the Commonwealth Fund Survey 2010.[17] Three further questions were added to assess (1) who referred the patient, (2) if the referral was seen as appropriate and (3) an overall evaluation of the institution. Table 1 presents the questions in the questionnaire. GS-PEQ and questions 11–12 use Likert-style response categories. The health

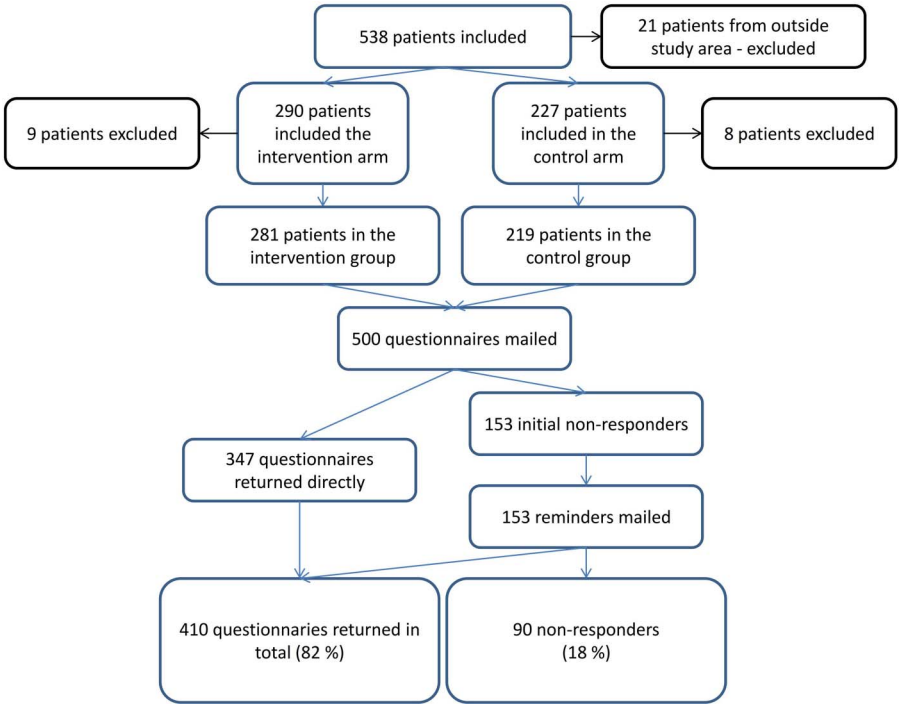

Figure 1 Patient inclusion and questionnaire response.

interaction questions had a yes/no response. The full questionnaire, including the demographic questions, is available on request.

The questionnaire was piloted for content validity with four local health professionals; these felt that it covered the important aspects of patient experience and care coordination. It was then piloted with five outpatients with a median age of 72 years (average 68.8 years) to ensure face validity and acceptability. Two patients needed clarification on one of the questions before they felt they could answer, and the wording of this question was adjusted accordingly. The patients felt the questionnaire was acceptable, with logical response categories and that the questions covered their clinical path during the referral process well. These patients did not take part when the project was later initiated. No further formal evaluation of the questionnaire was carried out.

Questionnaire distribution

The questionnaire was mailed to patients who had consented to take part in the referral project presented above. To increase response rates, a prepaid response envelope was included, addresses were handwritten, the questionnaire was kept short and association with research bodies was indicated.[3] For non-responders, one reminder was sent ~1 month after the first questionnaire, with a new questionnaire and prepaid response envelope.

Ethics

The study followed the principles of the Helsinki Declaration. Before recruitment started, it was presented to the Regional Committee for Medical and Health Research Ethics Northern Norway, who determined it not to be within the scope of the Health Research Act (REK NORD 2010/2259). The project has been approved by the Data Protection Officer for Research. The study is registered at http://www.clinicaltrials.gov, with trial registration number NCT01470963. All patients provided written informed consent.

Imputation

To further aid the assessment of clustering, missing data were imputed. For the imputation, answers set as 'not applicable' were counted as missing. Missing data were seen to be random and multiple imputation using chained equations was employed. This has been shown to perform well for a variety of variable scaling types.[18] Every variable used in further statistical analysis was entered into the imputation model, as failure to do so may bias estimates towards the null.[19] The ordinal response scales for each single question were to be combined into a continuous score, and as such, it was determined that imputation with predictive mean matching was appropriate. As shown by van Buuren,[19] the number of iterations can usually be quite low, between 5 and 20. In this study, the Stata standard of 10 iterations as burn-in period was used.

Statistical analysis

Results are presented on single question basis with comparison between the two groups using the Mann-Whitney U test for ordinal data and χ^2 test for nominal data. No correction for clustering was made as the estimated ICC was very low (shown below). Aggregation of scores was postulated in the methods paper,[11] but discarded as a main outcome as properties of the questionnaire, with a 'not applicable' answering

Table 1 Questionnaire details

Question no.	Wording of question
1	Did the clinicians* talk to you in a way that was easy to understand?
2	Do you have confidence in the clinicians' professional skills?
3	Did you get sufficient information about how examinations and tests were to be performed?
4	Did you get sufficient information about your diagnosis/conditions?
5	Did you perceive the treatment to be adapted to your situation?
6	Were you involved in decisions regarding your treatment?
7	Did you perceive the institution work practices to be well organised?
8	Did you perceive the equipment at the institution to be in good working order?
9	Overall, was the help and treatment you received at the institution satisfactory?
10	Do you believe that you were in any way given incorrect treatment (according to your own judgement)?
11	Did you have to wait before you were given an appointment at the institution?
12	Overall, what benefit have you had from the care at the institution?
13	Did the hospital specialist lack basic medical information from your GP about the reason for your visit or test results?
14	After you saw the hospital specialist, did your GP lack important information about the care you got from the specialist?
15	Was the referral to the outpatient department necessary (according to your own judgement)?
16a	Were you referred by your GP for the outpatient appointment?
16b	If no in question 16a; who referred you?
17	If you take an overview of your entire treatment process, how would you evaluate the institution?

*With 'clinicians', we mean those who had the main treatment responsibility. This is linguistically clearer in the Norwegian wording.

category, are not easily suitable for such an approach. However, to assess the effect of clustering, a sum of scores from the GS-PEQ part of the questionnaire was calculated and a multilevel regression model was built with the GS-PEQ score from the questionnaire as the dependent variable. Intervention status was included in the model as this is the main point of interest. Gender, age, education level and self-perceived health were included in the model, as these tend to influence patient experience.[20–22] Age was centred to ease interpretation in a mixed model analysis.[23] Self-perceived health was reported on a five-level Likert-style scale and education level in four categories. Both were included as dummy variables in the analysis. Other confounding variables were assessed in the model and included if their inclusion led to a >10% change in the main outcome when added to the base model (main outcome +intervention status). Relevant interactions were checked for relevant variables, where p<0.10 was set as the significance level. As imputation was used, Monte Carlo error estimates were employed to assess the level of simulation error, as suggested by White *et al*.[24] Normal evaluation of multilevel models with loglikelihood ratio tests were not carried out, as this is not well defined for multilevel models with imputed data. The analysis employed restricted maximum likelihood techniques throughout, as suggested when the number of clusters is small.[25] As described, multiple imputation was used to account for missing data in the multilevel regression model assessing the effect of clustering. Stata V.13.1 (StataCorp 2013, Texas, USA) were used for all analysis.

RESULTS

Response rate

The response rate was 69.4% before reminders were sent out, rising to 82.0% after reminders (figure 1). The mean age for responders was 61 years and for non-responders 47 years (t-test <0.0001). There was no significant gender difference between the responders and non-responders, and the response rate did not differ significantly between the intervention and control group (χ^2 test).

Missing data

Missing data for most questions were low, ranging from 0 to 11 out of 410 answered questionnaires. Statistically, these were considered missing completely at random (MCAR) with no clear relation to either age, gender, self-perceived health, disease severity or other variables.[26] However, questions 6, 10 and 12 in the general part of the questionnaire had higher amounts of not applicable ranging from 14 to 34 representing 3.4–8.3% of returned questionnaires. In these questions, the word 'treatment' was used. This was intended to cover the medical examination and interventions during the outpatient visit. However, it seems that this has been misunderstood by several patients. It seems reasonable to assume that patients who underwent 'only' diagnostic evaluation felt that they had received no 'treatment', and hence felt unable to answer the question. This was also highlighted by one patient in a free-text response in the questionnaire. 'Not applicable' to questions 6, 10 and 12 did not vary significantly with age (t-test), intervention group status (χ^2 test), gender (χ^2 test) or

self-reported health (χ^2 test). This was treated as missing at random for imputation purposes (MAR).[26] Question 14 had a missing rate of 15.9% but also yielded a high level of not applicable responses, at 46.0% of returned questionnaires. This was expected, as many people will not have had a new appointment with their GP following the hospital outpatient evaluation. It is also reasonable to assume that the high amount of missing was related to the same concept. The response 'not applicable' did not significantly vary with age (t-test p=0.868), intervention group status (χ^2 test p=0.064) or self-reported health (χ^2 test p=0.459).

A histogram of responses to questions with five categories showed all response sets to be skewed to the left. However, earlier work has indicated that multiple imputation can perform well, even when the categorical variable is non-normally distributed, as long as MAR does not exceed 10%.[27] In a 2010 article, Finch[26] argues that multiple imputation performs well for imputation of missing categorical questionnaire data. There was no association between levels of missing data and the multilevel structure of the data.

Baseline characteristics

Baseline characteristics are presented in table 2. There was no major difference between the intervention and control group with regard to gender, age, urban or rural residency or questionnaire response. The effect of the referral intervention on referral quality has previously been shown to be clinically significant with an effect of 18% (95% CI 11 to 25, p<0.001).[12] However, this was for the full data set of 500 patients. To ensure that this was also representative of the subpopulation who answered the questionnaire, the multilevel regression model was employed using data from only the 410 patients who answered it. This showed an intervention effect of 19% (95% CI 12 to 27, p<0.001) on referral quality, well within the 95% CI of the full analysis.

Questionnaire results

Overall satisfaction with services was high and as presented in table 3, there was little difference between the intervention and control group for the individual questions. Using the Mann-Whitney U test, χ^2 test and Fisher exact test, only two questions had significant p values (Q14 and Q17); however, in these questions, the absolute difference in numbers was very small. All response sets were skewed to the left, that is, towards more positive responses.

Interestingly, the highest numbers of scores indicating dissatisfaction were for questions 4 and 6, for the intervention and control group patients. These questions concern patient interaction and information on the treatment process.

The Cronbach α for questions 1–15 was 0.83 and for questions 1–10 0.88.

Assessment of clustering effect

In the regression model, no significant difference was seen in the GSPEQ score between the intervention and control group with the regression coefficient 0.55 (95% CI −0.37 to 1.47, p=0.24) when taking clustering into account and adjusted for confounding variables 0.57 (95% CI −0.31 to 1.46, p=0.20). No significant interaction was found, and the result was not confounded by GP specialist status, GP gender, specialist status of hospital doctor or seriousness of final diagnosis. The Monte Carlo error estimates were within the limits recommended.[24] Initial multilevel analysis of the data revealed virtually no variance of the intercepts. The ICC was estimated at $1.21e^{-11}$. Hence, very little of the variation in the data was related to the clustered design.

DISCUSSION

In the presentation of the data from each question in table 3, it is quite clear that, for the most part, patients in this project report positive experiences, with no differences between the intervention and control group. It hence seems that although the intervention has increased the referral quality significantly,[12] this has not translated into a more positive patient experience with the referral process and treatment, as measured by self-report questionnaires. In the current study, indepth data analysis with imputation and multilevel regression modelling was employed to further explore the effect of clustering. No clear effect of clustering was found.

Table 2 Selected patient baseline characteristics by intervention status

	Intervention group	Control group	p Value
Female/male, N (%)	140 (59.3)/96 (40.7)	102 (58.6)/72 (41.4)	0.89
Age (year), mean (±SD)	60.9±12.5	60.3±13.5	0.63
Urban/rural, N (%)	145 (61.4)/91 (38.6)	95 (54.6)/79 (45.4)	0.17
Clinical group, N (%)			
Dyspepsia	117 (49.6)	96 (55.2)	0.29
Suspected colorectal malignancy	75 (31.8)	57 (32.8)	
Chest pain	40 (17.0)	18 (10.3)	
Chronic obstructive pulmonary disease	4 (1.7)	3 (1.7)	
Hospital appointment with senior house officer/specialist, N (%)	107 (45.3)/129 (54.7)	78 (44.8)/96 (55.2)	0.92
Questionnaire returned promptly/after mailed reminder, N (%)	202 (85.6)/34 (14.4)	145 (83.3)/29 (16.7)	0.53

Table 3 Questionnaire results

Question	Answering categories*	Intervention	Control	p Value
Question 1†		5 (4, 5)	5 (4, 5)	0.92
Question 2†		5 (4, 5)	4 (4, 5)	0.39
Question 3†		5 (4, 5)	4 (4, 5)	0.23
Question 4†		4 (3, 5)	4 (4, 4)	0.12
Question 5†		4 (4, 5)	4 (4, 5)	0.88
Question 6†		4 (3, 5)	4 (3, 4)	0.19
Question 7†		4 (4, 5)	4 (4, 5)	0.22
Question 8†		4 (4, 5)	4 (4, 5)	0.81
Question 9†		5 (4, 5)	4 (4, 5)	0.15
Question 10†		5 (5, 5)	5 (5, 5)	0.60
Question 11‡	No	33 (14.0)	21 (12.1)	0.33
	Yes, but not too long	155 (66.0)	111 (64.2)	
	Yes, quite long	34 (14.5)	29 (16.8)	
	Yes, too long	13 (5.5)	12 (6.9)	
Question 12‡	No benefit	3 (1.4)	5 (3.1)	0.56
	Little benefit	12 (5.5)	7 (4.3)	
	Some benefit	59 (27.2)	44 (27.0)	
	Large benefit	106 (48.9)	86 (52.8)	
	Very large benefit	37 (17.1)	21 (12.9)	
Question 13‡	Yes	4 (1.7)	6 (3.5)	0.25
	No	229 (98.3)	165 (96.5)	
Question 14‡	Yes	4 (4.2)	8 (13.1)	0.04
	No	92 (95.8)	53 (86.9)	
Question 15‡	Yes	232 (99.2)	170 (99.4)	0.75
	No	2 (0.8)	1 (0.6)	
Question 17‡	Much poorer than expected	0 (0)	1 (0.6)	0.03
	Somewhat poorer than expected	0 (0)	5 (3.1)	
	As expected	119 (54.1)	94 (58.4)	
	Somewhat better than expected	50 (22.7)	32 (19.9)	
	Much better than expected	51 (23.2)	29 (18.0)	

*For questions 1–10, the following scoring was used: 1, not at all; 2, to a small extent; 3, to some extent; 4, to a large extent and 5, to a very large extent.
†Data presented as median (25th centile, 75th centile).
‡Data presented as number (%).

A strength of the current study is the fairly high response rate (82.0%) compared with other mail response studies.[28] However, the potential for non-response bias is always present. Others have previously shown the effect of this to be small.[29 30] Earlier Norwegian studies have suggested only minor differences between answers provided by responders and non-responders, when the latter have been obtained through telephone follow-up interviews.[31–33] A clear limitation is the use of short-form questionnaires with single items, which may be less valid than longer forms.[34] However, shorter forms will increase the response rate.[4 35] The current project aimed to assess the effect of a health system intervention and the patient experiences with care after this intervention. We hence decided to keep the questionnaire short to enable a high response rate and keep the patient and staff workload manageable.

The current project used a newly developed questionnaire to assess patient experience by combining previously validated questions. The general nature of the final questionnaire may be seen as a weakness, as small changes in the patient experience induced by the intervention may have been missed. Further piloting might have revealed more clearly if the questionnaire did indeed assess the patient experience with the referral and care process in an adequate way. However, in this clinically oriented project, the authors hoped that a more general questionnaire would highlight whether the intervention would cause a more overall positive, or even a negative, change. It is probable that for each individual patient, it is the experience with the entire process that matters, as opposed to the experience of a subpart of the process. If large-scale implementation of referral guidance is contemplated, a more specific questionnaire may need to be validated.

An additional weakness was the lack of a sound analytical plan proposed in the methods paper.[11] To ensure transparency, the analysis presented in this paper is therefore simple and based on single-question assessment. Given the clustered nature of the study, an assessment of clustering is given for a subsection of the questionnaire, but very little effect was seen.

Comparison with other studies was difficult as no clearly comparable analysis was found, except for the two health interaction questions. In the current study, 1.7% in the intervention group and 3.5% in the control group felt the hospital specialist lacked information from the GP. About 4.2% in the intervention and 13.1% in the control group felt the GP lacked information from the specialist. In the Norwegian part of the 2010 Commonwealth Fund Survey, the same questions gave much higher negative ratings, with 12.1% indicating that the specialist lacked information from the GP and 38.3% indicating that the GP lacked information from the hospital.[17] Data from the 2013 Commonwealth Fund Survey suggest similar ratings as in 2010, although the wording of the questions is slightly different.[36] A Norwegian report concerning patient experience as inpatients also suggests higher dissatisfaction with co-operation between the hospital and the GP[37] than in the current study. In total, this clearly suggests that the patient experience of the GP/specialist communication is better in a small district hospital than the country average suggests. It is therefore possible that the effect of the intervention on patient experience could have been higher if the level of dissatisfaction with the health-care cooperation had been higher in the local population. However, this also may suggest that although the hospital consultants often feel information is lacking in the referrals,[38 39] this is not necessarily experienced as a problem by patients.

In the current study, two questions were answered more negatively than others. These questions therefore probably provide the most interesting points for further quality improvement at the local facility. These two questions represent areas where communication is the main concept, namely patient involvement in the treatment process and information from doctors to patients. Others have previously shown communication and information errors as a cause for dissatisfaction,[40] and in other jurisdictions even malpractice claims.[41 42]

CONCLUSION

In this project, patient satisfaction, as measured by patient experience questionnaires, was generally high, with no major differences between the intervention and control group. No clear effect of the implementation of referral templates on patient satisfaction was evident.

Interestingly, the most negative feedback, from the intervention and control group, was concerning patient interaction, involvement and information. Effective communication and involving patients in decision-making may help to increase patient satisfaction to an even higher level.

Contributors The administration and daily running of the study was performed by HW, who was also the grant holder. ARB and HW developed the questionnaire. All authors participated in the analysis and interpretation of the data. All authors revised drafts of the manuscript and approved the final version.

Funding This work was funded by a research grant from the Northern Norway Regional Health Authority (Helse Nord RHF) with grant number HST1026-11.

Competing interests None declared.

Ethics approval The project has been approved by the Data Protection Officer for Research.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

REFERENCES

1. Crow R, Gage H, Hampson S, *et al*. The measurement of satisfaction with healthcare: implications for practice from a systematic review of the literature. *Health Technol Assess* 2002;6:1–244.
2. Garrat A, Solheim E, Danielsen K. *National and cross-national surveys of patient experiences: a structured review*. July 2008. Oslo: Norwegian Knowledge Centre for the Health Services, 2008.
3. Edwards PJ, Roberts I, Clarke MJ, *et al*. Methods to increase response to postal and electronic questionnaires. *Cochrane Database Syst Rev* 2009:MR000008.
4. Edwards P. Questionnaires in clinical trials: guidelines for optimal design and administration. *Trials* 2010;11:2.
5. Fitzpatrick R, Davey C, Buxton M, *et al*. Evaluating patient-based outcome measures for use in clinical trials: a review. *Health Technol Assess* 1998;2:74.
6. Ellins J. Great expectations? Reflections on the future of patient and public involvement in the NHS. *Clin Med* 2011;11:544–7.
7. Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open* 2013;3:pii: e001570.
8. McDonald K, Sundaram V, Bravata D, *et al*. *Closing the quality gap: a critical analysis of quality improvement strategies (Vol. 7: Care Coordination)*. Rockville, MD: Agency for Healthcare Research and Quality (US), 2007.
9. National Quality Forum. Preferred practices and performance measures for measuring and reporting care coordination: a consensus report. Washington, DC: National Quality Forum, 2010.
10. Pascoe SW, Veitch C, Crossland LJ, *et al*. Patients' experiences of referral for colorectal cancer. *BMC Fam Pract* 2013;14:124.
11. Wåhlberg H, Valle PC, Malm S, *et al*. Practical health co-operation—the impact of a referral template on quality of care and health care co-operation: study protocol for a cluster randomized controlled trial. *Trials* 2013;14:7.
12. Wåhlberg H, Valle PC, Malm S, *et al*. Impact of referral templates on the quality of referrals from primary to secondary care: a cluster randomised trial. *BMC Health Serv Res* 2015;15:353.
13. Carlsen B, Norheim OF. Introduction of the patient-list system in general practice. Changes in Norwegian physicians' perception of their gatekeeper role. *Scand J Prim Health Care* 2003;21:209–13.
14. Schultz EM, Pineda N, Lonhart J, *et al*. A systematic review of the care coordination measurement landscape. *BMC Health Serv Res* 2013;13:119.
15. Sjetne IS, Bjertnaes OA, Olsen RV, *et al*. The Generic Short Patient Experiences Questionnaire (GS-PEQ): identification of core items from a survey in Norway. *BMC Health Serv Res* 2011;11:88.
16. Sjetne IS, Bjertnes OA, Iversen HH, *et al*. *Pasienterfaringer i spesialisthelsetjenesten. Et generisk, kort spørreskjema*. Oslo: Nasjonalt kunnskapssenter for helsetjenesten, 2009.
17. Skudal KE, Bjertnes OA, Holmboe O, *et al*. *The 2010 Commonwealth Fund survey: results from a comparative population survey in 11 countries*. 21. Oslo: The Norwegian Knowledge Centre for the Health Services, 2010.
18. Lee KJ, Carlin JB. Multiple imputation for missing data: fully conditional specification versus multivariate normal imputation. *Am J Epidemiol* 2010;171:624–32.
19. van Buuren S. Multiple imputation of discrete and continuous data by fully conditional specification. *Stat Methods Med Res* 2007;16:219–42.
20. Xiao H, Barber JP. The effect of perceived health status on patient satisfaction. *Value Health* 2008;11:719–25.

21. Fitzpatrick R. Surveys of patient satisfaction: II—designing a questionnaire and conducting a survey. *BMJ* 1991;302:1129–32.
22. Da Costa D, Clarke AE, Dobkin PL, *et al*The relationship between health status, social support and satisfaction with medical care among patients with systemic lupus erythematosus. *Int J Qual Health Care* 1999;11:201–7.
23. Twisk J. *Applied multilevel analysis*. Cambridge: Cambridge University Press, 2006.
24. White IR, Royston P, Wood AM. Multiple imputation using chained equations: issues and guidance for practice. *Stat Med* 2011;30:377–99.
25. Eldridge S, Kerry S. *A practical guide to cluster randomised trials in health services research*. 1st edn. Chichester: John Wiley & Sons, Ltd, 2012.
26. Finch W. Imputation methods for missing categorical questionnaire data: a comparison of approaches. *J Data Sci* 2010;8:361–78.
27. Leite W, Beretvas S. The performance of multiple imputation for Likert-type items with missing data. *J Mod Appl Stat Methods* 2010;9:64–74.
28. Sitzia J, Wood N. Response rate in patient satisfaction research: an analysis of 210 published studies. *Int J Qual Health Care* 1998;10:311–17.
29. Lasek RJ, Barkley W, Harper DL, *et al*. An Evaluation of the impact of nonresponse bias on patient satisfaction surveys. *Med Care* 1997;35:646–52.
30. Perneger TV, Chamot E, Bovier PA. Nonresponse bias in a survey of patient perceptions of hospital care. *Med Care* 2005;43:374–80.
31. Guldvog B, Hofoss D, Pettersen KI, *et al*. PS-RESKVA—pasienttilfredshet i sykehus [PS-RESKVA—patient satisfaction in hospitals]. *Tidsskr Nor Laegeforen* 1998;118:386–91.
32. Do non-respondents' characteristics and experiences differ from those of respondents? Poster at the 25th International Conference by the Society for Quality in Health Care (ISQua). *25th International Conference by the Society for Quality in Healthcare (ISQua); 08*. 2008.
33. Using telephone interviews to explore potential non-response bias in a national postal survey. Poster at the 26th International Conference by the Society for Quality in Health Care (ISQua). *26th International Conference by the Society for Quality in Health Care (ISQua); 09*. 2009.
34. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992;30:473–83.
35. Eaker S, Bergström R, Bergström A, *et al*. Response rate to mailed epidemiologic questionnaires: a population-based randomized trial of variations in design and mailing routines. *Am J Epidemiol* 1998;147:74–82.
36. Haugum M, Bjertnes OA, Iversen HH, *et al*. *Commonwealth Fund's health policy survey in 11 countries: Norwegian results in 2013 and development since 2010*. 27 November 2014. Oslo: The Norwegian Knowledge Centre for the Health Services, 2014.
37. Skudal KE, Holmboe O, Iversen HH, *et al*. *Inpatients' experience with Norwegian hospitals: national results in 2011 and changes from 2006*. March 2012. Oslo: Norwegian Knowledge Centre for the Health Services, 2012.
38. Canadian Medical Association. *National survey: experiences with referrals from primary to specialty care*. Canadian Medical Association, 2013.
39. Bodek S, Ghori K, Edelstein M, *et al*. Contemporary referral of patients from community care to cardiology lack diagnostic and clinical detail. *Int J Clin Pract* 2006;60:595–601.
40. Hiidenhovi H, Nojonen K, Laippala P. Measurement of outpatients' views of service quality in a Finnish university hospital. *J Adv Nurs* 2002;38:59–67.
41. Levinson W, Roter DL, Mullooly JP, *et al*. Physician–patient communication. The relationship with malpractice claims among primary care physicians and surgeons. *JAMA* 1997;277:553–9.
42. Beckman HB, Markakis KM, Suchman AL, *et al*. The doctor–patient relationship and malpractice. Lessons from plaintiff depositions. *Arch Intern Med* 1994;154:1365–70.

PAPER III

Wåhlberg H, Valle PC, Malm S, Hovde Ø, Broderstad AR: **The effect of referral templates on out-patient quality of care in a hospital setting: a cluster randomized controlled trial.** *BMC Health Services Research* 2017, **17**:177

Wåhlberg et al. BMC Health Services Research (2017) 17:177
DOI 10.1186/s12913-017-2127-1

BMC Health Services Research

RESEARCH ARTICLE Open Access

The effect of referral templates on out-patient quality of care in a hospital setting: a cluster randomized controlled trial

Henrik Wåhlberg[1*], Per Christian Valle[2], Siri Malm[2,3], Øistein Hovde[4,5] and Ann Ragnhild Broderstad[2,6]

Abstract

Background: The assessment of quality of care is an integral part of modern medicine. The referral represents the handing over of care from the general practitioner to the specialist. This study aimed to assess whether an improved referral could lead to improved quality of care.

Methods: A cluster randomized trial with the general practitioner surgery as the clustering unit was performed. Fourteen surgeries in the area surrounding the University Hospital of North Norway Harstad were randomized stratified by town versus countryside location. The intervention consisted of implementing referral templates for new referrals in four clinical areas: dyspepsia; suspected colorectal cancer; chest pain; and confirmed or suspected chronic obstructive pulmonary disease. The control group followed standard referral practice. Quality of treatment pathway as assessed by newly developed quality indicators was used as main outcome. Secondary outcomes included subjective quality assessment, positive predictive value of referral and adequacy of prioritization. Assessment of outcomes was done at the individual level. The patients, hospital doctors and outcome assessors were blinded to the intervention status.

Results: A total of 500 patients were included, with 281 in the intervention and 219 in the control arm. From the multilevel regression model the effect of the intervention on the quality indicator score was insignificant at 1.80% (95% CI, −1.46 to 5.06, $p = 0.280$). No significant differences between the intervention and the control groups were seen in the secondary outcomes. Active use of the referral intervention was low, estimated at approximately 50%. There was also wide variation in outcome scoring between the different assessors.

Conclusions: In this study no measurable effect on quality of care or prioritization was revealed after implementation of referral templates at the general practitioner/hospital interface. The results were hindered by a limited uptake of the intervention at GP surgeries and inconsistencies in outcome assessment.

Trial registration: The study was registered under registration number NCT01470963 on September 5th, 2011.

Keywords: Quality of care, Referral, Care cooperation

Background

Quality of care is now an integral part of modern medicine, exemplified most recently in Norway by the National Patient Safety Programme [1], a national strategy for quality improvement in health and social services [2], and several national registries [3, 4]. To define quality in health care, though, is challenging because of its subjective nature [5]. The definition by Donabedian is "the application of medical science and technology in a manner that maximises its benefit to health without correspondingly increasing the risk" [6]; in many ways this represents what many physicians regard as high-quality care. Others have highlighted the need to take patient expectations and financial constraints into account in the definition of quality of care [7].

Measurement of quality is important both to ensure the quality of services and to aid hospital management. Several authors have highlighted the usefulness of quality measurement in documenting the quality of care,

* Correspondence: henrik.wahlberg@uit.no; henrik_waahlberg@hotmail.com
[1]Department of Community Medicine, UiT The Arctic University of Norway, 9037 Tromsø, Norway
Full list of author information is available at the end of the article

making comparisons, prioritizing, quality improvement, and accountability [8, 9]. However, as indicated in a recent editorial, care must be taken to ensure that quality—not the measuring of quality—remains the aim [10]. Quality measures are usually classified as structural, process, or outcome measures [11]. Structural measures are often easy to evaluate, and examples include equipment, facility, and staffing numbers. However, they tend to be weakly associated with outcomes [12]. Process measures are the components of the encounter between the patient and health-care professional, such as ordered tests [9, 13]. They aim to assess how often an intervention known to correlate with a favourable outcome takes place. Outcome measures use the health outcome, such as survival, complications, and quality of life, as a quality indicator [12]. The use of outcome measures is impeded by several factors, such as the infrequent occurrence of some events (e.g. mortality and morbidity), and the fact that the interval between intervention and event may extend for years [12, 14].

Many quality criteria have been developed [15–18], often following the RAND Corporation/UCLA (University of California) appropriateness method [19], but other methods have also been described [20, 21]. A perfect quality measure would fully correlate with positive outcomes for each individual patient. However, an error-free measure of quality of care is unlikely ever to be created [9]. Quality indicators are only "tools that can support quality improvement"—not necessarily direct measures of quality [22]. Some authors have expressed concern about quality measures that focus on small aspects of care; they fear that other aspects of equal, or greater, importance may receive less attention [23, 24]. In a recent article, Bishop emphasized that quality measurement in outpatient care is incomplete and that the focus is mainly on preventive care, chronic disease management, and patient experience [25]. Similarly, a review of performance measures in the specialist referral process identified multiple measures [26]; most of these concentrated, though, on the structural components of the referral process—as opposed to holistically depicting the quality of the entire treatment process.

The referral constitutes the handing over of care from one caregiver to another. For the purpose of this paper referral is defined as the handing over of care from the general practitioner (GP) to secondary care. To assure high quality further down in the treatment process, the referral letter from the GP should contain all the necessary information in a context of shared understanding among the GP, the patient, and hospital staff [27]. However, a number of publications have pointed to the varying quality and content of referrals in clinical practice [28–30]. Over the years, many interventions have been directed at the referral process. A Cochrane review on this subject indicates the complexities of research in this field and states that surprisingly few interventions on the referral system have been rigorously evaluated [31].

In Norway, the health-care system is relatively uniform throughout the country. Each GP has a list of patients for whom he/she provides care. GPs act as gatekeepers to secondary care [32]. Specialist health care is delivered through governmentally owned regional health authorities—mainly via public hospitals, but private health care is available to some extent. Communication between GPs and hospitals is almost exclusively electronic, with the automatic retrieval of demographic information, such as addresses, contact details, and GP details in each referral, according to a national standard [33]. Apart from this automatic retrieval referrals are, in normal practice, mainly written in free text format containing the information each referring GP deem necessary. Beyond basic demographical information the referrals therefore contain varying amount and type of clinical information.

According to several of the aspects indicated in the Cochrane report mentioned above [31], the current study is an attempt to evaluate a referral intervention in a setting with a well-organized GP care system electronically linked to the local hospital. Those aspects include referral quality, secondary-care management of patients, and patient outcomes and satisfaction. We have previously shown that the quality of the referrals in the intervention group improved by 18% (95% CI 11, 25), $p < 0.001$ [34]. This increase however, is of limited value unless it translates into a measurable change in outcomes that matter to patients and caregivers. The current article presents the effect of this increase in referral quality as measured by the assessment of individual patient pathways by quality of care indicators and other secondary measurements. The aim is to assess if an improvement that seem pertinent, given the referral deficiencies discussed above, also translate into a measurable care difference for the individual patient.

Methods

Study design

This study was designed as a cluster-randomized trial with the GP surgery as the clustering unit. The 14 community GP surgeries in the area served by the medical department at the University Hospital of North Norway Harstad (UNN Harstad) were randomized to an intervention or control group. We chose the cluster-randomized design to avoid potential "contamination" between GPs at the same surgery—as could have occurred with individual GP randomization. Randomisation was done by simple drawing by a person not connected to the research team, stratified by town vs countryside location of surgery.

Patients, hospital doctors, and outcome evaluators were blinded to the intervention status of the patient;

participating GPs could not be blinded since they actively used the intervention. Further details about the randomization and study methods are described elsewhere [35].

Intervention

The intervention consisted of the distribution of referral templates—in electronic and paper form—to be used as reference sheets when initiating a new referral to medical outpatients at UNN Harstad. The GPs could choose whether to use the electronic template directly or use the paper template as a reference, when initiating a new referral. The templates were to be used with the referral of new patients in four separate clinical areas: dyspepsia; suspected colorectal cancer; chest pain; and confirmed or suspected chronic obstructive pulmonary disease (COPD). We developed the referral templates based upon national and international literature in collaboration with local specialists in each medical field. To ensure the appropriateness of the templates, we also obtained assessments from specialists at other Norwegian hospitals. To promote adoption of the intervention, we included only information perceived as imperative in the referrals in the final templates. As an example, the items in the referral template for patients with dyspepsia appear in Table 1; other templates are available on request. The templates were distributed at educational or lunch meetings, and follow-up visits were provided twice a year during the inclusion phase. It was intended that the intervention referrals within the project would be sent to a specific electronic address at UNN Harstad to enable assessment of intervention uptake. The intervention was in use from September 2011 to November 2013 and stopped after the planned period of approximately 2 years [35]. The control group followed normal referral practice.

Table 1 Referral template for patients referred with dyspepsia

Item no.	Text item
1	Dysphagia
2	Odynophagia
3	Anorexia
4	Weight loss
5	Haematemesis
6	Melaena
7	Vomiting
8	Medications (especially NSAID[a], acetylsalicylic acid, bisphosphonates)
9	Nocturnal symptoms
10	Symptom duration
11	Previous peptic ulcer disease
12	Previous upper gastrointestinal tract operations
13	Jaundice
14	Cervical lymphadenopathy
15	Hepatomegaly
16	Anaemia
17	If <50 years, *Helicobacter pylori* status

[a]*NSAID* non-steroidal anti-inflammatory drugs

Participants

We included all 14 GP surgeries in the geographical area served by UNN Harstad in the randomization process. In 2013, they had a total list size of 39,253 patients. Individual consecutive patients referred from these GP surgeries received study information and a consent form together with their appointment letter from the hospital. They received an oral reminder regarding study participation at their first hospital appointment. Children (<18 years of age) and patients with reduced capacity to consent were excluded from the project. Patients were recruited from September 2011 until February 2014. Further details about the randomization and recruitment processes are described elsewhere [35].

Sample size

In the actual study, the intraclass correlation coefficient (ICC) turned out to be 0.02 (95% CI, 0.00–0.06). Estimating the sample size based on the study effect estimates and this ICC with the assumption of 80% power to detect a 10% difference with a p value set at 0.05 leads to a total sample size of 94 (84, 124). To detect a 5% difference, a total sample size of 576 (324, unattainable with only 14 clusters) would seem appropriate.

Data

We retrieved data by manual review of the electronic health records. Electronic retrieval was considered, but seen as too complex and imprecise for clinical quality indicators—a conclusion that has also been made by others [36].

Outcomes

The present study aimed to assess the quality of the care pathway by the following outcomes measures as outlined in our previous paper [35] and further detailed below.

- Quality indicator score
- Specialist's subjective quality assessment
- Positive predictive value of referral
- Adequacy of prioritization

Quality indicator score

Reviewing the literature few relevant quality indicators assessing information from individual patient's pathways were found. The quality indicators used to assess quality

of care were therefore developed from previous quality-assessment tools and treatment guidelines [13, 16, 18, 37–68]. The indicators were mainly process indicators. Some adaptation was made to align the criteria with locally accepted practice, which has been demonstrated elsewhere when transferring quality criteria to a new context [69]. The indicators were assessed by specialists in the appropriate field and reviewed based on the advice received. However, no formal approach was employed in developing the indicators. The full indicators are available on request, and the set for dyspepsia is available in a translated version as Additional file 1.

Each patient care pathway was scored according to the criteria. The indicator set for each clinical area consisted of a general section and disease specific subsections depending on the final diagnosis in the treatment pathway. Scoring was undertaken by a panel of specialists from different Norwegian hospitals—all blinded to the intervention status of the patient. Eight gastroenterologists, two cardiologists, and two pulmonologists participated. All scorers were independent from the GP surgeries and the hospital involved in the study. To allow assessment of scoring agreement, a subsample of the cases was evaluated by two scorers independently.

The quality indicator score was calculated as an adherence score (number of criteria met divided by number of applicable criteria), as developed by Ashton et al. [70]. If insufficient information was available to ascertain whether or not an applicable criterion was met, it was classed as "not met" [71], thereby producing a conservative quality score. We considered weighting of the criteria based on clinical importance, but this often adds complexity to the analysis without providing insight into the clinical analysis [72]. The total score was calibrated as a percentage to enable comparison and statistical analysis.

Subjective quality assessment

The panel of specialists also subjectively scored the treatment pathway for each patient in two ways. Firstly, they provided a quality rating of the treatment process on an ordinal scale of 1–10. Then, they assessed whether the treatment pathway was appropriate with a yes/no response.

Positive predictive value of referral

Based on the method of Bennett et al. [73], we calculated the positive predictive value (PPV) of a referral. This represents the chance of a referral leading to a relevant diagnostic or management decision. Adapting this concept from otolaryngology to a medical department, we defined the PPV as the number of referrals that resulted in a histological diagnosis, diagnostic clarification, or change in medical management.

Adequacy of prioritization

Prior to including the patients, potential outcome diagnoses within the four clinical areas were grouped into four categories according to severity. As no prior classification was found this was done by the main author based on WHO International Statistical Classification of Disease and Related Health problems 10th revision (ICD-10) disease codes. The groupings were adjusted after feedback from specialists within each clinical field. Each patient was placed in a severity group based on the final ICD-10 code from the hospital medical records. If several codes were set for an individual patient the code belonging to the most severe group was utilized. As an example a final diagnosis of C18.2 (cancer in the ascending colon) would be placed in the most severe group and a final pure symptomatic diagnosis of R19.4 (change in bowel habit) would be placed in the least severe group. When a diagnosis was encountered that could not be categorized according to the pre-planned severity grouping, consensus was achieved among the study organizers before putting it into the appropriate category. This severity grouping was then used to compare the adequacy of the waiting time between the intervention and control groups. Waiting time was defined as the time from the referral was received at the hospital until the first out-patient appointment, measured in days.

Statistical methods

To assess scoring agreement for the main outcome, we estimated repeatability coefficients [74]. We provide plots of the mean for each pair of scores vs the difference in score between the two raters for the clinical areas of chest pain and COPD (Bland-Altman plots). We did not produce such plots for gastroenterological clinical areas; as it was impossible to define primary and secondary raters for the individual observational pairs when eight raters overlapped, and Bland-Altman plots depend on the sign of the difference between raters.

The cluster design of the present study demanded an analysis that took into account the clustered nature of the data [75]. In this study, we used multi-level regression modelling to evaluate the effect of the intervention on the main outcome (quality indicator score). We employed likelihood ratio tests to assess the appropriateness of the model. To determine the effect of confounders to level one of the model, a change in the regression coefficient for the intervention effect of >10% was considered relevant. Based on prior assessment and subject knowledge, we included patient gender, age, speciality status of hospital doctor, and severity of final diagnosis in the model. We checked effect modification for relevant variables using $p < 0.05$ as the significance level. The CONSORT guideline for cluster randomised trials was adhered to [75].

For the subjective quality assessment, data are presented as medians with interquartile ranges since the values were not normally distributed. In addition, we employed multilevel ordinal regression analysis to confirm the findings. To assess PPV, we used a simple comparison of percentages—without correction for clustering.

We conducted the analyses throughout on an intention-to-treat basis. With this analysis, patients referred from intervention centres were regarded as belonging to the intervention group—even if it was evident that the intervention had not been used by the referring GP for that particular patient. In all analyses the patient was the unit of analysis and a two-level data structure was used.

Missing data

A small amount of data was missing from the outcome scoring, representing 2/500 (0.4%) for the subjective quality assessment score and 5/500 (1%) for the binary-outcome of adequate treatment process. To allow for a complete data-set analysis, these data were estimated. For the subjective quality score, the two missing values were set as the median value. For the binary outcome, the response was set to yes (numerical value 1) for subjective score values above six and no (numerical value 0) for scores of five and under. Where both the subjective and binary scores were missing, the median value was used for the binary score (yes, numerical value 1).

Results

Baseline characteristics

In all, 500 patients were available for analysis in this study: 281 in the intervention arm and 219 in the control arm after exclusion of nine in the intervention and eight in the control arm [34]. No clusters were lost to follow up. There were no significant baseline differences between the patients in the intervention and control arm, as seen in Table 2. The majority of referrals were within the dyspepsia and suspected colorectal cancer clinical areas. More of the GPs in the intervention than in the control group were board certified GPs, but the years of experience were similar in both groups. Significantly more referrals in the intervention arm were sent by female GPs, which probably relates to the higher number of female GPs in the intervention than in the control arm. Most referrals were electronic, but six paper referrals (2.7%) were received in the control arm versus none in the intervention arm. Half (49.5%) of the referrals in the intervention arm were sent to the designated electronic address established for the project; the rest were sent to the standard hospital electronic address.

Scorer agreement

A subsample of 86 care pathways was scored by two separate specialists to determine concordance between the scorers. For the quality indicator score, the mean difference between the two scoring measurements did not significantly differ from 0, and estimation of the repeatability coefficients, as suggested by Bland and Altman, is presented in Table 3. These suggest a wide variation in scoring between the different scorers. Bland-Altman plots are presented in Fig. 1 for chest pain and COPD since there were only two scorers. It is evident that for chest pain, one of the scorers gave a much higher range of scores than the other. In addition, there is quite clearly a wide variation in scoring between the two scorers for both clinical areas.

Using absolute values, the mean difference between the scorers was 14% (95% confidence interval [CI], 11.6–16.4) with a coefficient of variation of 80.6%.

For the subjective quality scoring, the repeatability coefficients were also high; Bland-Altman plots for the chest pain and COPD clinical areas showed similar results, with wide variation in scoring (data not shown).

Quality indicator score

Average quality score, not adjusted for clustering, in the intervention arm was 64.4% (95% CI, 62.4–66.3) and in the control arm 60.0% (95% CI, 57.9–62.2); the averages for each clinical area are presented in Table 4. Using a baseline multi-level model with patients from all clinical areas combined, the ICC was estimated at 0.02 (95%, CI 0.00–0.06). Adding a slope for the intervention status increased the −2 log likelihood of the model and did not make a large change in the residual variance. It was therefore not retained in the model. Postulating a three level data structure by allowing the results to vary randomly at the level of the referring GP only marginally reduced the −2 log likelihood and residual variance of the model. The two level structure proposed in the methods paper was therefore kept. No significant interaction was found. A significant effect of the intervention was seen in the baseline model; however, after correction for relevant confounders, the intervention effect was reduced to 1.80% (95% CI, −1.46 to 5.06, $p = 0.280$). Further regression coefficients appear in Table 5. No clear violation of normality assumptions was noted. Additional modelling for each individual rater revealed no significance of the intervention for any rater (data not shown). Given the significant difference (not corrected for clustering) shown for the dyspepsia group in Table 4 modelling was also performed for each of the four diagnostic groups. No significant effect of the intervention was seen, after correction for confounding factors (data not shown).

Subjective quality score

The subjective quality rating was done on an ordinal scale of 1–10. As evident in Fig. 2, the variable was not normally distributed. Overall, the median in the

Table 2 Selected baseline characteristics for patients and general practitioner surgeries by intervention status[a]

	Intervention group	Control group	*p* value
Patient demographics [b]			
Female/male, n (%)	166 (59.1)/115 (40.9)	127 (58.0)/92 (42.0)	0.807
Age, years	59.2 ± 13.6	57.1 ± 15.3	0.101
Urban/rural, n (%)	169 (60.1)/112 (39.9)	121 (55.3)/98 (44.7)	0.272
Clinical group, n (%)			
- Dyspepsia	144 (51.3)	120 (54.8)	
- Suspected colonic malignancy	87 (31.0)	68 (31.1)	
- Chest pain	46 (16.4)	27 (12.3)	
- COPD[c]	4 (1.4)	4 (1.8)	
Hospital appointment with senior house officer/specialist, n (%)	130 (46.3)/151 (53.7)	96 (43.8)/123 (56.2)	0.588
Given right to health care after assessment of referral, yes/no, n (%) [d]	222 (79.0)/59 (21.0)	168 (76.7)/51 (23.3)	0.587
GP surgery variables[b]			
List size	830.8 ± 208.8	865.5 ± 100.7	0.475
Female/male GP, n (%)	14 (58.3)/10 (41.7)	10 (43.5)/13 (56.5)	0.308
Board certified, yes/no, n (%)	18 (75.0)/6 (25.0)	11 (47.8)/12 (52.2)	0.055
Years experience	16.0 ± 10.4	15.2 ± 11.2	0.784
Number of GPs in surgery	4.3 ± 1.6	4.0 ± 1.6	0.536
- Median	5	5	
- Mode	5	5	
GP referral variables per referral in data set[b]			
Female/male referring GP, n (%)	182 (64.8)/99 (35.2)	93 (42.5)/126 (57.5)	<0.00001
Number of GPs in surgery	4.4 ± 1.5	4.0 ± 1.6	0.003
Specialist, yes/no n (%)	189 (67.3)/92 (32.7)	114 (52.1)/105 (47.9)	0.000556
Years experience	16.2 ± 12.0	15.4 ± 11.7	0.456
Other variables per referral in data set[b]			
Electronic/paper referral, n (%)	281 (100)/0 (0)	213 (97.3)/6 (2.7)	0.005

[a]Two GPs shared two lists at two separate surgeries, both in the intervention group. Weighted analysis that took this into account did not lead to significant changes in the baseline characteristics
[b]Data are presented as mean ± SD or number (%)
[c]*COPD* chronic obstructive pulmonary disease
[d]After assessment of the referral Norwegian hospital doctors decided whether or not a patient had a legal "right to health care" within a given time

Table 3 Repeatability coefficient overall and for the four clinical areas

Area	Repeatability Coefficient
Overall	+/− 35.18
Dyspepsia (*n* = 44)	+/− 40.71
Colorectal (*n* = 17)	+/− 23.20
Chest pain (*n* = 17)	+/− 20.25
COPD (*n* = 8)	+/− 46.68

intervention arm and control arm was 8, with an interquartile range of 2. Table 6 presents the median and interquartile range by clinical area and intervention status. No difference between the intervention and control arms appeared in the graph or interquartile ranges. This was confirmed with a multi-level ordinal regression model, in which no difference was noted (data not shown). No difference was observed between the intervention and control arms in the binary(yes/no) assessment of patient pathway appropriateness (data not shown).

PPV of referral

Table 7 shows the number of patients who had a histological diagnosis, diagnostic clarification, or change in medical management as a result of their outpatient

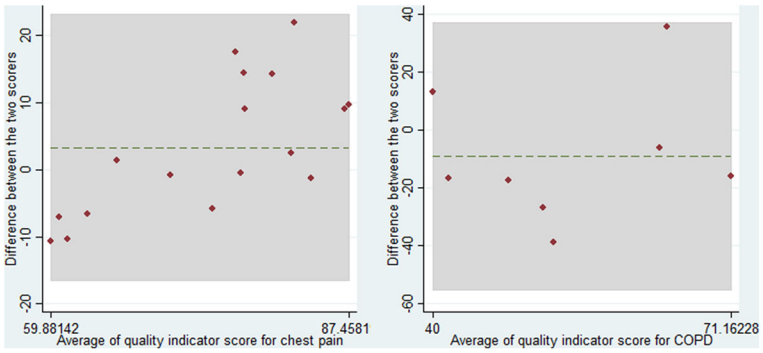

Fig. 1 Bland-Altman plot for quality indicator score for area chest pain and chronic obstructive pulmonary disease (COPD)

appointment. There were some missing items: this was because part of the scoring sheet with the PPV scoring box appeared on a separate page and may therefore have been overlooked. No clear difference was evident between the intervention and control arms.

Adequacy of prioritization

The average waiting time (time from referral to first outpatient appointment) was 46 days (95% CI, 42–50) in the intervention arm and 49 days (95% CI, 43–55) in the control arm ($p = 0.364$, t test). The waiting times for the four separate clinical areas appear in Table 8, with no significant differences between the intervention and control arms. The large difference in the COPD area is due to small numbers ($N = 8$) and random difference. The average waiting time stratified by intervention or control status and severity of final diagnosis is presented in Table 9. No significant differences were observed between the intervention and control arms. In addition, no definite trend was seen in the waiting time across severity groups—except that the waiting time was significantly shorter for patients with a final diagnosis classed as "very severe" than with the three other severity groupings ($p = 0.01$, t test). These average values are not corrected for clustering; however, a simple multi-level model with waiting time as the outcome variable and intervention status as predictor suggested very little effect of clustering, with an estimated ICC of <0.00001. In addition, allowing for clustering in the estimation of the mean led to narrower CIs, which is counterintuitive.

Table 4 Average quality score per diagnostic group, not corrected for clustering[a]

	Intervention	Control	p value
Dyspepsia	62.0 (59.2–64.8)	57.2 (54.1–60.3)	0.023
Suspected colorectal malignancy	65.0 (61.5–68.3)	61.4 (58.3–64.5)	0.138
COPD	48.3 (11.9–84.7)	51.0 (29.0–73.0)	0.847
Chest pain	72.1 (68.5–75.7)	70.8 (65.2–76.4)	0.669

[a]Presented as mean and 95% confidence interval

Waiting time was not normally distributed. To assess further the effect of the intervention on prioritization, we divided waiting times into deciles and used ordinal logistic regression, with waiting times in deciles as the dependent variable and severity group as predictor. We conducted a separate analysis for the intervention and control arms. This suggested a significant trend in the control arm only, as shown in Table 10. However, the significant effect found in the control arm did not persist if the variable waiting time was divided into ten groups with set intervals (41, 82, 123 … 410) rather than deciles. By way of sensitivity analysis, we also checked the analysis using a multi-level model; however, this did not represent the data significantly better, and so for simplicity we retained the one-level model. Also, standard linear regression did not show any significant variation in waiting time based on the severity score (data not shown); this, though, should be interpreted with caution since the variable was not normally distributed.

Discussion

In the present study, we aimed to assess whether implementing a referral intervention would lead to improved quality of care for medical outpatients. We have previously shown that the referral quality did increase [34], however there was no clear effect on the quality indicator score, subjective quality score, or PPV of referrals, as detailed above. In addition, there was no evidence that improving referrals enhanced prioritization at the hospital; in one analysis, prioritization even seemed more precise in the control arm. Hence, it would appear that the use of referral templates did not generate a clear clinical benefit for the individual patients.

In addition to the study limitations discussed below, several factors may explain the lack of effect. First, it is possible that care for patients has improved but that the measurement instruments and outcomes have been unable to quantify it. Guidelines and clinical practice allow

Table 5 Effect estimates for intervention on quality score

	Regression coefficient	95% CI	*p* value
Crude[a]	4.33	1.39–7.27	0.004
Adjusted[b]	1.80	−1.46–5.06	0.280
- Patient gender (male)	1.43	−1.45–4.32	0.330
- Patient age (centred)	0.05	−0.05–0.15	0.314
- Doctor in training[c] vs. specialist	−5.40	−8.21 to −2.60	<0.001
- Severity of final diagnosis			0.001*
- Not severe[d]			
- Less severe	3.20	0.11–6.29	
- Severe	6.20	1.70–10.69	
- Very severe	8.44	−0.17 to 17.05	
- Quality of referral	0.09	0.03–0.15	0.004

[a]Baseline model with intervention effect and random intercept
[b]Adjusted for variables listed in table
[c]Doctor in training (resident) reference
[d]Reference
*p value for trend

some flexibility for the treating clinician, whereas quality criteria often are rigid [76]. Thus, an ideal patient pathway—as was the goal in this study—will not necessarily be represented by 100% adherence to any given set of quality criteria; there will always be some level of subjectivity in the assessment of quality for each individual patient pathway. In future studies, therefore, even more effort is necessary to develop precise, valid outcomes measures to ensure that any potential effect is documented. The use of a mixed-methods approach may also help identify improvements that are hard to quantify; such an approach is regarded as especially useful in health services research [77]. Second, it is possible that the referrals in the control arm were of sufficiently high quality to ensure adequate referral assessment and prioritization at baseline. As such, the scope for improvement was small and therefore difficult to measure. As such further studies in areas with more varied referral quality may allow the effects of referral interventions to be quantified more precisely. Third, referrals are only part of the complex care pathway, and it is possible that improvement of only one part is insufficient to result in quantifiable improvements of the entire process. Other factors—medical, organizational, and individual—may also govern the process.

We have been unable to locate many comparable studies that aimed to assess the effect of a referral intervention on the further patient pathway in hospital—a shortcoming also addressed in a Cochrane review on referral intervention [31]. There are, however, some exceptions, with limited findings that are in line with those of the current project. In a UK study a referral intervention led to improved referral content, but it did not increase the amount of organic pathology revealed among those referred for colonoscopy. The authors commented that the value of the intervention may have been reduced by limited uptake [78]. In the study by Bennett et al. noted

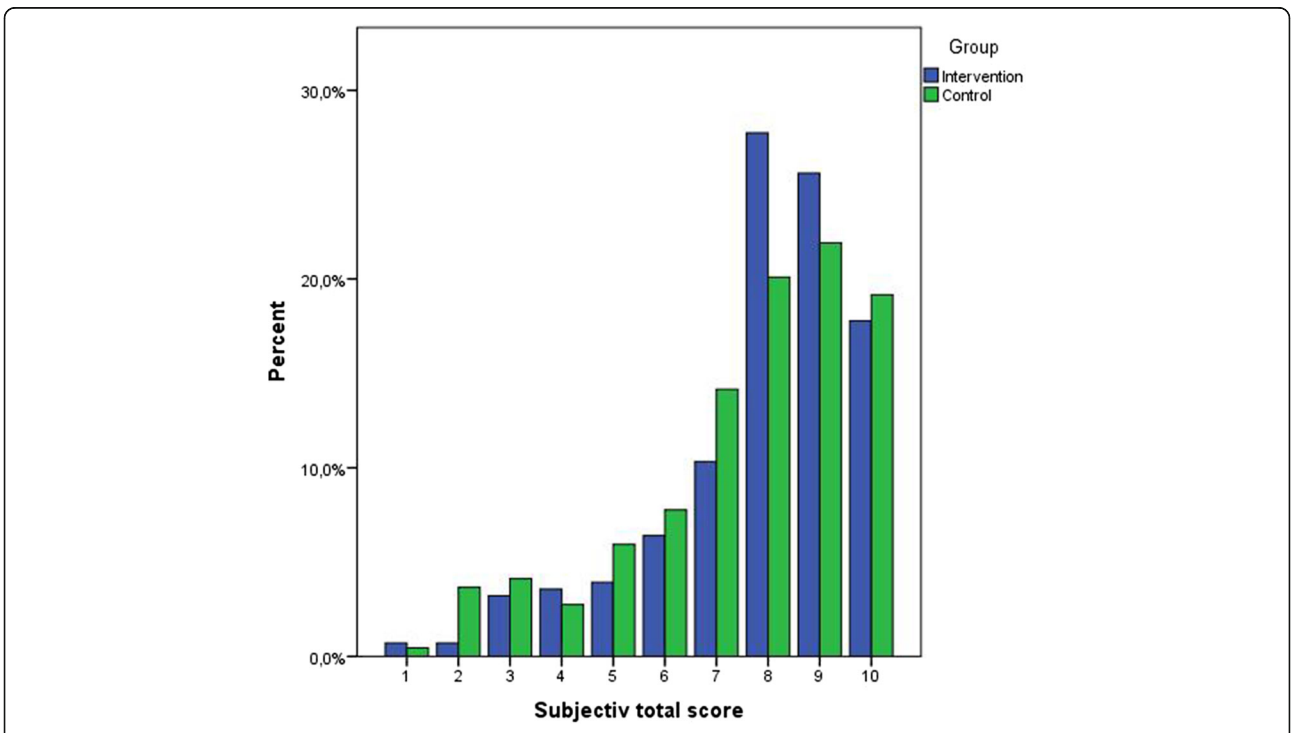

Fig. 2 Subjective quality score (1–10) for intervention and control groups

Table 6 Median of subjective total score[a]

	Intervention	Control
Dyspepsia	8 (2)	7.5 (3)
Suspected colorectal malignancy	9 (2)	9 (2)
COPD	4 (7)	4.5 (5)
Chest pain	8 (2)	8 (2)

[a]Presented as median and interquartile range

Table 8 Average waiting time by clinical area[a]

Clinical area	Intervention group	Control group
Dyspepsia	41 (28.6)	47 (46.3)
Suspicion of CRC	40 (31.4)	43 (37.5)
Chest pain	69 (42.5)	69 (39.1)
COPD	108 (59.6)	78 (44.3)

[a] Numbers are days (rounded to whole days) with SD in brackets; no significant differences between intervention and control groups

above, more appropriate patients were referred, but no information was presented regarding hospital management [73]. In a urology study, the implementation of education meetings and referral guidance led to a reduction in waiting time and an increase in the probability of receiving a management decision at the first appointment, but no difference in patient outcomes was found [79]. In Norwegian mental health services, a study is underway attempting to explore the effect of the quality of referrals on patient and organizational outcomes [80].

One way of promoting the use of referral interventions would be to make them a mandatory part of the referral process: they could appear as drop-down menus together with the relevant clinical information. This procedure would remove problems with uptake of the intervention and enable a more precise determination of the intervention effects. However, the present study found no clear effect of the referral templates, and, as seen in Tables 9 and 10, the prioritization was equally good in the control arm. It therefore seems that there are factors other than the pure informational quality in the referrals that guide the hospital clinician in identifying the most ill patients. It is possible that more subtle clinical details would disappear if the ability to enter free text were completely removed. Hence, the full implementation of obligatory referral guidance should occur only after further assessment has shown it to be of clinical importance.

Table 7 Tabulation of positive predictive value (PPV) of referral, not corrected for clustering[a, b]

	Intervention	Control
Histological diagnosis[c]		
- Yes	86 (37.2)	67 (35.6)
- No	137 (59.3)	112 (59.6)
- Missing	8 (3.5)	9 (4.8)
Diagnostic clarification		
- Yes	220 (78.3)	164 (74.9)
- No	51 (18.2)	46 (21.0)
- Missing	10 (3.5)	9 (4.1)
Change in medical management		
- Yes	154 (54.8)	105 (48.0)
- No	117 (41.6)	105 (48.0)
- Missing	10 (3.6)	9 (4.1)
PPV total		
- Yes	243 (86.5)	183 (83.6)
- No	28 (10.0)	27 (12.3)
- Missing	10 (3.5)	9 (4.1)

[a]Numbers are presented as positive outcomes in absolute numbers and percentages
[b]No significant differences seen between intervention and control groups
[c]Only for the clinical areas of dyspepsia and suspected CRC (not relevant for COPD and chest pain), $n = 419$

This study found no significant effect of the intervention. We included at total of 500 patients, with 281 in the intervention and 219 in the control arm. Given the sample size indicated above this means that the study was well powered to detect the 10% change in the quality indicator score that was set as clinically interesting; hence, the risk of a type II error is low. The power calculations do, however, underline the need to increase cluster numbers, rather than cluster size, to increase the power of cluster-randomized studies [81]. The current study would have been underpowered if the ICC had been at the upper end of the confidence interval of the ICC, regardless of how many patients were recruited.

Strengths and limitations

Certain aspects regarding recruitment and use of the intervention may have hampered the results. The aim of the study was to investigate the use of referral templates in actual clinical practice. In this real-world scenario, it would be pertinent to determine how many of the potential participants were actually recruited. Exact information about this would have required manual searches of outpatient lists and relevant electronic journals—this

Table 9 Average waiting time by severity of final diagnosis [a]

Severity of final diagnosis	Intervention group	Control group
Not severe ($n = 190$)	47 (35.4)	53 (40.6)
Less severe ($n = 227$)	45 (32.3)	49 (49.1)
Severe ($n = 68$)	55 (42.8)	41 (31.8)
Very severe ($n = 15$)	22 (14.0)	26 (17.7)

[a]Numbers are days (rounded to whole days) with SD brackets; no significant differences between intervention and control groups

Table 10 Ordinal regression of waiting time (in deciles) versus severity of final diagnosis

Severity of final diagnosis	Regression coefficient intervention group *	Regression coefficient control group **
Not severe [a]		
Less severe	−0.77 (−0.53 to 0.38)	−0.33 (−0.84 to 0.17)
Severe	.41 (−0.24 to 1.06)	−0.59 (−1.32 to 0.14)
Very severe	−1.42 (−2.41 to −0.42)	−1.90 (−4.06 to 0.27)

[a]Reference category
*$p = 0.333$ for trend
**$p = 0.032$ for trend

was incompatible with the ethical approval for the project and current legal regulations. However, indirect evidence indicates that 60% of potential patient participants were recruited. We have no indication that this figure varied between the intervention and control arms. Although we have no indication that the current sample differs from those not recruited the study did not assess this formally due to the constraints mentioned above. In addition, it is not clear how often the referring GPs actively utilized the intervention when initiating new referrals. The designated electronic project address was used approximately 50% of the time, which suggests a fairly modest uptake, although higher than in other studies [78]. This is likely to have attenuated the intervention effect since intention-to-treat analysis was employed. In total, these aspects are unlikely to have led to a significant selection bias, but may have attenuated the intervention effect.

The high variation in scoring among the scorers limits the applicability of the statistical analysis. This study opted to use numerous assessors, instead of just a few, to achieve a manageable assessment workload. The result was that a wide variety of scorers from different hospitals and clinical cultures took part. To try and ensure the validity of the conclusions, we performed subanalyses and ran the models individually for each rater. This of course yielded higher CIs, but the overall effects retained the same sign and magnitude. This was not suprising as the raters were given a mix of control and intervention patient pathways for scoring. We therefore feel that although the variation may limit the generalizability of the measurement instruments, it does not necessarily invalidate the conclusions of this study.

Since health-care quality is not a defined physical entity or even a clearly defined concept, it will always be difficult to measure precisely. Many authors have tried to measure quality of care and hospital quality and have used various ways, even Facebook [82]. The development of quality criteria is often challenging and should be based on accepted standards of care using sound evidence [83]. What is being measured should also represent an important aspect of care for the particular condition. In addition, an indicator has to be clearly defined, and the information must be available [83]. Most criteria in use today are accountability measures, designed to measure adherence to specific actions and employed for accreditation or reimbursement [24, 84]. In the present study, process indicators were developed for the care of patient groups, who ended up with a plethora of diagnoses instead of clearly defined diagnostic groups with simple measurements. This approach is clearly in line with the aim of this study, which was to investigate the use of referral guidance in normal clinical practice. Accordingly, it may be seen as reflecting a strength of the study. However, it added complexity to the development of the study outcome criteria. The criteria employed in this study do not, therefore, fulfil all requirements of ideal process criteria; overall, however, they represent an attempt to quantify the quality in everyday clinical practice at the level of the individual patient. This limits comparability with other studies, but we believe that this approach was more likely to identify the effects of referral intervention since such effects were expected to be subtle rather than obvious.

Another potential limitation is the quality of the source of clinical information. Hospital records were used to obtain the relevant information. Implicitly, this study did not therefore measure if a certain action was performed, but whether the action was performed and documented. Whereas the prospective collection of information from electronic health records is the most thorough way of acquiring information [85], the quality of medical records has been debated for some time [86–88]. Electronic health records have facilitated documentation, but the quality and completeness of the data is still under debate [89]. However, information gathering and assessment were performed the same way for both the intervention and control arms, and there was no indication that the manner of documentation gathering led to information bias.

The main strength of the present study is closely related to its weaknesses. This study was performed in a normal clinical setting without major intervention at any level other than the referral. This real-life approach should ensure that the results are applicable for many other health-care settings where referral from the GP to the hospital specialist is the norm.

Conclusions

This cluster-randomized trial was designed to assess the impact of a referral intervention on the quality of care and hospital management of patients. No measurable effect on quality of care or prioritization of patients was found. The results were hindered by a limited uptake of the intervention at GP surgeries and inconsistencies in outcome assessment. It seems reasonable to assume that more information in the referral will improve further management, but more stringent assessment may, in future research, be necessary.

Additional file

Additional file 1: Indicator set for dyspepsia translated into English. (DOC 108 kb)

Abbreviations

CI: Confidence interval; COPD: Chronic obstructive pulmonary disease; GP: General practitioner; ICC: Intraclass correlation coefficient; ICD-10: International Statistical Classification of Diseases and Related Health Problems 10th Revisions; PPV: Positive predictive value; REK NORD: Regional Ethical Committee for Medical Research in North Norway; UCLA: University of California; UNN Harstad: University Hospital of North Norway Harstad

Acknowledgements

The authors wish to express gratitude to the specialists who contributed with scoring within the project, Ove Juel Lange, Per Farup, Kristen Kaasen Jørgensen, Jan Gunnar Hatlebakk, Øistein Hovde, Trygve Hausken, Erik Peter Skogestad, Svein-Oskar Frigstad, Hanne Bjørnstad, Helge Ose Velle, Per Christian Moe, Audhild Hjalmarsen.

Funding

This work was funded by a research grant from the Northern Norway Regional Health Authority (Helse Nord RHF) with grant number HST1026-11. The funding body had no role in the design of the study, collection and analysis of the data or writing of the manuscript.

Availability of data and materials

Consent was not obtained for publication of patient data on an individual level. The dataset supporting the conclusions in this article may be available on request to the main author (HW).

Authors' contributions

The idea behind the study was conceived by PCV. The administration and daily running of the study was performed by HW, who was also the grant holder. ARB, PCV and HW developed the referral guidelines and outcome measures. All authors participated in the analysis and interpretation of the data and ØH was one of the scorers. All authors revised drafts of the manuscript and approved the final version.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

Before the study commenced, its details were presented to the Regional Ethical Committee for Medical Research in North Norway, who deemed that it was not within the scope of the Health Research Act (REK NORD 2010/2259). The Data Protection Official for Research approved the study, which is registered at https://clinicaltrials.gov/ct2/show/NCT01470963 under registration number NCT01470963. The study followed the directions of the Declaration of Helsinki, and all patients provided their written informed consent. Participating GPs gave informed, verbal consent to participate.

Publisher's Note

Author details

[1]Department of Community Medicine, UiT The Arctic University of Norway, 9037 Tromsø, Norway. [2]University Hospital of North Norway Harstad, St. Olavsgate 70, 9480 Harstad, Norway. [3]Department of Clinical Medicine, UiT The Arctic University of Norway, 9037 Tromsø, Norway. [4]Department of Gastroenterology, Innlandet Hospital Trust, 2819 Gjøvik, Norway. [5]Institute for Clinical Medicine, University of Oslo, P.O. Box 11710318 Oslo, Norway. [6]Centre for Sami Health Research, UiT The Arctic University of Norway, 9037 Tromsø, Norway.

Received: 29 July 2015 Accepted: 1 March 2017
Published online: 07 March 2017

References

1. Helsedirektoratet. The Norwegian Patient Safety Programme: In Safe Hands. http://www.pasientsikkerhetsprogrammet.no. The Norwegian Directorate of Health. 2014. Oslo, The Norwegian Directorate of Health. 19-11-2014.
2. The Norwegian Directorat of Health. … and it's going to get better! National Strategy for Quality Improvement in Health and Social Services (2005–2015). Oslo: The Norwegian Directorat of Health; 2005.
3. Jortveit J, Govatsmark RE, Digre TA, Risoe C, Hole T, Mannsverk J, et al. Myocardial infarction in Norway in 2013. Tidsskr Nor Laegeforen. 2014;134:1841–6.
4. Hoff G, Bretthauer M, Huppertz-Hauss G, Kittang E, Stallemo A, Høie O, et al. The Norwegian Gastronet project: Continuous quality improvement of colonoscopy in 14 Norwegian centres. Scand J Gastroenterol. 2006;41:481–7.
5. Mosadeghrad AM. Factors influencing healthcare service quality. Int J Health Policy Manag. 2014;3:77–89.
6. Donabedian A. The definition of quality and approaches to its assessment. Ann Arbor, Mich: Health Administration Press; 1980.
7. Øvretveit J. Health Service Quality. Oxford: Blackwell Scientific Press; 1992.
8. Mainz J. Developing evidence-based clinical indicators: a state of the art methods primer. Int J Qual Health Care. 2003;15:i5–i11.
9. Brook RH, McGlynn EA, Cleary PD. Measuring Quality of Care. N Engl J Med. 1996;335:966–70.
10. Perera R, Moriarty H. If quality is the answer … what is the question? Int J Qual Health Care. 2013;25:107–9.
11. Donabedian A. Evaluating the quality of medical care. Milbank Mem Fund Q. 1966;44:166–203. 12-3-2013.
12. Cooperberg MR, Birkmeyer JD, Litwin MS. Defining high quality health care. Urol Oncol: Semin Orig Investig. 2009;27:411–6.
13. Patwardhan M, Fisher DA, Mantyh CR, McCrory DC, Morse MA, Prosnitz RG, et al. Assessing the quality of colorectal cancer care: do we have appropriate quality measures? (A systematic review of literature). J Eval Clin Pract. 2007;13(6):831–45.
14. Birkmeyer JD, Dimick JB, Birkmeyer NJO. Measuring the quality of surgical care: structure, process, or outcomes? J Am Coll Surg. 2004;198:626–32.
15. Jencks SF, Huff ED, Cuerdon T. Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998–1999 to 2000–2001. JAMA. 2003;289:305–12.
16. Lindenauer PK, Pekow P, Gao S, Crawford AS, Gutierrez B, Benjamin EM. Quality of Care for Patients Hospitalized for Acute Exacerbations of Chronic Obstructive Pulmonary Disease. Ann Intern Med. 2006;144:894–903.
17. Spertus JA, Radford MJ, Every NR, Ellerbeck EF, Peterson ED, Krumholz HM. Challenges and Opportunities in Quantifying the Quality of Care for Acute Myocardial Infarction: Summary From the Acute Myocardial Infarction Working Group of the American Heart Association/American College of Cardiology First Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke. Circulation. 2003;107:1681–91.
18. Campbell SM, Roland MO, Shekelle PG, Cantrill JA, Buetow SA, Cragg DK. Development of review criteria for assessing the quality of management of stable angina, adult asthma, and non-insulin dependent diabetes mellitus in general practice. Qual Health Care. 1999;8:6–15.
19. Brook RH, Chassin MR, Fink A, Solomon DH, Kosecoff J, Park RE. A method for the detailed assessment of the appropriateness of medical technologies. Int J Technol Assess Health Care. 1986;2:53–63.
20. Hutchinson A, McIntosh A, Anderson J, Gilbert C, Field R. Developing primary care review criteria from evidence-based guidelines: coronary heart disease as a model. Br J Gen Pract. 2003;53(494):690–6.
21. Perera R, Dowell A, Crampton P. Painting by numbers: A guide for systematically developing indicators of performance at any level of health care. Health Policy. 2012;108:49–59.
22. Thomson RG, McElroy H, Kazandjian VA. Maryland Hospital Quality Indicator Project in the United Kingdom: an approach for promoting continuous quality improvement. Qual Health Care. 1997;6:49–55.
23. Casalino LP. The Unintended Consequences of Measuring Quality on the Quality of Medical Care. N Engl J Med. 1999;341:1147–50.
24. Panzer RJ, Gitomer RS, Greene WH, Webster P, Landry KR, Riccobono CA. Increasing demands for quality measurement. JAMA. 2013;310:1971–80.
25. Bishop TF. Pushing the outpatient quality envelope. JAMA. 2013;309:1353–4.
26. Guevara J, Hsu D, Forrest C. Performance measures of the specialty referral process: a systematic review of the literature. BMC Health Serv Res. 2011;11:168.

27. Goodwin N, Dixon A, Poole T, Raleigh V. In: Stanley E, editor. Improving the quality of care in general practice. London: The Kings Fund; 2011.
28. Ong SP, Lim LT, Barnsley L, Read R. General practitioners' referral letters–Do they meet the expectations of gastroenterologists and rheumatologists? Aust Fam Physician. 2006;35:920–2.
29. Syed AA, Large DM. Quality of GPs' referral letters to diabetes secondary care. Prac Diabetes Int. 2003;20:165–9.
30. Bodek S, Ghori K, Edelstein M, Reed A, MacFadyen RJ. Contemporary referral of patients from community care to cardiology lack diagnostic and clinical detail. Int J Clin Pract. 2006;60:595–601.
31. Akbari A, Mayhew A, Al-AlawiMA, Grimshaw J, Winkens R, Glidewell E, Pritchard C, Thomas R, Fraser C. Interventions to improve outpatient referrals from primarycare to secondary care. Cochrane Database Syst Rev. 2008;(4). Art. No.: CD005471. doi:10.1002/14651858.CD005471.pub2.
32. Carlsen B, Norheim OF. Introduction of the patient-list system in general practice. Changes in Norwegian physicians' perception of their gatekeeper role. Scand J Prim Health Care. 2003;21:209–13.
33. Ree AO. Medisinsk faglig innhold i henvisninger [Medical technical content in referral papers]. KITH 22/03. 19-9-2003. Trondheim, Norwegian Centre for Informatics in Health and Social Care (KITH 2003). 10-5-2010.
34. Wahlberg H, Valle P, Malm S, Broderstad A. Impact of referral templates on the quality of referrals from primary to secondary care: a cluster randomised trial. BMC Health Serv Res. 2015;15:353.
35. Wahlberg H, Valle PC, Malm S, Broderstad AR. Practical health co-operation–the impact of a referral template on quality of care and health care co-operation: study protocol for a cluster randomized controlled trial. Trials. 2013;14:7.
36. Roth CP, Lim YW, Pevnick JM, Asch SM, McGlynn EA. The Challenge of Measuring Quality of Care From the Electronic Health Record. Am J Med Qual. 2009;24:385–94.
37. Dyspepsia: Managing Dyspepsia in Adults in Primary Care. North of England Dyspepsia Guideline Development Group. 112. 1-8-2004. Newcastle upon Tyne, Centre for Health Services Research. 19-5-2010.
38. Talley NJ. American Gastroenterological Association Medical Position Statement: Evaluation of Dyspepsia. Gastroenterology. 2005;129:1753–56.
39. Talley NJ, Vakil N. Guidelines for the management of dyspepsia. Am J Gastroenterol. 2005;100:2324–37.
40. Riktlinjer handläggning av gastroesofageal refluxsjukdom [Guidelines for treatment of gastroesophageal reflux disease]. Svensk Gastroenterologisk Förening; 2008. http://www.svenskgastroenterologi.se/sites/default/files/pagefiles/Riktlinjer_handlaggning_av_gastroesofageal_refluxsjukdom_2008.pdf. Accessed 3 Mar 2017.
41. Valle PC, Breckan RK, Amin A, Kristiansen MG, Husebye E, Nordgard K, et al. "Test, score and scope": a selection strategy for safe reduction of upper gastrointestinal endoscopies in young dyspeptic patients referred from primary care. Scand J Gastroenterol. 2006;41:161–9.
42. Longstreth GF. Approach to the patient with dyspepsia. In: Basow DS, editor. UpToDate. Waltham; 2009. https://www.uptodate.com/contents/approach-to-the-adult-with-dyspepsia. Accessed Jun 2010.
43. Nygaard E, Kårikstad V. Prioriteringsveileder–Fordøyelsessykdommer [Prioritization guidelines–Gastrointestinal diseases]. Oslo: The Norwegian Directorate of Health; 2009.
44. Bourke MJ. Making every colonoscopy count: Ensuring quality in endoscopy. J Gastroenterol Hepatol. 2009;24 Suppl 3:S43–50.
45. Sharma VK, Nguyen CC, Crowell MD, Lieberman DA, de Garmo P, Fleischer DE. A national study of cardiopulmonary unplanned events after GI endoscopy. Gastrointest Endosc. 2007;66:27–34.
46. Enns R. Quality indicators in colonoscopy. Can J Gastroenterol. 2007;21:277–9.
47. Froehlich F, Wietlisbach V, Gonvers JJ, Burnand B, Vader JP. Impact of colonic cleansing on quality and diagnostic yield of colonoscopy: the European Panel of Appropriateness of Gastrointestinal Endoscopy European multicenter study. Gastrointest Endosc. 2005;61:378–84.
48. Ahnen DJ, Macrae FA. Clinical manifestations, diagnosis, and staging of colorectal cancer. In: Basow DS, editor. UpToDate. Waltham; 2010. https://www.uptodate.com/contents/clinical-presentation-diagnosis-and-staging-of-colorectal-cancer. Accessed Jun 2010.
49. Nygaard E, Kårikstad V. Prioriteringsveileder–Lungesykdommer. [Prioritization guidelines–Pulmonary diseases]. Oslo: The Norwegian Directorate of Health; 2008.
50. Rennard IS. Chronic obstructive pulmonary disease: Definition, clinical manifestations, diagnosis, and staging. In: Basow DS, editor. UpToDate. Waltham; 2009. https://www.uptodate.com/contents/chronic-obstructive-pulmonary-disease-definition-clinical-manifestations-diagnosis-and-staging. Accessed Jun 2010.
51. Kerr EA, ASMHEGMEA. Chronic Obstructive Pulmonary Disease. In: Quality of Care for Cardiopulmonary Conditions: A Review of the Literature and Quality Indicators. Santa Monica: RAND; 2000. p. 91–115.
52. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, mangement and prevention of chronic obstructive pulmonary disease. Medical Communications Resources, Inc.; 2009. 19-5-2010. http://www.goldcopd.org. Accessed Jun 2010.
53. Mularski RA, Asch SM, Shrank WH, Kerr EA, Setodji CM, Adams JL, et al. The Quality of Obstructive Lung Disease Care for Adults in the United States as Measured by Adherence to Recommended Processes*. Chest. 2006;130:1844–50.
54. Heffner JE, Mularski RA, Calverley PMA. COPD Performance Measures. Chest. 2010;137:1181–9.
55. American Gastroenterological Association, Spechler SJ, Sharma P, Souza RF, Inadomi JM, Shaheen NJ. American Gastroenterological Association Medical Position Statement on the Management of Barrett's Esophagus. Gastroenterology. 2011;140:1084–91.
56. Jones R, Hunt C, Stevens R, Dalrymple J, Driscoll R, Sleet S, et al. Management of common gastrointestinal disorders: quality criteria based on patients' views and practice guidelines. Br J Gen Pract. 2009;59:e199–208.
57. Ciclitira PJ, Dewar DH, McLaughlin SD, Sanders DS. The Management of Adult with Coeliac Disease. British Society of Gastroenterology; 2010. http://www.bsg.org.uk/images/stories/clinical/bsg_coeliac_10.pdf. Accessed Jun 2010.
58. Fisher L, Lee Krinsky M, Anderson MA, Appalaneni V, Banerjee S, Ben Menachem T, et al. The role of endoscopy in the management of obscure GI bleeding. Gastrointest Endosc. 2010;72:471–9.
59. Bull-Henry K, Al Kawas FH. Evaluation of occult gastrointestinal bleeding. Am Fam Physician. 2013;87(6):430–6.
60. Hofstad B, Andersen SN, Nesbakken A. Colorectal polyps. Tidskr Nor Lægeforen. 2007;127(20):2692–5. 23-5-2012.
61. Early DS, Ben Menachem T, Decker GA, Evans JA, Fanelli RD, Fisher DA, et al. Appropriate use of GI endoscopy. Gastrointest Endosc. 2012;75:1127–31.
62. Erhardt L, Herlitz J, Bossaert L, Halinen M, Keltai M, Koster R, et al. Task force on the management of chest pain. Eur Heart J. 2002;23:1153–76.
63. Kerr EA, ASMHEGMEA. Coronary artery disease–diagnosis and screening. In: Quality of Care for Cardiopulmonary Conditions: A Review of the Literature and Quality Indicators. Santa Monica: RAND; 2000. p. 141–59.
64. Buetow SA, Coster GD. New Zealand and United Kingdom experiences with the RAND modified Delphi approach to producing angina and heart failure criteria for quality assessment in general practice. Qual Health Care. 2000;9:222–31.
65. Kerr EA, ASMHEGMEA. Coronary artery disease–prevention and treatment. In: Quality of Care for Cardiopulmonary Conditions: A Review of the Literature and Quality Indicators. Santa Monica: RAND; 2000. p. 161–77.
66. Cooper A, Calvert N, Skinner J, Sawyer L, Sparrow K, Timmis A, et al. Chest pain of recent onset: Assessment and diagnosis of recent onset chest pain or discomfort of suspected cardiac origin. London: National Clinical Guideline Centre for Acute and Chronic Conditions (UK); 2010.
67. Fihn SD, Gardin JM, Abrams J, Berra K, Blankenship JC, Dallas AP, et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. Circulation. 2012;126:3097–137.
68. National Institute for Health and Care Excellence. Stable Angina: full guideline (CG126). London: National Institute for Health and Care Excellence; 2011.
69. Marshall MN, Shekelle PG, McGlynn EA, Campbell S, Brook RH, Roland MO. Can health care quality indicators be transferred between countries? Qual Saf Health Care. 2003;12:8–12.
70. Ashton CM, Kuykendall DH, Johnson ML, Wray NP. An empirical assessment of the validity of explicit and implicit process-of-care criteria for quality assessment. Med Care. 1999;37:798–808.
71. Ashton CM, Kuykendall DH, Johnson ML, Wun CC, Wray NP, Carr MJ, et al. A method of developing and weighting explicit process of care criteria for quality assessment. Med Care. 1994;32:755–70.

72. Lyons TF, Payne BC. The use of item importance weights in assessing physician performance with predetermined criteria indices. Med Care. 1975;13:432–9.
73. Bennett K, Haggard M, Churchill R, Wood S. Improving referrals for glue ear from primary care: are multiple interventions better than one alone? J Health Serv Res Policy. 2001;6:139–44.
74. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;327:307–10.
75. Campbell MKP. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012;345:e5661.
76. Baker R, Fraser RC. Development of review criteria: linking guidelines and assessment of quality. BMJ. 1995;311:370–3.
77. Wisdom JP, Cavaleri MA, Onwuegbuzie AJ, Green CA. Methodological Reporting in Qualitative, Quantitative, and Mixed Methods Health Services Research Articles. Health Serv Res. 2012;47:721–45.
78. Jiwa M, Skinner P, Coker AO, Shaw L, Campbell MJ, Thompson J. Implementing referral guidelines: lessons from a negative outcome cluster randomised factorial trial in general practice. BMC Fam Pract. 2006;7:65.
79. Thomas RE, Grimshaw JM, Mollison J, McClinton S, McIntosh E, Deans H, et al. Cluster randomized trial of a guideline-based open access urological investigation service. Fam Pract. 2003;20:646–54.
80. Hartveit M, Biringer E, Vanhaecht K, Haug K, Aslaksen A. The Western Norway mental health interface study: a controlled intervention trial on referral letters between Primary Care and Specialist Mental Health Care. BMC Psychiatry. 2011;11:177.
81. Medical Research Council. Cluster randomised trials: Methodological and ethical considerations. London: Medical Research Council; 2002.
82. Timian A, Rupcic S, Kachnowski S, Luisi P. Do Patients "Like" Good Care? Measuring Hospital Quality via Facebook. Am J Med Qual. 2013;28:374–82.
83. Mainz J. Defining and classifying clinical indicators for quality improvement. Int J Qual Health Care. 2003;15:523–30.
84. Chassin MR, Loeb JM, Schmaltz SP, Wachter RM. Accountability Measures–Using Measurement to Promote Quality Improvement. N Engl J Med. 2010;363:683–8.
85. Quality of Care and Outcomes Research in CVD, Stroke Working Groups. Measuring and Improving Quality of Care: A Report From the American Heart Association/American College of Cardiology First Scientific Forum on Assessment of Healthcare Quality in Cardiovascular Disease and Stroke. Circulation. 2000;101:1483–93.
86. Institute of Medicine; Committee on Improving the Patient Record; Richard S. Dick, Elaine B. Steen, and Don E. Detmer, Editors. The Computer-Based Patient Record: An Essential Technology for Health Care, Revised Edition. The National Academies Press; 1997.
87. Romm FJ, Putnam SM. The validity of the medical record. Med Care. 1981; 19:310–5.
88. Moran MT, Wiser TH, Nanda J, Gross H. Measuring medical residents' chart-documentation practices. J Med Educ. 1988;63(11):859–65.
89. Weiskopf NG, Weng C. Methods and dimensions of electronic health record data quality assessment: enabling reuse for clinical research. J Am Med Inform Assoc. 2013;20:144–51.

APPENDIX

Methods paper

Referral templates

Questionnaire

Quality criteria used in scoring

ICD-10 codes according to severity levels

Consent form

TRIALS

STUDY PROTOCOL Open Access

Practical health co-operation - the impact of a referral template on quality of care and health care co-operation: study protocol for a cluster randomized controlled trial

Henrik Wåhlberg[1,2*], Per Christian Valle[2], Siri Malm[2] and Ann Ragnhild Broderstad[2,3]

Abstract

Background: The referral letter plays a key role both in the communication between primary and secondary care, and in the quality of the health care process. Many studies have attempted to evaluate and improve the quality of these referral letters, but few have assessed the impact of their quality on the health care delivered to each patient.

Methods: A cluster randomized trial, with the general practitioner office as the unit of randomization, has been designed to evaluate the effect of a referral intervention on the quality of health care delivered. Referral templates have been developed covering four diagnostic groups: dyspepsia, suspected colonic malignancy, chest pain, and chronic obstructive pulmonary disease. Of the 14 general practitioner offices primarily served by University Hospital of North Norway Harstad, seven were randomized to the intervention group. The primary outcome is a collated quality indicator score developed for each diagnostic group. Secondary outcomes include: quality of the referral, health process outcome such as waiting times, and adequacy of prioritization. In addition, information on patient satisfaction will be collected using self-report questionnaires. Outcome data will be collected on the individual level and analyzed by random effects linear regression.

Discussion: Poor communication between primary and secondary care can lead to inappropriate investigations and erroneous prioritization. This study's primary hypothesis is that the use of a referral template in this communication will lead to a measurable increase in the quality of health care delivered.

Trial registration: This trial has been registered at ClinicalTrials.gov. The trial registration number is NCT01470963

Keywords: Cluster randomized trial, General practice, Quality of care, Referral

Background

Quality of healthcare is defined by the American Institute of Medicine as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge' [1]. The focus on prevention of medical errors and improved quality of medical care continues to increase [2,3]. This focus is evident in Norway by the publication of a national strategy for quality improvement in health and social services [4], and the multitude of clinical guidelines available from governmental and professional sources.

The referral of a patient from a general practitioner (GP) to a hospital environment represents a transition of care, in which the major information exchange is through the written referral letter [5]. This transition of care represents an important step in the quality of the care process, and it has been shown that key clinical information may not be communicated adequately at the transition of care interface [6]. There has been considerable research into the quality of a referral and its impact on the process of care. A Norwegian study from 2007 amongst elderly patients demonstrated that both referral

* Correspondence: henrik.wahlberg2@unn.no/henrik.wahlberg@uit.no
[1]Department of Community Medicine, Faculty of Health Sciences, University of Tromsø, 9037, Tromsø, Norway
[2]University Hospital of North Norway Harstad, St. Olavsgate 70, 9480, Harstad, Norway
Full list of author information is available at the end of the article

and discharge letters were missing vital information [7]. The consequences might represent a health hazard to older patients [7]. A Finnish assessment of the quality of referral letters for patients with asthma concludes that 45% of the referrals were of poor or unacceptable quality, based upon quality criteria developed by GPs and hospital respiratory consultants [8]. Others have also found varying quality and content of referrals [9-15].

Many studies have been designed for improving the referral process from GPs to the hospital [16,17]. A recent Cochrane review on interventions to improve outpatient referrals from primary to secondary care concludes that surprisingly few interventions on the referral system have been rigorously evaluated. Many of the studies evaluated focused only on referral rates or referral quality. The review highlights the complexities of research in this area, especially as no single study managed to present findings on all aspects of the referral process (referral behavior, management of non-referred patients, secondary care management of patients, the flow of patients through the referral system, patient outcomes and satisfaction, and resource use). However, structured referral sheets and local education interventions have an impact on referral rates [18].

The primary objective of the present study is to evaluate whether the implementation of a referral template in the referral from general practice to hospital care can lead to a measurable increase in the quality of care delivered at the hospital. As secondary objectives, we will assess patient satisfaction and effective prioritization at secondary care.

Methods

Study design

This study is a cluster randomized trial, with the GP clinics as the cluster. The local GP clinics are randomly assigned either to use a referral template or to continue standard referral practice.

Participants

The 14 community GP practices in the area primarily served by University Hospital of North Norway Harstad (UNN Harstad) were included in the randomization process, with a total list size of 35,490 patients. In Norway, each individual has a regular GP. These GPs act as gatekeepers to secondary care. The health care system is relatively uniform throughout the country. In the study area, access to specialist care is practically impossible without a GP referral, whereas some access is possible in other areas of the country.

The study population will consist of patients referred to the medical department at UNN Harstad. The referrals received are, almost exclusively, electronic. Children (<18 years of age) and patients with reduced capacity to consent will be excluded from participation in the study.

Randomization

The GP clinics were randomized stratified by location, to ensure adequate selection of cases and equal sociodemographic background data. Five of the centers are larger town-based centers and nine are smaller, more rural centers. The location of the center was not expected to influence the outcome variables. Initially, two centers approached declined the invitation to participate in the study, and therefore two additional GP clinics were randomly selected, as illustrated by Figure 1.

Recruitment

New patients referred to the medical department within one of the four diagnostic groups described below will receive written information and a consent form together with their appointment letter. These will be sent out by a clinic nurse unaware of the status of the GP center sending the referral (intervention or control). Patients will be orally reminded at the appointment and may be given a new consent form. This process is illustrated in Figure 2.

Intervention

The referral templates have been developed based upon international literature [19-27] and in collaboration with local specialists in the appropriate medical field. The templates have also been through a process of clinical assessment from subspecialists in other northern Norwegian hospitals. In acknowledging the problems in earlier studies with the uptake of referral interventions [17,18] we have deliberately reduced the number of items in the referral templates, to ensure ease of uptake. Only information that the medical consultants thought imperative in the referral have been included as items in the templates. The study will implement referral guidelines for the following four diagnostic groups:

- patients referred with dyspepsia;
- patients referred with suspected colonic malignancy;
- patients referred with chest pain;
- patients referred with chronic obstructive pulmonary disease or suspected chronic obstructive pulmonary disease.

These diagnostic groups were chosen as they represent a substantial number of the referrals to a medical department (own data, 2008). They also represent a clear diagnostic challenge in primary care and are adept for simple referral guidelines.

The GPs at the intervention offices will use the referral template when initiating a new referral process for a

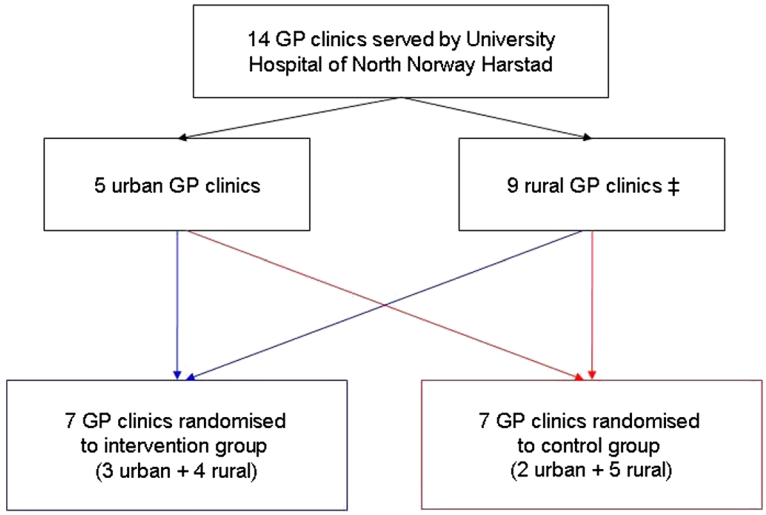

Figure 1 Flow chart of randomization process. ‡ From the four rural clinics initially randomized to the intervention group, two clinics refused. Therefore two additional rural clinics, from the five rural clinics initially randomized to the control group were randomized, and consented to, the intervention.

patient. To ensure adequate uptake of intervention, the templates have been distributed as electronic templates as well as hard copies. The templates function as guidelines, but are not implemented as compulsory electronic checklists. The intervention referrals are sent to a separate electronic inbox at the hospital. The further evaluation and process of care has not been altered in the intervention group compared with the standard referral practice in the control group (Figure 3).

In addition, questionnaires have been developed that assess patient experiences within the care framework, with one questionnaire designed for inpatients and one for outpatients. These questionnaires have been produced by combining questions from previously validated questionnaires regarding patient experiences in general and with transitional care. They include questions from a Norwegian patient experiences questionnaire [28]); two questions about health interaction from the Commonwealth Fund Survey 2010 [29]; the Care Transitions Measure 3 [30]; and demographic questions.

The questionnaires have been reviewed through an interview process with patients. This was done to ensure that the forms are acceptable to patients and to highlight possible issues that patients felt were missing from the questionnaires.

Objectives

We aim to examine the impact of a referral template on the process of care, at the individual level. The primary hypothesis is that the use of a referral template in the communication between the GP and secondary care will lead to a measurable increase in the quality of health

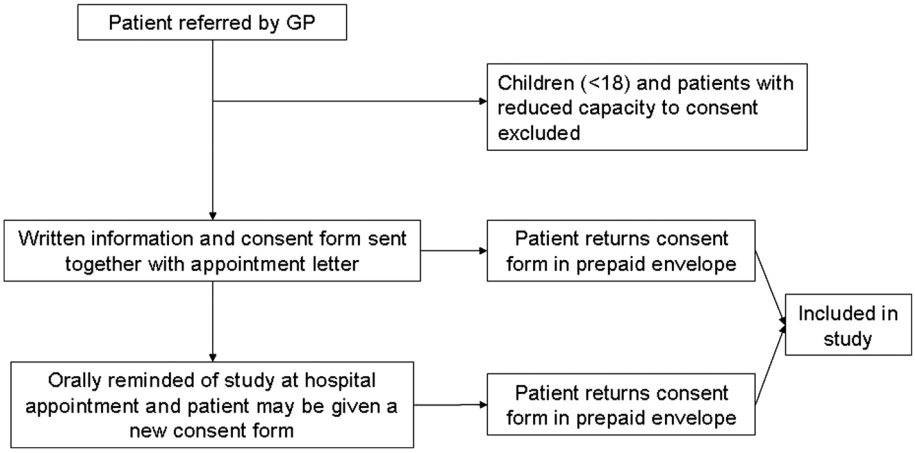

Figure 2 Recruitment process. Recruitment of patients in both the intervention and control groups follow the same procedure.

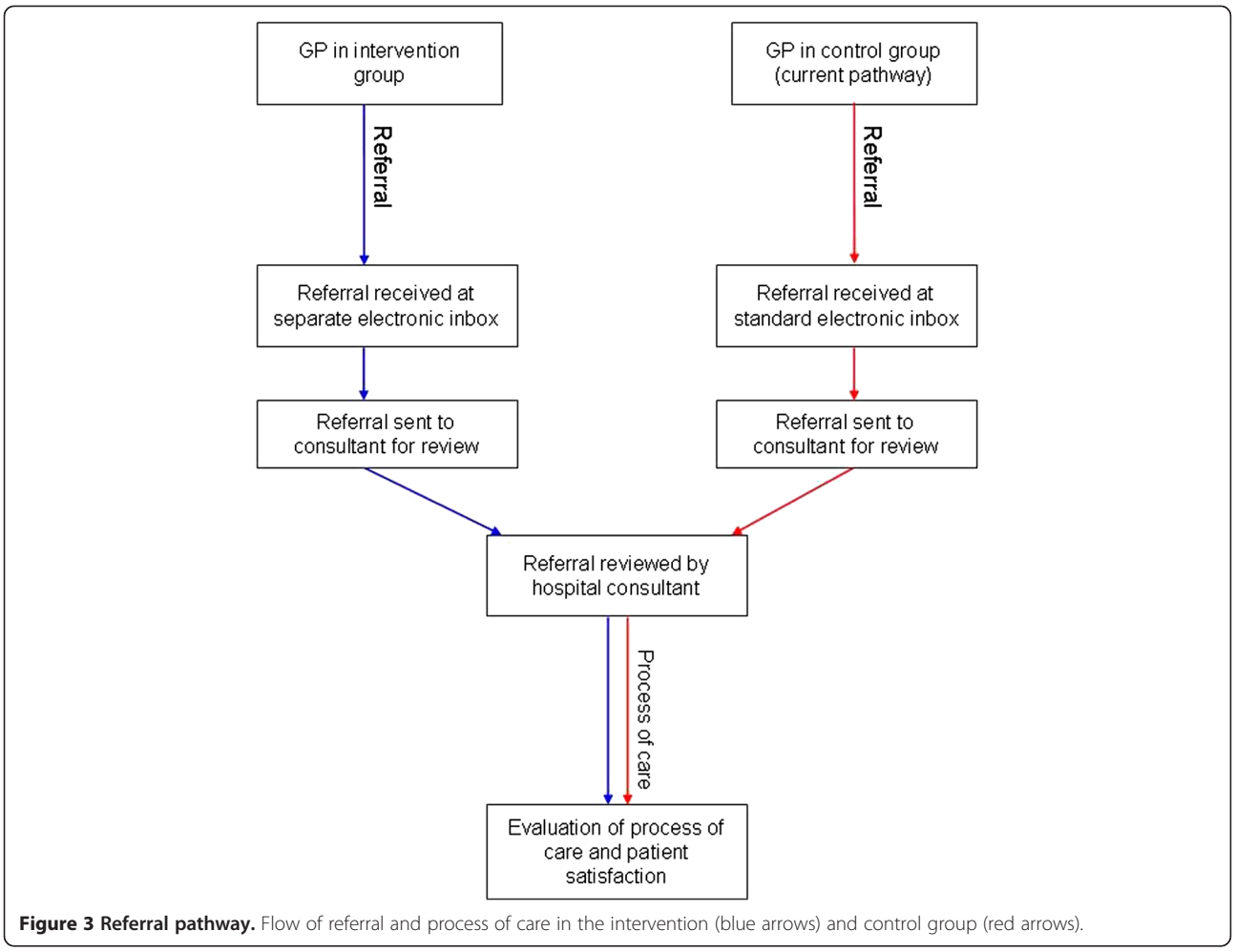

Figure 3 Referral pathway. Flow of referral and process of care in the intervention (blue arrows) and control group (red arrows).

care delivered. Secondary hypotheses include that the use of a referral template in the communication between a GP and secondary care will lead to:

- a measurable improvement in referral quality;
- a change (up or down) in the number of patients defined as being in need of prioritization (as defined in national guidelines for prioritization in health care [20,23,24]);
- more appropriate prioritization, as measured by final diagnosis;
- an increase in the 'appropriateness' of the referrals (positive predictive value (PPV) of referral [31];
- and better patient satisfaction, as measured by self-report questionnaires.

Outcomes

The primary outcome will be a quality indicator score compared between the intervention and the control group. The quality indicators have been generated from previous international quality assessment tools and national and international treatment guidelines. Some adaptation to locally accepted practice has been made, as demonstrated by others when quality indicators are used in a new context [32]. Each patient care process will be scored according to the criteria. Scoring will be done by a panel of specialists blinded to the intervention status of the patient. We will calculate the quality score as adherence scores (number of quality criteria met divided by number of applicable criteria expressed as a percentage) as illustrated by Ashton *et al.* [33]. If a criterion is applicable, but no information can be found (applicable, but not answerable), it will be noted 'not met' for statistical purposes [34]. Weighting of the criteria based upon clinical importance will not be used, as this adds complexity without adding much to the clinical findings, a finding discussed by Lyons and Payne in 1975 [35]. The scores will be compared between the intervention and control groups.

As secondary outcomes, the quality of the referrals will be evaluated against the developed referral template, to determine if the intervention has led to improved referral quality. It is important to measure referral quality, as the premise in the study is that more information will lead to improved care. In addition, health process outcomes such

as waiting time from referral to appointment, number of appointments before a diagnosis is reached, time before treatment is initiated, the application or not of appointment prioritization, and the outcome of any given referral (appointment, return information or referral rejected) will be collected and compared between the groups. Bennett *et al.* used the PPV of a referral as a measure of the appropriateness of the referral [31]. In adapting this concept from glue ear in otolaryngology to a medical department we have defined it as the proportion of the GP referrals that result in a histological diagnosis, diagnostic clarification or change in medical management. We will assess and compare the PPV of referrals in the study groups. Patient experiences will be compared between the intervention and control group. Finally, the possible outcome diagnoses have been grouped according to severity. We will correlate the continuous outcome variable 'waiting time' with the grouped severity, to see whether the prioritization in the intervention group is more aligned with disease severity.

Sample size

Sample size was calculated based upon the primary outcome, and the initial calculation was done without regard for clustering. A change in the quality score of 10% was determined to be clinically interesting. Setting the significance level at 0.05 and using PASS 2008 (NCSS, LLC, Kaysville, UT, USA) for the calculation provides that the study would require 855 patients in the control and 855 in the intervention group, for an 80% power to detect a 10% difference between the groups.

To correct for clustering, the design effect (DE) may be calculate as:

$$DE = 1 + \rho(m\text{-}1)$$

where ρ denoted the intracluster correlation coefficient (ICC) and m is the size of each cluster [36]. No ICC for equivalent designs was identified from literature searches. Reviewing primary care-based interventions from the literature [37-39], an expected ICC ranging from 0.001 to 0.08 does not seem improbable, giving a DE of 1.15 and 12.9, respectively, for a cluster size of 150 patients. Because only 14 GP clinics were available for randomization, further inflation of the number of clusters to achieve higher power was not possible, although this could have been advisable [40].

Based upon a review of patient data at UNN Harstad from 2008, the study is expected to achieve this relatively high inclusion number by recruiting over a two-year period (personal data).

Blinding

The referring GP cannot be blinded to the trial, as the intervention is actively used by the GP. The patient will not be aware of the intervention, but no active effort has been made to keep the patients blinded. The patients will be mixed with the general caseload to avoid bias in the treatment process at the hospital. For the GPs that use the electronic referral template, this usage will be visible to the hospital doctor in the presentation of the referral letter on the computer, but for the majority of the cases the hospital doctor will be blinded to the intervention status of the patient. The outcome assessors will be blinded.

Data gathering

Data will be extracted by both automated computer reports (for example, waiting times, number of appointments) and manual chart review (for example, PPV, group of final diagnosis). Data will be collected after the process of care that the referral initiated is completed.

Statistical methods

We will collect the following baseline characteristics:

- patient age (mean and confidence interval) and sex (number and percentage)
- practice list size (median and interquartile range, or mean and confidence interval if normally distributed)
- referral type - electronic or paper (number and percentage)
- referred by - GP or other doctor (number and percentage).

For the primary outcome (quality score), we will calculate adherence scores as described above and compare between treatment arms. We expect substantial variation in cluster size. Because of the small number of clusters, analysis based upon the cluster level was considered [41]. However, as there is no prior accurate estimate of variation between clusters, weighting for cluster size could not be achieved [41]. To offer increased precision and take into account between-cluster variation, random effects linear regression will be used [42] to generate estimates of intervention effect. It has been suggested that this can be used for studies with as few as 10 clusters [36]. The estimated effect and confidence intervals will be reported. A P-value <0.05 will be regarded as statistically significant. Intention to treat analysis will be employed.

The referrals will be scored using a simple scoring system related to the referral templates. Each unit of information specified in the referral template (for example, presence of weight loss specified) will provide one point in the scoring system, with no weighting applied. Scores will be compared between the groups as noted above.

For outcome severity, random effects linear regression will be used, with the severity group score as a categorical

variable, and the relationship compared between the intervention and control group.

In the questionnaire, answers noted as 'not applicable' or no answer will be counted as missing data. The questionnaire will be scored according to a pre-set scoring system. Scores will be analyzed using the regression technique outlined above. The data will also be analyzed to determine if factors such as self-perceived health, age, gender, and education level have an impact on patient experience.

The trial will be reported according to the CONSORT standards for reporting cluster randomized trials [43].

Pilot study

No pilot study has been carried out. To ensure acceptability of the intervention, GPs were invited to, and participated in, the development of the referral template. To ensure feasibility, the authors have collected all data specified in the protocol from the 20 patients included first. To ensure an adequate uptake of the intervention, regular reviews of all referrals received at UNN Harstad will be undertaken.

Ethics

The study will follow the directions in the Helsinki Declaration, and was presented to the Regional Ethical Committee for Medical Research in northern Norway, who determined it not to be within the scope of the Health Research Act (REK NORD 2010/2259). The project has been approved by the Data Protection Official for Research. The study is registered at ClinicalTrials.gov. The trial registration number is NCT01470963. All patients must provide written informed consent.

Discussion

Transitions of care represent a point of frequent adverse events [44,45]. The referral is the main form of communication in the transition from primary to secondary care [13,46]. Although many referral interventions have been evaluated, there appears to be limited knowledge on how the referral letters affect specialist care. A recent study protocol describes a similar project within mental health care [47], although this study is still ongoing. The primary objective of our study is to assess whether an improved referral letter will lead to a measurable change in the quality of care delivered in a medical department. The aim is to go beyond an assessment of referral quality and waiting times *per se*, and evaluate quality of care and the appropriateness of waiting times and treatment, and, as such, help fill parts of the knowledge gap identified in a Cochrane review on the subject [18].

However, research at the interface between primary and secondary care can be challenging [18,48]. The choice of using an intervention with intuitive content was made to make it acceptable in normal general practice. The assumption underlying this research project is that a referral guideline will increase the amount of information available to the hospital specialist, and that this increase in information will translate into better care.

The cluster design was chosen because randomization with this approach is well suited for interventions implemented at the level of the health care organizational unit [42]. In addition, randomizing at the individual patient level would undermine findings, as the GPs could use the information learned from the referral template in their non-intervention referrals and as such contaminate the data. For similar reasons, the GP clinic, as opposed to the individual GP, was randomized, as contamination between GPs in the same clinic was to be expected.

In choosing a cluster randomized design, we have a design that is less statistically efficient than a standard randomized design. A recent study involving a more complex intervention [49] used randomization at the patient level to avoid this problem. We feel that the dangers of contamination with individual randomization in our design would be so large that results would be difficult to interpret.

In cluster randomized trials, post randomization bias has been identified as a concern [40]. This entails the recruitment of different cohorts in the intervention and control groups, as the patients are recruited after randomization of the clusters. We hope to reduce this by actively recruiting the patients (obtaining signed consent) in conjunction with the hospital appointment, both for the intervention and control groups.

The intervention is intentionally simple to ensure that an effect seen can be attributed to the intervention. However, an intervention at an interface in a complicated health care system can quickly affect the entire process, in ways we have not yet envisaged.

There is also a risk of performance bias as systematic differences in the care may not be due to the intervention, but rather because the doctors will be aware of the study protocol. By ensuring the mixing of cases in normal workloads and, as much as possible, blinding the doctors involved, we hope to minimize this bias. The fact that the care process is being studied may change the behavior of the doctors in general, akin to a Hawthorn effect. This will potentially attenuate the effects of the intervention, as the quality of care may improve for both intervention and control patients.

The authors also recognize that many referrals from primary to secondary care are not made only to identify major pathology. Referrals are also made to reassure the patient, reduce medico-legal risk, obtain a second opinion or for handing over of care [50]. The authors fully appreciate these as valid reasons for referral. We, therefore, do not aim to reduce the number of referrals, but

rather assess the effect on hospital care of improved referrals.

This study aims to add to the knowledge regarding the effect of the referral on the patient pathway and quality of care. Simple diagnostic groups have been chosen. If the study can identify benefits from improving referrals in these areas, this may lead the way to further implementations of referral proforma, preferably electronically integrated into the standard software packages. This could improve the overall referral process to enable better care and effective prioritization based upon the need of the individual patients.

Trial status

The study began including patients in the fall of 2011 and inclusion is planned for approximately two years.

Abbreviations

GP: general practitioner; PPV: positive predictive value.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

The idea behind the study was conceived by PCV. All authors participated in the study concept and design. HW is the grant holder. ARB, PCV and HW developed the referral guidelines and outcome measures. All authors reviewed and approved the final version of the manuscript.

Acknowledgements

The study is funded by the Northern Norway Regional Health Authority. The funding source did not have any role in designing the study or writing the manuscript.

Author details

[1]Department of Community Medicine, Faculty of Health Sciences, University of Tromsø, 9037, Tromsø, Norway. [2]University Hospital of North Norway Harstad, St. Olavsgate 70, 9480, Harstad, Norway. [3]Centre for Sami Health Research, University of Tromsø, 9037, Tromsø, Norway.

Received: 29 May 2012 Accepted: 13 December 2012
Published: 7 January 2013

References

1. Lohr KN: *Medicare: A Strategy for Quality Assurance, Volume I*. Washington, DC: The National Academy Press; 1990.
2. Institue of Medicine: *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.
3. Varkey P, Reller MK, Resar RK: **Basics of quality improvement in health care.** *Mayo Clinic Proceedings* 2007, **82:**735–739.
4. The Norwegian Directorat of Health: *and it's going to get better! National Strategy for Quality Improvement in Health and Social Services (2005–2015)*. Oslo: The Norwegian Directorat of Health; 2005.
5. Piterman L, Koritsas S: **Part II. General practitioner-specialist referral process.** *Intern Med J* 2005, **35:**491–496.
6. Coleman EA: **Falling through the cracks: challenges and opportunities for improving transitional care for persons with continuous complex care needs.** *J Am Geriatr Soc* 2003, **51:**549–555.
7. Garasen H, Johnsen R: **The quality of communication about older patients between hospital physicians and general practitioners: a panel study assessment.** *BMC Health Serv Res* 2007, **7:**133.
8. Tuomisto LE, Erhola M, Kaila M, Brander PE, Kauppinen R, Puolijoki H, Kekki P: **The Finnish national asthma programme: communication in asthma care–quality assessment of asthma referral letters.** *J Eval Clin Pract* 2007, **13:**50–54.
9. Ong SP, Lim LT, Barnsley L, Read R: **General practitioners' referral letters - do they meet the expectations of gastroenterologists and rheumatologists?** *Aust Fam Physician* 2006, **35:**920–922.
10. Dentith GE, Wilson KE, Dorman M, Girdler NM: **An audit of patient referrals to the sedation department of Newcastle Dental Hospital.** *Prim Dent Care* 2010, **17:**85–91.
11. Syed AA, Large DM: **Quality of GPs' referral letters to diabetes secondary care.** *Practical Diabetes International* 2003, **20:**165–169.
12. Newton J, Hutchinson A, Hayes V, McColl E, Mackee I, Holland C: **Do clinicians tell each other enough? An analysis of referral communications in two specialties.** *Fam Pract* 1994, **11:**15–20.
13. Shaw I, Smith KM, Middleton H, Woodward L: **A letter of consequence: referral letters from general practitioners to secondary mental health services.** *Qual Health Res* 2005, **15:**116–128.
14. Jacobs LG, Pringle MA: **Referral letters and replies from orthopaedic departments: opportunities missed.** *BMJ* 1990, **301:**470–473.
15. Bodek S, Ghori K, Edelstein M, Reed A, MacFadyen RJ: **Contemporary referral of patients from community care to cardiology lack diagnostic and clinical detail.** *Int J Clin Pract* 2006, **60:**595–601.
16. Thomas RE, Grimshaw JM, Mollison J, McClinton S, McIntosh E, Deans H, Repper J: **Cluster randomized trial of a guideline-based open access urological investigation service.** *Fam Pract* 2003, **20:**646–654.
17. Jiwa M, Skinner P, Coker AO, Shaw L, Campbell MJ, Thompson J: **Implementing referral guidelines: lessons from a negative outcome cluster randomised factorial trial in general practice.** *BMC Fam Pract* 2006, **7:**65.
18. Akbari A, Mayhew A, Al-Alawi MA, Grimshaw J, Winkens R, Glidewell E, Pritchard C, Thomas R, Fraser C: **Interventions to improve outpatient referrals from primary care to secondary care.** *Cochrane Database Syst Rev* 2008, **4:**cd005471.
19. Jiwa M, Mathers N, Walters S: **Quality of information on referrals to colorectal surgeons: towards consensus.** *Curr Med Res Opin* 2002, **18:**72–77.
20. Nygaard E, Kårikstad V: *Prioriteringsveileder – Fordøyelsessykdommer (Prioritization guidelines – digestive diseases)*. Oslo: Helsedirektoratet; 2009.
21. Jiwa M, Coleman M, McKinley RK: **Measuring the quality of referral letters about patients with upper gastrointestinal symptoms.** *Postgrad Med J* 2005, **81:**467–469.
22. British Thoracic Society Standards of Care Committee: **BTS statement on criteria for specialist referral, admission, discharge and follow-up for adults with respiratory disease.** *Thorax* 2008, **63:**16.
23. Nygaard E, Kårikstad V: *Prioriteringsveileder – Lungesykdommer (Prioritization guidelines – respiratory diseases)*. Oslo: Helsedirektoratet; 2008.
24. Nygaard E, Kårikstad V: *Prioriteringsveileder - Hjertemedisinske sykdommer (Prioritization guidelines – cardiac diseases)*. Oslo: Helsedirektoratet; 2009.
25. Snow V, Barry P, Fihn SD, Gibbons RJ, Owens DK, Williams SV, Weiss KB, Mottur-Pilson C: **Evaluation of primary care patients with chronic stable angina: guidelines from the American College of Physicians.** *Ann Intern Med* 2004, **141:**57–64.
26. Malm S, Schirmer H: **Hjertesak: riktigere prioritering av pasienter (Heart issue: more correct prioritization of patients).** *Fastlegenytt (2)* 2010, **0012:**3–6.
27. Erhardt L, Herlitz J, Bossaert L, Halinen M, Keltai M, Koster R, Marcassa C, Quinn T, van Weert H: **Task force on the management of chest pain.** *Eur Heart J* 2002, **23:**1153–1176.
28. Sjetne IS, Bjertnæs ØA, Iversen HH, Olsen RV: *Pasienterfaringer i spesialisthelsetjenesten. Et generisk, kort spørreskjema (Patient experiences in specialist health care: A short generic questionnaire)*. Oslo: Norwegian Knowledge Centre for the Health Services; 2009.
29. Skudal KE, Bjertnæs ØA, Holmboe O, Bukholm G, Rottingen JA: *The 2010 Commonwealth Fund survey: Results from a comparative population survey in 11 countries*. Oslo: Norwegian Knowledge Centre for the Health Services; 2010.
30. Parry C, Mahoney E, Chalmers SA, Coleman EA: **Assessing the quality of transitional care: further applications of the care transitions measure.** *Med Care* 2008, **46:**317–322.
31. Bennett K, Haggard M, Churchill R, Wood S: **Improving referrals for glue ear from primary care: are multiple interventions better than one alone?** *J Health Serv Res Policy* 2001, **6:**139–144.
32. Marshall MN, Shekelle PG, McGlynn EA, Campbell S, Brook RH, Roland MO: **Can health care quality indicators be transferred between countries?** *Qual Saf Health Care* 2003, **12:**8–12.
33. Ashton CM, Kuykendall DH, Johnson ML, Wray NP: **An empirical assessment of the validity of explicit and implicit process-of-care criteria for quality assessment.** *Med Care* 1999, **37:**798–808.

34. Ashton CM, Kuykendall DH, Johnson ML, Wun CC, Wray NP, Carr MJ, Slater CH, Wu L, Bush GR: **A method of developing and weighting explicit process of care criteria for quality assessment.** *Med Care* 1994, **32:**755–770.
35. Lyons TF, Payne BC: **The use of item importance weights in assessing physician performance with predetermined criteria indices.** *Med Care* 1975, **13:**432–439.
36. Eldridge S, Kerry S: *A Practical Guide to Cluster Randomised Trials in Health Services Research*. Chichester, UK: John Wiley & Sons, Ltd; 2012.
37. Smeeth L, Ng ES-W: **Intraclass correlation coefficients for cluster randomized trials in primary care: data from the MRC Trial of the Assessment and Management of Older People in the Community.** *Control Clin Trials* 2002, **23:**409–421.
38. Cosby RH, Howard M, Kaczorowski J, Willan AR, Sellors JW: **Randomizing patients by family practice: sample size estimation, intracluster correlation and data analysis.** *Fam Pract* 2003, **20:**77–82.
39. Adams G, Gulliford MC, Ukoumunne OC, Eldridge S, Chinn S, Campbell MJ: **Patterns of intra-cluster correlation from primary care research to inform study design and analysis.** *J Clin Epidemiol* 2004, **57:**785–794.
40. Medical Research Council: *Cluster Randomised Trials: Methodological and Ethical Considerations*. London: Medical Research Council; 2002.
41. Hayes JH, Moulton LH: *Cluster Randomised Trials*. Boca Raton: Chapham & Hall/CRC; 2009.
42. Ukoumunne OC, Gulliford MC, Chinn S, Sterne JA, Burney PG: **Methods for evaluating area-wide and organisation-based interventions in health and health care: a systematic review.** *Health Technol Assess* 1999, **3:**92.
43. Campbell MK, Elbourne DR, Altman DG: **CONSORT statement: extension to cluster randomised trials.** *BMJ* 2004, **328:**702–708.
44. Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW: **The incidence and severity of adverse events affecting patients after discharge from the hospital.** *Ann Intern Med* 2003, **138:**161–167.
45. Richard IC, Marta R, David DW: **Gaps in the continuity of care and progress on patient safety.** *BMJ* 2000, **320:**791–794.
46. Newton J, Eccles M, Hutchinson A: **Communication between general practitioners and consultants: what should their letters contain?** *BMJ* 1992, **304:**821–824.
47. Hartveit M, Biringer E, Vanhaecht K, Haug K, Aslaksen A: **The Western Norway mental health interface study: a controlled intervention trial on referral letters between Primary Care and Specialist Mental Health Care.** *BMC Psychiatry* 2011, **11:**177.
48. Faulkner A, Mills N, Bainton D, Baxter K, Kinnersley P, Peters TJ, Sharp D: **A systematic review of the effect of primary care-based service innovations on quality and patterns of referral to specialist secondary care.** *Br J Gen Pract* 2003, **53:**878–884.
49. Augestad K, Revhaug A, Vonen B, Johnsen R, Lindsetmo RO: **The one-stop trial: does electronic referral and booking by the general practitioner (GPs) to outpatient day case surgery reduce waiting time and costs? A randomized controlled trial protocol.** *BMC Surgery* 2008, **8:**14.
50. Coulter A, Noone A, Goldacre M: **General practitioners' referrals to specialist outpatient clinics. I. Why general practitioners refer patients to specialist outpatient clinics.** *BMJ* 1989, **299:**304–306.

doi:10.1186/1745-6215-14-7
Cite this article as: Wåhlberg *et al.*: Practical health co-operation - the impact of a referral template on quality of care and health care co-operation: study protocol for a cluster randomized controlled trial. *Trials* 2013 **14**:7.

Dyspepsi henvisningsmal

I tillegg til standard informasjon i henvisning ønskes tilleggsinformasjon om følgende:

- dysfagi
- odynofagi
- anoreksi
- vekttap
- hematemese
- melena
- oppkast
- medikamenter (spes. NSAID, Albyl E, bisfosfonater)
- nattlige symptomer
- symptomvarighet
- tidligere ulcus
- tidligere operasjoner i øvre GI traktus
- ikterus
- cervical glandelsvulst
- hepatomegali
- anemi
- hvis <50 år – HP (Helicobacter pylori) status

Mistanke om ca coli henvisningsmal

I tillegg til standard informasjon i henvisning ønskes tilleggsinformasjon om følgende:

- endring i avføringsmønster
- blod i avføring
- vekttap
- familiær opphopning av ca. coli
- tidligere påvist tarmsykdom eller funn ved tidligere tarmundersøkelser
- funn ved rektal eksplorasjon
- jernmangelanemi
- funn ved us. av abdomen
- resultat av Hemo-fec
- allmennleges kliniske mistanke

Brystsmerte henvisningsmal

I tillegg til standard informasjon i henvisning ønskes tilleggsinformasjon om følgende:

- familieanamnese (plutselig død eller prematur koronarsykdom hos førstegradsslektninger)
- koronare risikofaktorer (røyking, fedme (BMI), diabetes, hypertensjon, hyperkolesterolemi)
- komorbiditet (perifer karsykdom, cerebrovaskulær sykdom, nyresvikt)
- brystsmerte (lokalisasjon, varighet, utstråling, effekt av aktivitet, effekt av nitro)
- dyspné (utløsende årsak, progresjon, hviledyspné)
- synkope (hvis ja – detaljer rundt omstendigheter)
- hjertebank
- symptomprogresjon
- funksjonsnivå (se Canadian Cardiovascular Society angina grading scale)
- allmennlegens kliniske vurdering/mistanke
- undersøkelse (BT/puls, halsvenestase, auskultasjon cor/pulm, ømhet thorax, perifere ødemer)
- EKG
- blodprøver (inkludert Hb, kreatinin, LDL kolesterol)

KOLS henvisningsmal

I tillegg til standard informasjon i henvisning ønskes tilleggsinformasjon om følgende:

- hovedplager (inkl. varighet, grad, dynamikk)
- dyspnoe (i hvile, ved anstrengelser osv)
- hoste
- slimproduksjon
- residiverende behandlingstrengende infeksjoner
- reaksjon på irritanter (kulde, værforandring ovs)
- funksjonsnivå i hverdagen
- hemoptyse
- vekttap (mengde, over hvor lang tid)
- stabil klinisk situasjon, eller akutt forverring
- røykestatus/røyekanamnese
- behandling forsøkt, effekt?
- komorbiditet og oppdater medikamentliste (inkl. inhalasjonsmedisiner)
- spirometri verdier
- RTG Thorax beskrivelse hvis tilgjengelig

UNIVERSITETSSYKEHUSET NORD-NORGE
DAVVI-NORGGA UNIVERSITEHTABUOHCCEVIESSU

Hvilke erfaringer hadde du på medisinsk poliklinikk UNN Harstad?

Ettersom du nylig har vært til time ved poliklinikken medisinsk avdeling UNN Harstad (Harstad Sykehus) spør vi deg med dette om du vil besvare dette spørreskjemaet. Spørsmålene handler om dine opplevelser på poliklinikken, og din opplevelse av samhandlingen mellom din fastlege og sykehuset. Svarene vil bli brukt i et forskningsprosjekt om samarbeidet mellom fastlege og sykehuset. Det er helt frivillig og svare, og svarene vil bli behandlet anonymt.

Vennligst sett kryss i den boksen som tydeligst tilsvarer din mening:

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt
1	Snakket behandlerne til deg slik at du forsto dem?	☐	☐	☐	☐	☐	☐
2	Har du tillit til behandlernes faglige dyktighet?	☐	☐	☐	☐	☐	☐
3	Fikk du vite det du syntes var nødvendig om hvordan prøver, tester og undersøkelser skulle foregå?	☐	☐	☐	☐	☐	☐
4	Fikk du tilstrekkelig informasjon om din diagnose/dine plager?	☐	☐	☐	☐	☐	☐
5	Opplevde du at behandlingen var tilpasset din situasjon?	☐	☐	☐	☐	☐	☐
6	Var du involvert i avgjørelser som angikk din behandling?	☐	☐	☐	☐	☐	☐
7	Opplevde du at institusjonens arbeid var godt organisert?	☐	☐	☐	☐	☐	☐
8	Fikk du inntrykk av at institusjonens utstyr var i god stand?	☐	☐	☐	☐	☐	☐
9	Var hjelpen og behandling du fikk på institusjonen, alt i alt, tilfredstillende?	☐	☐	☐	☐	☐	☐
10	Mener du at du på noen måte ble feilbehandlet (etter det du selv kan bedømme?)	☐	☐	☐	☐	☐	☐

		Nei	Ja, men ikke lenge	Ja, ganske lenge	Ja, altfor lenge
11	Måtte du vente for å få tilbud (poliklinisk time) ved institusjonen?	☐	☐	☐	☐

		Ikke noe utbytte	Lite utbytte	En del utbytte	Stort utbytte	Svært stort utbytte	Ikke aktuelt
12	Hvilket utbytte har du hatt, alt i alt, av behandlingen ved institusjonen?	☐	☐	☐	☐	☐	☐

UNIVERSITETSSYKEHUSET NORD-NORGE
DAVVI-NORGGA UNIVERSITEHTABUOHCCEVIESSU

		Ja	Nei
13	Opplevde du at sykehuset manglet viktig informasjon om deg fra fastlegen? (årsaken til at du var henvist, prøveresultater eller annet)	☐	☐

		Ja	Nei	Har ikke vært hos fastlegen etterpå
14	Etter at du hadde vært på sykehuset, opplevde du at fastlegen manglet viktig informasjon om helsehjelpen du fikk?	☐	☐	☐

		Ja	Nei
15	Synes du at henvisning til poliklinikken var nødvendig? (etter det du selv kan bedømme)	☐	☐

		Ja	Nei
16a	Ble du henvist fra din fastlege til den aktuelle polikliniske timen?	☐	☐

		Fastlege vikar	Annen lege på fastlegens kontor	Legevakts-lege	Annen lege
16b	Hvis Nei i spørsmål 16a; hvem henviste deg?	☐	☐	☐	☐

		Mye dårligere enn forventet	Noe dårligere enn forventet	Som forventet	Noe bedre enn forventet	Mye bedre enn forventet	Ikke aktuelt
17	Hvis du ser behandlingen ved institusjonen under ett, hvordan vil du vurdere institusjonen?	☐	☐	☐	☐	☐	☐

Bakgrunnsopplysninger

		Pasient selv	Pårørende
18a	Hvem har fylt ut skjemaet?	☐	☐

		Fylt ut skjemaet basert på egne vurdering (uten å snakke med pasienten)	Jeg fylte ut skjemaet for pasienten, men svarene er stort sett basert på pasientens vurderinger	Annet
18b	Hvis det er pårørende som har fylt ut skjemaet, hvordan er dette gjort?	☐	☐	☐

UNIVERSITETSSYKEHUSET NORD-NORGE
DAVVI-NORGGA UNIVERSITEHTABUOHCCEVIESSU

		Dårlig	Nokså god	God	Meget god	Utmerket
19	Stort sett, vil du si at din helse er	☐	☐	☐	☐	☐

		Mann	Kvinne
20	Er du mann eller kvinne?	☐	☐

		Årstall
21	Hvilket år er du født?	☐

		Grunnskole	Videregående skole	Høyskole eller universitet (1-4 år)	Høyskole eller universitet (4 år eller mer)
22	Hva er din høyeste fullførte utdanning?	☐	☐	☐	☐

		0-10 km	11-50km	51-100 km	over 100 km
23	Hvor langt fra sykehuset bor du?	☐	☐	☐	☐

		Ja	Nei
24a	Er det noe du synes er viktig, og som du ikke er blitt spurt om i dette skjemaet?	☐	☐

24b Hvis Ja i 24a, vil vi gjerne vite hva du synes mangler. Skriv kort i boksen under

Pasient nr:

Samhandling i praksis – en randomisert kontrollert intervensjonsstudie

Indikatorer for kvalitet i behandling av pasienter henvist med dyspepsi[1-11]

Ved spørsmål kontakt:
Henrik Wåhlberg
93 80 42 40
77 01 52 59
henrik.wahlberg2@unn.no

Vennligst fyll ut følgende:

- Del I
  - 1.1 – *"Utredning":* Fylles ut på hver pasient
  - 1.2 – *"Felles elementer"* i behandling: Fylles ut på hver pasient
  - 1.3 – 1.8 – Fra *"Behandling av gastroøsofagal refluks"* til og med *"Okkult blødning"* fylles relevant subseksjon ut for pasienten ut i fra diagnose
  - 1.9 – *"Generelle indikatorer"*: Fylles ut på hver pasient

- Del II – Fylles ut på hver pasient

Del I – Kvalitetsindikatorsett

Angi kriterium som ”ikke oppfylt” hvis det er relevant, men informasjon ikke kan lokaliseres.

Nr	Indikator	Oppfylt	Ikke oppfylt	Ikke relevant
1.1 – Utredning				
1	Diagnose fastlagt i første kontakt, alternativt videre utredningsforløp planlagt			
2	Videre oppfølging planlagt eller ansvaret for dette tydelig overlatt til fastlege/annen instans			
3	Pasienter >50 år eller yngre med alarm symptomer* fått helsehjelp innen 6 uker fra henvisningsdato			
4	Burde denne pasienten, basert på henvisningen, fått ’rett til helsehjelp’ i henhold til prioriteringsveileder (oppfylt = ja, ikke oppfylt = nei)			
5	Gastroskopi kun utført hvis: • > 50 år • < 50 år og H. pylori positiv *eller* anemi *eller* NSAID bruk i anamnesen • andre pasienter som ikke responderer på PPI eller har tilbakefall av symptomer etter adekvat medikamentelt forsøk			
6	Ved gastroskopi dokumentert informasjon til pasient om prosedyre og samtykke			
7	Dokumentert anamnese om alarmsymptomer*			
8	Dokumentert anamnese om NSAID bruk			
1.2 – Felles elementer i behandling				
9	Livsstilsråd, så som sunne matvaner, røykeslutt, vektnedgang dokumentert gitt			
10	Råd om å unngå utløsende faktorer, som stress, posisjon og lignende, dokumentert gitt			
11	For pasienter med langtidsbehandling råd om bruk av laveste effektive dose, intermitterende dosering (ved behov) og håndkjøpsprodukter gitt			

1.3 – Behandling av gastroøsofagal refluks				
12	Ved typisk anamnese eller gastroskopi funn, full dose PPI i 1-2 måneder tilbudt, med plan om revurdering effekt og videre behandling etter dette			
13	Ved symptom residiv laveste dose som kontrollerer symptomer tilbudt			
14	pH måling vurdert ved dårlig effekt av medikamentell behandling, inkludert dobbel dose PPI			
15	Henvisning til kirurgi vurdert kun ved uttalte plager på tross av maksimal medikamentell behandling			
1.4 – Behandling av peptiske sår				
16	Test for H. pylori utført			
17	Hvis H. pylori positiv tilbudt/anbefalt eradikasjon			
18	Hvis NSAID assosiert, tilby full dose PPI i to måneder, deretter eradikere H. pylori hvis til stede			
19	Hvis ulcus i ventrikkel (magesekk) og positiv H. pylori, planlagt retesting for H. pylori og regastroskopi 6-8 uker etter behandlingsstart			
20	Tilby full dose PPI i 1-2 måneder til H. pylori negative pasienter som ikke bruker NSAID			
21	For pasienter som bruker NSAID videre etter peptisk sykdom, dose reduksjon av NSAID *eller* substitusjon *eller* ved behovs behandling vurdert.			
22	Hos høy risiko pasienter (tidligere sår) som trenger videre NSAID, tilby beskyttende behandling (PPI eller H2)			
23	Hos pasienter med ulcus som ikke tilheler vurder non-compliance, malignitet, falsk negativ H. pylori test, utilsiktet NSAID bruk og uvanlige sykdommer som Chron og Zollinger-Ellison			
1.5 – Behandling av endoskopi verifisert non-ulcus dyspepsi				
24	Test for H. pylori utført			
25	Hvis H. pylori positiv, dokumentert at eradikasjon vurdert			

26	Ikke planlagt eller utført retesting etter eradikasjonsbehandling			
27	Forsøkt behandling med lav dose PPI eller H2 blokker i 1 måned			
28	Ved vedvarende symptomer lavdose PPI/H2 blokker, alternativt behandling med dette ved behov tilbudt			
1.6 – Behandling av Barrets øsofagus/mistanke om Barrets øsofagus				
29	Funn klassifisert etter Prague klassifisering (CM)			
30	Anbefalinger om biopsering fulgt, eller dokumentert grunn til annen biopseringsstrategi - ingen kjent dysplasi: 4 kvadrant biopsier hver andre centimeter + biopsier fra suspekte områder - kjent dysplasi: 4 kvadrant biopsier hver centimeter + biopsier fra suspekte områder)			
31	Pasient satt opp til kontroll - om 3 år hvis ingen dysplasi - om 6-12 måneder ved lavgradig dysplasi - 3 måneder ved ubehandlet høygradig dysplasi			
32	Ved funn av høygradig dysplasi videre behandling planlagt			
33	Hvis symptomer eller refluks øsofagitt full dose PPI i 1-2 måneder tilbudt			
34	Dokumentert diskusjon om indikasjon for langvarig PPI bruk			
1.7 – Cøliaki				
35	Diagnosen sikret med duodenalbiopsier *eller* dokumentasjon på hvorfor dette ikke er utført			
36	Dokumentert informasjon om blodprøvestatus med tanke på ernæring (ferritin, vitamin B12, folat osv)			
37	Gitt råd om glutenfritt kosthold og henvist til kostveiledning			
38	Informasjon gitt om pasientorganisasjon (NCF)			
39	Plan for videre oppfølging klarlagt			

1.8 – Okkult GI blødning				
40	Koloskopi vurdert ved positiv Hemo-fec *eller* jern-mangel anemi *og* normale funn ved gastroskopi			
41	Ved okkult blødning og ingen forklarende funn ved gastro- og koloskopi fornyet endoskopisk undersøkelse *eller* henvisning til kapsel endoskopi vurdert			
42	Tynntarmsbiopsier med tanke på cøliaki tatt			
1.9 – Generelle indikatorer				
43	Totalt sett et adekvat behandlingsforløp (helt fra henvisning til avsluttet behandling)			
44	Sett en total score for behandlingsforløpet fra 1-10 (1: dårlig forløp – 10: svært godt forløp)	1 2 3 4 5 6 7 8 9 10		

* Alarmsymptomer
- vekttap
- progredierende dysfagi
- odynofagi
- gjentatte oppkast
- tegn på GI blødning
- familie anamnese på cancer
- ikterus
- palpabel tumor
- tidligere ulcus
- >50 år med nye symptomer
- tidligere øsofagogastrisk kreft

Del II - "Positiv prediktiv verdi" av henvisning [12]

Har helsehjelpen i spesialisthelsetjenesten ført til

	Ja	Nei
a) en histologisk diagnose		
b) diagnostisk avklaring		
c) endring i behandling		

Reference List

1. *Dyspepsia: Managing Dyspepsia in Adults in Primary Care.* Newcastle upon Tyne; 2004.

2. **American Gastroenterological Association Medical Position Statement: Evaluation of Dyspepsia.** *Gastroenterology* 2005, **129:**1753-1756.

3. Talley NJ, Vakil N: **Guidelines for the management of dyspepsia.** *Am J Gastroenterol* 2005, **100:**2324-2337.

4. **Riktlinjer handläggning av gastroesofageal refluxsjukdom.** 2008. Svensk Gastroenterologisk Förening.

5. Valle PC, Breckan RK, Amin A, Kristiansen MG, Husebye E, Nordgard K, Mortensen L, Kildahl-Andersen OA, Wessel-Berg AM: **"Test, score and scope": a selection strategy for safe reduction of upper gastrointestinal endoscopies in young dyspeptic patients referred from primary care.** *Scand J Gastroenterol* 2006, **41:**161-169.

6. Longstreth GF: **Approach to the patient with dyspepsia.** In *UpToDate*. Edited by Edited by Basow DS. Waltham, MA: 2009.

7. **American Gastroenterological Association Medical Position Statement on the Management of Barrett's Esophagus.** *Gastroenterology* 2011, **140:**1084-1091.

8. Jones R, Hunt C, Stevens R, Dalrymple J, Driscoll R, Sleet S, Blanchard SJ: **Management of common gastrointestinal disorders: quality criteria based on patients' views and practice guidelines.** *Br J Gen Pract* 2009, **59:**e199-e208.

9. Ciclitira PJ, Dewar DH, McLaughlin SD, Sanders DS: *The Management of Adult with Coeliac Disease.* 2010.

10. Fisher L, Lee Krinsky M, Anderson MA, Appalaneni V, Banerjee S, Ben Menachem T, Cash BD, Decker GA, Fanelli RD, Friis C et al.: **The role of endoscopy in the management of obscure GI bleeding.** *Gastrointestinal Endoscopy* 2010, **72:**471-479.

11. Bull-Henry K, Al Kawas FH: **Evaluation of occult gastrointestinal bleeding.** *Am Fam Physician* 2013, **87:**430-436.

12. Bennett K, Haggard M, Churchill R, Wood S: **Improving referrals for glue ear from primary care: are multiple interventions better than one alone?** *J Health Serv Res Policy* 2001, **6:**139-144.

Pasient nr:

Samhandling i praksis – en randomisert kontrollert intervensjonsstudie

Indikatorer for kvalitet i behandling av pasienter henvist med mistanke ca. coli [1-7]:

Ved spørsmål kontakt:
Henrik Wåhlberg
93 80 42 40
77 01 52 59
henrik.wahlberg2@unn.no

Del I – Kvalitetsindikatorsett

Angi kriterium som ”ikke oppfylt” hvis det er relevant, men informasjon ikke kan lokaliseres.

Nr	Indikator	Oppfylt	Ikke oppfylt	Ikke relevant
Generelle indikatorer i utredning				
1	Diagnose fastlagt i første kontakt på sykehus, alternativt videre utredningsforløp planlagt			
2	Videre oppfølging planlagt eller kontakt avsluttet, eller ansvaret for dette tydelig overlatt til fastlege/annen instans			
3	Pasient vurdert innen vurderingsfrister som angitt under: - uforklart endring i avføringsmønster o pas. >55 år: 4 uker o pas. 45-55 år: 6 uker o pas. <45 år: ikke rett til helsehjelp - GI blødning uten anemi o > 40 år: 4 uker o <40 år og lav klinisk risiko for malignitet: 6 uker - synlig GI blødning med jernmangelanemi o >40 år: 2 uker o <40 år og lav klinisk risiko for malignitet: 4 uker - klinisk signifikant ikke forklart vekttap o alder >40 år: 2 uker o alder< 40 og lav klinisk risiko for malignitet: 4 uker			
4	Burde denne pasienten, basert på henvisningen, fått ’rett til helsehjelp’ i henhold til prioriteringsveileder (oppfylt = ja, ikke oppfylt = nei)			
Pre-prosedyre				
5	Koloskopi kun utført når det foreligger indikasjon (se vedlegg 1 ved usikkerhet)			
6	Informasjon til pasient om undersøkelse og informert samtykke dokumentert i journal			
7	Risikofaktorer for undersøkelsen vurdert (for eksempel antikoagulantia, platehemmere, sedasjonsbehov)			

8	Dokumentasjon i journal av tilstedeværelse, eller ikke, av symptomer tydende på cancer coli (3 av 5) - magesmerter - endring i avføringsvaner - hematochezia eller melena - asteni - vekttap			
9	Dokumentasjon i journal av familiær opphopning av ca. coli eller ikke			
10	Dokumentasjon i journal om tidligere tarmsykdommer			
11	Dokumentasjon av anemi (tatt, eller fått fra henvisende lege, Hb, MCV, MCH, ferritin)			
Prosedyre				
12	Kvalitet av tarmtømming vurdert og dokumentert			
13	Intubasjon av coecum dokumentert (fullstendig us.)			
14	Retraksjonstid dokumentert			
15	Ukomplisert prosedyre (ingen akutte komplikasjoner som krever intervensjon)			
Lesjon dokumentasjon				
16	Ved funn beskrivelse av funn, med mål, overflate, type lesjon			
Post-prosedyre				
17	Ved ikke komplett koloskopi, planlagt enten - ny koloskopi etter bedre tømming *eller* - røntgen undersøkelse av tarm			
18	Ved signifikante biopsifunn, resultatet fulgt opp av ansvarlig lege (tiltak satt i verk ved indikasjon, enten ved konsultasjon eller i etterkant)			
19	Ved funn av klinisk mistenkt malignitet pasient umiddelbart henvist til kirurgisk vurdering, *eller* dokumentert i journal konsultasjon med kirurg			
20	Ved histologisk funn av malignitet (uten oppfylt kriterium 21) videre tilleggsbehandling planlagt innen 2 dager			

21	Ved funn av polypp *og ikke polyppfri tarm* videre kontroller planlagt etter nasjonale retningslinjer angitt under ***eller*** annet avvikende kontroll opplegg planlagt med dokumentert begrunnelse for avvik[8] - infiltrerende cancer – umiddelbar tilleggsbehandling - høygradig intraepitelial neoplasi/carcinoma in situ – kontroll innen 3 måneder - lavgradig intrepitelial – individuell vurdering			

22	Ved funn av polypp *og vurdert til å foreligge polyppfri tarm*; videre kontroll planlagt etter nasjonale retningslinjer angitt under ***eller*** annet avvikende kontroll opplegg planlagt med dokumentert begrunnelse for avvik[8]
	- malign stilket slyngeresecert polypp fjernet med sikker fri margin endoskopisk og histologisk – kontroll hver 6 måned i 3 år
	- malign slyngeresecert bredbaset polypp fjernet med sikker fri margin
	  o infiltrasjon øvre lag submucosa og fjernet in toto – kontroll ved 6 måned
	  o dypere infiltrasjon eller fjernet i biter – henvise for colonreseksjon
	- 1-2 små, fjernede adenomer (<1 cm) uten grov dysplasi eller tubulovilløse elementer – ingen endoskopikontroll
	- >2 fjernede adenomer – kontroll om 5 år
	- 1-2 store, fjernede adenomer (>9 mm) eller tubulovilløse/villøse elementer – kan gis kontroll om 5 eller 10 år
	- kontroll fortsetter til 70-75 års alder, avhengig av allmenntilstand og komorbiditet			

Generelle indikatorer				
23	Totalt sett et adekvat behandlingsforløp (helt fra henvisning til avsluttet behandling)			
24	Sett en total score for behandlingsforløpet fra 1-10 (1: dårlig forløp – 10: svært godt forløp)	1 2 3 4 5 6 7 8 9 10		

Del II - ”Positiv prediktiv verdi” av henvisning [9]

Har helsehjelpen i spesialisthelsetjenesten ført til

	Ja	Nei
a) en histologisk diagnose		
b) diagnostisk avklaring		
c) endring i behandling		

Vedlegg 1: Indikasjon for koloskopi kan faststilles basert på European Panel on the Appropriateness of Gastrointestinal Endoscopy (www.epgae.ch) eller i henhold til kriterier fra American Society for Gastrointestinal Endoscopy [10] redegjort under:

Colonoscopy is generally indicated in the following circumstances

A. Evaluation of an abnormality on barium enema or other imaging study that is likely to be clinically significant, such as a filling defect and stricture

B. Evaluation of unexplained GI bleeding:

    1. Hematochezia
    2. Melena after an upper GI source has been excluded
    3. Presence of faecal occult blood

C. Unexplained iron deficiency anaemia

D. Screening and surveillance for colonic neoplasia
    1. Screening of asymptomatic, average-risk patients for colonic neoplasia
    2. Examination to evaluate the entire colon for synchronous cancer or neoplastic polyps in a patient with treatable cancer or neoplastic polyps
    3. Colonoscopy to remove synchronous neoplastic lesion at or around the time of curative resection of cancer followed by colonoscopy at 1 year and, if normal, then 3 years, and, if normal, then 5 years thereafter to detect metachronous cancer (i Norge kontroll etter 5 år – i henhold til Norsk Gastro Intestinal Cancer Gruppe)
    4. Surveillance of patients with neoplastic polyps
    5. Surveillance of patients with a significant family history of colorectal neoplasia

E. For dysplasia and cancer surveillance in select patients with long-standing ulcerative or Crohn's colitis. For evaluation of patients with chronic inflammatory bowel disease of the colon, if more precise diagnosis or determination of the extent of activity of disease will influence management

F. Clinically significant diarrhoea of unexplained origin

G. Intraoperative identification of a lesion not apparent at surgery (eg. polypectomy site, location of a bleeding site)

H. Treatment of bleeding from such lesions as vascular malformation, ulceration, neoplasia and polypectomy site

I. Intraoperative evaluation of anastomotic reconstructions typical of surgery to treat diseases of the colon and rectum (eg. evaluation of anastomotic leak and patency, bleeding, pouch formation)

J. As an adjunct to minimally invasive surgery for the treatment of diseases of the colon and rectum

K. Management or evaluation of operative complications (eg. dilation of anastomotic strictures)

L. Foreign body removal

M. Excision or ablation of lesions

N. Decompression of acute megacolon or sigmoid volvulus

O. Balloon dilation of stenotic lesions (eg. anastomotic strictures)

P. Palliative treatment of stenosing or bleeding neoplasms (eg. laser, electrocoagulation, stenting)

Q. Marking a neoplasm for localization

Colonoscopy is generally not indicated in the following circumstances

A. Chronic, stable, irritable bowel syndrome or chronic abdominal pain; there are unusual exceptions in which colonoscopy may be done once to rule out disease, especially if symptoms are unresponsive to therapy

B. Acute diarrhoea

C. Metastatic adenocarcinoma of unknown primary site in the absence of colonic signs or symptoms when it will not influence management

D. Routine follow-up of inflammatory bowel disease (except for cancer surveillance in chronic ulcerative colitis and Crohn's colitis)

E. GI bleeding or melena with a demonstrated upper GI source

Colonoscopy is generally contraindicated in:

A. Fulminant colitis

B. Documented acute diverticulitis

Reference List

1. Nygaard E KV: *Prioriteringsveileder - Fordøyelsessykdommer.* Oslo: Helsedirektoratet; 2009.

2. Bourke MJ: **Making every colonoscopy count: Ensuring quality in endoscopy.** *J Gastroenterol Hepatol* 2009, **24 Suppl 3:**S43-S50.

3. Sharma VK, Nguyen CC, Crowell MD, Lieberman DA, de GP, Fleischer DE: **A national study of cardiopulmonary unplanned events after GI endoscopy.** *Gastrointest Endosc* 2007, **66:**27-34.

4. Enns R: **Quality indicators in colonoscopy.** *Can J Gastroenterol* 2007, **21:**277-279.

5. Froehlich F, Wietlisbach V, Gonvers JJ, Burnand B, Vader JP: **Impact of colonic cleansing on quality and diagnostic yield of colonoscopy: the European Panel of Appropriateness of Gastrointestinal Endoscopy European multicenter study.** *Gastrointest Endosc* 2005, **61:**378-384.

6. Patwardhan M, Fisher DA, Mantyh CR, McCrory DC, Morse MA, Prosnitz RG, Cline K, Samsa GP: **Assessing the quality of colorectal cancer care: do we have appropriate quality measures? (A systematic review of literature).** *J Eval Clin Pract* 2007, **13:**831-845.

7. Ahnen DJ, Macrae FA: **Clinical manifestations, diagnosis, and staging of colorectal cancer.** In *UpToDate*. Edited by Edited by Basow DS. Waltham, MA: 2010.

8. Hofstad B, Andersen SN, Nesbakken A: **Kolorektale polypper.** *Tidskr Nor Lægeforen* 2007, **127:**2692-2695.

9. Bennett K, Haggard M, Churchill R, Wood S: **Improving referrals for glue ear from primary care: are multiple interventions better than one alone?** *J Health Serv Res Policy* 2001, **6:**139-144.

10. Early DS, Ben Menachem T, Decker GA, Evans JA, Fanelli RD, Fisher DA, Fukami N, Hwang JH, Jain R, Jue TL et al.: **Appropriate use of GI endoscopy.** *Gastrointestinal Endoscopy* 2012, **75:**1127-1131.

Pasient nr:

Samhandling i praksis – en randomisert kontrollert intervensjonsstudie

Indikatorer for kvalitet i behandling av pasienter henvist med brystsmerter[1-8]:

Ved spørsmål kontakt:
Henrik Wåhlberg
93 80 42 40
77 01 52 59
henrik.wahlberg2@unn.no

Del I – Kvalitetsindikatorsett

Angi kriterium som ”ikke oppfylt” hvis det er relevant, men informasjon ikke kan lokaliseres.

Nr	Indikator	Oppfylt	Ikke oppfylt	Ikke relevant
Generelle indikatorer i utredning				
1	Røykestatus kartlagt og dokumentert			
2	Risk score – NORRISK /risikofaktorer dokumentert: røyking, diabetes, hypertensjon, hyperkolesterolemi, familie anamnese (kjent koronar arterie sykdom), overvekt, fysisk inaktivitet, kjønn, alder			
3	Dokumentert anamnese om brystsmerte - symptomer: frekvens, varighet, utstråling, styrke, kvalitet, lokalisasjon, forverrende/forbedrende faktorer - progresjon, hvilesmerter - fysisk kapasitet - assosierte symptomer - effekt av nitroglycerin hvis dette er forsøkt			
4	Dokumentert andre komorbiditeter *eller* angitt som tidligere frisk (eks nyresvikt, depresjon osv)			
5	Dokumentert klinisk undersøkelse inkludert BT, puls, cor, pulm og thorax			
6	EKG utført og tolkning dokumentert			
7	Dokumentert Hb status			
8	Dokumentert kolesterol nivå			
9	Ved indikasjon TSH/T4 dokumentert			
10	A-EKG utført hvis indikasjon			
11	A-EKG ikke utført hvis ikke indikasjon			
12	Hvis A-EKG indisert men gjennomført med suboptimal belastning, videre utredning utført *eller* planlagt			
13	Hvis a-EKG er indisert med ikke kan gjennomføres videre utredning utført *eller* planlagt			

14	Diagnose fastlagt i første kontakt, alternativt videre utredningsforløp planlagt			
15	Videre oppfølging planlagt *eller* avsluttet, *eller* ansvaret for dette tydelig overlatt til fastlege/annen instans			
16	Burde denne pasienten, basert på henvisningen, fått 'rett til helsehjelp' i henhold til prioriteringsveileder (oppfylt = ja, ikke oppfylt = nei)			
Felles elementer i behandling				
17	Hvis røyker gitt råd om røykeslutt			
18	Hvis overvektig råd om vektreduksjon			
19	Informasjon om øvrig risiko modifikasjon (hypertensjon, lipider, fysisk aktivitet, diet)			
20	Ekkokardiografi utført/henvist til ekkokardiografi hvis indikasjon (tidligere hjerteinfarkt, tegn til/mistanke om hjertesvikt, Q-bølger i EKG, bilyd, ventrikulære arytmier)			
21	Hos pasienter med diabetes mellitus utført vurdering av glycemisk kontroll (primært ved hjelp av HbA1c)			
Behandling ved mistanke om koronar iskemisk sykdom				
22	Pasient innlagt hvis mistanke om akutt koronart syndrom (AKS)			
23	Henvisning til koronar angiografi vurdert, eventuelt på bakgrunn av risikovurdering			
24	Hvis henvisning til koronar angiografi vurdert, er pasientens ønsker om egen behandling dokumentert			
25	Behandling med platehemmer igangsatt/kontinuert hvis ingen kontraindikasjon			
26	Behandling med kolesterolsenkende (statin) igangsatt/kontinuert hvis indikasjon og ingen kontraindikasjon			
27	Behandling med beta-blokker igangsatt/kontinuert hvis indikasjon og ingen kontraindikasjon			

28	Behandling med behovs nitroglycerin igangsatt/kontinuert hvis indikasjon og ingen kontraindikasjon			
29	Hvis klar indikasjon for betablokker behandling men også klar kontraindikasjon, behandling med kalsium blokker (verapamil *eller* diltiazem) vurdert			
30	Hvis behandling allerede igangsatt og vedvarende symptomer tillegg av langtidsvirkende nitrat vurdert			
31	Hvis hypertensjon under konsultasjon, behandling igangsatt *eller* videre utredning/kontroll planlagt			
32	Dokumentert informasjon til pasient om rekontakt med helsepersonell ved forverring av angina symptomer			
Behandling/vurdering ved tidligere kjent tilstedeværelse av koronar iskemisk sykdom				
33	Anamnese om endring i symptomer fra tidligere dokumentert			
34	Anamnese om effekt, bivirkninger og etterlevelse av behandling dokumentert			
35	Pasient innlagt hvis mistanke om AKS			
36	Behandling med platehemmer igangsatt/kontinuert hvis ingen kontraindikasjon			
37	Behandling med kolesterolsenkende (statin) igangsatt/kontinuert hvis indikasjon og ingen kontraindikasjon			
38	Hvis pasient allerede er under behandling med kolesterolsenkende (statin), behandlingseffekt vurdert ved hjelp av LDL og totalkolesterol			
39	Behandling med beta-blokker igangsatt/kontinuert hvis indikasjon og ingen kontraindikasjon			
40	Behandling med behovs nitroglycerin igangsatt/kontinuert hvis indikasjon og ingen kontraindikasjon			
41	Hvis klar indikasjon for betablokker behandling men også klar kontraindikasjon, behandling med kalsium blokker (verapamil *eller* diltiazem) vurdert			

42	Hvis behandling allerede igangsatt og vedvarende symptomer tillegg av langtidsvirkende nitrat vurdert			
43	Hvis hypertensjon under konsultasjon, behandling igangsatt *eller* videre utredning/kontroll planlagt			
44	Henvisning til koronar angiografi vurdert			
45	Hvis henvisning til koronar angiografi vurdert, er pasientens ønsker om egen behandling dokumentert			
Behandling/plan når ikke mistanke om koronar iskemisk sykdom				
46	Adekvat vurdering av årsak til smerter hvis ikke mistanke om koronar genese			
47	Ved thoraxmyalgier gitt informasjon om ufarlig tilstand *og/eller* ved vedvarende plager anbefalt smertelidring *og/eller* henvisning til fysioterapi			
48	Ved gastrointestinal årsak til symptomer vurdert indikasjon for gastroskopi/videre undersøkelse/behandling			
49	Ved mistanke om annen alvorlig årsak (respiratorisk, anemi, hyperthyroidisme osv) adekvat videre utredning/behandling dokumentert igangsatt			
Generelle indikatorer				
50	Totalt sett et adekvat behandlingsforløp *(eller en global score 1-10 for behandlingen?)*			
51	Sett en total score for behandlingsforløpet fra 1-10 (1: dårlig forløp – 10: svært godt forløp)	1 2 3 4 5 6 7 8 9 10		

Del II - ”Positiv prediktiv verdi” av henvisning[9]

Har helsehjelpen i spesialisthelsetjenesten ført til

	Ja	Nei
a) en histologisk diagnose		
b) diagnostisk avklaring		
c) endring i behandling		

Reference List

1. Erhardt L, Herlitz J, Bossaert L, Halinen M, Keltai M, Koster R *et al*.: **Task force on the management of chest pain.** *Eur Heart J* 2002, **23:** 1153-1176.

2. Kerr E.A ASMHEGMEA: **Coronary artery disease - diagnosis and screening.** In ***Quality of Care for Cardiopulmonary Conditions A Review of the Literature and Quality Indicators***. Santa Monica, CA: RAND; 2000:141-159.

3. Buetow SA, Coster GD: **New Zealand and United Kingdom experiences with the RAND modified Delphi approach to producing angina and heart failure criteria for quality assessment in general practice.** *Quality in Health Care* 2000, **9:** 222-231.

4. Campbell SM, Roland MO, Shekelle PG, Cantrill JA, Buetow SA, Cragg DK: **Development of review criteria for assessing the quality of management of stable angina, adult asthma, and non-insulin dependent diabetes mellitus in general practice.** *Quality in Health Care* 1999, **8:** 6-15.

5. Kerr E.A ASMHEGMEA: **Coronary artery disease - prevention and treatment.** In ***Quality of Care for Cardiopulmonary Conditions A Review of the Literature and Quality Indicators***. Santa Monica, CA: RAND; 2000:161-177.

6. Cooper A, Calvert N, Skinner J, Sawyer L, Sparrow K, Timmis A *et al*.: *Chest pain of recent onset: Assessment and diagnosis of recent onset chest pain or discomfort of suspected cardiac origin*. London: National Clinical Guideline Centre for Acute and Chronic Conditions (UK).; 2010.

7. Fihn SD, Gardin JM, Abrams J, Berra K, Blankenship JC, Dallas AP *et al*.: **2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons.** *Circulation* 2012, **126:** 3097-3137.

8. National Institute for Health and Care Excellence: *Stable Angina: full guideline (CG126)*. London: National Institute for Health and Care Excellence; 2011.

9. Bennett K, Haggard M, Churchill R, Wood S: **Improving referrals for glue ear from primary care: are multiple interventions better than one alone?** *J Health Serv Res Policy* 2001, **6:** 139-144.

Pasient nr:

Samhandling i praksis – en randomisert kontrollert intervensjonsstudie

Indikatorer for kvalitet i behandling av pasienter henvist med KOLS[1-9]:

Ved spørsmål kontakt:
Henrik Wåhlberg
93 80 42 40
77 01 52 59
henrik.wahlberg2@unn.no

Del I – Kvalitetsindikatorsett

Angi kriterium som "ikke oppfylt" hvis det er relevant, men informasjon ikke kan lokaliseres.

Nr	Indikator	Oppfylt	Ikke oppfylt	Ikke relevant
Generelle indikatorer i utredning				
1	Burde denne pasienten, basert på henvisningen, fått 'rett til helsehjelp' i henhold til prioriteringsveileder (oppfylt = ja, ikke oppfylt = nei)			
2	Diagnose fastlagt i første kontakt, alternativt videre utredningsforløp planlagt			
3	Videre oppfølging planlagt, eller ansvaret for dette tydelig overlatt til fastlege/annen instans			
Diagnose				
4	Røykeanamnese dokumentert i journal			
5	Anamnese om eksponering for andre lunge irritanter (f.eks. gjennom yrkesanamnese) dokumentert			
6	Anamnestisk vurdering av forverringsfrekvens og alvorlighetsgrad av forverringer dokumentert			
7	Dokumentasjon av funksjonsnivå			
8	Klinisk us. av lunger dokumentert			
9	Spirometri utført			
10	Måling av Hb, hematocrit (EVF), hvite, *og* arteriell blogass *eller* pulsoksimetri utført			
11	ABG utført *hvis* - hematocrit (EVF) >55, *eller* - dokumentert cyanose eller cor pulmonale, *eller* - FEV_1< 1 L, eller FEV1 <50%, *eller* - SaO2 <92% i stabil fase			
12	Kroppsmasseindeks (KMI) dokumentert			
13	RTG Thorax utført, hvis ikke utført nylig			
14	Dokumentasjon av komorbide faktorer (så som koronar sykdom, depresjon, osteoporose, lungekreft,			

	underernæring og muskel svakhet)			
15	Pasient klassifisert etter GOLD inndeling (stadium I-IV)			
16	Et verktøy for sammensatt vurdering av sykdomsalvorlighet brukt – for eksempel BODE			
Behandling i stabil fase				
17	Råd om røykeslutt eller henvisning for dette i løpet av 3 måneder etter diagnose/første kontakt			
18	Oppfølging av komorbiditet (koronar sykdom, osteoporose osv), eller henvisning for dette i løpet av 3 måneder etter diagnose/første kontakt			
19	Langtidsvirkende bronkodilatering hos alle med behandlingstrengende KOLS grad II eller høyere			
20	Behandling med inhalerte glukokortikoider hos de med FEV1<60% og gjentatte forverringer			
21	Ved foreskriving av inhalasjonmedisin utdanning i bruk av inhalator eller spacer dokumentert			
22	Compliance og teknikk med inhalasjoner dokumentert diskutert/kontrollert ved hver kontroll			
23	Ved bruk av forstøverbehandling effekt vurdert symptomatisk *og* behandling kun videreført hvis effekt			
24	Tillegg av theophyllin vurdert hvis annen behandling ikke fører til oppnådd behandlingsmål			
25	Ved gjentatte forverringer og FEV1<50% vurdert oppstart med roflumilast (Daxas)			
26	Ved >2 prednisolonkurer pr år forebyggende behandling mot osteoporose igangsatt, hvis ingen kontraindikasjon			
27	Kontinuerlig oksygenbehandling (LTOT) vurdert hvis - SaO2 i hvile <88% eller pO2 <7,3 kPa, i stabil fase - pO2 7,3-8,0 kPa og dokumenterte tegn til/kjent pulmonal hypertensjon, tegn til/kjent kongestiv hjertesvikt eller polycytemi,			

	vurdering utført med tanke på kontinuerlig oksygenbehandling (LTOT)			
28	Dokumentasjon av bruk av influensa vaksine			
29	Dokumentasjon av pneumokokkvaksine bruk/status hos de med KOLS og alder >65 år			
30	Ved KOLS grad ≥2 henvist til, *eller* vurdert henvist til, lungerehabilitering			
31	Ernæringsmessige tiltak startet ved KMI <21 kg/m^2 *eller* KMI 21-25 kg/m^2 og vekttap			
32	Pasient fått skriftlig plan for tiltak ved forverring (behandlingsplan)			
Behandling ved akutt forverrelse				
32	Dokumentasjon ved vurdering/innleggelse av følgende:			
33	Dokumentasjon ved vurdering/innleggelse av faste KOLS medisiner			
34	Informasjon om tidligere innleggelser og forverrelser, f. eks. alvorlighetsgrad og antall/år			
35	Dokumentasjon ved vurdering/innleggelse av tilstedeværelse eller fravær av nytilkommet hoste			
36	Dokumentasjon ved vurdering/innleggelse av vitale parametre: BT, RR, temp, puls, SaO2			
37	Dokumentasjon ved vurdering/innleggelse av somatisk lungeundersøkelse			
38	RTG Thorax tatt ved vurdering/innleggelse			
39	Arteriell blodgass tatt ved vurdering/innleggelse			
40	Ved tidligere koronar sykdom EKG i løpet av 24 timer etter innleggelse med akutt KOLS forverring			
41	Ved teofyllin behandling speil tatt ved innleggelse med forverring			
42	Tilbud om inhalasjonsbehandlig hvis RR >24			
43	Ved KOLS forverring tilførsel av O2 hvis SaO2			

	<88% eller pO2 <7,3 kPa			
44	Hvis poliklinisk vurdering tilby innleggelse hvis - akutt iskemi, eller - pneumoni, - signifikant nytilkommet hypoxemi, SaO2 <88% eller pO2 <7,3 kPa - alvorlig underliggende kols - arytmi - manglende effekt av initial behandling			
45	Monitorering (telemetri og pulse oximetri) ved innleggelse hvis - alvorlig dyspnoe (RR >35 og bruk av aksessorisk resp. muskler på tross av initial behandling) - forvirring eller "lethargy" - persisterende eller forverring av hypoxemi på tross av tilførsel av oksygen - alvorlig acidose (pH<7,3)			
46	Ved akutt forverring behandling med økt bronkodilatasjon igangsatt/vurdert			
47	Ved akutt forverring behandling med steroider igangsatt/vurdert			
48	Ved akutt forverring behandling med antibiotika igangsatt/vurdert			
49	Ved forverring antibiotika igangsatt ved - øket dyspnoe, øket ekspektorat og øket purulens av ekspektorat *eller* - forverring med 2 av 3 tegn over, så fremt øket purulens er et av tegnene *eller* - behov for mekanisk ventilasjon			
50	KOLS pasienter innlagt med forverring utskrevet/vurdert utskrevet med hjemme oksygen hvis siste SaO2 før utreise < 88%			
Generelle indikatorer				
51	Totalt sett et adekvat behandlingsforløp *(eller en global score 1-10 for behandlingen?)*			
52	Sett en total score for behandlingsforløpet fra 1-10 (1: dårlig forløp – 10: svært godt forløp)	1 2 3 4 5 6 7 8 9 10		

Del II - ”Positiv prediktiv verdi” av henvisning

Har helsehjelpen i spesialisthelsetjenesten ført til

	Ja	Nei
a) en histologisk diagnose		
b) diagnostisk avklaring		
c) endring i behandling		

Reference List

1. Rennard IS: **Chronic obstructive pulmonary disease: Definition, clinical manifestations, diagnosis, and staging.** In *UpToDate*. Edited by Basow DS. Waltham, MA: 2009.

2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of COPD. 2014. Global Initiative for Chronic Obstructive Lung Disease (GOLD). 23-5-2014. Ref Type: Report

3. Gulsvik A, Lund J, Austegard E, Henrichsen SH, Langhammer A, Refvem OK *et al*.. Kols. Nasjonal faglig retningslinje og veileder for forebygging, diagnostisering og oppfølging. IS-2029. 2012. Oslo, Helsedirektoratet. 22-5-0013. Ref Type: Report

4. Nygaard E KV: *Prioriteringsveileder - Lungesykdommer*. Oslo: Helsedirektoratet; 2008.

5. Kerr E.A ASMHEGMEA: **Chronic Obstructive Pulmonary Disease.** In *Quality of Care for Cardiopulmonary Conditions A Review of the Literature and Quality Indicators*. Santa Monica, CA: RAND; 2000:91-115.

6. Lindenauer PK, Pekow P, Gao S, Crawford AS, Gutierrez B, Benjamin EM: **Quality of Care for Patients Hospitalized for Acute Exacerbations of Chronic Obstructive Pulmonary Disease.** *Annals of Internal Medicine* 2006, **144:** 894-903.

7. Mularski RA, Asch SM, Shrank WH, Kerr EA, Setodji CM, Adams JL *et al*.: **The Quality of Obstructive Lung Disease Care for Adults in the United States as Measured by Adherence to Recommended Processes*.** *Chest* 2006, **130:** 1844-1850.

8. Heffner JE, Mularski RA, Calverley PMA: **COPD Performance Measures.** *Chest* 2010, **137:** 1181-1189.

9. Bennett K, Haggard M, Churchill R, Wood S: **Improving referrals for glue ear from primary care: are multiple interventions better than one alone?** *J Health Serv Res Policy* 2001, **6:** 139-144.

Kommentar: Beholdt eldre GOLD kriterier da nye kom i løpet av prosjektperioden

Dyspepsi diagnoser delt opp i grupper med tanke på prioritering

Dyspepsi diagnosene i 2 grupper

Gruppe 1 – Alvorlig
C15 Ondartet svulst i spiserør
C16 Ondartet svulst i magesekk
D37 Svulst med usikkert eller ukjent malignitetspotensiale i munnhule og fordøyelsesorganer
I85 Øsofagusvaricer
K20 Øsofagitt
K22.0 Akalasi
K22.1 Sår i spiserør
K22.2 Obstruksjon av spiserør
K22.3 Perforasjon av spiserør
K22.7 Barrets øsofagus
K22.8 Andre spesifiserte sykdommer i spiserør (blødning i spiserør)
K25 Sår i magesekk
K26 Sår i tolvfingertarm
K27 Magesår, uspesifisert lokalisasjon
K28 Gastrojejunalt sår
K29 Gastritt og duodenitt
K31.0 Akutt ventrikkeldilatasjon
K31.1 Hypertrofisk pylorusstenose hos voksne
K31.5 Obstruksjon av tolvfingertarm
K31.6 Fistel i magesekk og tolvfingertarm
K90.0 Coeliaki
Gruppe 2 – Mindre alvorlig
B37.8 Candida infeksjon med annen spesifisert lokalisasjon
D13.0-2 Godartet svulst i andre og ufullstendig angitte deler av fordøyelsessystemet
K21 Gastroøsofageal reflukssykdom
K22.4 Øsofagusdyskinesi
K22.5 Ervervet øsofagusdivertikkel
K22.6 Gastroøsofagealt sår og blødningssyndrom (Mallory Weiss)
K22.9 Uspesifisert sykdom i spiserør
K30 Dyspepsi
K31.2 Timeglassformet striktur og stenose av magesekk
K31.3 Pylorusspasme
K31.4 Magedivertikkel
K31.7 Polypp i magesekk og tolvfingertarm
K31.8 Andre spesifiserte sykdommer i magesekk og tolvfingertarm
K31.9 Uspesifisert sykdom i magesekk og tolvfingertarm
K44 Mellomgulvsbrokk
K92 Hematemese (og uspesifisert GI blødning)
R10 Smerte i buk og bekken
R11 Kvalme og oppkast
R12 Halsbrann
R13 Dysfagi
K90 Intestinal malabsorpsjon

Dyspepsi diagnosene i 3 grupper

Gruppe 1 – Meget alvorlig
C15 Ondartet svulst i spiserør
C16 Ondartet svulst i magesekk
I85.0 Øsofagusvaricer med blødning
K22.1 Sår i spiserør
K22.2 Obstruksjon av spiserør
K22.3 Perforasjon av spiserør
K25 Sår i magesekk
K26 Sår i tolvfingertarm
K27 Magesår, uspesifisert lokalisasjon
K28 Gastrojejunalt sår
Gruppe 2 – Alvorlig
D37 Svulst med usikkert eller ukjent malignitetspotensiale i munnhule og fordøyelsesorganer
I85.9 Øsofagusvaricer uten blødning
K20 Øsofagitt
K21 Gastroøsofageal reflukssykdom
K22.0 Akalasi
K22.7 Barrets øsofagus
K22.8 Andre spesifiserte sykdommer i spiserør (blødning i spiserør)
K29 Gastritt og duodenitt
K31.0 Akutt ventrikkeldilatasjon
K31.1 Hypertrofisk pylorusstenose hos voksne
K31.2 Timeglassformet striktur og stenose av magesekk
K31.3 Pylorusspasme
K31.5 Obstruksjon av tolvfingertarm
K31.6 Fistel i magesekk og tolvfingertarm
K31.7 Polypp i magesekk og tolvfingertarm
K90.0 Coeliaki
K90 Intestinal malabsorpsjon
K92.0 Hematemese
K92.1 Melena
K92.2 Uspesifisert GI blødning
Gruppe 3 – Mindre alvorlig
B37.8 Candida infeksjon med annen spesifisert lokalisasjon
D13.0-2 Godartet svulst i andre og ufullstendig angitte deler av fordøyelsessystemet
K22.4 Øsofagusdyskinesi
K22.5 Ervervet øsofagusdivertikkel
K22.6 Gastroøsofagealt sår og blødningssyndrom (Mallory Weiss)
K22.9 Uspesifisert sykdom i spiserør
K30 Dyspepsi
K31.4 Magedivertikkel
K31.8 Andre spesifiserte sykdommer i magesekk og tolvfingertarm
K31.9 Uspesifisert sykdom i magesekk og tolvfingertarm
K44 Mellomgulvsbrokk
K92.8 Andre spesifiserte sykdommer i fordøyelsessystemet
K92.9 Uspesifisert sykdom i fordøyelsessystemet
R10 Smerte i buk og bekken
R11 Kvalme og oppkast
R12 Halsbrann
R13 Dysfagi

Dyspepsi diagnosene i 4 grupper

Gruppe 1 – Meget alvorlig
C15 Ondartet svulst i spiserør
C16 Ondartet svulst i magesekk
I85.0 Øsofagusvaricer med blødning
K25.0-2 og 4-6 Sår i magesekk (med perforasjon eller blødning)
K26.0-2 og 4-6 Sår i tolvfingertarm (med perforasjon eller blødning)
K27.0-2 og 4-6 Magesår, uspesifisert lokalisasjon (med perforasjon eller blødning)
K28.0-2 og 4-6 Gastrojejunalt sår (med perforasjon eller blødning)(inkl. anastomose sår)
Gruppe 2 – Alvorlig
D37 Svulst med usikkert eller ukjent malignitetspotensiale i munnhule og fordøyelsesorganer
I85.9 Øsofagusvaricer uten blødning
K22.0 Akalasi
K22.1 Sår i spiserør
K22.2 Obstruksjon av spiserør
K22.3 Perforasjon av spiserør
K22.7 Barrets øsofagus
K22.8 Andre spesifiserte sykdommer i spiserør (blødning i spiserør)
K25.3, 7 og 9 Sår i magesekk (uten blødning eller perforasjon)
K26.3, 7 og 9 Sår i tolvfingertarm (uten blødning eller perforasjon)
K27.3, 7 og 9 Magesår, uspesifisert lokalisasjon (uten blødning eller perforasjon)
K28.3, 7 og 9 Gastrojejunalt sår (uten blødning eller perforasjon)
K31.0 Akutt ventrikkeldilatasjon
K31.5 Obstruksjon av tolvfingertarm
K31.6 Fistel i magesekk og tolvfingertarm
K90.0 Coeliaki
K92.0 Hematemese
K92.1 Melena
K92.2 Uspesifisert GI blødning
Gruppe 3 – Mindre alvorlig
K20 Øsofagitt
K21 Gastroøsofageal reflukssykdom
K29 Gastritt og duodenitt
K31.1 Hypertrofisk pylorusstenose hos voksne
K31.2 Timeglassformet striktur og stenose av magesekk
K31.3 Pylorusspasme
K31.7 Polypp i magesekk og tolvfingertarm
K31.8 Andre spesifiserte sykdommer i magesekk og tolvfingertarm
K90 Intestinal malabsorpsjon
K92.8 Andre spesifiserte sykdommer i fordøyelsessystemet
Gruppe 4 – Ikke alvorlig
B37.8 Candida infeksjon med annen spesifisert lokalisasjon
D13.0-2 Godartet svulst i andre og ufullstendig angitte deler av fordøyelsessystemet
K22.4 Øsofagusdyskinesi
K22.5 Ervervet øsofagusdivertikkel
K22.6 Gastroøsofagealt sår og blødningssyndrom (Mallory Weiss)
K22.9 Uspesifisert sykdom i spiserør
K30 Dyspepsi
K31.4 Magedivertikkel
K31.9 Uspesifisert sykdom i magesekk og tolvfingertarm
K44 Mellomgulvsbrokk
K92.9 Uspesifisert sykdom i fordøyelsessystemet
R10 Smerte i buk og bekken
R11 Kvalme og oppkast
R12 Halsbrann
R13 Dysfagi

Mistanke cancer coli diagnoser delt opp i grupper med tanke på prioritering

Mistanke cancer coli diagnoser i 2 grupper

Gruppe 1 – Alvorlig
C18 Ondartet svulst i tykktarm
C19 Ondartet svulst i overgang mellom sigmoideum og endetarm
C20 Ondartet svulst i endetarm
C21 Ondartet svulst i endetarmsåpning og analkanal
C26 Ondartet svulst i andre og ufullstendig angitte fordøyelsesorganer
D37 Svulst med usikkert eller ukjent malignitetspotensiale i munnhule og fordøyelsesorganer
K50 Crohns sykdom
K51 Ulcerøs kolitt
K55.0 Akutt vaskulær forstyrrelse i tarm
K56 Paralytisk ileus og tarmobstruksjon uten brokk
K57.0 Divertikkelsykdom i tynntarm med perforasjon og abscess
K57.2 Divertikkelsykdom i tykktarm med perforasjon og abscess
K57.4 Divertikkelsykdom i både tynn- og tykktarm med perforasjon og abscess
K57.8 Divertikkelsykdom i tarm, uspesifisert del, med perforasjon eller abscess
K59.3 Megacolon, ikke klassifisert annet sted
K60 Fissur og fistel i anal- og rektalområdet
K63.0 Tarmabscess
K63.1 Perforasjon av tarm (ikke-traumatisk)
K63.2 Tarmfistel
K92.0 Hematemese
K92.1 Melena
K92.2 Uspesifisert GI blødning
Gruppe 2 – Mindre alvorlig
D12 Godartet svulst i tykktarm, endetarm, analkanal og endetarmsåpning
D13 Godartet svulst i andre og ufullstendig angitte deler av fordøyelsessystemet
D50 Jernmangelanemi (**da denne står igjen *etter* utredning)**
I84 Hemoroider
K52 Annen ikke infeksiøs gastroenteritt og kolitt
K55.1 Kronisk vaskulær forstyrrelse i tarm
K55.2 Angiodysplasi i tykktarm
K55.8 Annen spesifisert vaskulær forstyrrelse i tarm
K55.9 Uspesifisert vaskulær forstyrrelse i tarm
K57.1 Divertikkelsykdom i tynntarm uten perforasjon og abscess
K57.3 Divertikkelsykdom i tykktarm uten perforasjon og abscess
K57.5 Divertikkelsykdom i både tynn- og tykktarm uten perforasjon og abscess
K57.9 Divertikkelsykdom i tarm, uspesifisert del, uten perforasjon eller abscess
K58 Irritable tarm-syndrom
K59 Andre funksjonelle forstyrrelser i tarm (unntatt K59.3)
K63.3 Sår i tarm
K63.4 Tarmdescens (enteroptose)
K63.5 Polypp i tykktarm
K63.8 Andre spesifiserte sykdommer i tarm
K63.9 Uspesifiserte sykdommer i tarm
K92.8 Andre spesifiserte sykdommer i fordøyelsessystemet
K92.9 Uspesifisert sykdom i fordøyelsessystemet
R10 Smerte i buk og bekken
R19.4 Endring i avføringsvane
R53 Uvelhet og tretthet
R63.0 Anorexi
R63.4 Unormalt vekttap
R70.0 Økt senkningsreaksjon
Z03.1 Observasjon ved mistanke om ondartet svulst
Z03.8 Observasjon ved mistank om annen spesifisert sykdom og tilstand
Z12.1 Målrettet undersøkelse med henblikk på svulst i tarm

Mistanke cancer coli diagnoser i 3 grupper

Gruppe 1 – Meget alvorlig
C18 Ondartet svulst i tykktarm
C19 Ondartet svulst i overgang mellom sigmoideum og endetarm
C20 Ondartet svulst i endetarm
C21 Ondartet svulst i endetarmsåpning og analkanal
C26 Ondartet svulst i andre og ufullstendig angitte fordøyelsesorganer
K55.0 Akutt vaskulær forstyrrelse i tarm
K56 Paralytisk ileus og tarmobstruksjon uten brokk
K57.0 Divertikkelsykdom i tynntarm med perforasjon og abscess
K57.2 Divertikkelsykdom i tykktarm med perforasjon og abscess
K57.4 Divertikkelsykdom i både tynn- og tykktarm med perforasjon og abscess
K57.8 Divertikkelsykdom i tarm, uspesifisert del, med perforasjon eller abscess
Gruppe 2 – Alvorlig
D37 Svulst med usikkert eller ukjent malignitetspotensiale i munnhule og fordøyelsesorganer
K50 Crohns sykdom
K51 Ulcerøs kolitt
K55.1 Kronisk vaskulær forstyrrelse i tarm
K59.3 Megacolon, ikke klassifisert annet sted
K60 Fissur og fistel i anal- og rektalområdet
K63.0 Tarmabscess
K63.1 Perforasjon av tarm (ikke-traumatisk)
K63.2 Tarmfistel
K63.3 Sår i tarm
K55.8 Annen spesifisert vaskulær forstyrrelse i tarm
K55.9 Uspesifisert vaskulær forstyrrelse i tarm
K92.0 Hematemese
K92.1 Melena
K92.2 Uspesifisert GI blødning
R63.4 Unormalt vekttap
Gruppe 3 – Mindre alvorlig
D12 Godartet svulst i tykktarm, endetarm, analkanal og endetarmsåpning
D13 Godartet svulst i andre og ufullstendig angitte deler av fordøyelsessystemet
D50 Jernmangelanemi (**da denne står igjen *etter* utredning)**
I84 Hemoroider
K52 Annen ikke infeksiøs gastroenteritt og kolitt
K55.2 Angiodysplasi i tykktarm
K57.1 Divertikkelsykdom i tynntarm uten perforasjon og abscess
K57.3 Divertikkelsykdom i tykktarm uten perforasjon og abscess
K57.5 Divertikkelsykdom i både tynn- og tykktarm uten perforasjon og abscess
K57.9 Divertikkelsykdom i tarm, uspesifisert del, uten perforasjon eller abscess
K58 Irritable tarm-syndrom
K59 Andre funksjonelle forstyrrelser i tarm (unntatt K59.3)
K63.4 Tarmdescens (enteroptose) **(hva er dette?)**
K63.5 Polypp i tykktarm
K63.8 Andre spesifiserte sykdommer i tarm
K63.9 Uspesifiserte sykdommer i tarm
K92.8 Andre spesifiserte sykdommer i fordøyelsessystemet
K92.9 Uspesifisert sykdom i fordøyelsessystemet
R10 Smerte i buk og bekken
R19.4 Endring i avføringsvane
R53 Uvelhet og tretthet
R63.0 Anorexi
R70.0 Økt senkningsreaksjon
Z03.1 Observasjon ved mistanke om ondartet svulst
Z03.8 Observasjon ved mistank om annen spesifisert sykdom og tilstand
Z12.1 Målrettet undersøkelse med henblikk på svulst i tarm

Mistanke cancer coli diagnoser i 4 grupper

Gruppe 1 – Meget alvorlig
C18 Ondartet svulst i tykktarm
C19 Ondartet svulst i overgang mellom sigmoideum og endetarm
C20 Ondartet svulst i endetarm
C21 Ondartet svulst i endetarmsåpning og analkanal
C26 Ondartet svulst i andre og ufullstendig angitte fordøyelsesorganer
K55.0 Akutt vaskulær forstyrrelse i tarm
K56 Paralytisk ileus og tarmobstruksjon uten brokk
K57.0 Divertikkelsykdom i tynntarm med perforasjon og abscess
K57.2 Divertikkelsykdom i tykktarm med perforasjon og abscess
K57.4 Divertikkelsykdom i både tynn- og tykktarm med perforasjon og abscess
K57.8 Divertikkelsykdom i tarm, uspesifisert del, med perforasjon eller abscess
Gruppe 2 – Alvorlig
D37 Svulst med usikkert eller ukjent malignitetspotensiale i munnhule og fordøyelsesorganer
K50 Crohns sykdom
K51 Ulcerøs kolitt
K59.3 Megacolon, ikke klassifisert annet sted
K60 Fissur og fistel i anal- og rektalområdet
K63.0 Tarmabscess
K63.1 Perforasjon av tarm (ikke-traumatisk)
K63.2 Tarmfistel
K63.3 Sår i tarm
K55.8 Annen spesifisert vaskulær forstyrrelse i tarm
K92.0 Hematemese
K92.1 Melena
K92.2 Uspesifisert GI blødning
Gruppe 3 – Mindre alvorlig
D12 Godartet svulst i tykktarm, endetarm, analkanal og endetarmsåpning
D13 Godartet svulst i andre og ufullstendig angitte deler av fordøyelsessystemet
K52.0 Gastroenteritt og kolitt som skyldes stråling
K52.1 Toksisk gastroenteritt og kolitt
K52.2 Allergisk og diettbetinget gastroenteritt og kolitt
K52.3 Ubestemt kolitt
K52.8 Annen spesifisert ikke-infeksiøs gastroenteritt og kolitt
K55.1 Kronisk vaskulær forstyrrelse i tarm
K55.9 Uspesifisert vaskulær forstyrrelse i tarm
D50 Jernmangelanemi (**da denne står igjen *etter* utredning)**
K55.2 Angiodysplasi i tykktarm
K57.1 Divertikkelsykdom i tynntarm uten perforasjon og abscess
K57.3 Divertikkelsykdom i tykktarm uten perforasjon og abscess
K57.5 Divertikkelsykdom i både tynn- og tykktarm uten perforasjon og abscess
K57.9 Divertikkelsykdom i tarm, uspesifisert del, uten perforasjon eller abscess
K63.4 Tarmdescens (enteroptose) **(hva er dette?)**
K63.5 Polypp i tykktarm
K63.8 Andre spesifiserte sykdommer i tarm
K92.8 Andre spesifiserte sykdommer i fordøyelsessystemet
R63.4 Unormalt vekttap
Gruppe 4 – Ikke alvorlig
I84 Hemoroider
K52.9 Uspesifisert ikke-infeksiøs gastroenteritt og kolitt
K58 Irritable tarm-syndrom
K59 Andre funksjonelle forstyrrelser i tarm (unntatt K59.3)
K63.9 Uspesifiserte sykdommer i tarm
K92.9 Uspesifisert sykdom i fordøyelsessystemet
R10 Smerte i buk og bekken
R19.4 Endring i avføringsvane
R53 Uvelhet og tretthet
R63.0 Anorexi
R70.0 Økt senkningsreaksjon
Z03.1 Observasjon ved mistanke om ondartet svulst
Z03.8 Observasjon ved mistank om annen spesifisert sykdom og tilstand
Z12.1 Målrettet undersøkelse med henblikk på svulst i tarm

Brystsmerte diagnoser delt opp i grupper med tanke på prioritering

Brystsmerte diagnosene i 2 grupper

Gruppe 1 - alvorlig
I11.0 Hypertensiv hjertesykdom med stuvningssvikt
I15 Sekundær hypertensjon
I20 Angina pektoris
I21 Akutt hjerteinfarkt
I25 Kronisk iskemisk hjertesykdom
I30 Akutt perikarditt
I35 Ikke-reumatisk aortaklaffefeil
I42 Kardiomyopati
I44 Atrioventrikulært og venstresidig grenblokk
I45.6 Preeksitasjonssyndromer
I48 Atrieflimmer og atrieflutter
I49.0 Ventrikkelflimmer og ventrikkelflutter
I50 Hjertesvikt
Gruppe 2 – mindre alvorlig
B02 Herpes zoster
F41 Angstlidelser (inkl. panikklidelse)
I10 Hypertensjon
I11.9 Hypertensiv hjertesykdom uten stuvningssvikt
I45 Andre ledningsforstyrrelser (eksl. I45.6)
I47 Paroxysmal takykardi
I49.1-9 Annen hjertearytmi
K21 Gastroøsofageal reflukssykdom
K22.4 Øsofagusdyskinesi
K30 Dyspepsi
M 79.1 Thorax myalgi
M94.0 Smerte på overgang mellom ribben og ribbensbrusk
R00 Unormale hjerteslag
R07.4 Brystsmerte
R09.1 Pleuritt
R55 Synkope og kollaps
Z03.5 Observasjon ved mistanke om andre hjerte-kar sykdommer

Brystsmerte diagnosene i 3 grupper

Gruppe 1 – meget alvorlig
I20.0 Ustabil angina
I21 Akutt hjerteinfarkt
I44.2 Atrioventrikulært blokk, totalt
I49.0 Ventrikkelflimmer og ventrikkelflutter
Gruppe 2 – alvorlig
I11.0 Hypertensiv hjertesykdom med stuvningssvikt
I15 Sekundær hypertensjon
I20.1-9 Angina pektoris
I25 Kronisk iskemisk hjertesykdom
I30 Akutt perikarditt
I35 Ikke-reumatisk aortaklaffefeil
I42 Kardiomyopati
I44.0-1 og 3-7 Atrioventrikulært og venstresidig grenblokk
I45.6 Preeksitasjonssyndromer
I47 Paroxysmal takykardi
I48 Atrieflimmer og atrieflutter
I49.5 Syk-sinus syndrom (SSS)
I50 Hjertesvikt
Gruppe 3 – mindre alvorlig
B02 Herpes zoster
F41 Angstlidelser (inkl. panikklidelse)
I10 Hypertensjon
I11.9 Hypertensiv hjertesykdom uten stuvningssvikt
I45 Andre ledningsforstyrrelser (eksl. I45.6)
I49.1-4 og 8-9 Annen hjertearytmi
K21 Gastroøsofageal reflukssykdom
K22.4 Øsofagusdyskinesi
K30 Dyspepsi
M 79.1 Thorax myalgi
M94.0 Smerte på overgang mellom ribben og ribbensbrusk
R00 Unormale hjerteslag
R07.4 Brystsmerte
R09.1 Pleuritt
R55 Synkope og kollaps
Z03.5 Observasjon ved mistanke om andre hjerte-kar sykdommer

Brystsmerte diagnosene i 4 grupper

Gruppe 1 – Meget alvorlig
I20.0 Ustabil angina
I21 Akutt hjerteinfarkt
I44.2 Atrioventrikulært blokk, totalt
I49.0 Ventrikkelflimmer og ventrikkelflutter
Gruppe 2 – Alvorlig
I11.0 Hypertensiv hjertesykdom med stuvningssvikt
I15 Sekundær hypertensjon
I20.1-9 Angina pektoris
I30 Akutt perikarditt
I35 Ikke-reumatisk aortaklaffefeil
I42 Kardiomyopati
I45.6 Preeksitasjonssyndromer
I48 Atrieflimmer og atrieflutter
I49.5 Syk-sinus-syndrom (SSS)
I50.0-1 Hjertesvikt
Gruppe 3 – Mindre alvorlig
I10 Hypertensjon
I11.9 Hypertensiv hjertesykdom uten stuvningssvikt
I25 Kronisk iskemisk hjertesykdom
I44.0-1 og 3-7 Atrioventrikulært og venstresidig grenblokk
I45 Andre ledningsforstyrrelser (eksl. I45.6)
I47 Paroxysmal takykardi
I49.1-4 og 8-9 Annen hjertearytmi
I50.9 Uspesifisert hjertesvikt
K21 Gastroøsofageal reflukssykdom
Gruppe 4 – Ikke alvorlig
B02 Herpes zoster
F41 Angstlidelser (inkl. panikklidelse)
K22.4 Øsofagusdyskinesi
K30 Dyspepsi
M 79.1 Thorax myalgi
M94.0 Smerte på overgang mellom ribben og ribbensbrusk
R00 Unormale hjerteslag
R07.4 Brystsmerte
R09.1 Pleuritt
R55 Synkope og kollaps
Z03.5 Observasjon ved mistanke om andre hjerte-kar sykdommer

KOLS diagnoser delt opp i grupper med tanke på prioritering

KOLS diagnosene i 2 grupper

Gruppe 1 - alvorlig
C34 Ondartet svulst i bronkie eller lunge
C45 Mesoteliom
C78.0, 2 og 3 Lungemetastase, .2 i brysthinne og .3 andre åndedrettsorganer
D02 Carcinoma in situ i mellomøre og åndedrettsorganer
D14.2 Godartet svulst i trachea
D14.3 Godartet svulst i bronkie eller lunge
D14.4 Godartet svulst i åndedrettsorgan, uspesifisert
D38.1 Svulst med usikkert eller ukjent malignitetspotensiale i luftrør, bronkie eller lunge
D38.2 Svulst med usikkert eller ukjent malignitetspotensiale i brysthinne
D38.6 Svulst med usikkert eller ukjent malignitetspotensiale i åndedrettsorgan, uspesifisert
J46 Akutt alvorlig astma
Gruppe 2 – mindre alvorlig
D19.0 Godartet svulst i pleura
E84 Cystisk fibrose
J40 Bronkitt, ikke spesifisert som akutt eller kronisk
J41 Ukomplisert og mukopurulent kronisk bronkitt
J42 Uspesifisert kronisk bronkitt
J43 Emfysem
J44 KOLS
J45 Astma
J47 Bronkiektasier
J60-67 Pneumokoniose og luftveissykdom pga. organisk støv
J84 Interstitielle lungesykdommer
Z03.9 Observasjon ved mistanke om uspesifisert sykdom eller tilstand

KOLS diagnosene i 3 grupper

Gruppe 1 – meget alvorlig
C34 Ondartet svulst i bronkie eller lunge
C45 Mesoteliom
C78.0, 2 og 3 Lungemetastase, .2 i brysthinne og .3 andre åndedrettsorganer
D02 Carcinoma in situ i mellomøre og åndedrettsorganer
D14.2 Godartet svulst i trachea
D14.3 Godartet svulst i bronkie eller lunge
D14.4 Godartet svulst i åndedrettsorgan, uspesifisert
D38.1 Svulst med usikkert eller ukjent malignitetspotensiale i luftrør, bronkie eller lunge
D38.2 Svulst med usikkert eller ukjent malignitetspotensiale i brysthinne
D38.6 Svulst med usikkert eller ukjent malignitetspotensiale i åndedrettsorgan, uspesifisert
J46 Akutt alvorlig astma
Gruppe 2 – alvorlig
J44 KOLS stadium IV
J84 Interstitielle lungesykdommer
Gruppe 3 – mindre alvorlig
D14.2 Godartet svulst i trachea
D14.3 Godartet svulst i bronkie eller lunge
D14.4 Godartet svulst i åndedrettsorgan, uspesifisert
D19.0 Godartet svulst i pleura
E84 Cystisk fibrose
J40 Bronkitt, ikke spesifisert som akutt eller kronisk
J41 Ukomplisert og mukopurulent kronisk bronkitt
J42 Uspesifisert kronisk bronkitt
J43 Emfysem
J44 KOLS – stadium I-III
J45 Astma
J47 Bronkiektasier
J60-67 Pneumokoniose og luftveissykdom pga. organisk støv
Z03.9 Observasjon ved mistanke om uspesifisert sykdom eller tilstand

KOLS diagnosene i 4 grupper

Gruppe 1 – Meget alvorlig
D14.2 Godartet svulst i trachea
D14.3 Godartet svulst i bronkie eller lunge
D14.4 Godartet svulst i åndedrettsorgan, uspesifisert
C34 Ondartet svulst i bronkie eller lunge
D38.1 Svulst med usikkert eller ukjent malignitetspotensiale i luftrør, bronkie eller lunge
D38.2 Svulst med usikkert eller ukjent malignitetspotensiale i brysthinne
D38.6 Svulst med usikkert eller ukjent malignitetspotensiale i åndedrettsorgan, uspesifisert
C45 Mesoteliom
C78.0, 2 og 3 Lungemetastase, .2 i brysthinne og .3 andre åndedrettsorganer
D02 Carcinoma in situ i mellomøre og åndedrettsorganer
J46 Akutt alvorlig astma
Gruppe 2 – Alvorlig
J44 KOLS stadium IV
Gruppe 3 – Mindre alvorlig
E84 Cystisk fibrose
J43 Emfysem
J44 KOLS I-II
J44 KOLS – stadium III
J45 Astma
J47 Bronkiektasier
J84 Interstitielle lungesykdommer
Gruppe 4 – Ikke alvorlig
D19.0 Godartet svulst i pleura
J40 Bronkitt, ikke spesifisert som akutt eller kronisk
J41 Ukomplisert og mukopurulent kronisk bronkitt
J42 Uspesifisert kronisk bronkitt
J60-67 Pneumokoniose og luftveissykdom pga. organisk støv
Z03.9 Observasjon ved mistanke om uspesifisert sykdom eller tilstand

Forespørsel om deltakelse i forskningsprosjektet

"Samhandling i praksis – en randomisert kontrollert intervensjonsstudie "

Bakgrunn og hensikt: Dette informasjonsskrivet er et spørsmål til deg om å delta i en forskningsstudie som skal utvikle samarbeidet mellom fastlegen og sykehuset. Medisinsk avdeling UNN Harstad er ansvarlige for prosjektet.

Hva innebærer studien? Studien innebærer at en gruppe fastleger benytter et forhåndsbestemt skjema ved henvisning til sykehuset, mens noen bruker vanlige henvisninger. Videre utredning og behandling vil være helt lik i de to gruppene. Vi kommer deretter til å undersøke om bruken av dette skjemaet har ført til endringer i behandlingsløpet for den enkelte pasient. Vi kommer også til å sende et spørreskjema til pasientene, for å se hvor fornøyde de er med behandlingen.

Mulige fordeler og ulemper: Vi tror at denne studien kan hjelpe oss å finne bedre måter å samarbeide mellom fastleger og sykehuset, og dermed kunne gi bedre behandling til hver enkelt pasient. For deg vil ikke studien medføre spesielle fordeler eller ulemper, men vi kommer til å be deg fylle ut et kort spørreskjema i forbindelse med sykehusbesøket. En doktor på sykehuset vil også gå gjennom din journal for å kartlegge ditt behandlingsforløp i etterkant. Denne informasjonen vil bli anonymisert.

Hva skjer med informasjonen om deg? Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene og prøvene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en konfidensiell navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse: Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte:

Prosjektmedarbeider assistent lege Henrik Wåhlberg – 770 15 000 eller henrik.wahlberg2@unn.no
Prosjektleder overlege dr. med. Ann Ragnhild Broderstad – 770 15 000

Vennligst ta dette skjemaet med til din time, eller bruk vedlagte konvolutt til å sende det i posten.

Ytterligere informasjon om personvern og studien finnes i kapittel A

Kapittel A - Personvern

Personvern: Opplysninger som registreres om deg vil bli hentet fra din elektroniske journal ved medisinsk avdeling UNN Harstad. Det som vil bli registrert er demografiske variabler (som kjønn og alder), og detaljer om behandlingsforløpet (ventetid før time, antall legetimer før diagnose osv) og vi vil ut fra forhåndsoppsatte kriterier gi en totalt kvalitetsskår på ditt behandlingsforløp. Dataene vil bli lagt anonymt inn i en database, og i alle publikasjoner vil være fullt ut anonyme.

Universitetssykehuset Nord-Norge ved administrerende direktør Tor Ingebrigtsen er databehandlingsansvarlig.

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver: Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi og rolle: Studien er finansiert gjennom forskningsmidler fra Helse Nord.

Informasjon om utfallet av studien: Hvis du ønsker å få vite om utfallet av studien, kan du kontakte prosjektmedarbeider Henrik Wåhlberg på **henrik.wahlberg2@unn.no** (prosjektet forventes ferdig i løpet av 2014)

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Fødselsdato

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)