UiT
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Too much medicine?

A study investigating unwarranted regional variation and use of medical care

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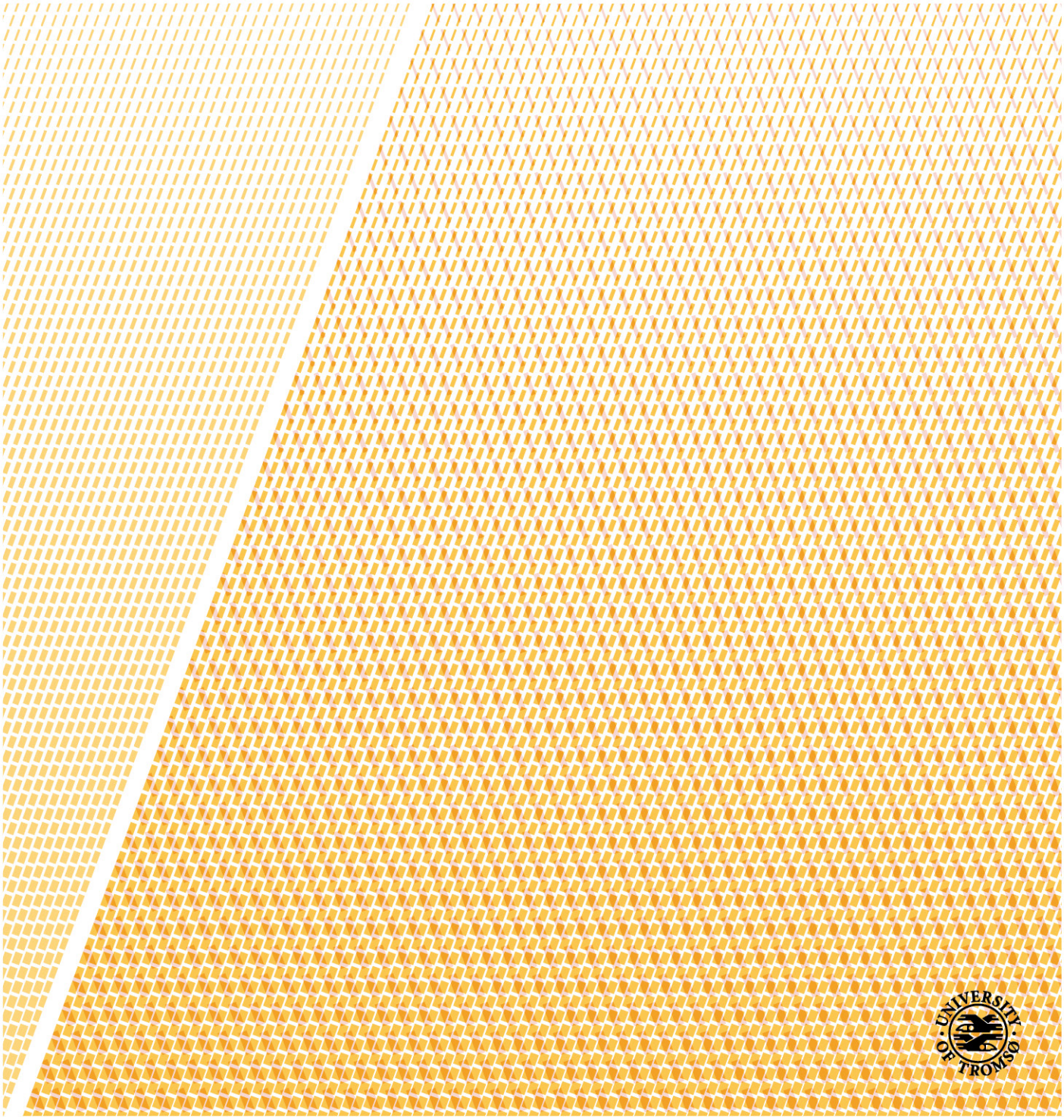
A dissertation for the degree of Philosophiae Doctor – March 2019



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ACKNOWLEDGEMENTS

I did the present work between 2013 and 2019 at the Department of Clinical Medicine, Faculty of Health Sciences, UiT The Arctic University of Norway.

I would not have been able to carry out this thesis without the help and support from many. I am deeply grateful.

I am most grateful to my main supervisor, Arthur Revhaug. You have generously supported – and challenged me, in a well-balanced way. You have always made time for me, even when you had more than enough on your plate. I am very thankful that you open-mindedly and curiously wanted to investigate the subject of this thesis together with me. I have greatly benefitted from your experience as a researcher, supervisor, physician, and health care organizer. I appreciate all our talks.

I am very thankful to Olav Helge Førde, my co-supervisor. I could not have carried out this work without your knowledge in epidemiology and your experience in health services research. Also, thanks for advising me to do a PhD the very first time we met.

Linda Leivseth, I am very happy Center for Clinical Documentation and Evaluation designated you as my co-author for paper 2 and 3. Your careful and detail-oriented work has both improved this thesis and also taught me how high methodological standards can be implemented in practice. I am very thankful.

Thanks to Arthur, Olav Helge, and Linda for making methodological debates thorough, loud, and sometimes intensely frustrating, but still humorous and rewarding.

Thanks to Ingard Nilsen for your expertise in gynecology and contributions as co-author for paper 2.

Thanks to Johannes Walsøe for technical support and Anna Bågenholm for radiological expertise for paper 1. Thanks to Geir Hoff and Stig Norderval for critical review of drafted manuscript for paper 3. Thanks to Cecilie Øen for linguistic revisions.

Stefán Hjörleifsson, thank you for your effort to include me in the Too much medicine community. Thank you for support, encouragement, and feedback both on written and oral presentations.

Kristin Modalsli Sand, thank you for linguistic revisions and manuscript feedback. Thank you for support in all aspects of PhD life. Moreover, thank you for being a marvelous friend.

Thanks to my aunt and medical professor, Ellisiv Bøgeberg Mathiesen. I am very thankful for your comments on drafted manuscripts and for always helping me when unsure on different aspects of the PhD work. It has been very valuable for me to discuss academic uncertainties with someone I have so much confidence in, both on a personal and professional level.

Thanks to all the patients at Kvaløysletta legekontor for entrusting me with your health issues. You always remind me that providing the right level of care, not too little and not too much, is an ongoing and challenging task.

Siren Hoven, thank you for invaluable support in life.

Special thanks to my sister, Nina, parents, Grete and Frimann, Klaus, Maria, Henning, and all other family and friends for support and living life together.

In the mood of gratefulness; I am always and forever very thankful to Ellinor, my most precious daughter. Your direct input on this thesis is the great work you do by structuring my every day. More importantly, I truly love life with you and being your mom.

ABBREVIATIONS

CT	Computed tomography
CT KUB	Computed tomography of kidneys, ureters, and bladder
ICD-10	The International Classification of Diseases version 10
LGI	Lower gastrointestinal
NPR	Norwegian Patient Registry
NCSP	NOMESCO Classification of Surgical Procedures
NOMESCO	Nordic Medico-Statistical Committee
OECD	The Organisation for Economic Co-operation and Development
UNN	University Hospital of Northern Norway

LIST OF PAPERS

I. Rosenlund IM, Førde OH, Revhaug A. Routine deferred computed tomography for patients with suspected urolithiasis is low-value healthcare. Scand J Urol. 2017;51(1):62-67.

II: Rosenlund IM, Leivseth L, Nilsen I, Førde OH, Revhaug A. Extent, regional variation and impact of gynecologist payment models in routine pelvic examinations: a nationwide cross-sectional study. BMC Women's Health. 2017;17(1):114.

III: Rosenlund IM, Leivseth L, Førde OH, Revhaug A. Regional variation in hospitalizations and outpatient appointments for diverticular disease in Norway: a nationwide cross-sectional study. Scand J Gastroenterol 2018;53(10-11):1228-35.

SUMMARY

The overall theme of this thesis is overuse and regional variation in use of health care services. Overuse and unwarranted variation are of global concern. Unnecessary health care services are recognized as harmful both to patients and health care systems. We have examined three different clinical scenarios where guidelines are either lacking evidence or where current practice is not in coherence with evidence-based recommendations.

The aims of the thesis were: 1) to examine if deferred computed tomography (CT) for patients with a self-limiting episode of suspected urolithiasis lead to surgical treatment, 2) to quantify the extent and regional variation of routine pelvic examinations within publicly funded specialized health care in Norway, and assess if the use of colposcopy and ultrasound differs with gynecologists' payment models, and 3) to assess if there are regional differences in rates of hospitalization and outpatient appointments for diverticular disease in Norway.

In paper 1 we did a retrospective case series with data from the electronic health records at the University Hospital of Northern Norway. We identified the proportion of asymptomatic patients that were treated as a consequence of a positive finding on CT. Paper 2 and 3 were both national cross-sectional studies with data from the Norwegian Patient Registry and Statistics Norway. In paper 2 we quantified the number of appointments for routine pelvic examination per 1000 women in Norway and for the 21 different hospital referral regions. We examined the use of colposcopy and ultrasound in these appointments for both fixed salary and fee-for-service gynecologists. In paper 3 we calculated the regional rates of hospitalizations and outpatient appointments for diverticular disease.

Deferred CT for patients with self-limiting episodes of suspected urolithiasis led to surgical intervention in 1.8% of asymptomatic patients. Annually 22 per 1000 women in Norway had a routine pelvic examination with variation across regions from 7 to 44 per 1000. Gynecologist with fixed salaries used colposcopy in 1.6% and ultrasound in 75% of routine pelvic examinations. Fee-for-service gynecologists used the same procedures in 49% and 96% of appointments. Hospitalization rates for diverticular disease ranged from 95 to 179 per 100 000 across regions. Outpatient appointment rates ranged from 258 to 655 per 100 000.

Our results indicate that the practice of deferred CT for suspected urolithiasis is a low-value health care service. Pelvic examinations are widespread with substantial regional variation. Fee-for-service reimbursements seem to skyrocket the use of colposcopy and increase the use of ultrasound in screening examinations. We found regional variation in both hospitalizations and outpatient appointments for diverticular disease.

1. PREFACE

"Be sure to consult your physician before starting a new exercise program"

Safety sign on tread mills in SATS Elixia Langnes, Tromsø

The questions I address in this thesis all raised when I was serving as a junior doctor and observed what to me seemed like unexplainable differences in provided care among the different senior doctors I encountered. I was also intrigued by how various aspects of human life increasingly appeared to be considered as medical problems. Whenever I go to the local gym and read the safety signs on the tread mill, I get bewildered by the public faith in my profession. As a physician, I wonder what the content of such a consultation would be. What tests should I offer and what expectations might patients seeking me have? There are no specified screening tests to clear persons "fit for running." Most likely, people themselves, without any professional help, are able to identify when tread mill running is a bad idea.

The overall theme of this thesis is overuse and unwarranted regional variation of health care services. I have examined use of certain health care services in three distinct clinical scenarios; urolithiasis, routine pelvic examinations in asymptomatic women, and colonic diverticular disease. The three papers in this thesis examine frequently used health care services where guidelines are either lacking evidence or where current practice is not in coherence with evidence-based recommendations.

2. INTRODUCTION

2.1 Too much medicine

"Much of clinical medicine remains empirical, and everyday practice is characterized by wide variations that have no basis in clinical science"

Dr. John E. Wennberg[1]

In 2002 BMJ published their theme issue "Too Much Medicine?". Thirteen years later, the journal launched the Too Much Medicine campaign, this time without the question mark.[2] The 2010 editorial "How Less Health Care Can Result in Better Health"[3] was the start of JAMA's Less is More series,[4] "documenting the ways that overuse of medical care fails to improve outcomes, harms patients, and wastes resources." The Lancet published their Right Care Series in 2017.[5]

The different terms used to describe the phenomenon of unnecessary health care services are overlapping and poorly defined.[6-8] The term *overdiagnosis* is widely used, however, its definition is not settled and the concept is perceived differently by different people. In this thesis I will use the word *overdiagnosis* as a collective term for *overdetection* and *overdefinition* as defined by Brodersen et al.[7] *Overdetection* is the mechanism of detection and diagnosis of asymptomatic abnormalities that never will progress to symptomatic disease. *Overdefinition* includes expanding disease definition to include very mild cases and lowering thresholds for defined risk factors without evidence on beneficial outcomes for the patients concerned. I will use the broader term *overuse* as defined by Chassin and Galvin for health care services where the "potential for harm exceeds the possible benefit."[9] Overuse include the subcategories *overinvestigation* and *overtreatment*. *Overinvestigation* and *overtreatment* deals with diagnostic and therapeutic procedures that do not alter patient outcomes to the better. I will also describe medical services that do not benefit the patient as *unnecessary health care services*. *Low-value health care* describe services that provide very little health benefit given the resources used.[8,10] To me, the concept of "too much medicine" is not merely a strict medical assessment of harmful overdiagnosis and overuse, but also an ethical and philosophical notion that deals with medicalization of life, as described by Illich.[11]

2.2 Extent of overuse

The Too Much Medicine, Less is More and Right Care campaigns reflect the international

attention to the accumulating evidence of unnecessary health care utilization and overtreatment.[10] Conferences,[12,13] research institutes,[14,15] professional organizations,[16,17], popular science books,[18,19] and medical campaigns[20] address the harms of overuse and low-value health care. Overuse is common in both high and low income countries.[10] The Organisation for Economic Co-operation and Development (OECD) reckons that 20% of medical spending within OECD could have been spent more effectively, this number includes both overuse and ineffective economic management. OECD identify 20% of emergency department visits as inappropriate, 50% of antibiotic consumption as overuse with percentages as high as 90% in general practice, and 15% of all births as inappropriate cesarean sections without medical indications.[21]

2.3 Measurement of overuse

Overuse is understudied with limited practices directly reviewed.[10,22] Methodologically, it is challenging to measure and document unnecessary health care services. Alongside a vaguely defined terminology the concepts of "benefit," "harm," and "value" are hard to operationalize. When do harms exceed benefits? How to measure whether outcomes could be the same, worse or better if "we did not do what we did?"

2.3.1 Direct measures of overuse

For established practices with well-documented appropriateness criteria, we can directly measure whether or not the right care is provided. All though there are limitations in regard to appropriateness applied to the individual patient using register data, and limitations in regard to external validity using patient case files, direct measurement is methodologically the most robust way to document overuse.[10,23] However, only a minority of practices have well-defined appropriateness criteria.[10] Consequently, only a subset of practices can be studied directly. For the many practices where well-established criteria are missing, or where limitations in data render direct measurement difficult, indirect approaches are used to identify overuse.

2.3.2 Regional variation as an indirect measure of overuse

"And what should they know of England who only England know?"

Rudyard Kipling[24]

Studies of regional variation in health care providing is an indirect, much used method to investigate potential overuse.[25,26] Already in 1938 Glover documented regional variation in

tonsillectomy rates that could not be explained by illness.[27] In 1973 Wennberg and Gittelsohn published their first study on small area variation.[28] What was planned as a project to reveal potential insufficient medical providing in Vermont, gave evidence on high utilization and variation that was not explained by medical needs. Neighboring communities, with no acknowledged differences in morbidity, showed striking differences in use of numerous health care services.

In studies of regional variation in health care utilization, three categories of health services emerge; *effective care, preference-sensitive care,* and *supply-sensitive care*.[26] Immunization of children and insulin to diabetes type 1 patients are examples of effective care. The proven benefits of effective care far outweigh the associated risks and harms. Preference-sensitive care is health care services where more than one intervention is medically acceptable. Examples are the choice between watchful waiting and prostatectomy after a diagnosis of early stage prostate cancer and whether or not a gallstone patient chooses to have an elective cholecystectomy. The last category, supply-sensitive care, deals with the frequency and threshold for using different services. How often should a patient on hypertensive drugs be controlled? When should a specialist be consulted? What are the indications for an elective tonsillectomy? These questions and countless others are left unanswered. Observed regional variation in these services is commonly caused by variation in supply, organization, and professional opinion rather than morbidity.[26] The more specialists offering their services, the more patients will see a specialist. The more hospital beds provided, the more patients will be hospitalized. The more radiologists and imaging machines in an area, the more likely the inhabitants of that area will have an imaging exam.

Documentation of regional variation in health care providing cannot directly be taken for evidence of either overuse or underuse. However, when regional variation cannot be explained by regional differences in morbidity or patient preferences, the variation is characterized as *unwarranted*.[1] Indirectly, regional variation of effective care can indicate underuse in low-use area, while variation in preference- and supply-sensitive care might point to unnecessary health care services in high rates regions. Reports from the Dartmouth Institute and the Institute of Medicine have demonstrated extensive regional variation in use of supply-sensitive care and medical spending with no associated improvement in outcomes or quality of care for patients in high use areas.[29-31] Critics of variation studies raise concerns of inadequate adjustments for differences in morbidity and regional price differences.[32] Even if interpretations are debated, regional variation in health service utilization is demonstrated internationally and is recognized as medically unwarranted.[33]

2.4 Drivers of overuse

Overuse may seem counter-intuitive at first glance. As health care aims to help, it is difficult to perceive that less can be more, and to many it may seem incomprehensible that too much medicine can tip the balance towards harm. In the next section I will elaborate upon different contributing factors to unnecessary health care services before the backgrounds specific for the individual papers are provided.

2.4.1 Lack of evidence

There is a common belief among doctors, patients, policy makers, and the general public alike that medical practice is based on scientific evidence. However, shortage of evidence is rather the rule than the exception in everyday medical care. In less than 5% of Cochrane reviews the authors find sufficient evidence and no need for further studies on the conclusions drawn.[34] Where knowledge on a condition is insufficient, medical providers make clinical choices supported by best evidence available, logical thinking, and experience. Based on deductive reasoning and a strong belief in beneficial outcomes, physicians performed bloodletting as a remedy of innumerable maladies for millennia.[35] Modern examples of treatments recommended by expert opinion include radical mastectomy for all cases of breast cancer, class 1c antiarrhythmics for stroke prevention, advising parents to make their babies sleep face down, synthetic estrogen to prevent stillbirth, and pulmonary artery catheters for heart failure patients.[36] When set to test, none of these interventions have proven beneficial, on the contrary; they have all caused considerably harm including numerous unnecessary deaths. While the listed practices are now abolished, there are still countless other tests and treatments that are recommended purely by expert opinion.

For recommendations truly based on scientific studies, many do not measure up when retested. In a 2018 study Silberzahn et al. demonstrated how statistical analyses applied to data material can highly influence study results.[37] The researchers provided the same data set to 29 different analytical teams. Whereas two thirds of teams found a significant positive effect for the study outcome, one third found no relationship. In New England Journal of Medicine, 40% of articles testing standard of care conclude with medical reversal; the established medical practice is contradicted by new and superior evidence.[38] Also highly cited original research articles claiming effective interventions are commonly reversed. In 2005 Ioannidis showed that 16% of such articles with more than 1000 citations published in New England Journal of Medicine, JAMA, and Lancet were contradicted in subsequent studies.[39]

Publication bias adds additional burden to the shortcomings of evidence in today's medical practice. Approximately 50% of all clinical trials are never reported, and positive findings are more likely to be published compared to studies with negative results.[40] In a review of 74 industry-sponsored studies of 12 different antidepressants, 37 of the 38 studies with positive results were published. As a contrast, only 3 of the 22 studies perceived by the Food and Drug Administration to have negative results were published accordingly, and 5 studies were published as being positive. While the analysis by the Food and Drug Administration showed that 51% of all trials were positive, only analyzing the published trials, 94% were positive.[41]

2.4.2 Shortcomings of medical guidelines

In order to avoid the dangers of unscientific medical care, evidence-based medicine emerged as a paradigm shift in the early 1990s.[42] Evidence-based guidelines have an increasing role in everyday clinical practice and are internationally recognized as a tool to enable quality and improve patients outcomes.[43,44] Guidelines aim to improve the quality of medical care by providing a balanced, unbiased, and easy accessible summary of current medical evidence.[45] Unfortunately, lack of evidence, methodological standards, and implementation cause for concern.[44] Lower level evidence and expert opinion commonly account for the majority of recommendations presented.[46-49] A shortcoming of numerous guidelines is the absence of primary care perspectives.[50] Half of recommendations for primary care are based on expert consensus, usual care, or disease-oriented evidence, while only 18% are based on high quality, patient-oriented evidence.[51] Also, as reported by Pétursson et al. and Vinther et al., the sometimes monumental work load imposed on primary care by implementation of guideline recommendations is failed to be considered.[52,53]

By starting with a specific condition, guidelines often provide the gold standard for establishing the correct diagnosis. However, basic questions are neither answered nor critically examined: When will a correct and proven diagnosis benefit the patient? When is it safe to wait and see? For how long time and to what degree should symptoms be present before advanced diagnostic testing is initiated?[54,55]

Medical guidelines have the position to define both normal and disease, hence special caution to disease definition is warranted. When guidelines are updated, the definition of disease is commonly expanded without thorough balancing of benefits and harms of the proposed changes.[56] The expanded definitions can lead to overdiagnosis through overdefinition. According to the updated blood pressure guideline from the American College

of Cardiology and the American Heart Association, where the cut off for hypertension is lowered from 140/90 to 130/80 mm Hg, the majority of adult Americans and Chinese are now defined as in need of intervention.[57]

2.4.3 Early diagnosis

A strong belief in the benefits of early detection and treatment has prevailed in medical societies for a century.[58,59] In 1923 Dr. Bloodgood published an article on breast cancer research at Johns Hopkins Hospital: "If the lump felt by the patient proves to be cancer, its duration is the only controllable factor in the ultimate cure. If the lump felt by the patient is not cancer, it remains curable no matter how long its duration, and becomes dangerous only when it changes into cancer. Its removal, therefore, is protection from cancer."[58]

Dr. Bloodgood did not take into consideration that many lumps never progress to cancer. And many cancerous lumps will never progress to symptomatic disease. In a systematic review on autopsy studies 59% of all men >79 years old had prostate cancer.[60] Only 4.8% of men who died in Norway in 2017 died of prostate cancer.[61] For thyroid cancer an autopsy study from Finland found occult papillary carcinoma in 36% of cases.[62] The section interval was 2 to 3 mm. As many of the tumors found were small, the authors calculated on reducing the section interval, and concluded that by examining thorough enough almost every thyroid gland, if not all, would be identified as cancerous.

Unfortunately, diagnoses of cancers that will never cause symptoms or death left untreated, overdiagnosed and overdetected cancers, are not only limited to corpses. As opposed to standard of care in 1923, today many women are diagnosed with breast cancer not after feeling a lump, but after screening participation. Exact estimates on rates of overdiagnosis within screening programs are vigorously debated. In 2012, Kalager et al. reported 15 to 25% of breast cancer cases diagnosed within the Norwegian Breast Cancer Screening Program to be overdiagnosed.[63] The study was criticized for overestimating the rate of overdiagnosis by researchers from the Cancer Registry of Norway. The Research Council of Norway report 7% of invasive cancers diagnosed within the Norwegian Breast Cancer Screening Program as likely overdiagnosed, increasing to 15 to 17% when ductal carcinoma in situ diagnoses are included.[64] These numbers are contrasted by substantially higher estimates reported by others. Jørgensen and Gøtzsche estimate the rate of overdiagnosis to be 37%, increasing to 52% if ductal carcinoma in situ is included.[65] Zahl and Mæhlen report that 50% of cancer diagnoses within the Norwegian Breast Cancer Screening Program represent overdiagnosis, increasing to two thirds if ductal carcinoma in situ is included.[66]

The Nordic Cochrane Centre have reported that 50% of men screened for and diagnosed with prostate cancer are likely overdiagnosed.[67] More than half a million people in 12 high income countries are estimated to be overdiagnosed with thyroid cancer following screening.[68] Despite controversy on exact estimates, overdetection is anticipated in screening. Contrary to Dr. Bloodgood's believe, removal of lumps is not necessary protection from cancer. A healthy person cannot gain any extra health benefit by treatment of a case of overdiagnosed cancer.

Acknowledging some of the shortages and harms of screening, the World Health Organization already in 1968 introduced criteria for screening tests.[69] The Norwegian Directorate of Health recommends to use the same criteria with some amendments for screening programs in Norway. In a 16-point list considerations on test validity, treatment benefit, and evidence among others are emphasized. It is explicitly listed that the health benefits should be greater than the negative effects and that information on participation should be evidence-based and contribute to informed choice.[70] The Norwegian Ministry of Health and Care Services has adopted many of the criteria in its national cancer strategy for 2018-22.[71] Foremost, national cancer screening programs should reduce disease specific morbidity and mortality. Test validity need to be high and the risk of adverse events low. Both the Norwegian Directorate of Health and the Norwegian Ministry of Health and Care Services stress the importance of defined, monitored screening programs, and that opportunistic screening should be reduced.[70,71]

2.4.4 Diagnostic intensity of imaging diagnostics

Imaging diagnostics plays a crucial role in every day clinical care and contributes to earlier diagnosis without invasive procedures. Concurrent with improved accuracy, the use of advanced imaging exams has increased tremendously the last decades. From 1996-2010 the use of magnetic resonance imaging and computed tomography (CT) increased by close to 10% annually.[72] Use of CT diagnostics for emergency departments patients in the US has increased by 330% from 1996-2007.[73] There are several risks and harms embedded with imaging diagnostics; among others false positive exams, overdiagnosis, radiation exposure, and incidentalomas.[74] Incidentalomas are asymptomatic findings, either benign or pathologic, that are shown on imaging exams ordered for an unrelated condition. In a study of whole-body imaging screening, 86% of the 1192 participants had at least one abnormal finding. On average the participants had 2.8 findings each and 37% of participants were recommended further follow-up.[75] Despite the high positive rates, whole-body imaging screening is

recommended against due to lack of evidence on improved patients outcomes in addition to high risk of false positive results.[76] If current use of imaging examinations continues, an estimated 2% of all future cancer cases will develop as a result of radiation exposure.[72]

2.4.5 Economic incentives

Medical care accounts for more than 12% of the gross domestic product in OECD countries and the expenses are increasing.[77] Economically, health care systems stand out. While other markets are regulated by demand and consumers' willingness to pay, the public health care system itself to a large degree defines the need of the population. Trust is embedded in the patient-doctor relationship. Patients are not expected to possess the medical knowledge necessary to question the validity of recommendations provided by health care professionals. In addition, health care is in many countries, including Norway, to a large degree financed not by the patient, but by public reimbursements according to quantity of care. Contrary to other economic systems, the patients have no economic interest in refusing a diagnostic test or treatment offer. General practitioners and private specialists with public reimbursement in Norway are better paid if they perform numerous procedures. Likewise, also hospitals have fee-for-service reimbursements for selected procedures and care. Hence, there is an economic incentive to perform more, independently of medical need.

Economic interests also affect medical care through control of medical evidence available with substantial influence on study questions, design, analysis, and reporting.[78,79] Economically biased publications have a substantial impact on clinical care.[79]

2.4.6 Defensive medicine

Defensive medicine is defined as the ordering of tests, treatments, and consultations in order to protect the health professional from malpractice litigation rather than improving patient outcomes.[80] In an American survey study on overtreatment, physicians reported 21% of overall medical care as unnecessary with fear of malpractice as the most common cause (85%).[81] In Norway malpractice litigation is seldom[82] and the impact of fear of lawsuits is understudied.

Compared to American conditions, malpractice litigation nevertheless seem to be less of a worry for Norwegian physicians. 14% of obstetricians report that perceived threats of lawsuit would influence their willingness to offer cesarean sections.[83] Even if litigation is rare, Norwegian physicians have to deal with increasing expectations from the general public.[84] General practitioners report that "to avoid overlooking anything" is a contributing

factor to 28% of referrals to specialized health care.[85] Fear of complaints and pressure from patients and next of kin are frequent causes of overtreatment according to Norwegian physicians.[86]

2.5 Norwegian public health

All citizens of Norway have a legal right to equal access to good quality health care.[87] Specialized health care is organized into four Regional Health Authorities which in turn run altogether 21 different health enterprises. The Norwegian municipalities are allocated into different hospital referral regions, each region is served by a defined health enterprise. The health enterprises run one or several public hospitals and collaborate with a varying number of private providers. All citizens are entitled to a regular general practitioner. General practitioners function as gate keepers who, at need, refer patients to specialized health care. With few exceptions, all appointments within specialized health care warrant referrals. The morbidity is relatively homogeneous across regions.[88] Nevertheless, there is considerable variation in health care provided for inhabitants of different regions.[89]

The Regional Health Authorities are financed by block grants in addition to activity-based funding. In 2012-13 block grants accounted for 60% and activity-based funding for 40% of total funding. From 2014 the split has been 50/50.[90,91] At public hospitals physicians are paid a fixed salary independent of quantity of care. Both private physicians and private hospitals that collaborate with the health enterprises are paid through a fee-for-service scheme; they receive reimbursements based on quantity of procedures and patient contacts.

2.6 Background for the individual papers

2.6.1 CT for suspected urolithiasis (paper 1)

Urolithiasis is the formation of urinary stones, which are stones located anywhere in the urinary system including kidneys, ureters, and bladder. A calculus that passes from the kidney may cause urinary obstruction and renal colic. Acute episodes of urolithiasis are characterized by renal colic and hematuria.[92] Pain relief is the number one priority for patients suffering an acute stone episode.[55] Most stones pass spontaneously and thus do not require surgical intervention.[93,94] Urolithiasis is common, affecting 5 to 10% of Europeans and North Americans.[95,96]

Urolithiasis guidelines by the European Association of Urology and the American Urological Association recommend that patients presenting with suspected urolithiasis should be radiologically examined.[55,97] This recommendation is not evidence-based. The guidelines

do not provide any advice on specific symptoms or clinical findings that should warrant imaging diagnostics, or when to rule out the necessity of such an examination.

In Norway, patients with self-limiting episodes of suspected urolithiasis are recommended referral to CT of kidneys, ureters, and bladder (CT KUB) after 4 weeks to control stone passage.[98] Again, this recommendation is not evidence-based. The radiation exposure, risk for incidentalomas, and costs associated with CT cause for concern.[74,99]

2.6.2 Routine pelvic examinations (paper 2)

Routine pelvic examinations are physical examinations of women's pelvic organs used for screening purposes. Apart from cervical cancer screening at set time intervals, routine pelvic examinations lack evidence on positive outcomes and the practice is strongly recommended against in asymptomatic women.[100-102] Neither screening colposcopy nor screening ultrasound is warranted.[103,104] Pelvic ultrasound in asymptomatic women is associated with high rates of false positive findings with a 33% increased risk of oophorectomy[105] and extensive use of unnecessary surgery.[105,106]

2.6.3 Diverticular disease (paper 3)

Diverticular disease is an umbrella term for diverticulosis, diverticular bleeding, and diverticulitis. Diverticulosis is a condition with several outpouchings of the colon. Diverticulosis is prevalent in developed countries with 50% of people aged 60 years or older being affected.[107,108] The majority of affected patients will remain asymptomatic throughout their lifetime, while a subset will experience diverticulitis or diverticular bleeding.[107,109] Diverticular disease is a frequent cause of both hospitalizations and outpatient appointments for gastrointestinal disease.[110]

Standard treatment for acute uncomplicated diverticulitis has until recently been hospital admission with intravenous antibiotics and dietary restrictions.[111] This treatment approach is not based on evidence of beneficial outcomes. Lack of evidence and inconsistency in recommendations between different diverticular disease guidelines is rather the rule than the exception.[54,112]

3. AIMS OF THE STUDY

The aims of the study were:

- To investigate if deferred routine CT KUB for patients with a self-limiting episode of suspected urolithiasis lead to surgical treatment.

- To quantify the extent of routine pelvic examinations within publicly funded specialized health care in Norway.

- To assess if the use of routine pelvic examinations differs across hospital referral regions

- To assess if the use of colposcopy and ultrasound in routine pelvic examinations differs with gynecologists' payment models.

- To assess if there are regional differences in rates of hospitalization and outpatient appointments for diverticular disease in Norway.

4. MATERIALS AND METHODS

4.1 CT for suspected urolithiasis (paper 1)

4.1.1 Study population and data collection

Data for paper 1 was extracted from electronic health records at the state-owned University Hospital of Northern Norway (UNN). UNN is the only provider of CT diagnostics in the hospital referral region, serving 200 000 inhabitants. Through the radiological information system used at UNN, we identified all patients examined with a deferred CT KUB between January 1st, 2010 and December 31st, 2013. Based on the referral information, we included patients who were examined on the suspicion of urolithiasis. We excluded patients who had a CT verified urinary stone within 1 year prior to the CT where the stone was not removed, patients under the age of 18 years, pregnant women, and patients with persistent symptoms for more than 3 weeks at the time of referral. We sent all eligible patients (n=410) a letter of information and a consent form. Among invited patients, 48% (n=197) accepted to participate. Due to exclusion criteria, final analysis yielded 189 CT KUBs.

4.1.2 Variables

Patients who by the time of CT KUB were described as asymptomatic in the electronic health record were defined as asymptomatic in our analyses. For many patients we had no symptom description after CT referral, as they did not have any contact with specialized health care apart from the CT scan itself. We classified these patients as asymptomatic in our analyses, under the assumption that they did not suffer symptoms in need of specialized health care services. Information in the referral letter was used to classify symptom duration and whether or not patients had previous urolithiasis or hematuria at the time of referral. We defined surgical interventions as any surgical procedure to alleviate or treat urolithiasis including ureteroscopic lithotripsy, extracorporeal shock wave lithotripsy, and ureteral stenting. We classified interventions in asymptomatic patients as interventions induced by the CT KUB.

4.1.3 Statistical analysis

The primary endpoint was the proportion of asymptomatic patients who within 1 year from the initial CT KUB had surgical intervention induced by a positive finding of urolithiasis on the CT scan. To analyze the probability of both surgical intervention and a confirmed diagnosis of urolithiasis on CT KUB, we performed logistic regression analyses with age, sex, hematuria, history of urolithiasis, duration of symptoms at referral, and time to CT as

covariates.

4.2 Routine pelvic examinations (paper 2)

4.2.1 Study population and data collection

Data for paper 2 were extracted from the Norwegian Patient Registry (NPR) in addition to demographic statistics from Statistics Norway. All public hospitals and private providers of publicly funded specialized health care in Norway are obliged to report diagnoses, procedures, and patient's residency of every patient discharge and outpatient appointment to NPR. The reports are linked to the patients through the unique personal identification number of all inhabitants of Norway. Diagnoses are reported to NPR according to the annual Norwegian version of the International Classification of Diseases version 10 (ICD-10).[113] Surgical, radiological, and medical procedures are reported according to the NOMESCO Classification of Surgical Procedures (NCSP), the Norwegian Classification of Radiological Procedures, and the Norwegian Classification of Medical Procedures.[114] Fee-for-service physicians also include tariff codes from "Tariff for publicly funded private physicians"[115] in their reports.

We included all Norwegian women aged 18 years and older in Norway in the years 2014-16 (n=2 016 852).

4.2.2 Variables

Routine pelvic examinations were defined as a primary diagnosis of ICD-10 Z01.4; "Encounter for gynecological examination without complaint, suspected or reported diagnosis." We defined colposcopy by the allocation of any of the procedural codes for colposcopy in the 2014-16 versions of NCSP (XLE 00, LXE 00) or "Tariff for publicly funded private physicians" (208). Likewise, we defined ultrasound by the allocation of any of the procedural codes for transvaginal ultrasound in the 2014-16 versions of the Norwegian Classification of Radiological Procedures and the Norwegian Classification of Medical Procedures (LXDE05, SLXOBK, SLXOAK) or "Tariff for publicly funded private physicians" (211c). Fee-for-service physicians can claim reimbursement for "complete examination performed by a specialist (after referral)" through the tariff code 4b1. We defined "complete examination" by the allocation of code 4b1.

The term "fixed salary gynecologist" refers to gynecologists working in public hospitals. Private gynecologists who receive public reimbursement are called "fee-for-service gynecologists."

4.2.3 Statistical analysis

We quantified the number of appointments for routine pelvic examination per 1000 women in Norway and for the 21 different hospital referral regions, standardized for age. We examined the use of colposcopy and ultrasound in these appointments for both fixed salary and fee-for service gynecologists. Pearson's chi-square test was used to compare differences between provider types. The impact registered secondary diagnoses had on regional variation and use of colposcopy and ultrasound, was examined. The use of "complete examination" at appointments at fee-for-service gynecologists, was also quantified. All numbers reported are the mean for 2014–16, unless otherwise stated. All regional rates were standardized by age with Jan 1st, 2016 as the standard population. We used SAS Enterprise Guide 7.1 for statistical analyses.[116]

4.3 Diverticular disease (paper 3)

4.3.1 Study population and data collection

Data for paper 3 were extracted as described for paper 2. In this paper, we included all Norwegian citizens aged 40 years and older in Norway in the years 2012-16 (n=2 517 938).

4.3.2 Variables

We defined colonic diverticular disease as a primary diagnosis of any of the ICD-10 codes K57.2–57.9: "Diverticular disease of large intestine" and "Diverticular disease of intestine, part unspecified." Discharges with codes for colitis or colon or rectal cancer, ICD-10 codes K50-52 and C18-C21, were excluded.

Hospitalizations and outpatient appointments were defined by length of stay. Discharges with length of stay ≥ 1 day were defined as hospitalizations while appointments with length of stay of stay = 0 day were defined as outpatient appointments. Both hospitalizations and outpatient appointments were separated into acute or elective care according to allocated codes.

Lower gastrointestinal (LGI) endoscopy was defined by the allocation of any procedural code for colonoscopy or sigmoidoscopy in the 2012-16 versions of NCSP (UJF 32, JUF 32, UJF 35, JUF 35, UJF 42, JUF 42, UJF 45, JUF 45, JFA 15) or in "Tariff for publicly funded private physicians" (115a, 114a).[115] We defined "LGI endoscopy for any indication" as any use of LGI endoscopy, independent of allocated ICD-10 codes.

We defined surgery by the allocation of a procedural code for colonic resection (JFB 20-97), colostomy (JFF 20-31 and 96-7), colectomy (JFH 00-96), or peritoneal drainage and irrigation (JAK 00-04) in NCSP. Surgery was classified as acute or elective according to the degree of urgency allocated for the relevant admission.

The term "private physicians" refers to both fee-for-service physicians and physicians working at private hospitals with public reimbursement. As for paper 2, we used SAS Enterprise Guide 7.1 for the statistical analyses.[116]

4.3.3 Statistical analysis

We calculated the national and regional age- and sex-standardized rates of hospitalizations and outpatient appointments for diverticular disease per 100 000 inhabitants. We examined the use of LGI endoscopy in both hospitalizations and outpatient appointments for diverticular disease. We obtained the age- and sex-standardized rates of surgery for diverticular disease by the four Regional Health Authorities. Length of stay was analyzed for hospitalizations. We used Spearman's correlation coefficient to examine the correlation between outpatient appointments and hospitalizations. In additional analyses we quantified the use of LGI endoscopy for any indication. We used Spearman's correlation coefficient to examine the correlation between regional rates for outpatient appointments for diverticular disease and LGI endoscopy for any indication performed in outpatient appointments. All reported numbers are the mean for 2012-16, unless otherwise stated. We standardized all regional rates by age and sex with Jan 1st, 2015 as the standard population.

4.4 Ethics

Study approval for paper 1 was obtained from the Regional committee for medical and health research ethics (Rec North, 2014/1904-13). All participants gave written informed consent.

For paper 2 and 3 The Norwegian Data Inspectorate licensed the data registry at Centre for Clinical Documentation and Evaluation (ref. 15/00271–2/CGN and 16/00289–2/CGN).

5. MAIN RESULTS

5.1.1 CT for suspected urolithiasis (paper 1)

At the time of CT examination, 90% (n=171) of patients were asymptomatic, of whom 23% (n=40) had a positive finding of urolithiasis on the CT scan. Of asymptomatic patients, three (1.8%) were treated surgically and two (1.2%) had hydronephrosis.

The three asymptomatic patients who underwent treatment were all middle-aged men. Two patients of whom one had hydronephrosis were each diagnosed with a 7 mm ureteral stone. The patient with silent hydronephrosis had suffered symptoms for 7 days before he spontaneously turned asymptomatic. The final treated asymptomatic patient had a 10 mm stable kidney stone.

Among the asymptomatic patients with a positive finding of urolithiasis on CT KUB, 62.5% (n=25) had kidney stones, 27.5% (n=11) had ureteral stones, and 10% (n=4) had bladder stones. Median size for kidney, ureteral, and bladder stones were 3 mm (range 1-14), 4 mm (range 3-7), and 4 mm (range 4-4), respectively.

In logistic regression models men had an odds ratio of 2.50 (95% CI 1.12-5.58) for a positive finding of urolithiasis compared to women. None of the other covariates were significant for a confirmed diagnosis of urolithiasis. Surgical intervention could not be predicted by any of the covariates.

In addition to urolithiasis, the CT scans also revealed numerous other findings. One asymptomatic patient received treatment for an incidental finding of a small intestine adenocarcinoma and three symptomatic patients were diagnosed and treated for other abdominal conditions. Physician visits and/or further imaging diagnostics was offered to 8.5% (n=16) of patients on the suspicion of a potential calculus or malignant process. All cases were concluded as insignificant findings with no need for further follow-up.

5.1.2 Routine pelvic examinations (paper 2)

Annually, there were 43 439 routine pelvic examinations in Norway, constituting 22.2 examinations per 1000 women. Both the mean and the median age for women examined were 47 years. Women between 25 and 69 years constituted 87.6% of appointments.

The number of examinations ranged from 6.6 to 43.9 per 1000 women across the hospital referral regions. Fixed salary gynecologists performed one third (n=14 115) of pelvic examinations with the mean age of women examined being approximately the same as at fee-for-service gynecologists (46.7 vs. 47.8 years, respectively).

In comparison of payment models, gynecologists with fixed salaries performed colposcopy in 1.6% (n=249) of appointments with 49.2% (n=14 427) as corresponding number for fee-for-service gynecologists. Ultrasound was used in 74.5% (n=11 810) of appointments at fixed salary gynecologists while fee-for-service gynecologists used ultrasound in 96.2% (n=28 216) of appointments. Differences between provider types were statistically significant for both colposcopy ($p < .001$) and ultrasound ($p < .001$). Fee-for-service gynecologists claimed reimbursement for "complete examination" in 87.3% of routine pelvic exams.

Secondary diagnoses were registered in 16.5% of examinations. More than 850 different secondary diagnoses were used, many with no relevance to the female genitalia. Both fixed salary and fee-for-service gynecologists used colposcopy and ultrasound slightly more frequently in appointments with secondary diagnoses than appointments without such diagnoses. Excluding appointments with secondary diagnoses caused minor sequence replacements of five regions in the analysis of regional variation and did not diminish the differences between provider types in use of colposcopy and ultrasound.

5.1.3 Diverticular disease (paper 3)

Hospitalization rates were stable during the study period with 132 hospitalizations per 100 000 inhabitants. Across regions there was a 1.9-fold variation in hospitalization rates from 95 to 179 per 100 000 inhabitants. In all regions the median length of stay was either two or three days. Acute hospitalizations accounted for 84% of admissions.

Surgery rates for diverticular disease were stable during the study period with 16 surgery admissions per 100 000 inhabitants. Acute surgery was less common than elective and accounted for 32% of the overall amount. Across the Regional Health Authorities regions, there was a 1.3-fold variation in surgery rates, from 15 to 19 per 100 000 inhabitants.

Over the study years, the mean rate of outpatient appointments for diverticular disease was 381 per 100 000 inhabitants, with a 37% increase in annual rates from 2012-16. Across regions there was a 2.5-fold variation in outpatient appointment rates from 258 to 655 per 100 000 inhabitants. Outpatient appointments were mainly elective (92%). Outpatient appointments and hospitalizations across regions were strongly correlated (r_s=0.69, p<0.001).

LGI endoscopy was frequently performed in outpatient appointments for diverticular disease and less commonly during hospitalizations, 76% vs. 15%, respectively. In outpatient appointments at public hospitals LGI endoscopy was used in 72% of appointments. Private physicians performed LGI endoscopy 1.3 times as often and used the procedure in 96% of appointments. During the study period there was a 39% increase in the annual rates of outpatient appointment with LGI endoscopy for diverticular disease.

From 2012-16, the annual rates of LGI endoscopy for any indication increased by 6% in hospitalizations and by 35% in outpatient appointments. Regional outpatient LGI endoscopy for any indication and outpatient appointments for diverticular disease was strongly correlated (r_s=0.72, p<0.001).

6. GENERAL DISCUSSION

6.1 Methodological considerations

The Too Much Medicine Movement and studies of overuse are criticized for oversimplifying the complexity of medical practice.[32] Admittedly, the terms used are often hard to conceptualize and clearly value dependent. To directly measure overuse necessitates well-accepted appropriateness criteria, which for most conditions are lacking. The updated American College of Cardiology/American Heart Association high blood pressure guideline and the following debate exemplify how hard it is to achieve consensus even for conditions with a massive evidence base.[117-119] Assessing the same evidence, different guideline panels suggest a small reduction in the risk of cardiovascular events with lower blood pressure targets. However, panels differ in how they value the estimated risk reduction. While the American College of Cardiology and the American Heart Association emphasize the treatment benefit when they define hypertension as blood pressure ≥130/80 mm Hg,[117] the Norwegian Directorate of Health, the American Academy of Family Physicians, The American College of Physicians, the European Society of Cardiology, and the European Society of Hypertension judge differently. Based on no reduction in either cardiovascular disease mortality or all-cause mortality, lack of systematic assessment of harms associated with blood pressure treatment, and risk of overdiagnosis and overtreatment, the latter guidelines keep blood pressure ≥140/90 mm Hg as hypertension cutoff. [119-121]

How to balance small benefits or benefits to very few patients versus harms of overuse and medicalization is not answered by medical trials. In Paper 1 we argue that the practice of deferred CT KUB following a self-limiting episode of suspected urolithiasis is *low-value*. The term is commonly used to describe services that provide very little health benefit given the resources used, with neither "low" nor "value" precisely defined.[8,10] Some argue that *low-value health care* only should describe services that have been assessed with a systematic cost-effectiveness analysis, as it would make the term more operational.[8] This approach would emphasize the economic aspect when assessing the value of a health service, and rendering low-cost services with minimal health benefits excluded from the term. Moreover, also cost-effectiveness analyses are left with subjective assessments in balancing costs versus effectiveness and benefits. The perils of medicalization cannot be properly covered by cost-effectiveness analysis. To appreciate the complexity of health and the impact of medical practice, we have in the papers included in this thesis accepted the vagueness of "value."

There are many gray areas in medical practice where definite answers regarding right or wrong care is hard to achieve.[10] It is challenging to assess whether a little too much is better than the risk of a little too little. Nevertheless, this acknowledgement should not limit the scope of medical research to questions that can be addressed only by more rigorous methods.

Studies of regional variation are recognized as useful indirect tools for identifying overuse.[1,25,26] A methodological concern is how to identify unwarranted variation within observed variation.[122] Observed variation consists of both a random and a systematic component. Some degree of variation is expected due to chance and is hence warranted. Also, within the systematic component of observed variation, some variation is medically explainable due to differences in disease burden. Unwarranted variation is the part of systematic variation that cannot be explained by differences in morbidity or patient preferences.[1]

The statistical analyses applied in variation analyses are understudied and their validity in identifying unwarranted variation is questioned.[123] There is no acknowledged method to discriminate between random and systematic variation.[124] The size of our studies is in this regard an advantage. The studied conditions are common, and the numbers are so high that the impact of random variation should be limited.

Variation studies are criticized for incapacities in adjusting for severity of illness.[122] This is less of a concern in Norway, where there are few acknowledged differences in morbidity.[88] To adjust for differences in demographic factors we standardized all analyses in paper 2 by age and in paper 3 by sex and age. Though theoretically a concern, studies so far have shown that patient preferences have little impact on regional variation.[125]

6.2 Methodologic considerations related to the individual papers

6.2.1 CT for suspected urolithiasis (paper 1)

The practice of CT KUB for suspected urolithiasis is acknowledged as well-appropriate, and it is highly recommended. Hence, rather than measuring overuse, paper 1 is a study questioning established, though not evidence-based appropriateness criteria.

Paper 1 is a case series. Due to the observational, descriptive, and retrospective design, we have not been able to directly compare outcomes between patients examined with deferred CT KUB and patients not examined. As deferred CT KUB is recommended practice, and presumably the majority of eligible patients get examined, comparison between groups in

regular clinical practice would be very limited. We could not carry out a medical trial to test for differences in outcomes due to lack of support from the Departments of Urology and Radiology at UNN.

Specific concerns for our study was non-response bias due to low participation rate and bias as a result of missing information in the patient files. Low participation rates are expected in epidemiological studies, especially when postal recruitment is carried out years after the relevant episode. However, people who perceive the study question important on a personal level are more likely to participate than others.[126] It seems unlikely that the non-responders in our study would constitute a subgroup more severely afflicted with urolithiasis than those who participated. Hence, our low benefit conclusion is probably not threatened by differences between responders and non-responders. To increase participation rate, we could have pre-contacted invited patients, used incentives, or sent postal follow-up to non-responders.[127] However, these approaches were not approved by the ethical committee.

Urolithiasis is referred to as *kidney stone* in Norwegian lay language, encompassing both kidney and ureteral stones. This term is used also by professionals.[98] We could not differentiate between patients referred to CT KUB under the suspicion of ureteral or kidney stones, as most referrals asked for kidney stone diagnostics, while describing common ureteral stone symptoms.

For the great majority of CT KUBs studied, the information in the medical record was limited to the referral letter and the radiological description of the CT scan. As symptom description in many case files were incomplete, there are uncertainties about symptom assessment for defined asymptomatic patients. The primary endpoint, the proportion of asymptomatic patients with CT KUB confirmed urolithiasis where the CT image led to surgical intervention, has consequently weaknesses. Patients we defined as asymptomatic might have suffered symptoms that were handled outside specialized health care. The medical record of one of the three treated asymptomatic patients did not provide information on symptoms after CT KUB referral. Hence, we were unfortunately not able to assess whether this patient was treated due to symptoms or the CT KUB report itself. As we did not want to minimize the benefits of CT diagnostics, we counted the patient as asymptomatic, even if we did not know the clinical presentation at the time of treatment.

Some referral letters had missing or vague information on symptoms, hematuria, and/or previous urolithiasis. Hence, the regression analyses have several biases due to missing information and the results should be interpreted with caution. Especially information on previous urolithiasis and hematuria was limited, so unfortunately, our study cannot conclude

on the impact of these matters. Furthermore, even when precise information was given, we could not validate if the information was correct.

The major strength of our study is that we have investigated a recommended and well-established practice, a practice supported by expert opinion in the absence of studies on the topic. Even though some referral letters were insufficient in regard to patient history and clinical findings, our study still show the likelihood of surgical intervention after referral to deferred CT KUB. In real life, insufficient information in referral letters is a part of everyday clinical care. We believe our study, despite methodological shortcomings, gives important knowledge about outcomes of the routine practice of deferred CT KUB for suspected urolithiasis.

6.2.2 Variation studies with data from the Norwegian Patient Registry (paper 2 and 3)

The two cross-sectional studies of this thesis share some strengths and limitations. By investigating differences in health care utilization rates across the different regions, we have found differences in provided care for the population independent of where the treatment was given. In this way, any intended collaboration between the providers will not affect the analyses.

Imbedded in the registry study design are potential coding errors. We cannot validate the registered diagnoses. We have knowledge only of the discharge diagnoses, not the referral symptoms. Local code practice might vary. However, variation in code practice on the individual level is not likely to cause systematic variation over regions.

Our studies are not able to demonstrate the causes of the observed regional variation. Regional variation might reflect regional differences in disease burden. Practice variation within a hospital referral region is often larger than between regions,[128] hence reported regional utilization patterns might not represent any particular practice. Our studies examined only health care utilization in publicly funded specialized health care. Differences in primary care management may influence both outpatient appointment and hospitalization patterns. Also, we were not able to assess use and possible influence of privately out-of-pocket paid health care services with the data available.

Secondary diagnoses are known to be underreported.[129] Either reported or not-reported secondary conditions might have influenced the utilization patterns of health care services reported on in paper 2 and 3. Adjusting for comorbidities for routine pelvic examinations or diverticular disease is challenging, as there are no predefined lists of conditions of interest.

Moreover, by adjusting for comorbidities by other registered diagnoses, we would risk adjusting for differences in code practice and diagnostic intensity instead of real morbidity. Hence, we omitted adjusted analyses for paper 2 and 3. In paper 2 we did additional analyses were all appointments allocated a secondary diagnosis were excluded, to compare utilizations patterns between patients with and without registered secondary diagnoses. Registered secondary diagnoses had minimal impact on regional use.

A major strength of the studies is that they include the entire sex- and age- defined population and contain every outpatient appointment and hospitalization for the given conditions in Norway during the study periods. The studied codes are the codes used for actual reimbursement payments to hospitals and fee-for-service physicians. Correct reporting is mandatory, economically important, and focused on in both settings.

6.2.3 Routine pelvic examinations (paper 2)

Our study on routine pelvic examinations is both a variation study and a direct measurement of overuse. The given premise for the latter approach is that routine pelvic examinations are unwarranted. We perceive routine pelvic examinations within special health care in Norway as unwarranted based on lack of evidence on beneficial outcomes,[100] explicit recommendations against the practice,[100-102] and the Norwegian health authorities' warnings against screening outside of screening programs.[70,71] However, as with blood pressure thresholds, there is some professional disagreement among different guideline panels. Based on moderate quality evidence, the American College of Physicians, the Canadian Task Force on Preventive Health Care, and the American Academy of Family Physicians strongly recommend against routine pelvic examination.[100-102] The US Preventive Task Force and the American College of Obstetricians and Gynecologists conclude that there is insufficient evidence to either support or recommend against the practice.[130,131]

In ICD-10, the Z01 codes are limited to "persons without complaint or reported diagnosis," and the Z01.4 code is specified for "Gynaecological examinations (general/routine)."[113] It is possible that women referred to specialized health care for evaluation of various symptoms receive a Z01.4 diagnosis if the examination is negative. This would represent coding error, as ICD-10 codes Z03 should be used for "[m]edical observation and evaluation for suspected diseases and conditions" in "persons who present some symptoms or evidence of an abnormal condition which requires study, but who, after examination and observation, show no need for further treatment or medical care."[113]

Fee-for-service gynecologists receive personal reimbursement for reported codes of colposcopy or ultrasound. The same procedures reported by hospital physicians do not lead to extra payment neither to the physician personally nor to the hospital. Thus, fixed salary physicians are potentially less thorough in their reporting with a consequently underreporting of the use of colposcopy and ultrasound in hospitals. Nevertheless, the magnitude of the observed differences can hardly be explained by hospital underreporting.

6.2.4 Diverticular disease (paper 3)

ICD-10 codes for diverticular disease, K57, do not differentiate between diverticulosis, diverticular bleeding, or diverticulitis. Our study is therefore not able to differentiate across a spectrum of disease severity where also asymptomatic patients may have been diagnosed with diverticular disease. However, it seems hypothetical that patients were hospitalized without symptoms, especially as the great majority of admissions were acute.

ICD-10 differentiate between diverticular disease with and without perforation. We wanted to examine if differences in code severity influenced regional utilization patterns. However, variation studies can only be applied to services of some extent; for rare conditions and seldom procedures observed regional variations is likely to be random and not systematic.[123] The numbers of hospitalizations and outpatient appointments for diverticular disease with and without perforation were too small for further analysis. Similarly, it was not possible for us to analyze regional yearly rates or investigate surgery rates at the health enterprise level.

Regional differences in code setting for diverticular disease and less specified conditions might be a source of error. It is possible that some patients with diverticular disease were coded as ICD-10 code R10, “Abdominal and pelvic pain.” We explored the distribution of R10 and chose to omit this code from the analyses as R10 was the discharge diagnosis in almost twice as many hospitalizations and over three times as many outpatient appointments as K57 and the age distribution of the two codes differed substantially. Moreover, we only had access to discharge diagnoses. Consequently, if the regional variation observed was due to regional differences in code accuracy this would seemingly reflect regional variation in diagnostic intensity including use of LGI endoscopy and CT examinations. The observed correspondence between LGI endoscopy for any indication and outpatient appointments for diverticular disease strengthens this interpretation.

6.3 Discussion of main findings

In paper 1 we found that the practice of deferred CT KUB for patients with self-limiting episodes of suspected urolithiasis did not lead to surgical intervention in the great majority of asymptomatic patients. In paper 2 we found extensive use and regional variation of routine pelvic examinations. Fee-for-service gynecologists used colposcopy and ultrasound strikingly more frequent than fixed salary gynecologists. In paper 3 we demonstrated that hospitalization and outpatient rates for diverticular disease were about twice as high in high use regions compared to low use regions. Outpatient appointment rates for diverticular disease were strongly correlated to outpatient use of LGI endoscopy performed on any indication.

6.3.1 CT for suspected urolithiasis (paper 1)

In paper 1, we found the practice of routine deferred CT KUB to be low-value. Three asymptomatic patients (1.8%) received surgical treatment after a positive finding of urolithiasis on CT KUB, whereas only one treated patient had hydronephrosis, a scenario where treatment is clearly indicated.[132] The great majority of patients referred to deferred CT KUB remained asymptomatic after the initial suspected stone episode.

Wimpissinger et al. has reported some level of hydronephrosis in almost two thirds of asymptomatic ureteral stones. In this study, 1.1% of all patients (40 of 3711) diagnosed with ureteral stones were asymptomatic.[133] In a screening trial, Boyce et al. found asymptomatic urolithiasis and hydronephrosis in 0.0008% of adults (4 of 5047).[134] Unquestionably, asymptomatic urolithiasis exists and can cause both hydronephrosis and potential kidney damage.[133-135] The question is how to balance the small risk of asymptomatic urolithiasis and kidney damage following an acute symptomatic suspected stone event versus the benefits and harms associated with CT diagnostics.

We believe one case of a week-long symptomatic period followed by asymptomatic urolithiasis and hydronephrosis should not alone justify routinely referring all patients with self-limiting episodes of suspected urolithiasis for imaging diagnostics. Others might argue differently. The reliability of symptom assessment in prediction of obstruction is debated also for post-operative urolithiasis patients. The incidence of asymptomatic obstruction following treatment is exceedingly low, reported from 0 to 4%.[97] The American Urological Association states that “Imaging all ureteroscopy patients to detect the rare case of silent obstruction is not cost-effective” and “This need-to-treat value is hardly justifiable from a strictly economic

viewpoint. Nonetheless, the Panel believes that the relatively low cost and lack of ionizing radiation associated with renal sonography justifies its use in routine follow-up of patients treated for ureteral stones."[97] The panel does not address harms of false positive findings or incidentalomas associated with imaging diagnostics.

Traditionally, a confirmed diagnosis is perceived as beneficial. A quarter of asymptomatic patients got a confirmed diagnosis of urolithiasis after CT KUB. However, two thirds of CT diagnosed asymptomatic patients had kidney stones with median stone size 3 mm. It is unlikely that such small kidney stones were causing the acute symptoms patients were experiencing at the time of referral.[136] It is reasonable to believe that the referral symptoms of many patients had no connection to the finding on CT KUB. Hence, it is possible that a considerable proportion of the CT diagnosed cases represent incidental findings.

Our positive yield was considerably lower than 66 to 70%, which was reported in the studies the European Association of Urology refer to in their support for CT diagnostics.[137-140] Those reports dealt with acute investigation and are therefore not directly comparable to our results. Furthermore, the referred studies are twenty years old. The positive yield today will likely be lower as the use of CT KUB has seemingly increased 20-fold from 1996 to 2011 while a comparable increase in diagnosed urolithiasis has not been seen.[141,142] Chen et al. reported a drop in diagnosed cases from 49% to 28% from one year to the other, presumably caused by more liberal use of CT diagnostics.[143]

In the acute setting, CT KUBs ordered by an urologist or emergency room physician are significantly more likely to confirm a stone diagnosis than CTs ordered by any other doctor (67-73% vs. 39-43%, respectively).[144,145] Comparing our results with the latter group, our results indicate that the suspicion of urolithiasis is less likely to be well-founded when the clinical presentation not necessitate acute investigation. Our lower diagnostic yield might to some degree also be explained by spontaneous passage before deferred CT diagnostics. However, time from referral to CT was not a significant predictor for a confirmed stone diagnosis. Women in our study had a lower positive yield than men, which is in accordance with previous studies.[144-147]

In close to one out of ten CT KUBs we examined, the patient received either a false positive urolithiasis diagnosis or a diagnosis of a potential malignant process where further testing concluded with insignificant findings. All cases led to either additional CT scans, physician visits, or both. In the benefit-to-harm balance of CT diagnostics for urolithiasis, these findings should be appraised.

The practice of deferred CT KUB for patients with self-limiting episodes of suspected urolithiasis is yet to be proven beneficial for patients with symptoms for less than a week, for younger patients, and for women in general. We recommend that the routine practice should be discontinued. Patients who remain pain free after an initial short episode should be informed about potential benefits and harms of CT diagnostics and participate in shared decision making on whether or not CT KUB should be performed.

6.3.2 Routine pelvic examinations (paper 2)

In our paper we demonstrated widespread use of routine pelvic examinations in Norway with extensive variation across hospital referral regions. Our study revealed extensive overuse of health care services and inappropriate and unnecessary screening procedures.

The majority of women examined were between 25 and 69 years old. The age distribution in our study is in correspondence with the age group invited for cervical cancer screening in Norway.[148] This finding suggests that a large proportion of women who received a routine pelvic examination, probably had the examination as an expanded part of cervical cancer screening.

It is not surprising that women seek gynecologists for cervical screening. The Norwegian Consumer Council have reported that one out of ten regular general practitioners do not offer pelvic examinations at all.[149] The Norwegian Cervical Cancer Screening Programme lists general practitioners and gynecologists as equal alternatives for performing the screening exam.[148] Also for insertion of intrauterine contraception, there is an observed shift from primary to specialized health care.[150] However, the World Health Organization stresses that "all aspects of health care performance can suffer" if health care systems fail to provide "the right care at the right time in the right place."[151] There is no medical need for gynecological expertise when performing cytology screening. Accordingly, "the right place" for cervical screening should be primary care. If women in our study were examined by gynecologists for cervical screening, our study demonstrates overuse of specialized health care services.

The extensive use of colposcopy and ultrasound adds to this overuse. Whether or not women in our study received specialized health care for cervical screening or a routine examination outside the screening program, colposcopy and pelvic ultrasound are either way not indicated in asymptomatic women. The procedures are not a routine part of the Norwegian Cervical Cancer Screening Programme and should not be performed as a part of the screening program unless there is a visible lesion, or the cytology test result is abnormal.

The variation in routine pelvic examinations across regions was substantial. As all examined women were gynecologically healthy by definition, differences in morbidity should not explain the regional variation. With our data we cannot identify the causes for the observed variation. Possible explanations include regional differences in supply of both gynecologists and general practitioners and differences across regions in professional opinions regarding routine examinations. Either way, apart for cytology testing, there is no pelvic screening program in Norway. Both the substantial regional variation and any routine pelvic examination outside a screening program are per se unwarranted in regard to the Norwegian Patients' Rights Act[87] and in regard to the Norwegian health authorities' concerns about opportunistic screening.[70,71] We perceive the observed use of routine pelvic examinations as unwarranted overuse of health care services and an example of supply-sensitive care.[26]

The differences between fixed salary and fee-for-service gynecologists in use of colposcopy and ultrasound were striking. Patient preferences might hypothetically explain some of the variation observed both between provider types and across regions. However, it seems highly unlikely that women examined by fee-for-service gynecologists actively seek colposcopy while women examined at public hospitals opt out the procedure. Moreover, the procedures are not recommended screening examinations and do not fulfill the screening criteria set by the Norwegian Directorate of Health.[70] Colposcopy and pelvic ultrasound are, to our knowledge, not a routine part of any public screening program anywhere in the world. Screening colposcopy and vaginal ultrasound should not be offered within publicly funded health care regardless of patient preferences.

Fee-for-service is acknowledged as the main driver for the high medical expenditures in the USA. The National Commission on Physician Payment Reform recommends payers to "largely eliminate stand-alone fee-for-service payment to medical practices because of its inherent inefficiencies and problematic financial incentives."[152] The World Health Organization warns against fee-for-service as "over-servicing is the inevitable result."[153] For primary care, there is some evidence that fee-for-service results in more physician visits compared to capitation and salary payment, and in more specialist visits and both diagnostic and curative procedures compared to capitation.[154] In gynecology, more elective services are performed under fee-for-service compared to capitation.[155] However, evidence on practice differences between physicians with different payment models is limited and reviews on patient outcomes are missing.[154,156]

In studies examining differences between provider types, it is difficult to assess if the observed differences in provided care are caused by payment differences or other aspects, i.e. differences in population, morbidity etc. These potential biases should hardly affect our results as the women by definition were healthy and the examinations unwarranted for any healthy woman. We feel convinced that the observed differences in use of colposcopy and ultrasound are examples of fee-for-service led unnecessary health care services.

The tariff code for "complete examination" is a potential co-driver to this overuse. In Norway, all publicly funded private specialists, not only gynecologists, are motivated to perform thorough examinations through the tariff code for "complete examination." The code can be claimed when the physician has taken a precise history and a complete status preasens specific for the respective specialty. The necessity of such an examination is not questioned. As fee-for-service physicians already get extra reimbursement for every procedure they perform, the value of this additional "complete" code should be evaluated. In our study, we wonder if fee-for-service gynecologists might have been motivated to perform both colposcopy and ultrasound not only by the procedures themselves, but also to justify reimbursements claims for the well-paid "complete examination."

Contrary to popular belief, recommendations against screening pelvic examinations is not about depriving women of a well-documented beneficial health examination due to cost containment. The recommendations are based on lack of evidence on beneficial outcomes in addition to evidence on negative adverse effects. For the well-being of Norwegian women, we argue that Norwegian gynecologists should stop their practice of routine pelvic examinations in healthy women.

This discontinuation of specialist practice should include cervical screening. Health authorities should take steps to transfer cervical screening within the Norwegian Cervical Cancer Screening Programme to primary care. Gynecologists, general practitioners, and health authorities alike should inform patients and the general public about the pitfalls of screening and why pelvic screening exams including additional procedures are unnecessary and unwarranted. Today, the Cancer Registry of Norway informs women that they can have their Pap test taken either by a general practitioner or by a gynecologist.[148] We recommend that the Cancer Registry change this information and informs Norwegian women that there is no need for gynecological expertise when performing a Pap test.

Pelvic examinations are intimate and may cause physical discomfort and emotionally distress.[157,158] Due to the nature of the exam, some women might prefer to be examined by a female physician or any other physician than their regular general practitioner for cervical

screening. However, we believe that the organization of the screening program should be debated and settled on a national level to ensure equality in health services across the country. If special circumstances, i.e. history of abuse, warrants referral to specialized health care for cervical screening, the screening exam should be limited to Pap or human papillomavirus tests and visual inspection of the cervix.[100]

6.3.3 Diverticular disease (paper 3)

We demonstrated considerable regional variation in both hospital admission and outpatient appointment rates for diverticular disease. Regional outpatient appointment rates for diverticular disease were strongly correlated to the use of LGI endoscopy for any indication. The degree of regional variation and the correlation with diagnostic intensity of LGI endoscopy point to health care utilization that is influenced by regional differences in clinical practice independent from disease burden.

The stable hospitalization and surgery rates over the study years indicate a relatively stable disease burden. This observation is contrasted by the large increase in outpatient appointment rates in the same period. The increase in outpatient appointment rates for diverticular disease closely follows the increase in rates of outpatient LGI endoscopy for any indication. Diverticulosis is a very frequent finding on LGI endoscopy for any indication, with 43% of examinations ending with a diverticulosis diagnosis.[108] Hence, it is not surprising that diagnoses of diverticular disease follow the diagnostic intensity of LGI endoscopy. As outpatient appointments for diverticular disease were correlated to both time trends and regional rates of LGI endoscopy for any indication, the diagnostic intensity of LGI endoscopy seem to highly influence outpatient appointment trends for diverticular disease. In 2019 a national colorectal cancer screening program will be launched in Norway.[159] Based on our results, we predict a high increase in diverticular disease diagnoses following colonoscopy screening implementation.

Regional hospitalization and outpatient appointment rates were strongly correlated and might reflect increased morbidity in high rate regions. The correspondence might also reflect regional variation independent of disease burden where differences in clinical practice and professional views influence both hospitalizations and outpatient care in a similar way. As outpatient appointments also were strongly correlated to LGI endoscopy, it is possible that labeling patients with a diverticular disease diagnosis might affect hospitalization patterns.

Surgery for diverticular disease has been used as a surrogate for disease severity.[160] The observed differences across regions in surgery rates might reflect real differences in

morbidity. However, the majority of surgery performed was elective. Evidence for optimal long-term follow-up and recurrence prevention for symptomatic diverticular disease is very limited.[54,161] There are no routine indications for elective surgery after uncomplicated cases of diverticulitis, and guidelines lack criteria for when elective surgery should be recommended.[112] An American study on acute diverticulitis showed that surgeon characteristics predicted surgical decisions independent of disease severity.[162] In our study, the regions of South-Eastern Norway Health Authority had both the lowest rates of surgery and the lowest proportion of elective surgery. Hence, the low surgery rate might be explained not by low morbidity, but by a more defensive clinical practice regarding elective surgery.

It is well known that the prevalence of diverticular disease varies across countries and continents. Due to the geographical differences, diverticulosis has been described as a disease of the Western world.[107] Several factors including urbanization, low fiber intake, and obesity have been studied and are thought to play a role in the development of diverticulosis, though the pathogenesis is not fully understood.[107,163,164] Variation studies within countries are limited. Neither dietary fiber nor body mass can explain the differences observed in admission rates across different American regions.[163] Data on body mass, lifestyle, and diet is not collected on a population level in Norway, so unfortunately, we could not adjust for these perceived risk factors. Even though we were unable to identify the exact causes of the observed variation, we believe that the extent of variation across regions points to health care utilization that is associated with supply-sensitive care.[26] Documented lack of clinical consensus internationally and lack of a national implemented guideline support our interpretation. Although there may be regional differences in disease burden, it seems unlikely that morbidity alone can explain an almost doubling of hospitalizations between low and high rate regions and an even bigger variation in outpatient appointments. We believe that regional variation in clinical care independent of disease burden is likely to explain at least some of the demonstrated regional variation in health care utilization for diverticular disease.

6.4 Further studies

In this thesis we have demonstrated uncertainties and shortcomings of very common practices. Different clinical settings will have different questions to raise. There is a shortage of Norwegian publications under the overall heading of overuse. We would encourage medical professionals and communities to consciously identify practices that should be further studied in regard of unwarranted use and variation. Properly designed studies testing both benefits and harms of established, but understudied practices, are warranted.

For suspected urolithiasis, further studies are needed to answer what is the best diagnostic approach for patients with varying demographic and symptom characteristics. The practice of routine deferred CT KUB should be tested in a clinical trial. For diverticular disease, further studies should identify the causes of observed variation and whether or not patient outcomes differs across regions. The demonstrated differences in provided care between provider types in paper 2 and 3 should be further investigated.

6.5 Consequences for care

This thesis has highlighted the need for guidelines not only to provide a gold standard of disease diagnostics and treatment, but also to describe which patients who are likely to benefit from the proposed procedures and at what risk. Guidelines on urolithiasis and diverticular disease should be updated according to exiting international guideline standards where potential harms of recommended procedures should be described and weighted against potential benefits, and where patients' values are taken into account.[165]

The regional variation seen in paper 2 is not directly comparable to the variation demonstrated in paper 3. For paper 2, given that all of the registered routine pelvic examinations were truly examinations of asymptomatic women, the right level of care is close to, if not zero. The practice should be discontinued. For paper 3, as for variation studies in general, we cannot use the variation figures alone to judge what the right level of care is. We cannot conclude on either overuse or underuse in any given hospital referral area. Nevertheless, the variation demonstrated in both studies should be critically appraised by national, regional, and local health providers. Reasons for the observed regional variation should be identified and addressed.

Health authorities should identify remedies to level off unwarranted differences between provider types. Paper 2 adds to previous reports on the negative impact fee-for-service has on health care performance. The continuation of fee-for-service payments in its present form should be scrutinized. However, until reform, Norwegian health authorities can use the reimbursement system in a likewise manner as the National Health Service England to achieve a reduction in unwarranted procedures. The National Health Service England has listed 17 inappropriate interventions they aim to reduce by cancelling reimbursements.[166] We believe neither routine pelvic examinations nor cervical screening should be reimbursed in specialized health care unless special indication. In addition, the tariff code for "complete examination" for fee-for service physicians should be thoroughly reviewed for all specialties.

The path from evidence to clinical change and improved clinical outcomes is challenging and time consuming for medical research in general.[167] As with obstacles in medical guideline implementation,[44] decades of regional variation studies have had some, but limited impact on clinical care.[168] In Norway, years of atlas publications have not levelled of differences.[89] Whereas documentation of regional variation is a first step, clinical change and improved patient outcomes are unlikely to happen without further involvement of health authorities in collaboration with clinicians.[168] In this regard, I am happy that both the Minister of Health and the Norwegian Medical Association pay attention to unwarranted variation in healthcare and engage in reducing overuse.[16,169,170] In September 2018 the Norwegian Medical Association launched the Norwegian version of Choosing Wisely: "Gjøre kloke valg." In Choosing Wisely, different medical societies identify practices within their own specialty that are unnecessary or low-value. With reference to relevant evidence, the societies publish recommendations on common practices to avoid or question. I hope Choosing Wisely and likewise initiatives will be incorporated into every day clinical care.

There are many questions yet to be answered in regard of potential unnecessary health care services in the clinical settings presented. It is easy to state that further studies are needed. However, the much more demanding task of dealing with uncertainties and shortage of evidence cannot be escaped by health care providers. Acknowledging the uncertainties embedded in medical practice and the potential harms of overdiagnosis, overtreatment and unnecessary health care should be an ongoing exercise for all health professionals and health authorities. In Norway, many hospital departments have routines for monthly or weekly "complication meetings." By discussing procedure complications, the aim is to learn from mistakes and improve clinical care. I argue that unnecessary tests and treatments should be discussed in likewise formal settings. Harms, risks, and shortcomings of procedures should be addressed in guidelines and communicated to patients. Patients should be encouraged to ask the questions raised by Choosing Wisely; "Why do I need to take this test/treatment? What are the risks and adverse events? What will happen if I don´t do it? Is there an alternative?"[170]

7. CONCLUSIONS

In the papers included in is thesis, we have studied unwarranted regional variation and use of health care services for three clinical conditions. Our results confirm that the increasing international focus on too much medicine and variation is relevant also for Norwegian health care. Based on our results, we conclude that the practice of deferred CT KUB for patients with a self-limiting episode of suspected urolithiasis is a low-value health care service. Unwarranted pelvic examinations are widespread with substantial regional variation. Fee-for-service reimbursements seem to skyrocket the use of colposcopy and increase the use of vaginal ultrasound in screening examinations. We found regional variation in both hospitalizations and outpatient appointments for diverticular disease.

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SCANDINAVIAN JOURNAL OF UROLOGY, 2017
VOL. 51, NO. 1, 62–67
http://dx.doi.org/10.1080/21681805.2016.1254680

ORIGINAL ARTICLE

Routine deferred computed tomography for patients with suspected urolithiasis is low-value healthcare

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ABSTRACT

Objective: The aim of this study was to investigate the benefits of deferred routine computed tomography of the kidneys, ureters and bladder (CT KUB) for patients with a self-limiting episode of suspected urolithiasis.

Materials and methods: The study comprised a case series of consecutive patients examined with deferred routine CT KUB for control of suspected urolithiasis. Patients examined with CT KUB at the University Hospital of North Norway, between 1 January 2010 and 31 December 2013, were included. The final analysis included 189 CT KUBs (response rate 48%). All data were extracted from the patient case files. The primary endpoint was the proportion of asymptomatic patients with a confirmed diagnosis of urolithiasis on CT KUB that led to surgical intervention within 1 year from the initial CT scan.

Results: At the time of CT KUB, 171 patients (90%) were asymptomatic, of whom three (1.8%) were treated. Urolithiasis was confirmed on CT KUB in 23% of asymptomatic patients.

Conclusion: Deferred CT KUB did not alter the clinical outcome for the great majority of asymptomatic patients. The majority of patients who received adequate pain relief in primary care remained asymptomatic, and did not need specialized healthcare. Refraining from CT KUB involves little risk. Deferred CT KUB for patients with suspected urolithiasis is a low-value healthcare service.

ARTICLE HISTORY
Received 26 May 2016
Revised 31 August 2016
Accepted 26 October 2016

KEYWORDS
Computed tomography; guidelines; low-value healthcare; urolithiasis

Introduction

Calculi in the urinary tract are common: in the USA, one person in 11 will have a kidney stone during their lifetime [1]. It is unknown whether the observed increase in urolithiasis [1–3] is due to a real increase in incidence, increased use and sensitivity of imaging modalities [4], and/or a lower threshold for contacting the healthcare system. The charges for emergency department visits for urolithiasis increased by 10% annually between 2006 and 2009, and amounted to 5 billion USD in 2009 [2]. Emergency department visits due to flank or kidney pain increased significantly from 1996 to 2007, together with a more than 10-fold increase in the use of computed tomography of the kidneys, ureters and bladder (CT KUB). The proportion of patients who were diagnosed with urolithiasis did not increase [5].

There is consensus in the urology community that patients presenting with suspected urolithiasis should have their tentative diagnosis supported by appropriate imaging. The European Association of Urology (EAU), American Urological Association (AUA) and American College of Radiology recommend CT KUB because of its high sensitivity and specificity compared to other imaging modalities [6–8]. The high expenses and radiation exposure associated with CT KUB are a cause for concern [2,5,6,8]. In the EUA's 2015 guideline, ultrasound is described as the preferred initial imaging modality; however, the recommendation on CT KUB remains: 'Following initial ultrasound assessment, non-contrast computerized tomography should be used to confirm a stone diagnosis in patients presenting with acute flank pain, because it is superior to intravenous urography' [6].

The guidelines do not specify when to suspect urolithiasis, and when to refer a patient for CT KUB, and when not to. The EUA states: 'Patients with ureteral stones usually present with loin pain, vomiting, and sometimes fever, but may also be asymptomatic' [6]. When to suspect urolithiasis is therefore largely left to the individual physician's clinical discretion. The guidelines do not describe management of suspected urolithiasis in primary care.

Most ureteral stones pass spontaneously [7,9,10]. Only 1.1% of asymptomatic stones need intervention [11]. In Norway, patients with ongoing severe symptoms of suspected urolithiasis are commonly hospitalized acutely. However, in cases where the pain resolves either spontaneously or conservatively they are discharged from the emergency room or leave their general practitioner (GP) with a referral to CT KUB within 2–6 weeks [12]. The practice is not based on evidence of patient outcomes. The argument is that most ureteral stones pass spontaneously within 40 days [3,9], and a deferred CT KUB can both control passage and be diagnostic for stones remaining after the expected time of passage.

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The aim of this study was to investigate the clinical benefits for patients managed with deferred routine CT KUB after a self-limiting initial episode of suspected urolithiasis.

Materials and methods

Study design

This study is a case series of consecutive patients investigated with deferred CT KUB. The probability of a positive finding of urolithiasis was determined, along with the extent of interventions performed on both symptomatic and asymptomatic patients.

Setting

The University Hospital of Northern Norway (UNN) is a state-owned hospital with locations in Tromsø, Harstad and Narvik. UNN is the local hospital for 200,000 inhabitants. In the attachment area there are no other CT scan providers. The GP refers the patients to specialized health services including imaging investigation, when needed.

Participants

From a search of patient case files at UNN from 1 January 2010 to 31 December 2013, patients with suspected urolithiasis and deferred CT KUB were identified and included on the basis of the referral information. All patients referred to CT KUB with a suspicion of urolithiasis were included, regardless of how the symptoms were described. Patients with a CT-verified calculus within 1 year before the CT where the calculus was not removed, patients under 18 years of age, pregnant patients and patients with persistent symptoms for more than 3 weeks at the time of referral were excluded from the study.

The inclusion criteria were fulfilled in 438 patients, of whom 28 were not invited, 10 because they had died and 18 because no contact address could be obtained. Patients were contacted by letter with information on the study and a consent form. Of the 410 invited patients, 197 (48%) agreed to participate and gave permission to study their hospital records (Figure 1). Fourteen cases were excluded from the analysis because further investigation of their hospital records showed that five patients had had symptoms for more than 3 weeks at the time of referral, four patients had a stone diagnosis within 1 year before the CT and five patients had been converted to immediate imaging owing to worsening of clinical symptoms. Six participants had two independent episodes of suspected urolithiasis and were referred to deferred CT KUB twice in the period of investigation, yielding 203 CT KUBs. The final analysis included 189 CT KUBs.

Data collection

All data were extracted from the patient case files. CT findings, age, gender, previously known urolithiasis, time from symptom onset to referral, time from referral to CT imaging, clinical symptoms after referral, additional imaging diagnostics, urological appointments and treatment within 1 year from the initial CT were registered.

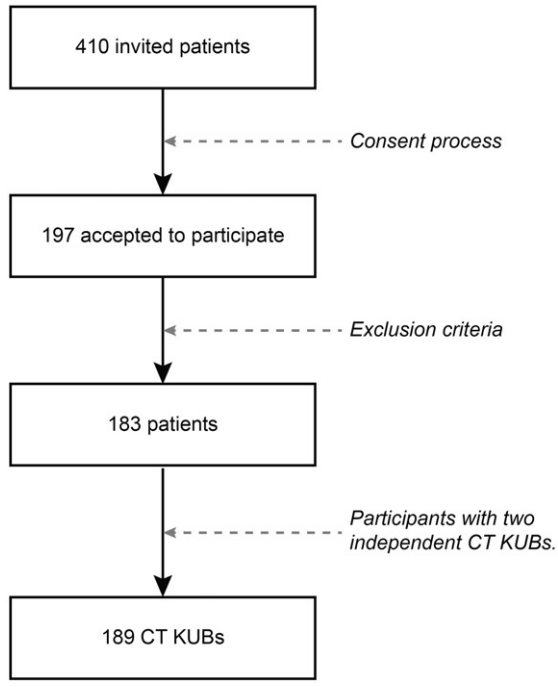

Figure 1. Flow of patients and computed tomography of the kidneys, ureters and bladder (CT KUBs) through the study.

Ethics

The Regional Committee for Medical and Health Research Ethics approved the study. Written consent was obtained from all participants.

Outcome measurements and statistical analysis

The primary endpoint was the proportion of asymptomatic patients with a confirmed diagnosis of urolithiasis on CT KUB that led to surgical intervention within 1 year from the initial CT scan. Patients with absence of pain or discomfort by the time of CT KUB were classified as asymptomatic. For patients without any clinical follow-up visit at the hospital, the authors had no knowledge about symptoms after the CT referral. These patients were classified as asymptomatic in the analysis, as they did not exhibit symptoms judged necessary for specialized healthcare. Surgical intervention was defined as any intervention performed to treat or alleviate urolithiasis, including extracorporeal shockwave lithotripsy, ureteroscopic lithotripsy and ureteral stenting. At UNN, common indications for active stone removal are severe or persistent symptoms of urolithiasis combined with a confirmed radiological diagnosis. Interventions in asymptomatic patients were regarded as interventions induced by the CT KUB.

The secondary endpoints were the proportion of asymptomatic patients and the amount of intervention performed on symptomatic patients. Logistic regression analysis of the probability of both positive findings and intervention was

Table 1. Characteristics of patients examined with deferred routine computed tomography of the kidneys, ureters and bladder (CT KUB) after a self-limiting episode of urolithiasis.

All participants	Total	Women	Men
Patients, *n* (%)	189 (100)	79 (42)	110 (58)
Age (years), median (mean)	55 (55.4)	55 (55.0)	57 (55.7)
range	18–89	19–89	18–84
Previously known urolithiasis,[a] *n* (%)	80 (42)	31 (39)	49 (45)
Haematuria,[b] *n* (%)	109 (58)	49 (62)	60 (55)
Duration of symptoms at referral (days), median (mean)	1 (3.3)	2 (3.7)	1 (3.1)
range	1–20	1–19	1–20
Time from referral to CT (days), median (mean)	23 (30.2)	25 (31.2)	22 (29.5)
range	1–106	3–106	1–105

[a]Missing information in 67 cases (35%), defined as not having a history of urolithiasis in calculation of percentage;
[b]missing information in 59 cases (31%), defined as not having haematuria in calculation of percentage.

Table 2. Asymptomatic patients examined with routine computed tomography of the kidneys, ureters and bladder (CT KUB).

Asymptomatic patients	Total	Women	Men
Patients, *n* (%)	171 (90)	73 (92)	98 (89)
Age (years), median (mean)	56 (55.7)	55 (55.6)	57 (55.9)
range	18–89	19–89	18–84
Duration of symptoms at referral (days),[a] median (mean)	1 (3.3)	2 (3.7)	1 (3.1)
range	1–20	1–19	1–20
Previously known urolithiasis,[b] *n* (%)	71 (41.5)	29 (40)	42 (43)
Haematuria[c]	98 (57.3)	46 (63)	52 (53)
Time from referral to CT (days), median (mean)	17 (26.4)	21 (28.5)	16 (24.8)
range	1–106	1–106	1–105
Urolithiasis on CT KUB, *n* (%)	40 (23)	12 (16)	28 (29)
Surgical intervention, *n* (%)	3 (1.8)	0 (0)	3 (3.1)

[a]Missing information in 48 cases (28%);
[b]missing information in 64 cases (37%), defined as not having a history of urolithiasis in calculation of percentage;
[c]missing information in 52 cases (30%), defined as not having haematuria in calculation of percentage.

performed with the following covariates: age, gender, haematuria, previously known urolithiasis, duration of symptoms at referral and time from referral to CT.

Results

Out of 189 CT KUBs, 79 (42%) were performed on women and 110 (58%) on men (Table 1). The mean age was 55 years. The majority was referred to CT KUB after a maximum of 1 day of symptoms. GPs had ordered 95% of the referrals. By the time of CT KUB, 90% were asymptomatic, of whom 23% received a confirmed diagnosis of urolithiasis (Table 2). Three asymptomatic patients underwent surgical intervention.

Of asymptomatic patients with a confirmed diagnosis of urolithiasis, 25 had kidney stones, 11 ureteral stones and four bladder stones (Table 3). The majority had one stone while 10 patients had two to nine stones, all located in the kidneys. The median size for all calculi was 4 mm (range 1–17 mm). The median sizes for kidney and ureteral stones were 3 mm (1–14 mm) and 4 mm (3–7 mm), respectively. Hydronephrosis was present in two asymptomatic patients, of whom one received intervention and one passed a 3 mm ureteral stone spontaneously. The subsequent follow-up CT showed no sign of hydronephrosis. In 168 patients, there was no information on urolithiasis in the case record after referral, including 37 patients with positive CT. Of these patients, 24 had kidney stones, nine ureteral stones and four bladder stones; the median stone size was 3.5 mm.

In logistic regression analysis, only gender was significant in the probability of positive findings, with an odds ratio of 2.50 for men ($p = 0.025$, 95% confidence interval 1.12–5.58). None of the variables was a significant predictor for intervention.

The characteristics of asymptomatic patients who received intervention are shown in Table 4. Three male patients were classified as asymptomatic and received treatment, two with ureteral stones and one with a kidney stone. Out of 18 symptomatic patients, 12 underwent surgical intervention and six passed a stone spontaneously. The characteristics of symptomatic patients who received intervention are shown in Table 5. All symptomatic patients who were treated had symptoms for a minimum of 7 weeks before intervention. Four symptomatic patients had hydronephrosis, all of whom were treated.

Follow-up for conditions other than urolithiasis revealed on CT KUB was offered to 20 patients (11%). Four patients received treatment, one each for small intestine adenocarcinoma, bladder cancer, ureterocele and gallstones. The carcinoid tumour was an incidental finding, while the three other patients presented symptoms that induced intervention. CT findings of possible calculi or incidental findings of possible malignant processes resulted in both imaging and physician consultation for 16 patients. All 16 cases were concluded as benign conditions with no need for treatment.

Discussion

This study found close to no benefit of CT KUB for patients remaining asymptomatic after a self-limiting episode of suspected urolithiasis. The great majority of patients with

Table 3. Asymptomatic patients with urolithiasis on computed tomography of the kidneys, ureters and bladder (CT KUB).

Asymptomatic patients	Total	Women	Men
Patients, *n* (% of all asymptomatic patients)	40 (24)	12 (16)	28 (29)
Age (years), median (mean)	55.5 (56.7)	55 (54.9)	55.5 (57.4)
range	29–84	36–79	29–84
Previously known urolithiasis,[a] *n* (%)	18 (45)	3 (25)	15 (54)
Haematuria,[b] *n* (%)	23 (58)	6 (50)	17 (60)
Hydronephrosis, *n* (%)	2 (5)	1 (8.3)	1 (3.6)
Size all calculi (mm),[c] median (mean)	4 (4.4)	3 (3.75)	4 (4.7)
range	1–14	1–12	1–14
Location			
Kidney			
Patients/calculi,[c] *n*	25/57	8/20	17/43
Stone size (cm), median (mean)	3 (4.4)	3 (3.9)	4 (4.7)
range	1–14	1–12	1–14
Ureter			
Calculi, *n*	11	8	3
Stone size (cm), median (mean)	4 (4.5)	4.5 (4.9)	3 (3.3)
range	3–7	3–7	3–4
Bladder			
Calculi, *n*	4	3	1
Stone size (cm), median (mean)	4 (4)	4 (4)	4 (4)
range	4–4	4–4	4–4

[a]Missing information in 13 cases (33%), defined as not having a history of urolithiasis in calculation of percentage;
[b]missing information in 15 cases (38%), defined as not having haematuria in calculation of percentage;
[c]10 patients with kidney stones had more than one calculus. Only the largest calculus of each patient is included in the calculation of size.

Table 4. Characteristics of three asymptomatic patients who received intervention after deferred routine computed tomography of the kidneys, ureters and bladder (CT KUB).

Gender	Male	Male	Male
Age (years)	50	54	62
Duration of symptoms at referral (days)	1	1	7
Previous history of urolithiasis	Yes	No	Yes
Haematuria	Yes	Yes	Yes
Hydroureter or hydronephrosis	No	No	Yes
Location	Ureter	Kidney	Ureter
Stone size (mm)	7	10	7
Known duration of symptoms before intervention (days)	Unknown	1–7	7
Symptom-free period before intervention (months)	Unknown	6	2

Table 5. Symptomatic patients receiving surgical intervention after computed tomography of the kidneys, ureters and bladder (CT KUB).

Symptomatic patients	Total	Women	Men
Patients, *n* (%)	12	4	8
Age (years), median (mean)	48 (53.3)	47 (46.8)	58.5 (56.5)
range	31–83	44–49	31–83
Previously known urolithiasis, *n* (%)	7 (58)	2 (50)	5 (63)
Haematuria[a]	6 (50)	1 (25)	5 (63)
Location			
Kidney			
Patients/calculi,[b] *n*/*n*	4/5	2/3	2
Size (cm), mean	10.2	8	13.5
range	7–17	7–9	10–13
Pyeloureteral junction			
Calculi, *n*	3	0	3
Size (cm), mean	7.7		7.7
range	5–10		5–10
Ureter			
Calculi, *n*	5	2	3
Size (cm), mean	6.8	6	7.3
range	5–8	5–7	7–8

[a]Missing information in six cases (50%), defined as not having a history of haematuria in calculation of percentage;
[b]all four kidney patients had more than one calculus; only the treated calculi are included in calculation of size.

suspected urolithiasis who do not need immediate specialized care, do not need specialized care at all. In this population, 90% of patients remained asymptomatic and without specialized healthcare follow-up.

These data suggest that routine CT KUB for all patients with suspected urolithiasis represents a low-value healthcare service. The risk associated with refraining from CT KUB for asymptomatic patients is marginal. Only one examined patient had an asymptomatic calculus that caused persistent hydronephrosis, which untreated could represent a risk for kidney damage. There is international attention on reducing the use of medical interventions that provide no or marginal benefit [13,14]. Overuse of CT is of public concern [15] and it can be argued that managing self-limiting episodes of urolithiasis with routine CT KUB is overdiagnosis, and accordingly should be avoided.

Surgical treatment was offered to three patients with registered symptoms for less than 1 month. For the 62-year-old patient with ureteral calculi and hydronephrosis, active stone removal was induced by the CT KUB. For the other ureteral patient, the case record is insufficient with regard to symptoms. The available sources gave no information on his symptoms and one can only speculate on whether symptoms or the CT image itself caused the intervention. The final treated asymptomatic patient had a kidney stone without hydronephrosis, which had been asymptomatic for 6 months. It is questionable whether this intervention was necessary as there is no advantage in the prophylactic treatment of asymptomatic calyceal stones [6].

The present findings also indicate that the practice of deferred imaging is safe, as Lindqvist et al. have demonstrated [16]. The majority of patients with a confirmed diagnosis of urolithiasis had calculi smaller than 5 mm in renal calices, calculi that most often are asymptomatic [6]. Two asymptomatic patients received a confirmed diagnosis of kidney stones that were 6 mm or smaller on their CT KUB while their ureter was slightly dilated. The calculi causing the symptoms of urolithiasis had most probably already passed at the time of CT KUB. Knowing this, it is reasonable to believe that the symptoms of a proportion of patients had no connection to the finding on CT KUB, and thus the benefit of the confirmed diagnosis is questionable. It is impossible to assess whether the total 69% with negative CT KUBs had passed a calculus already or were suffering symptoms of conditions other than urolithiasis.

Hydronephrosis was present in 22% of symptomatic patients. The symptomatic patients in this analysis constitute a subgroup easily identified by the persistence of their symptoms, as everyone had symptoms for more than 7 weeks before intervention. The results show that patients with persistent symptoms should undergo an imaging examination both for treatment planning and for the assessment of possible hydronephrosis.

GPs had ordered almost every CT, which demonstrates that the decision regarding deferred CT is made in primary care. This corresponds well with the clinical distinction between patients in urgent need of hospitalization for severe symptoms of urolithiasis and patients with a shorter self-limiting episode. The results indicate that almost every patient admitted to the hospital acutely underwent CT KUB during their admission.

The extensive cost and considerable radiation exposure of CT KUB for managing urolithiasis are well documented [2,8,17]. In a multicentre study, Smith-Bindman et al. compared patient outcomes when the initial investigation was either ultrasound or CT KUB, and found no significant differences in complication rates, pain scores, emergency department visits or hospitalization rates. The CT KUB group had a significantly higher radiation exposure [17]. Many recommend ultrasound as the primary imaging modality [6,17–19]. Ultrasound screening for asymptomatic patients would, in the present study population, have detected potential damaging conditions due to urolithiasis with equal sensitivity to CT KUB. The sensitivity of ultrasound in detecting hydronephrosis is close to 100% [20]. Therefore, the authors support the recommendation of ultrasound as the primary modality if imaging diagnostics are chosen for asymptomatic patients.

However, implementation of low-dose CT KUB can limit the radiation exposure to 0.6 mSv [21], and would make the radiation argument for avoiding CT less relevant. Falling outside the scope of this study, further research should assess the costs of deferred ultrasound diagnostics compared to low-dose CT KUB. The cost and clinical implications of incidental findings using the two modalities should also be assessed.

As reported by others, the positive rate for urolithiasis was lower for women than for men [18,19] and could not be explained by other covariates. No asymptomatic woman was treated for urolithiasis. Special caution towards the use of CT KUB in women has been advocated [18,19], and the present results support this recommendation.

Apart from one incidental finding of a gastrointestinal tumour, patients treated for conditions other than urolithiasis had persistent symptoms. These patients would probably have been recognized and treated without routine CT KUB after a self-limiting episode of suspected urolithiasis. In this group, there were more patients receiving unnecessary follow-ups for findings that turned out to be benign than there were patients being treated for urolithiasis. The economic burden of incidental findings is substantial while the medical benefit is questionable [22]. The one incidental finding of clinical importance is not an argument for routine CT KUB.

The strength of this study is the fact that UNN is the only provider of specialized care and CT diagnostics in the area, creating a representative patient population. The participation rate was only 48%; however, such a rate is not uncommon when postal written consent has to be obtained several years after the relevant episode. The degree to which this sample is representative of all patients examined with CT KUB is therefore hard to assess. It is nevertheless reasonable to believe that patients who are more afflicted with urolithiasis are more motivated than others to participate in a urolithiasis study. It is therefore not likely that the low-benefit conclusion is threatened by a low participation rate.

The information in some of the referral letters was insufficient. For some of the patients, the duration of symptoms at referral, status regarding haematuria and previously known urolithiasis, and/or symptoms after referral were not known. Furthermore, the descriptions of pain were sometimes imprecise. This study cannot answer how primary care physicians dealt with the CT findings. Further studies are warranted to assess whether more information on the duration and characteristics of symptoms could identify potential subgroups with increased or diminished risk associated with refraining from imaging diagnostics. Separate gender and age analysis should be performed.

In conclusion, the practice of imaging diagnostics for all patients with suspected urolithiasis is not evidence based. In this study, the great majority of patients with suspected urolithiasis who received adequate pain relief in primary care remained asymptomatic, and did not need specialized healthcare. Deferred CT KUB did not alter the clinical outcome for the great majority of asymptomatic patients. Refraining from CT KUB involves little risk. Deferred CT KUB for patients with suspected urolithiasis is a low-value healthcare service. The authors recommend that its routine use should be avoided and replaced by a process of shared decision making. Asymptomatic patients should receive information on the benefits and risks of imaging examination, in addition to thorough information on when to seek help again. If a patient experiences persistent symptoms, CT KUB should be recommended.

Acknowledgements

Johannes Walsøe is appreciated for technical assistance, Anna Bågenholm for expertise in radiology reports and Kristin Modalsli Sand for linguistic revision.

Disclosure statement

The authors have nothing to disclose.

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Errata

In the article “Routine deferred computed tomography for patients with suspected urolithiasis is low-value healthcare” there are some errors in Table 3 and 5.

1. In Table 3 ureteral stones and bladder stones of women and men have swapped places. The term “cm” should correctly read “mm” throughout the table. Please see the correct table below.

2. In Table 5 the term “cm” should correctly read “mm” throughout the table.

Asymptomatic patients	**Total**	**Women**	**Men**
Patients, *n* (% of all asymptomatic patients)	40 (24)	12 (16)	28 (29)
Age (years), median (mean)	55.5 (56.7)	55 (54.9)	55.5 (57.4)
range	29–84	36–79	29–84
Previously known urolithiasis,[a] *n* (%)	18 (45)	3 (25)	15 (54)
Haematuria,[b] *n* (%)	23 (58)	6 (50)	17 (60)
Hydronephrosis, *n* (%)	2 (5)	1 (8.3)	1 (3.6)
Size all calculi (mm),[c] median (mean)	4 (4.4)	3 (3.75)	4 (4.7)
range	1–14	1–12	1–14
Location			
Kidney			
Patients/calculi,[c] *n*	25/57	8/20	17/43
Stone size (mm), median (mean)	3 (4.4)	3 (3.9)	4 (4.7)
range	1–14	1–12	1–14
Ureter			
Calculi, *n*	11	3	8
Stone size (mm), median (mean)	4 (4.5)	3 (3.3)	4.5 (4.9)
range	3–7	3–4	3–7
Bladder			
Calculi, *n*	4	1	3
Stone size (mm), median (mean)	4 (4)	4 (4)	4 (4)
range	4–4	4–4	4–4

[a] Missing information in 13 cases (33%), defined as not having a history of urolithiasis in calculation of percentage;

[b] missing information in 15 cases (38%), defined as not having haematuria in calculation of percentage;

[c] 10 patients with kidney stones had more than one calculus. Only the largest calculus of each patient is included in the calculation of size.

Rosenlund et al. BMC Women's Health (2017) 17:114
DOI 10.1186/s12905-017-0471-2

BMC Women's Health

RESEARCH ARTICLE Open Access

Extent, regional variation and impact of gynecologist payment models in routine pelvic examinations: a nationwide cross-sectional study

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Abstract

Background: Based on moderate quality evidence, routine pelvic examination is strongly recommended against in asymptomatic women. The aims of this study was to quantify the extent of routine pelvic examinations within specialized health care in Norway, to assess if the use of these services differs across hospital referral regions and to assess if the use of colposcopy and ultrasound differs with gynecologists' payment models.

Methods: Nationwide cross-sectional study including all women aged 18 years and older in Norway in the years 2014–16 (2,038,747). Data was extracted from the Norwegian Patient Registry and Statistics Norway. The main outcome measures were 1. The number of appointments per 1000 women with a primary diagnosis of "Encounter for gynecological examination without complaint, suspected or reported diagnosis." 2. The age-standardized number of these appointments per 1000 women in the 21 different hospital referral regions of Norway. 3. The use of colposcopy and ultrasound in routine pelvic examinations, provided by gynecologists with fixed salaries and gynecologists paid by a fee-for-service model.

Results: Annually 22.2 out of every 1000 women in Norway had a routine pelvic examination, with variation across regions from 6.6 to 43.9 per 1000. Gynecologists with fixed salaries performed colposcopy in 1.6% and ultrasound in 74.5% of appointments. Corresponding numbers for fee-for-service gynecologists were 49.2% and 96.2%, respectively.

Conclusions: Routine pelvic examinations are widely performed in Norway. The variation across regions is extensive. Our results strongly indicate that fee-for-service payments for gynecologists skyrocket the use of colposcopy and increase the use of ultrasound in pelvic examinations of asymptomatic women.

Keywords: Routine pelvic examination, Unwarranted examination, Fee-for-service, Regional variation, Ultrasonography, Colposcopy

Background

Based on moderate quality evidence, routine pelvic examination is strongly recommended against in asymptomatic women [1–3], as is screening colposcopy [4] and routine screening for ovarian cancer in asymptomatic women [5–7]. In the Prostate, Lung, Colorectal and Ovarian Cancer Screening Randomized Controlled Trial, including 78,000 women, bimanual examination of the ovaries was discontinued as no ovarian cancer was detected merely by palpation [8]. Use of screening CA 125 and transvaginal ultrasound does not reduce ovarian cancer mortality [8, 9] and is advised against [5, 10]. High rates of colposcopy do not decrease cervical cancer incidence or mortality [11]. False positive screening test results are associated with harm. Women screened for ovarian cancer have a 33% increased risk of oophorectomy [8] and for every screening detected cancer ten women undergo surgery following a false positive ultrasound examination [9]. Ultrasound of the pelvis should not be performed unless clear indications are present

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[12]. Pelvic examination prior to provision of hormonal contraceptives does not identify women who should avoid these contraceptives and is not recommended as routine practice [13].

The Norwegian public health system is well developed with access for all inhabitants. All citizens have a legal right to equal access to good quality health care [14]. All citizens are entitled to a regular general practitioner who, if necessary, refers the patient to specialized care. Apart from abortions, women themselves cannot make an appointment at a publicly reimbursed gynecologist without a referral.

The municipalities of Norway are allocated into 21 different hospital referral regions. Each region has a defined health enterprise responsible for providing specialized health care for their inhabitants. The health enterprises collaborate with private physicians to varying degrees. In Norway all gynecologists at public hospitals are paid a fixed salary, while a fee-for-service model pays private gynecologists that collaborate with the health enterprises.

Methods

Aims

1. To quantify the extent of routine pelvic examinations within specialized health care in Norway.
2. To assess if the use of these services differs across hospital referral regions.
3. To assess if the use of colposcopy and ultrasound differs with gynecologists' payment models.

Study design

Nationwide cross-sectional study on routine pelvic examinations within specialized health care in Norway.

Setting

The Norwegian Patient Registry (NPR) contains health reports on every appointment within publicly funded specialized health care in Norway. Both public hospitals and private gynecologists that collaborate with the health enterprises report diagnoses of every patient appointment to NPR. The appointments are linked to the patients through the personal identification number of all inhabitants of Norway. Data from NPR is used for central planning of specialized health care, activity based financing, quality indicators, and health care research. Through Centre for Clinical Documentation and Evaluation (SKDE) we had access to reports for 2014–16 in addition to annual population statistics from Statistic Norway. One author (LL) had access to indirect personally identifiable data from NPR. All analyses and results are anonymous.

Participants

We included all Norwegian women aged 18 years and older in Norway in the years 2014–16 (n = 2,038,747).

Variables and data sources

In this study private gynecologists who get public reimbursement are for simplicity called "fee-for-service gynecologists." The term "fixed salary gynecologists" is used for gynecologists working in public hospitals, as the salaries of these gynecologists are independent of quantity of care. Data from privately out-of-pocket paid gynecologists' practice is not included in the study as such data is not recorded in Norway.

Both fixed salary and fee-for-service gynecologists used the International Classification of Diseases version 10 (ICD-10) for reports to NPR. The Norwegian versions for 2014–16 were in use during the study years. The three versions are identical for the codes we have studied [15]. All gynecologists also reported the municipality and city district code for the patients' residency. We used these codes to allocate appointments to the different hospital referral regions.

We defined routine pelvic examination as a primary diagnosis of ICD-10 Z01.4; "Encounter for gynecological examination without complaint, suspected or reported diagnosis." Cervical screening was defined as a primary diagnosis of the ICD-10 code Z12.4; "Encounter for screening for malignant neoplasm of cervix."

For hospital appointments colposcopy was defined by the allocation of the code LXE00 (colposcopy) in the 2014–16 versions of The NOMESCO Classification of Surgical Procedures (NCSP) [16]. Ultrasound was defined by the allocation of any of the codes LXDE05 (transvaginal ultrasound), SLXOBK or SLXOAK (transvaginal ultrasound of female pelvic organs) in the 2014–16 versions of the Norwegian Classification of Medical Procedures (NCMP) and the Norwegian Classification of Radiological Procedures (NCRP) [16]. For fee-for-service gynecologists colposcopy and ultrasound were defined either by the same procedure codes or by the allocation of the codes 208 (colposcopy) and 211c (transvaginal ultrasound) in "Tariff for publicly funded private physicians" versions 2014–16 [17]. In addition "complete examination" at a fee-for-service gynecologist was defined by the allocation of the tariff code 4b1 (allowance for complete examination performed by a specialist (after referral)).

Both publicly funded hospitals and fee-for-service gynecologists that get public funding are obligated to report surgical, medical, and radiological procedures according to NCSP, NCMP, and NCRP to NPR. In addition, fee-for-service gynecologists include tariff codes from "Tariff for publicly funded private physicians" in the reports sent to NPR. For each individual tariff code they report they get extra reimbursement. It is known that some fee-for-service

physicians underreport NCSP and NCMP codes. Therefore we also included the more thoroughly reported tariff codes to the definition of colposcopy and ultrasound for fee-for-service gynecologists.

Statistical analysis

We obtained the age-standardized number of appointments for routine pelvic examination per 1000 women in Norway, and for the 21 different hospital referral regions. We also quantified the use of colposcopy and ultrasound in appointments for routine pelvic examination for women examined by gynecologists with fixed salaries and fee-for-service gynecologists, respectively. Differences between provider types were compared with Pearson's chi-square test. For fee-for-service gynecologists the number of appointments with codes for "Allowance for complete examination performed by a specialist (after referral)" was also examined. All numbers reported are the annual mean for 2014–16, unless otherwise stated.

There were missing data for municipality code in 0.5% (215) of appointments annually. As it is likely that patients do not travel far for routine pelvic examinations, we analyzed these appointments according to the referral region where the examination took place.

In additional analyses, we quantified the extent of cervical screening tests within specialized health care in Norway, and we examined if differences across hospital referral regions in routine pelvic examinations were depended on differences in cervical screening tests. We also examined if the use of colposcopy and ultrasound, and variation across regions in pelvic examinations were depended on registered secondary diagnosis.

We used SAS Enterprise Guide 7.1 [18] to analyze the data.

Patient involvement

Patients were not formally involved in the planning or conduction of the study. However, the subject under investigation involves all Norwegian adult women including the female authors of this paper.

Results

The estimated adult female population of Norway in the years 2014–16 was 2,038,747. Nationally there were 22.2 pelvic examinations per 1000 women (Table 1). Of women who received a pelvic examination during the years of investigation, the majority (88.9%) had only one exam. The number of appointments per patient was 1.04 annually and 1.14 during the 3 year period.

Women aged 25–69 years constituted 87.6% (39,589) of appointments. Annually, 2.6% (38,065) of women aged 25–69 years had a routine pelvic examination, while 0.97% (2231) of younger women and 0.96% (3143) of those aged 70 years or older were examined (Fig. 1).

Table 1 Appointments for routine pelvic examinations in Norway, 2014–16

Measures	2014	2015	2016	Annual mean 2014–16
Patients, n	44,731	41,941	43,644	43,439
Appointments, n	46,619	43,534	45,382	45,178
Appointments per 1000 women	23.1	21.3	22.0	22.2
Age, years, mean/ median (range)	47.7/47 (18–98)	47.5/47 (18–101)	47.1/46 (18–100)	47.4/47 (18–101)

Pelvic examinations per 1000 women ranged from 6.6 to 43.9 across hospital referral regions (Fig. 2). Fee-for-service gynecologists performed two thirds (29,324) of pelvic examinations with the mean age of women examined being 1.1 years higher than at fixed salary gynecologists (47.8 vs. 46.7 years). Colposcopy was used in 1.6% (249) and ultrasound in 74.5% (11,810) of appointments at fixed salary gynecologists, while fee-for-service gynecologists used colposcopy in 49.2% (14,427) and ultrasound in 96.2% (28,216) of appointments (Fig. 3). Differences in use of colposcopy ($p < .001$) and ultrasound ($p < .001$) between provider types were statistical significant.

In addition 87.3% (29,324) of appointments in private practice had a procedural code for "complete examination performed by a specialist."

Additional analysis showed that there were 2013 appointments within publicly funded specialized health care for cervical screening appointments annually. Cervical screening constituted 4.3% of the combined number of appointments for cervical screening and routine pelvic examinations. The use of ultrasound was equivalent in appointments for cervical screening and routine pelvic examinations (91.3 vs. 88.6%). Both fixed salary and fee-for-service gynecologists used colposcopy more frequently in appointments for cervical screening compared to routine pelvic examinations. Fixed salary gynecologists used colposcopy in 9.8% (13) of cervical screening appointments (routine pelvic examination: 1.2%). The corresponding number fee-for-service gynecologists was 69.8% (1310) (routine pelvic examination: 49.2%). Fee-for-service gynecologists performed 93.3% (1877) of cervical screening examinations. Out of these 87.4% (1641) had a reimbursement code for "complete examination performed by a specialist." Adding cervical screening appointments to the analysis of regional variation caused minor sequence replacements for three regions while the national extent of variation did not change (Additional file 1).

In 16.5% (7472) of appointments one or more secondary diagnoses were registered. During the 3 year period there were 856 different secondary diagnoses from almost all

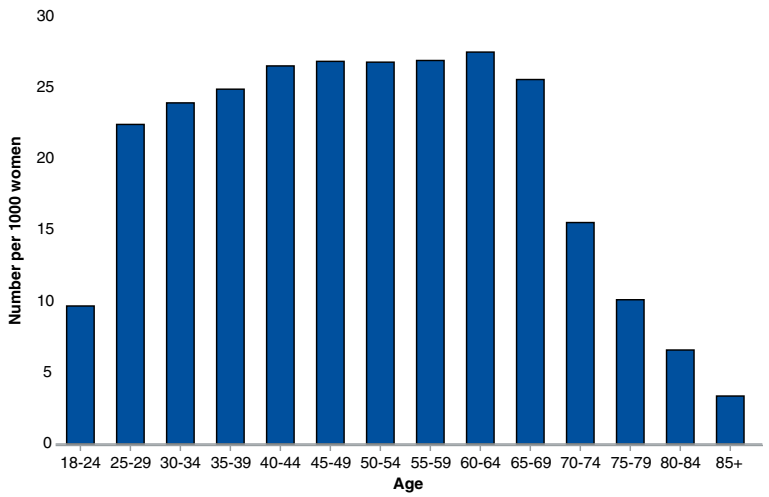

Fig. 1 Number per 1000 women receiving routine pelvic examinations by age groups. Annual mean for the years 2014–16

chapters in ICD-10. The variation in use of colposcopy and ultrasound between appointments with and without secondary diagnoses was minimal compared to the differences between fixed salary and fee-for-service gynecologists (Table 2).

Excluding appointments with secondary diagnoses in the analysis of regional variation caused minimal sequence replacements of five regions (Additional file 2).

Discussion

Principal findings

Routine pelvic examinations are widespread in Norway. Annually, 22.2 per 1000 adult women received a pelvic examination that is recommended against. The variation across hospital referral regions was extensive and ranged from 6.6 to 43.9 per 1000 women. Gynecologists with fixed salaries performed colposcopy in 1.6% and ultrasound in 74.5% of appointments, while fee-for-service gynecologists performed colposcopy in 49.2% and ultrasound in 96.2% of appointments. Fee-for-service payments for gynecologists seem to drive the utilization of colposcopy and ultrasound in routine pelvic examinations.

Interpretation

This is the first study to document the widespread use of unwarranted routine pelvic examinations in Norway. The great majority of examinations were performed on women aged 25–69 years. The Norwegian Cervical

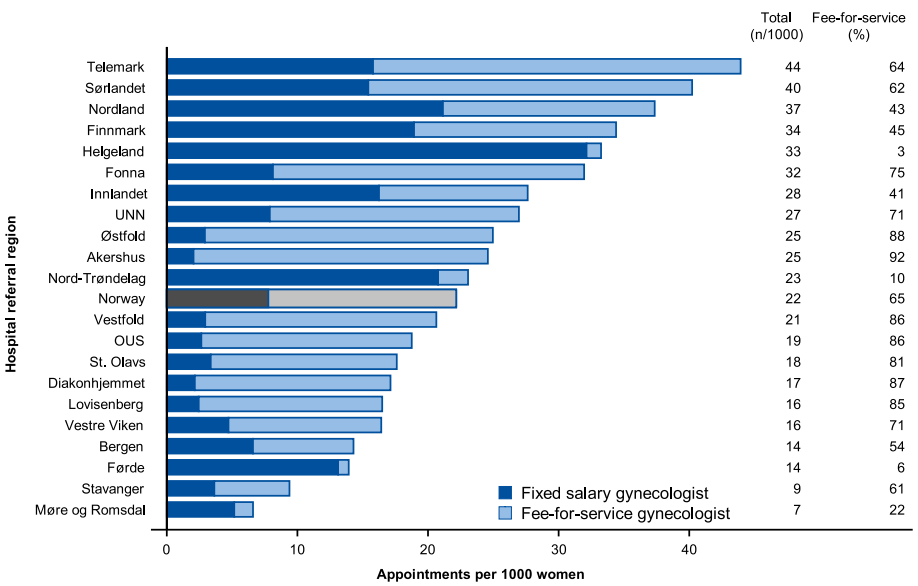

Fig. 2 Age-standardized number of appointments for routine pelvic examination per 1000 women by hospital referral region and type of provider

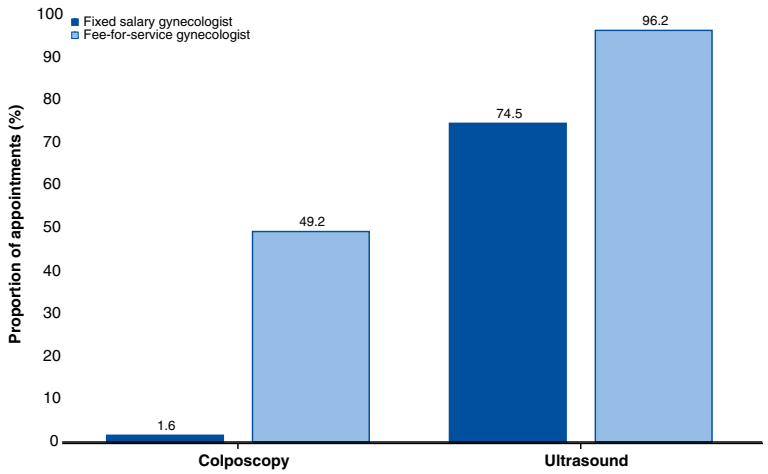

Fig. 3 Proportion (%) of appointments with colposcopy and ultrasound in routine pelvic examinations by comparison of fixed salary and fee-for-service gynecologists

Cancer Screening Programme recommends and reminds all women between the age of 25 and 69 years to have a cytology test done every 3 years [19]. The correlation between cervix screening age and the age distribution in this study indicates that a large proportion of women with a routine pelvic examination may have had the extended examination as part of cervix screening. The number of appointments for each woman was 1.14 during the 3 years study period, which further strengthens this interpretation.

The real extent of routine pelvic examination in specialized health care seems to be higher than our study reveals, as the content of health care delivered in cervical screening appointments is equivalent to what is demonstrated in routine pelvic examinations. Pelvic examination, pelvic ultrasound and colposcopy are not indicated in asymptomatic women and are not part of The Norwegian Cervical Cancer Screening Programme, unless the result of the cytology test shows cause for concern [19]. There are separate ICD-10 codes for abnormal cervical cytological findings [15]. If women in our study actually were referred to specialized health care for routine testing within The Norwegian Cervical Cancer Screening Programme, our results demonstrate overuse of specialist health care services as cervical screening is supposed to be a primary care undertaking. This reflects a recently observed shift from primary to specialized health care for insertion of intrauterine contraception [20]. The finding of high numbers of colposcopy, ultrasound, and "complete examinations" in cervical screening appointments adds to this overuse. Based on our findings, we argue that primary care physicians should perform cervix screening.

Table 2 Colposcopy and ultrasound in routine pelvic examinations by comparison of payment model and whether or not the appointment had a registered secondary diagnosis. Annual mean for the years 2014–16

	Fixed salary gynecologist		Fee-for-service gynecologist	
	Secondary diagnosis		Secondary diagnosis	
Outcomes	No (n = 14,314)	Yes (n = 1540)	No (n = 23,393)	Yes (n = 5932)
Colposcopy, % (n)	1.5% (220)	1.8% (28)	47.3% (11061)	56.8% (3366)
Ultrasound, % (n)	74.2% (10,616)	77.6% (1195)	95.7% (22,381)	98.4% (5835)

Concomitant cervix screening cannot explain the extensive regional variation observed. Neither can differences in morbidity across the regions, as the women examined were by definition healthy. Geographical variation is shown to be associated with supply sensitive care [21]. The extent of variation in the present study points to examinations that are dependent on local health care practice and supply.

While the American College of Physicians, the Canadian Task Force on Preventive Health Care and the American Academy of Family Physicians strongly recommend against routine pelvic screening examinations, the debate is not settled. The US Preventive Services Task Force Recommendation Statement concludes "that the current evidence is insufficient to assess the balance of benefits and harms of performing screening pelvic examinations" [22]. The American Congress of Obstetricians and Gynecologists reaffirmed in 2016 their Committee Opinion which purpose is "to explain the need for annual assessments" albeit "at this time, this recommendation is based on expert opinion" [23].

The academic ambiguity concerning routine pelvic examinations might be reflected in our findings of extensive regional variation. As all the appointments required

a referral, the regional variation might be explained by regional differences in referral pattern. However our study cannot answer if the observed variation is due to regional differences in: supply (i.e. the number of gynecologists to refer to); professional belief in and tradition for routine examinations; or the proportion of examinations performed by primary care physicians and gynecologists, respectively.

Either way, there is no pelvic screening program in Norway. Both the extensive regional variation and the extent of routine pelvic examinations per se are unwarranted in regard to the Norwegian Patients' Rights Act [14] and in regard to the Norwegian Medical Associations concerns on opportunistic screening [24].

Health expenditures are increasing worldwide and account for more than 12% of gross domestic product in OECD countries [25]. Apart from Luxembourg, no country spends more on publicly financed health care per capita than Norway [26]. It is recognized that fee-for-service reimbursement is the most important driver of high medical expenditures in the United States [27]. Fee-for-service in primary care has been reported to be associated with more visits, diagnostic tests and referrals compared to salary payment, though evidence is limited [28]. Ransom et al. have demonstrated that elective gynecological procedures are performed more frequently under fee-for-service than capitation payment [29]. The present study supports these findings as fee-for-service gynecologists used colposcopy and ultrasound 31.2 and 1.3 times more often than gynecologists with fixed salaries, respectively. Fee-for-service gynecologists have an economic incentive to extend the examination not only through the tariff for colposcopy and ultrasound, but also through reimbursement for "complete examination." This code was used in 87.3% of fee-for service appointments.

Theoretically, patient preferences might explain some of the differences between provider types and also the regional differences. However there is no evidence that patient preferences have much impact on regional variation [30]. It is highly unlikely that healthy women referred to fixed salary physicians opt out colposcopy while the majority of women examined by fee-for-service gynecologists actively want this procedure. Moreover colposcopy and ultrasound are advised against in the screening setting, and should not be an offer within publicly funded healthcare regardless of preferences. Our results strongly imply that fee-for-service payments for gynecologists skyrocket the use of colposcopy and drive the use of "complete examinations" and ultrasound in pelvic examinations of asymptomatic women.

Recalibrating fee-for-service payments is recommended as one measure to constrain unsustainable health care expenditures [27]. Based on our findings, we argue that reimbursements for routine pelvic examinations including complete examination, colposcopy and ultrasound in women not registered with any symptom, complain or diagnosis should be discontinued. If gynecologists perform cytology screening in healthy women, any extra reimbursement should be removed.

Generalizability

To our knowledge, no other studies have quantified the national extent of routine pelvic examinations within publicly funded specialized health care. In Norway there has never been a national guideline recommending pelvic examination in asymptomatic women, nor a screening program for ovarian cancer. "Well-woman visits" [23] are not advocated by any Norwegian health authorities and the majority of women are unfamiliar with the practice. It is reasonable to believe that Norway scores relatively low on the number of routine pelvic examinations compared to countries with traditions and recommendation for annual assessments, and countries with a higher degree of fee-for-service-reimbursements for gynecologists.

This study only quantifies the use of pelvic examinations within publicly funded specialized health care. Private gynecologists with public funding constitute 43.5% of all private gynecologists in Norway [31]. The remainders are privately paid. The number of routine pelvic examinations paid out-of-pocket is unknown, as is the number performed by primary physicians. There is no reason to believe that privately paid gynecologists perform routine pelvic examinations any less than publicly funded gynecologists. On the contrary, privately paid gynecologists commonly advertise for routine pelvic examinations, hence, we believe that our study substantially underestimates the total amount of unwarranted pelvic examinations in Norway.

Strengths and limitations

The major strength of the study is the inclusion of all Norwegian adult women and that the studied codes give the basis for actual reimbursements paid to hospitals and fee-for-service gynecologists. Registration and reporting of appointments is compulsory and economically important for both hospitals and fee-for-service gynecologists. Correct reporting is focused on and stressed in both settings.

There are several limitations inherent in the methodology of register studies. Code practice may vary across regions. Underreporting of secondary diagnosis is expected [32]. Fee-for-service gynecologists get reimbursement according to the procedures they perform, while fixed salary gynecologists neither get compensated personally nor get more reimbursements to the hospital by performing colposcopy or ultrasound in routine pelvic examinations. Hence, it is possible that fee-for-service gynecologists are more thorough in their reporting, and that the actual use

of colposcopy and ultrasound especially in hospitals is underreported. Still, it is highly unlikely that this can explain the huge differences observed.

Conclusions

Annually, 22.2 per 1000 adult women in Norway received a publicly funded pelvic examination that is recommended against. The variation across regions was extensive. Our results strongly indicate that fee-for-service payments for gynecologists skyrocket the use of colposcopy and increase the use of ultrasound in routine pelvic examinations. We argue that the reimbursement for these examinations should be discontinued, not only as a measure to constrain the unsustainable growth in health care expenditures, but also for the wellbeing of healthy women.

Additional files

Additional file 1: Age-standardized number of appointments for routine pelvic examination and cervical screening per 1000 women by hospital referral region and type of provider. (PDF 146 kb)

Additional file 2: Age-standardized number of appointments for routine pelvic examination per 1000 women by hospital referral region and type of provider. Appointments with secondary diagnoses are excluded. (PDF 146 kb)

Abbreviations

ICD-10: The International Classification of Diseases version 10; NCMP: The Norwegian Classification of Medical Procedures; NCRP: The Norwegian Classification of Radiological Procedures; NCSP: The NOMESCO Classification of Surgical Procedures; NPR: The Norwegian Patient Registry

Acknowledgements

Not applicable

Funding

The publication charges for this article have been funded by a grant from the publication fund of UiT The Arctic University of Norway. The publication fund had no influence in the design of the study, the collection, analysis, or interpretation of data or in writing the manuscript.

Availability of data and materials

The data that support the findings of this study are available from The Norwegian Patient Registry and Statistics Norway, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of The Norwegian Patient Registry.

Authors' contributions

IMR conceptualized the study. LL undertook data extraction. IMR and LL undertook data analysis. AR, OHF, LL and IN made substantial contributions to design, data selection, methods, statistical analyses, and interpretation of findings. IMR drafted the manuscript. All authors critically revised the paper for important intellectual content and approved the final manuscript.

Ethics approval and consent to participate

The Norwegian Data Inspectorate licensed the data registry at Centre for Clinical Documentation and Evaluation (ref. 15/00271–2/CGN and 16/00289–2/CGN). Further ethical approval was not required according to Norwegian law [33, 34]. Data from the Norwegian Patient Registry has been used in this publication. The interpretation and reporting of these data are the sole responsibility of the authors, and no endorsement by the Norwegian Patient Registry is intended nor should be inferred.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Received: 15 September 2017 Accepted: 13 November 2017
Published online: 21 November 2017

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Erratum

In the article “Extent, regional variation and impact of gynecologist payment models in routine pelvic examinations: a nationwide cross-sectional study” the definition of colposcopy at hospital appointments should correctly read:

“For hospital appointments colposcopy was defined by the allocation of any of the codes XLE00 or LXE00 (colposcopy) in the 2014–16 versions of The NOMESCO Classification of Surgical Procedures (NCSP).”

SCANDINAVIAN JOURNAL OF GASTROENTEROLOGY
2018, VOL. 53, NO. 10-11, 1228–1235
https://doi.org/10.1080/00365521.2018.1506047

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ORIGINAL ARTICLE

Regional variation in hospitalizations and outpatient appointments for diverticular disease in Norway: a nationwide cross-sectional study

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ABSTRACT

Objective: To investigate the use of specialized health care services for diverticular disease in different hospital referral regions in Norway.

Materials and methods: Nationwide cross-sectional study with data from the Norwegian Patient Registry and Statistics Norway. All Norwegian inhabitants aged 40 years and older in the years 2012–16 (2,517,938) were included. We obtained the rates (*n*/100,000 population) for hospitalizations, outpatient appointments, and surgery for diverticular disease for the population in each hospital referral region. We also quantified the use of lower gastrointestinal (LGI) endoscopy in hospitalizations and outpatient appointments for diverticular disease and the use of LGI endoscopy performed on any indication.

Results: There were 131 hospitalizations and 381 outpatient appointments for diverticular disease per 100,000 population annually. Hospitalization rates varied 1.9-fold across regions from 94 to 175. Outpatient appointment rates varied 2.5-fold across regions from 258 to 655. Outpatient appointments were strongly correlated to hospitalizations (r_s=0.75, $p < .001$) and outpatient LGI endoscopy for any indication (r_s=0.67, $p < .001$). Hospitalization and surgery rates remained stable over the study period, while outpatient appointment rates increased by 37%. Concurrently, rates of outpatient LGI endoscopy performed on any indication increased by 35%.

Conclusion: There was considerable regional variation in both hospitalizations and outpatient appointments for diverticular disease. The extent of variation and the correlation with diagnostic intensity of LGI endoscopy indicate that the regional variation in health care utilization for diverticular disease to a large extent can be explained by regional differences in clinical practice rather than disease burden.

ARTICLE HISTORY
Received 16 May 2018
Revised 23 July 2018
Accepted 23 July 2018

KEYWORDS
Diverticular disease; hospitalizations; outpatient appointments; regional variation; LGI endoscopy

Background

Diverticular disease is common in Western countries. Two thirds of people above the age of 80 are affected with diverticulosis [1]. In an American study diverticulosis were found in ~30% of 50–59 years old, 50% of 60–69 years and 65% of 70–79 years old [2]. However, only 4% of patients with diverticulosis will develop symptomatic disease during their lifetime [3]. Studies from North America and Europe have reported increasing hospitalization rates for both diverticulitis and diverticular disease for various time spans since 1988, reaching a plateau in recent years [4–9]. The mortality has remained relatively stable [4,10]. In the United States diverticular disease is the most common discharge diagnosis in hospital admissions for gastrointestinal disease and the 6th most common physician diagnosis in outpatient visits [11]. The economic burden of diverticular disease on health care services is increasing [10–12].

Diverticular disease is a condition with great variation in severity, and care is often based on the individual physician's clinical discretion [9]. Traditionally, acute uncomplicated diverticulitis has been treated with hospitalization, dietary restrictions and antibiotics intravenously [13]. These approaches are not supported by evidence. Several randomized controlled trials have shown no evidence of benefit of antibiotic treatment for acute uncomplicated diverticulitis [14]. Outpatient management without antibiotics is demonstrated to be effective, safe and feasible [15]. Guidelines on diverticular disease commonly lack reference to high quality evidence for diagnostics, treatment, and follow-up and different guidelines provide opposing recommendations [16,17]. Internationally there is more non-consensus than consensus on management approaches with variation in care also within regions [18].

In Norway there is no national guideline for diverticular disease. However, the Norwegian Directorate of Health publishes guidelines on use of antibiotics in both hospitals and primary care. The international non-consensus seems reflected in these two separate national guidelines: For primary care, antibiotics and a liquid diet is recommended for mild diverticulitis [19]. For hospitalized patients, however, antibiotics are not recommended in uncomplicated cases

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and the guideline offers no recommendation on dietary restrictions [20].

For various medical conditions with poor evidence for optimal treatment and care, local practice and utilization of health care services varies considerably over regions and hospitals. Regions with higher utilization do not achieve better health outcomes, patient satisfaction or lower mortality as compared to regions with less utilization [21–23]. Lack of guidelines increases the possibility for practice variation and guidelines without a sound scientific basis do not contribute to leveling of differences [21]. Within the United States there is considerable variation in admission rates for diverticulitis over different geographical regions with a 54% higher rate in the Northeast compared to the West [8]. Such variation within European countries has not been investigated.

Objective

To investigate if there are regional variation in hospitalization and outpatient appointment rates for diverticular disease in Norway.

Methods

Study design

Nationwide cross-sectional study on hospitalization and outpatient appointment rates for diverticular disease of the large intestine in different hospital referral regions.

Setting

Norwegian municipalities are distributed into 21 different hospital referral regions, run by separate Hospital Trusts. Within each referral region there are one or more public hospitals and a varying number of private hospitals and specialists, practicing on the basis of reimbursement agreement with the Hospital Trust. The Hospital Trusts are in turn run by four regional health authorities [24]. By investigating differences in health care utilization across the different regions, we can find differences in provided care for the population independent of where the treatment was given.

All providers of publicly funded specialized health care in Norway are obliged to report diagnoses and procedures of every patient appointment to the Norwegian Patient Registry. Through Centre for Clinical Documentation and Evaluation (SKDE) we have access to reports for 2012–16 in addition to annual population statistics from Statistic Norway. One author (LL) has access to indirect personally identifiable data from the Norwegian Patient Registry. All presented analyses and results are anonymous. The Norwegian Data Inspectorate licensed the data registry at SKDE (ref. 15/00271-2/CGN and 16/00289-2/CGN).

Participants

We included all Norwegian inhabitants aged 40 years and older in the years 2012–16 (2,517,938).

Variables and data sources

Diagnoses were reported to the Norwegian Patient Registry according to the International Classification of Diseases version 10 (ICD-10). The annual Norwegian editions for 2012–16 were in use during the study years [25].

We defined diverticular disease of the colon as a primary diagnosis of any of the ICD-10 codes K57.2–57.9: 'Diverticular disease of large intestine' and 'Diverticular disease of intestine, part unspecified'. We excluded appointments with concurrent colon or rectal cancer (ICD-10 codes C18-C21) or colitis (ICD-10 codes K50-52). Due to few hospitalizations and outpatients appointments among younger age groups, we included only patients 40 years old or older.

Hospitalizations were defined as hospital discharges with length of stay $\geq$1 day and outpatient appointments were defined as appointments with length of stay =0 day. Patients discharged as dead were classified as hospitalized regardless of length of stay. For both hospitalizations and outpatient appointments the degree of urgency was reported as acute or elective. If patients were transferred between different wards, each ward stay was coded separately as acute or elective in the data from the Norwegian Patient Registry. We defined hospitalizations as acute where the first ward stay had a code for acute admission. Private physicians commonly report degree of urgency incorrectly. Hence, outpatient appointments at private physicians were defined as elective as the responsibility to provide acute care with emergency duty, emergency rooms and out-of-hours organisation is delegated to public hospitals [26,27].

For outpatient appointments in hospitals lower gastrointestinal (LGI) endoscopy was defined by the allocation of a procedure code for colonoscopy (UJF 32, JUF 32), colonoscopy with biopsy (UJF 35, JUF 35), sigmoidoscopy (UJF 42, JUF 42), sigmoidoscopy with biopsy (UJF 45, JUF 45) or endoscopic polypectomy in colon (JFA 15) in the Norwegian 2012–16 versions of The NOMESCO Classification of Surgical Procedures [28]. For outpatient appointments at private physicians LGI endoscopy was defined either by the same procedure codes or by the allocation of any of the codes for colonoscopy (115a) or sigmoidoscopy (114a) in 'Tariff for publicly funded private physicians', versions 2012–16 [29]. 'LGI endoscopy for any indication' was defined as LGI endoscopy use independent of allocated ICD-10 codes.

Surgery was defined by the allocation of a procedure code for colonic resection (JFB 20-97), colectomy (JFH 00-96), colostomy (JFF 20-31 and 96-7) or peritoneal drainage and irrigation (JAK 00-04) in The NOMESCO Classification of Surgical Procedures. We defined acute and elective surgery as surgery performed in acute and elective admissions, respectively. We only registered whether or not discharges had surgery codes, not the extent of procedures within one stay.

We defined 'private physicians' as either physicians working at private hospitals with public reimbursement, or physicians with public reimbursement for their private practices, so called fee-for-service physicians. Fee-for-service physicians get extra reimbursement for every procedure they perform, as do the private hospitals. Details on how physicians at

private hospitals are paid are not official. Physicians at public hospitals are paid a fixed salary independent of quantity of care. In Norway there is no recorded data on privately out-of-pocket paid practices, hence, such data is not included in this study.

Data on municipality code was missing in 0.5% (15) of hospitalizations and 0.3% (31) of outpatient appointments. We analyzed these admissions and appointments according to the referral region where the patient received care.

Statistical analysis

We obtained the rates (*n*/100,000 population) for hospitalizations and outpatient appointments for diverticular disease for the population of Norway and the 21 different hospital referral regions. We also quantified the use of LGI endoscopy in hospitalizations and outpatient appointments for diverticular disease. Due to small numbers, we analyzed surgery by the four Regional Health Authority regions. For hospitalizations, we calculated length of stay. To estimate the correlation between outpatient appointments and hospitalizations for diverticular disease we used Spearman's correlation coefficient.

In additional analyses we quantified LGI endoscopy for any indication. We obtained the rates of hospitalizations and outpatient appointments with a procedure code for LGI endoscopy. To estimate correlation between regional rates of outpatient appointments for diverticular disease and outpatient LGI endoscopy for any indication and we used Spearman's correlation coefficient.

All reported numbers are the annual mean for 2012–16, unless otherwise stated. All regional rates were standardized by age and sex with January 1 2015 as the standard population. We used SAS Enterprise Guide 7.1 (SAS Institute Inc., Cary, NY, USA) to perform all statistical analyses [30].

Results

Hospitalizations

In 2012–16, there were annually 3295 hospitalizations for diverticular disease. Hospitalization rates were stable over the study period (Table 1). More women than men were admitted and admitted women were older than men (Table 1 and Figure 1). Hospitalization rates across regions varied 1.9-fold from 94 to 175 per 100,000 population (Figure 2). Most patients (85%) had only one hospitalization for diverticular disease during the 5-year period. The median length of stay across regions varied from two to three days. The majority (84%) of hospitalizations were acute admissions.

Surgery

In 13% of hospitalizations patients underwent surgery (Table 1). National surgery rates for diverticular disease were stable during the study years. Mean surgery rates for diverticular disease in the study period varied 1.3-fold across regions from 15 to 19. Elective surgery accounted for 53% of the total amount (Table 2).

Outpatient appointments

In the study period, there were annually 9614 outpatient appointments for diverticular disease. Rates for outpatient appointments increased by 37% (Table 3). Differences between women and men are shown in Table 3 and Figure 3. Outpatient appointments rates across regions varied 2.5-fold from 258 to 655 per 100,000 population (Figure 4). Most outpatient appointments (94%) were elective. The correlation between outpatient appointments and hospitalizations across regions was strong (r_s=0.75, $p < .001$). Private physicians accounted for 17% of all outpatient appointments, and fee-for-service physicians accounted for 86% of these.

LGI endoscopy

In 15% of hospitalizations and 76% of outpatient appointments for diverticular disease LGI endoscopy was performed (Table 1 and 3). Physicians at public hospitals performed LGI endoscopy in 72% of outpatient appointments for diverticular disease, a percentage that was stable during the study years (72–71%). In the same period private physicians increased their use of this procedure from 94 to 99% of appointments. Rates for outpatient appointments for diverticular disease with LGI endoscopy increased by 39%. In absolute numbers, outpatient LGI endoscopy for diverticular disease increased by 33% at public hospitals and by 121% at private physicians.

Table 1. Hospitalizations for diverticular disease for patients 40 years and older.

Year	2012	2013	2014	2015	2016
Hospitalizations, *n*	3212	3217	3253	3268	3524
Hospitalizations per 100,000[a]	131	130	129	128	136
Women, *n* (%)[b]	2084 (65)	2062 (64)	2107 (65)	2056 (63)	2250 (64)
Men, *n* (%)[b]	1128 (35)	1155 (36)	1146 (35)	1212 (37)	1274 (36)
Age, y, mean (w/m)	68 (70/64)	67 (69/65)	68(69/65)	67 (69/64)	67 (69/65)
Acute hospitalizations, *n* (%)[b]	2646 (82)	2715 (84)	2791 (86)	2753 (84)	2975 (84)
Elective hospitalizations, *n* (%)[b]	566 (18)	502 (16)	462 (14)	515 (16)	549 (16)
Surgery, *n* (%)[b]	438 (14)	396 (12)	379 (12)	412 (13)	440 (12)
Surgery per 100,000[a]	18	16	15	16	17
LGI endoscopy, *n* (%)[b]	493 (15)	477 (15)	476 (15)	484 (15)	546 (15)
LGI endoscopy per 100,000[a]	20	19	19	19	21

[a]Population by January 1 the following year as denominator.
[b]Proportion of annual number of hospitalizations.

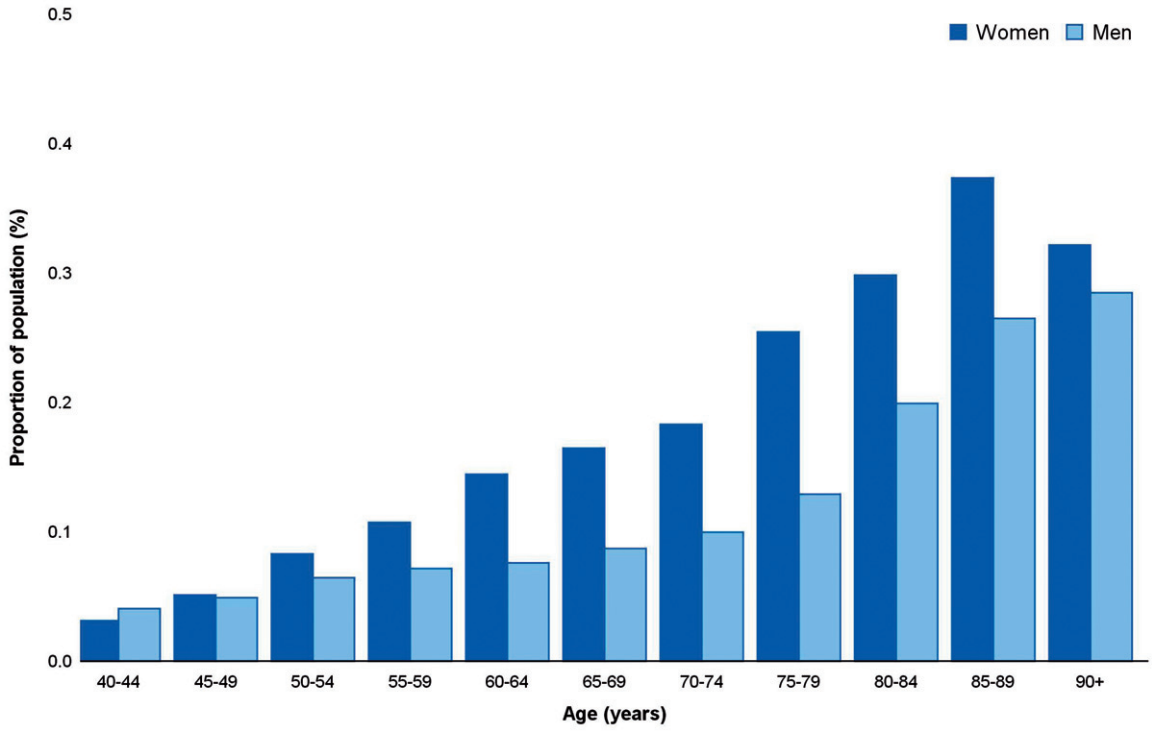

Figure 1. Hospitalizations as proportion of population by sex and age.

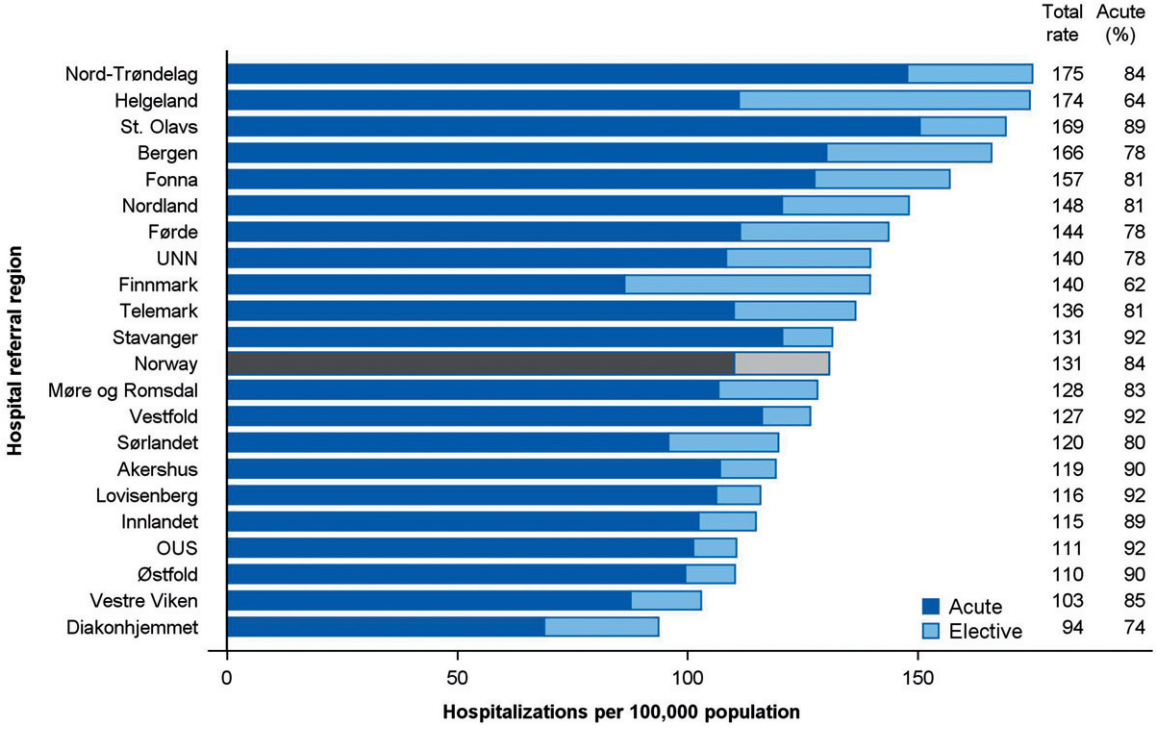

Figure 2. Age- and sex-standardized rate of hospitalizations for diverticular disease by hospital referral region.

Table 2. Surgery for diverticular disease for patients aged 40 years or older by Regional Health Authority region. Annual mean 2012–16.

	Surgery, *n*	Surgery per 100,000 population[a]	Acute, *n* (%)
Northern	48	19	21 (44)
Central	67	19	31 (46)
Western	89	18	40 (45)
Southern and Eastern	209	15	101 (48)

[a]Age- and sex-standardized.

In the same time period the rate of LGI endoscopy for any indication increased by 31% with a 6% increase in hospitalizations and a 35% increase in outpatient appointments (Table 4). Outpatient LGI endoscopy for any indication was strongly correlated to outpatient appointments for diverticular disease across regions (r_s=0.67, $p < .001$).

Table 3. Outpatient appointments for diverticular disease for patients 40 years and older.

Year	2012	2013	2014	2015	2016
Appointments, *n*	8057	8742	9465	10,163	11,642
Appointments per 100,000[a]	329	352	375	398	450
Women, *n* (%)[b]	4900 (61)	5334 (61)	5699 (60)	6024 (59)	6944 (60)
Men, *n* (%)[b]	3157 (39)	3408 (39)	3766 (40)	4139 (41)	4698 (40)
Age, y, mean (f/m)	67 (68/66)	67 (68/66)	67 (68/66)	68 (68/66)	68 (68/66)
Acute appointments, *n* (%)[b]	488 (6)	514 (6)	526 (6)	620 (6)	711 (6)
Elective appointments, *n* (%)[b]	7569 (94)	8228 (94)	8939 (94)	9543 (94)	10,931 (94)
LGI endoscopy, *n* (%)[b]	6022 (75)	6573 (75)	7275 (77)	7807 (77)	8864 (76)
LGI endoscopy per 100,000[a]	246	265	289	306	343

[a]Population by January 1st the following year as denominator.
[b]Proportion of annual number of hospitalizations.

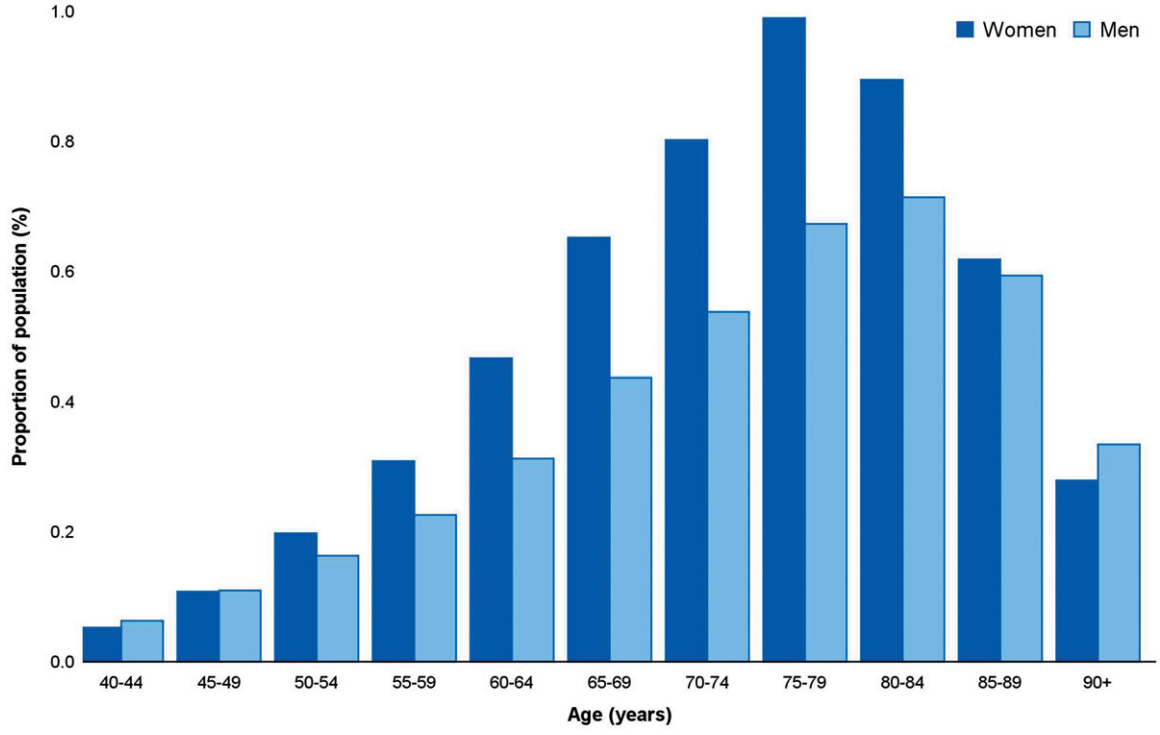

Figure 3. Outpatient appointments as proportion of population by sex and age.

Discussion

There was substantial variation in both hospitalizations and outpatient appointments for diverticular disease across hospital referral regions in Norway. Outpatient appointments were strongly correlated to outpatient LGI endoscopy for any indication in the general population. It is probable that the regional differences observed in outpatient appointments reflect regional differences in LGI endoscopy and not differences in diverticular disease morbidity alone.

The stable hospitalization and surgery rates point towards a relatively stable disease burden, however contrasted by the 37% increase in outpatient appointment rates. In the same time period rates of outpatient LGI endoscopy for any indication increased by 35%. Diverticulosis is the most common finding on LGI endoscopy. In a large US study examining more than half a million colonoscopies performed on any indication including screening, diverticulosis was diagnosed in 43% of cases [2]. The observed correspondence between time trends of increased outpatient care for diverticular disease and increased use of LGI endoscopy for any indication supports the interpretation that diagnostic intensity of LGI endoscopy for any indication can explain trends in outpatient appointments for diverticular disease. In Norway, a national colorectal cancer screening program is planned to be implemented from 2019 [31]. Health authorities and clinicians should be aware that diagnoses of diverticular disease are likely to increase concurrently with increased use of colonoscopy.

The strong correlation between hospitalization and outpatient appointment rates might reflect a higher disease burden in high rate regions. On the other hand, knowing the strong correlation between LGI endoscopy for any indication and outpatient appointments for diverticular disease, there are other plausible explanations. Labeling patients with a diverticular disease diagnosis after LGI endoscopy could possibly influence hospitalization patterns.

Variation in surgery rates may reflect real differences in morbidity, although documentation on such differences in Norway is nonexistent. The regions of Southern and Eastern Norway Health Authority, with the lowest rates of surgery,

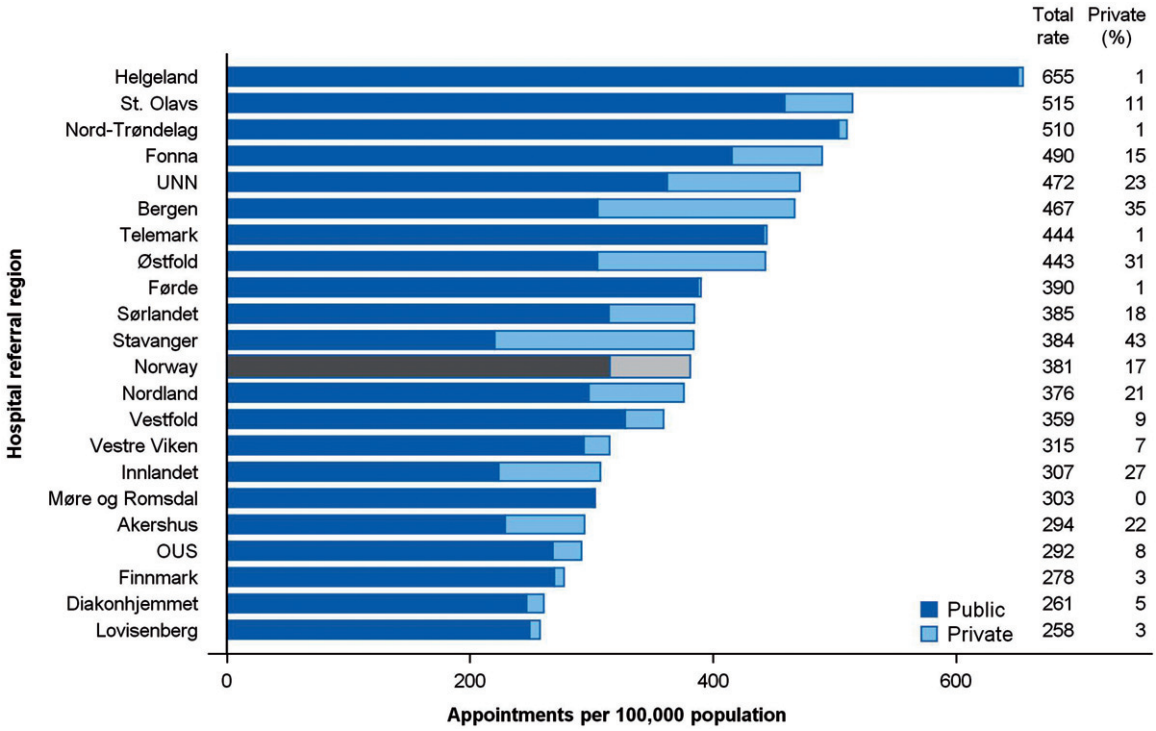

Figure 4. Age- and sex-standardized rate of outpatient appointments for diverticular disease by hospital referral region and type of provider.

Table 4. The number and rates of LGI endoscopy for any indication for patients aged 40 years or older by year and type of care.

Year	2012	2013	2014	2015	2016
Hospitalizations with LGI endoscopy, *n*	8176	8437	8899	9037	9194
Hospitalizations with LGI endoscopy per 100,000[a]	334	340	353	354	356
Outpatient appointments with LGI endoscopy, *n*	50,919	56,704	61,632	66,690	72,474
Outpatient appointments with LGI endoscopy per 100,000[a]	2081	2283	2445	2611	2804

[a]Population by January 1st the following year as denominator.

also had the lowest proportion of elective surgery. While evidence for optimal treatment and care for the acute phase of symptomatic diverticular disease is scarce, evidence for the best approach for long-term follow-up and prevention of recurrence is almost non-existent [16,32]. Surgery following acute uncomplicated cases of diverticulitis should not be performed routinely, and guidelines lack criteria for when such surgery should be performed [17]. Hence, the regional variation observed in surgery rates might rather reflect practice differences. Jafferji et al. have shown that surgical decisions for diverticulitis are predicted by surgeon characteristics independent of patient factors [33].

Geographical differences in the prevalence of diverticular disease are well-known [1]. Western civilization, low fiber diet and overweight have been associated with diverticulosis in epidemiological studies and are frequently used to explain geographical variations [1,8]. In Norway we have little data on diet and body mass on an adult population level, so unfortunately, we could not adjust for these variables in our analyses. Neither overweight nor low fiber diet can explain the geographical variation in hospitalizations for diverticulitis within the United States [8]. The lack of high quality evidence and guidelines regarding treatment and care, and the extent of regional variation, suggest that health care utilization for diverticular disease might be associated with supply-sensitive care [21]. Although there may be regional differences in risk factors and morbidity, it is unlikely that this explains all observed variation. We believe that the demonstrated regional variation in hospitalization and outpatient rates at least in part are explained by local practices that are independent of morbidity.

The sex difference in our study is in accordance with other European and North American findings where more men than women are hospitalized with diverticulitis in the lower age groups and the opposite for older age groups [4–9]. Causes to the observed sex differences is yet to be demonstrated.

Important differential diagnoses to diverticular disease is symptom diagnoses of abdominal pain. The diagnoses reported in this study are the discharge diagnoses. Any difference in code accuracy would presumably mean differences in diagnostic intensity, i.e., the use of CT colonography, CT abdomen and LGI endoscopy. As there is no national guideline on diverticular disease, it is difficult to assess how diverticular disease is dealt with both in primary and specialized care. In the manual for primary care out-of-hours service, the manual recommends to 'Consult the local guideline' when advising on hospitalization for diverticulitis [34]. For

patients handled ambulatory, the manual states 'The GP assesses need for further investigation (CT colonography)', not giving any further assistance on how to assess that need. A national guideline on diagnostics, treatment and follow-up for diverticular disease seems warranted and might level off some of the regional variation observed in this study.

By 2016 private physicians used LGI endoscopy in 99% of outpatient appointments for diverticular disease compared to 71% for physicians with fixed salaries. Fee-for-service reimbursements are demonstrated to be associated with high rates of unnecessary procedures [35]. Our findings indicate that the threshold for performing LGI endoscopy is lower for physicians who benefit economically than for fixed salary physicians.

Strengths and limitations

A major strength of our study is that we included all patients with a primary diagnosis of diverticular disease within publicly funded specialized health care. With data from the Norwegian Patient Registry and through the unique personal identification number of every Norwegian citizen, we could follow individuals over time. The limitations of our study are inherent to patient registry analyses. We have only data on discharge diagnosis. We could not validate the ICD-10 codes reported. Unfortunately, ICD-10 codes do not allow for differentiating between diverticulosis, diverticular bleeding or diverticulitis. Appointments labeled with a diverticular disease diagnosis might have included also asymptomatic cases. However, it is highly unlikely that patients were hospitalized for asymptomatic diverticulosis; especially as more than five out of six hospitalizations were acute admissions. Variation in health care utilization across regions may represent both differences in morbidity and code practice. Additionally, our study evaluated only rates of hospitalizations and outpatient appointments within specialized health care and did not include cases of diverticular disease managed in a primary care setting.

Conclusions

There was substantial regional variation in both hospitalizations and outpatient appointments for diverticular disease. The extent of variation and the correlation with diagnostic intensity of LGI endoscopy strongly indicate that regional health care utilization for diverticular disease can partially be explained by regional differences in clinical practice rather than disease burden. Such unwarranted variation in clinical practice should be addressed by the health authorities.

Acknowledgements

Data from the Norwegian Patient Registry has been used in this publication. The interpretation and reporting of these data are the sole responsibility of the authors, and no endorsement by the Norwegian Patient Registry is intended nor should be inferred. We wish to thank Stig Norderval for important feedback on the project and coding validation. We are also thankful to Geir Hoff for his thorough review of the manuscript and advice on interpretation.

Disclosure statement

No potential conflict of interest was reported by the authors.

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