Helicobacter pylori and dyspepsia from a public health perspective

The Sørreisa Gastrointestinal Disorder Study

By

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I. Asfeldt AM, Løchen ML, Straume B, Steigen, SE, Florholmen J, Goll, R Nestegard, Paulssen EJ. Accuracy of a monoclonal antibody-based stool antigen test in the diagnosis of *Helicobacter pylori* infection. *Scand J Gastroenterol* 2004;**39**(11):1073-7.

II. Asfeldt AM, Straume B, Paulssen EJ. Impact of observer variability on the usefulness of endoscopic images for the documentation of upper gastrointestinal endoscopy. *Scand J Gastroenterol* 2007;**42**(9):1106-12.

III. Asfeldt AM, Straume B, Steigen SE, Løchen ML, Florholmen J, Bernersen B, Johnsen R, Paulssen EJ. Changes in the prevalence of dyspepsia and *Helicobacter pylori* infection after 17 years: The Sørreisa gastrointestinal disorder study. *Eur J Epidemiol* 2008;**23**(9):625-33.

IV. Asfeldt AM, Steigen SE, Løchen ML, Straume B, Johnsen R, Bernersen B, Florholmen J, Paulssen EJ. The natural course of *Helicobacter pylori* in gastritis, peptic ulcer disease and reflux oesophagitis in a population-based prospective cohort: The Sørreisa gastrointestinal disorder study. Submitted.

ABBREVIATIONS

H. pylori	*Helicobacter pylori*
NSAID	Non-steroidal anti-inflammatory drugs
ASA	Acetylsalicylic acid
GORD	Gastro-oesophageal reflux disease
GSRS	Gastrointestinal Symptoms Rating Scale
MST	Minimal Standard Terminology for Digestive Endoscopy
OMED	Organisation Mondiale Endoscopie Digestive / The World Organisation of Gastrointestinal Endoscopy.
NPE	Norsk Pasientskadeerstatning (The Norwegian System of Compensation to Patients)
MALT	Mucosa-associated lymphoid tissue
BMI	Body mass index
CI	Confidence interval
PPI	Proton pump inhibitor

1. INTRODUCTION

The discovery of *Helicobacter pylori* infection in 1983 and its association with peptic ulcer disease was a major achievement in medicine, which brought by a major change in the understanding of peptic ulcer disease, a common chronic disease, which now could be explained by a bacterial infection [1;2]. From a public health view, the last three decades have been most interesting concerning *H. pylori* and related disorders. In Western countries the prevalence and incidence of peptic ulcer disease have decreased [3], parallel to a decrease of the prevalence of *H. pylori* (Paper III) [4-7]. As a consequence of this, the role of *H. pylori* infection in peptic ulcer disease is now less prominent than earlier [8], and the enthusiasm that followed the idea that we had a simple cure for peptic ulcer disease has levelled out. However, the remaining cases have a broader spectre of causes, of which the use of ulcerogenic medications such as acetylsalicylic acid (ASA) [9] and non-steroidal anti-inflammatory drugs (NSAID) [10], as well as smoking deserves special attention [11;12].

Dyspepsia is world-wide a highly prevalent health issue [13;14], involving substantial and increasing costs [15;16]. Previously, when peptic ulcer disease was more common, a larger proportion of dyspepsia was linked to peptic ulcer disease, and thus to *H. pylori*. So far, the research of the relationship between dyspepsia and *H. pylori* reflects a period with a higher prevalence of *H. pylori* than today, in most developed countries. The 2007 Maastricht III consensus report [17], that advocates an approach of testing for and treating *H. pylori,* in cases of dyspepsia in the absence of alarm signals, is thus based on premises that are changing. The prevalence of *H. pylori* thus has implications for the effectiveness of management strategies for dyspepsia [18].

When discussing strategies of management of dyspepsia and *H. pylori*, upper endoscopy is often considered an option [19-21]. Endoscopy is a costly, time consuming procedure and not free of risk, even though complications are rare [22;23].The benefit of the method may not justify its common use in cases of mild dyspepsia, and the diagnostic uncertainty attached to upper endoscopy deserves more attention [24] [25].

In 1987 Bjørn Bernersen and co-workers initiated the Sørreisa Gastrointestinal Disorder Study, a population-based study on non-ulcer dyspepsia and its possible risk factors. Sørreisa was chosen because Per Stakkevold, a general practitioner in Sørreisa for many years, worked at the Department of Gastroenterology in Tromsø at the time of planning the study. Dr. Stakkevold joined the group, and thus made the choice of Sørreisa evident. The cross-sectional study in Sørreisa in 1987 forms a good basis both for a follow-up study, and a study of the changing epidemiology of *H. pylori* and dyspepsia.

2. AIMS OF THE THESIS

After two decades of awareness of *H. pylori* as a potential pathogen and the subsequent management of *H. pylori* related disorders, it is time to reflect upon its role in the general population. What is the role of dyspepsia in a general population in Norway today, and is there an association between *H. pylori* and dyspepsia? The specific aims of this thesis are:

1. To investigate if *H. pylori* antigen detection in stool is a valid and accurate diagnostic test
2. To examine the extent of inter- and intra-observer variation in assessment of images from upper endoscopy, in order to assess their usefulness in the reports of upper endoscopy.
3. To study the changes in prevalence of dyspepsia and *H. pylori* infection, as well as their mutual relationship in a general population.
4. To investigate the natural course of *H. pylori* infection with regard to gastritis, peptic ulcer and oesophagitis.

3. MATERIAL AND METHODS

3.1. Data sources

3.1.1. Validation of the H. pylori stool antigen test

From October 2002 to October 2003 patients with upper abdominal complaints, referred to the outpatient Clinic of Gastroenterology, University Hospital of North Norway, were enrolled in the study of the *H. pylori* stool antigen test. The test chosen was the Amplified IDEIA Hp StAR (DacoCytomation Norden, Denmark), which uses an enzyme-linked immunosorbent assay amplifying technique. The stool specimens were sent by regular mail and processed according to the manufacturer's instructions. A total of 131 subjects were enrolled, which was about half of those considered for the study. As 9 dropped out, the primary validation was thus based on 122 persons. In the subsequent study of whether test performance was influenced by treatment with proton pump inhibitor, 39 persons contributed (43 were enrolled, 4 were excluded due to misunderstanding of instructions). The final part of the test validation study, in which 32 persons contributed, concerned patients after eradication treatment (Paper I). Reasons for not enrolling intended subjects in the study varied from the presence of exclusion criteria, refusal, to logistic reasons, the latter being the most common. For ethical reasons, we could not ask the patients for reasons for not participating.

3.1.2. Data acquisition in Sørreisa

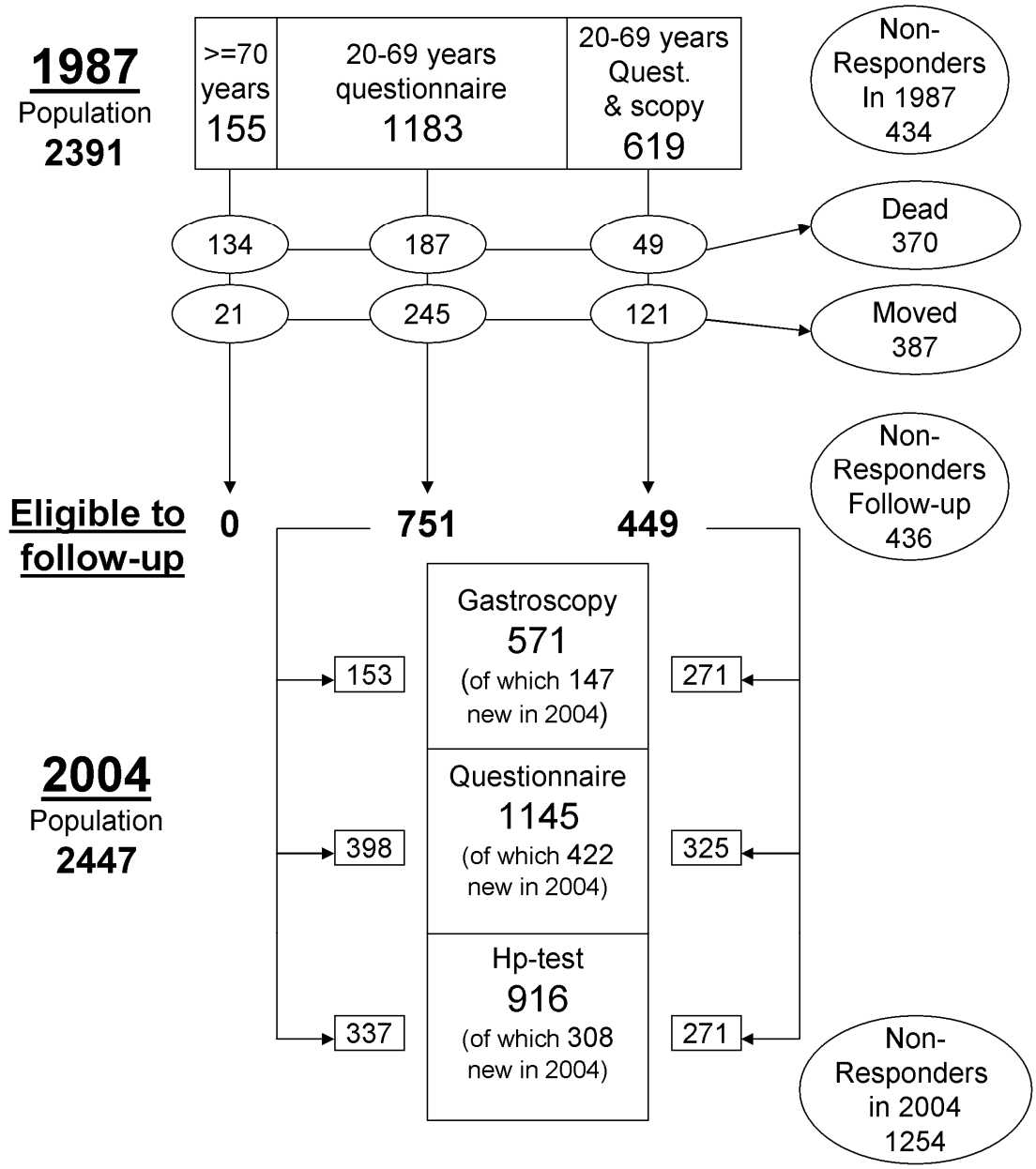
Both the first and the second part of the Sørreisa Gastrointestinal Disorder Study were initiated and conducted by the University of Tromsø. The first part took place in 1987, in which Bjørn Bernersen and co-workers invited all adults aged 20 or above to answer a questionnaire on gastrointestinal disorders. Responders with dyspepsia, and an age and gender matched control group were invited to upper endoscopy.

The second part of the Sørreisa Gastrointestinal Disorder Study took place in 2004, in which we invited all adults aged 18 to 85 to answer a questionnaire and send stool samples for *H. pylori* detection. In the questionnaire we asked permission to invite

responders to partake in upper endoscopy. Those who accepted were all invited, and the endoscopy study in 2004 had thus a cross-sectional design in contrast to the case-control design in 1987. We also invited the cohort who underwent endoscopy in 1987, to have a new examination again in 2004, regardless of whether or not they answered the questionnaire. Follow-up of the cohort of participants from 1987 was for formal reasons restricted to those still living in Sørreisa.

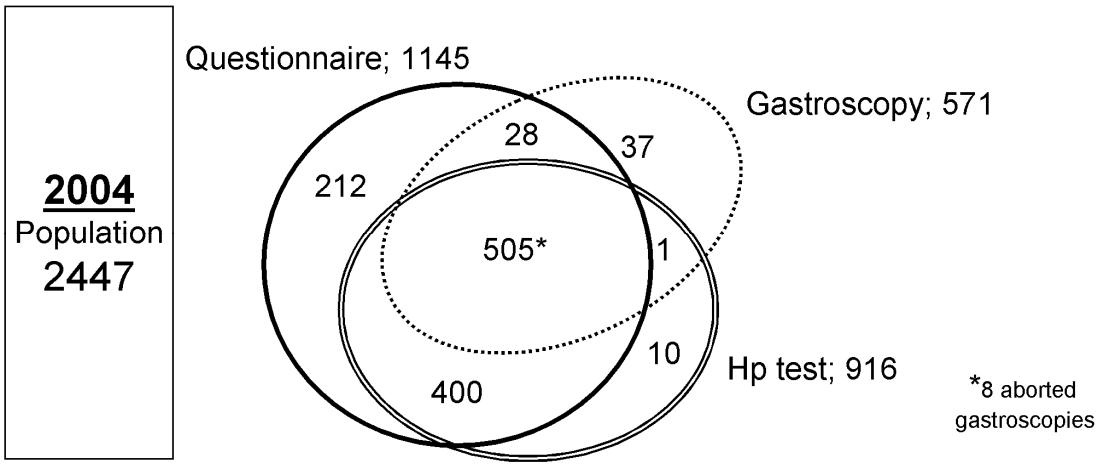
The combination of two cross-sectional studies, one in 1987 and one in 2004, in addition to a cohort study including the participants of both studies, challenged us methodologically. In paper III, we chose to supplement our cross-sectional analyses of the relationship between dyspepsia and *H. pylori* with a longitudinal analysis. In the longitudinal analysis all subject participating either in 1987 or in 2004 were included, and in addition it was taken into consideration if they provided information at both times.

Figure 1. Sørreisa Gastrointestinal Disorder Study 1987 and 2004



The arrows present the flow of participants of the study in 1987 into the study in 2004, and thus the cohort we followed. Rectangular boxes indicate participants. Oval boxes indicate non-responders or those who were lost to follow-up. The boxes presenting participants in 1987 are exclusive, whereas the boxes presenting participants in 2004 are not exclusive. (See 9. Errata p. 45)

Figure 2. Distribution of the 1193 Participants in the Sørreisa Gastrointestinal Disorder Study - 2004



3.1.2.1. Questionnaires

In 1987 there were no generally accepted international criteria for the definition of dyspepsia, thus the study group had to make questions and definitions themselves. The following two questions were used to define subjects with dyspepsia; "Have you ever had abdominal pain located in the upper abdomen for at least 2 weeks?" and "Have you ever had heartburn or acid regurgitation almost daily for at least one week?" A positive answer to either or both questions defined dyspepsia. In 2004 we chose to repeat these questions in order to secure the internal validity of the study, this time with a slightly different phrasing: "Have you since 1987 had abdominal pain located in the upper abdomen for at least 2 weeks?" and "Have you since 1987 had heartburn or acid regurgitation almost daily for at least one week?" Again, a positive answer to one or both questions defined dyspepsia. In addition we added the Gastrointestinal Symptom Rating Scale (GSRS) [26], one of several validated questionnaires on gastrointestinal disorders, in order to secure the external validity. The original GSRS scale of scores (0 to 3) were expanded to include half-points (0 to 7), as used by others [27;28].

A first reminder was sent to non-responders asking for both questionnaire and stool samples, and a second reminder asking just for the questionnaire. The complete questionnaires are shown in Appendices 2 and 3.

3.1.2.2. Endoscopy in Sørreisa

The endoscopy examinations of the population based study in Sørreisa in 2004 were done in a provisional endoscopy unit at the local Community Health Centre. Four Olympus GIF-160 video endoscopes, complete with light source and processor, as well as a washing machine were leased from Olympus Norway. The computer software Endobase III (Microsoft Corporation, Redmond, Wash., USA) was used for keeping records and capturing and storing of images from the examinations. The records followed a simplified version of the Minimal Standard Terminology of Digestive Endoscopy (MST) [29] recommended by the World Organization of Gastrointestinal Endoscopy (OMED). The MST defines peptic ulcer as a mucosal defect with a diameter of more than 5 mm, which appears to deeply involve the wall of the stomach or duodenum. Peptic ulcer was defined in the same way in 1987 [30]. The protocol included capturing four routine images; one each from the distal oesophagus, the gastric fundus, the pyloric antrum, and the duodenal bulb. All subjects were offered local anaesthesia of the pharynx with lidocaine spray of the pharynx. Biopsies were sampled for histological examination, one each from the pyloric antrum and one from the greater curvature. Two further biopsies were stored in a special buffer solution ("RNA Later") for subsequent DNA/RNA analysis (this material has not yet been used).

We encountered only minor problems in the endoscopy unit in Sørreisa. In 16 cases there were technical problems with either capturing pictures or writing the report. In 8 cases examination was aborted due to lack of compliance. Only in one examination did we encounter a minor complication, which was prolonged bleeding after biopsy. In addition to the examinations related to the study protocol, additional diagnosis or follow up was done in 62 subjects, e.g. histological examination of polyps, examination of celiac disease on request, histological examination of ulcers. Of these, the 20 subjects who had findings requiring medical treatment, such as ulcers or severe oesophagitis, were referred to the outpatient clinic at the University Hospital of North Norway.

3.1.2.3. Laboratory analysis

The stool samples were sent by mail to the Gastroenterology laboratory at the University Hospital of North Norway for analysis with the Amplified IDEIA Hp StAR® according to the manufacturer's instructions, by the same personnel who did the analyses in the test validation study.

Blood samples were collected in connection to the endoscopy examinations. Serum was stored at -20^{o} C (this material has not yet been used).

3.1.3. Statistics Norway and Cancer Registry

Additional information regarding the participants of the study in 1987 was obtained from health registers. Specific causes of death were obtained from the Cause of Death Registry at Statistics Norway. Cancer diagnoses were obtained from the Cancer Registry of Norway. Only 9 of the 1957 participants had developed gastric cancer during follow up (5 men, 4 women; 4 with dyspepsia, 5 without dyspepsia; Birth year 1913-1933). Gastric cancer was the primary cause of death in five of these subjects. One of the subjects who developed gastric cancer had undergone gastroscopy in 1987, where she was found *H. pylori* negative. Four participants died from peptic ulcer disease during follow up, and only in two cases was peptic ulcer disease the primary cause of death. None of these four subjects had been tested for *H. pylori* in 1987. The limited number of cancer and causes of death due to upper GI diseases is the reason why these endpoints are not addressed further in the papers, or the thesis.

3.1.4. Internet survey on observer variation

Ten images from the oesophagus and 10 from the pyloric antrum were used to set up an internet interface with a questionnaire for assessment of the images. The images were obtained at the endoscopy examinations in Sørreisa in 2004, and were selected to ensure both normal and pathological findings as well as good technical quality. A simplified version of the Minimal Standard Terminology for Digestive Endoscopy [31] was used in the questionnaire (Appendix 1). Twenty physicians practising endoscopy in Northern Norway were invited to partake in the study, of which 13 responded. Responders could

answer anonymously, but were also given the opportunity to identify themselves in order to be contacted again. The assessment of the images was entered directly into a database at the Department of Community Medicine. After 5 months the 11 physicians who had initially identified themselves were invited to assess the same images again. This time 10 responded. Analysis of inter-observer variation was done after the first assessments, and analysis of intra-observer variation was done after the second assessment. All responses were made anonymous before analysis.

3.2. Statistical analyses

Estimates of effect and differences are reported with 95% confidence intervals. From univariable logistic regression models, p-values less than 0.25 were used for building multivariable logistic regression models. P-values of 0.05 or less in final models were considered significant. Analyses were done using SPSS statistical software (SPSS Inc., Chicago, Ill., USA), Microsoft® Office Excel 2003 (Microsoft, Redmond, WA, USA) and SAS software package version 9.1 (SAS Institute Inc, Cary, USA). Agreement between observations was measured with kappa statistics [32], and values were categorized as described by Altman [33] as poor ($\kappa \leq 0.2$), fair ($0.21 \leq \kappa \leq 0.4$), moderate ($0.41 \leq \kappa \leq 0.6$), good ($0.61 \leq \kappa \leq 0.8$), or excellent ($\kappa \geq 0.8$). Measures of sensitivity, specificity and likelihood ratio were used for presenting test performance.

3.3. Ethical and legal aspects

The Regional Committee for Medical Research Ethics approved the Sørreisa study both in 1987 and in 2004, as well as the *H. pylori* test validation study. Participants gave written informed consent. License to register participants was granted by the Norwegian Data Inspectorate, in addition to a license to link the person registry of the 1987 study to the Cause of Death Registry at Statistics Norway and the Cancer Registry of Norway.

4. MAIN RESULTS

4.1. Paper I. Accuracy of a monoclonal antibody-based stool antigen test in the diagnosis of *Helicobacter pylori* Infection

A total of 131 patients referred for upper abdominal pain were enrolled in the study, of which 9 failed to send a stool sample. The test in question, the Amplified IDEIA Hp StAR® was found to have a sensitivity of 98% and a specificity of 94%, and a likelihood ratio for positive test results of 16.7, and likelihood ratio for negative test results of 0.02. The specificity of 94% reflects a false negative rate of 6%. In the subsequent analyses of the influence of proton pump inhibitor (PPI) on test performance, none of 43 *H. pylori* infected had a negative test result after one week of treatment. After two weeks, 2 of 39 (5%) had a negative test result, which is within the expected number of false negatives. Up to two weeks use of PPI did thus not influence on test performance. The last part of the study, concerning control after *H. pylori* eradication, showed that all study subjects had successfully been treated and that there were no positive results of the test. In conclusion, the Amplified IDEIA Hp StAR was considered an accurate, convenient diagnostic instrument in an outpatient setting.

4.2. Paper II. Impact of observer variability on the usefulness of endoscopic images for the documentation of upper gastrointestinal endoscopy

Ten images from the distal oesophagus and 10 images from the pyloric antrum were presented on an internet interface together with a multiple choice questionnaire. Inter-observer agreement varied between poor ($\kappa \leq 0.2$), and moderate ($0.41 \leq \kappa \leq 0.6$). Intra-observer agreement varied between moderate ($0.41 \leq \kappa \leq 0.6$), and good ($0.61 \leq \kappa \leq 0.8$). Higher experience did not lead to higher agreement. Concise findings, such as ulcers, yielded higher agreement than less definable findings. The variation in assessment of images from endoscopy was large, and the incorporation of standard images in the endoscopy record could be useful to reveal and improve this.

4.3. Paper III. Changes in the prevalence of dyspepsia and Helicobacter pylori infection after 17 years: The Sørreisa gastrointestinal disorder study

We compared changes in the prevalence of dyspepsia and *H. pylori* in two cross-sectional studies, in 1987 and in 2004. Dyspepsia was persistently prevalent and affected 31.9% of men and 31.7% of women in 2004, compared with 30.7% and 26.3% respectively in 1987. In both subjects with and without dyspepsia, the prevalence of *H. pylori* infection had decreased significantly during the 17 years of observation, though the decrease of 6% in men without dyspepsia was not statistically significant. The overall age-adjusted prevalence of *H. pylori* infection was 25% in 2004. A longitudinal logistic regression model revealed that among men *H. pylori* was positively associated with dyspepsia in 1987, whereas in 2004 there was a negative association between *H. pylori* and dyspepsia. Among women there was no association between *H. pylori* and dyspepsia at any time. In conclusion, a decreasing prevalence of *H. pylori* infection, a persistently high prevalence of dyspepsia, and a divergent distribution between *H. pylori* and dyspepsia in the two genders all together question a causal relationship.

4.4. Paper IV. The natural course of Helicobacter pylori in gastritis, peptic ulcer disease and reflux oesophagitis in a population-based prospective cohort: The Sørreisa Gastrointestinal Disorder Study

In this prospective cohort study *H. pylori* was a strong risk factor for inflammation of the gastric mucosa, a moderate risk factor for atrophy of the antrum, but not a risk factor for atrophy of the gastric body or intestinal metaplasia. The elimination of *H. pylori* infection led to regression of both inflammation and atrophy, but did not cause regression of intestinal metaplasia once it had developed. *H. pylori* was a moderate risk factor for peptic ulcer in men only. In women the use of acetylsalicylic acid was a more important risk factor for peptic ulcer. In analyses including both genders, smoking was an independent risk factor for peptic ulcer. In men *H. pylori* was protective against oesophagitis. Men ran a higher risk of both peptic ulcer and oesophagitis than women.

5. GENERAL DISCUSSION

5.1. Insurance of participants

Whereas the research ethics and legal aspects of registering participants in the *H. pylori* test validation study was uncomplicated, we had major challenges with the endoscopy study in Sørreisa. The Regional Committee for Medical Research Ethics raised questions about the health insurance of the study participants. A month before we presented the study for the committee, it had become clear that the issue of insurance of healthy research subjects was not clear in "The Norwegian System of Compensation to Patients" (NPE). Invasive procedures such as endoscopy were not considered by NPE. Even though similar studies had been done before, we were asked to clarify the issue of insurance of our intended participants. This process took about a year, including much correspondence. Our study, among others, eventually brought about a clarification of this issue, and now healthy research subjects are considered in NPE.

5.2. Methodological considerations

5.2.1. Study design

Both the questionnaire survey in 1987 by Bernersen and co-workers, as well as the survey including *H. pylori* testing in 2004, were done in a cross-sectional population-based design. The endoscopy survey in 1987 had a case-control design with subjects suffering dyspepsia being cases [30]. This caused some restrictions in further analyses and interpretations of results. First, the analyses of changes in the prevalence of *H. pylori* had to be stratified by dyspepsia. Second, there is a potential selection bias in the sense that the prevalence of *H. pylori* infection in the cohort that we have followed was somewhat higher than expected in the general population. In 2004, we found an overall age-adjusted prevalence of *H. pylori* of 25 % in both men and women (Paper III). For the sake of comparison, we have estimated the overall prevalence of *H. pylori* in 1987. The age adjusted prevalence of *H. pylori* in subjects (both genders) with dyspepsia in 1987 was 48.0%, and a corresponding 36.3% in subjects without dyspepsia [34]. The age

adjusted prevalence of dyspepsia in 1987 (both genders) was 29.3%. An estimate of the overall prevalence of *H. pylori* infection in 1987 was thus 39.7% $(48.0\% * 0.293 + 36.3\% * 0.707)$.

At the start of the endoscopy examinations in 2004, we had limited time, as the endoscopy unit in Sørreisa was planned to be functioning for three months only. We therefore started by inviting those who had undergone endoscopy in 1987, parallel to sending out the questionnaire. We were surprised to find that the willingness to undergo endoscopy was higher than the willingness to answer the questionnaire in this cohort. We have thus 38 subjects who had endoscopy in 2004 without answering the questionnaire. It was less surprising that 240 chose to answer the questionnaire without providing stool samples. Only 10 subjects sent stool samples for *H. pylori* detection without further participation. This is probably explained by losing or forgetting the questionnaire, but misclassification of identification in the laboratory is also a possibility, which occurred in a few cases.

5.2.2. Bias

Bias can be defined as a systematic error seen when a risk factor or a characteristic applies unequally to comparison groups and thus distort the results [35;36]. Bias should always be considered as an alternative explanation of a finding.

5.2.2.1. Selection bias

If the population enrolled in the study differs in a characteristic way from the population not enrolled we may encounter selection bias [35;36]. Beside the geographical location of our study in the municipality of Sørreisa, the only selection criterion of our study subjects was age between 18 and 85 years. A study focusing on gastrointestinal complaints may be more appealing to subjects suffering dyspeptic symptoms than to those without symptoms, a phenomenon called self-selection. A study of non-participants could clarify if selection bias is present, but this can only be done if information from registers is available. In our case this would mean a need for information about peptic ulcer, gastro oesophageal reflux disease (GORD), use of anti-secretory medication and other specific diagnoses, as well as the use of health services. Such information from health registers

did not exist in Norway in 2004. We have studied non-participants regarding their age and gender distribution, and could not find differences in the age distribution between those who accepted gastroscopy and those who only answered the questionnaire. Men and women were equally represented in the upper endoscopy examinations. Dyspepsia was reported by 33.2% of the questionnaire responders and 37.6% of the participants of the endoscopy examinations, a non-significant difference of proportions. The proportions of women who answered the questionnaire and sent stool samples were somewhat higher than the corresponding proportion of men. Predominance of women in health surveys is common [37-39]. Some argue that in epidemiologic studies in general, non-participants have a lower socioeconomic status than participants [40]. Others argue that in a country such as Norway with a small social gradient, and the availability of a personal identification number enabling the study population to be unbiased *a priori*, no major source of selection bias is expected in a population-based study [41]. As seen from figures 3-5 the patterns of participation are very similar in the various parts of the study. The slightly higher proportion of women participating is not believed to interfere with our results. In addition, we have presented our analyses stratified by gender, or incorporated gender in the analyses. The overall response rate of the survey in Sørreisa was 40%, which is further discussed in section 5.3.

Figure 3. Age distribution (%) of participants and non-participants of the questionnaire survey in 2004. Ten years intervals.

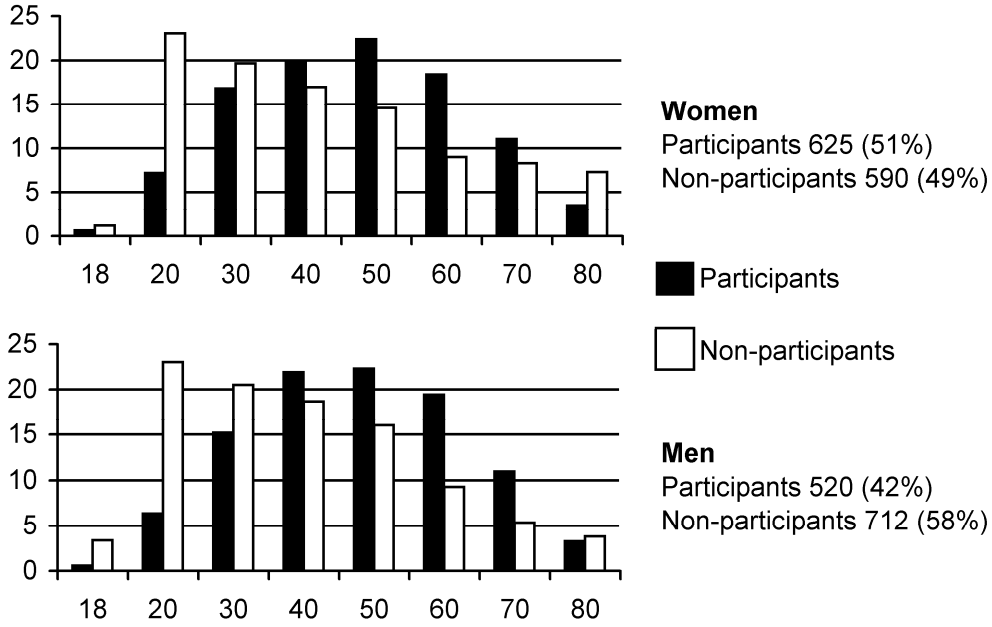


Figure 4. Age distribution (%) of participants and non-participants of the *H. pylori* testing in 2004. Ten years intervals.

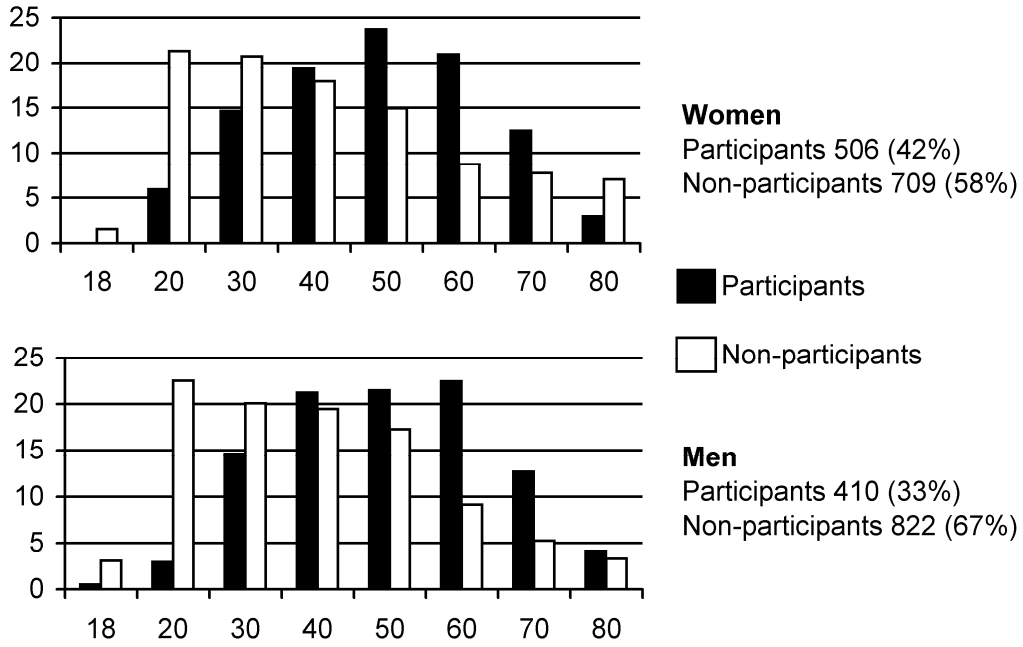
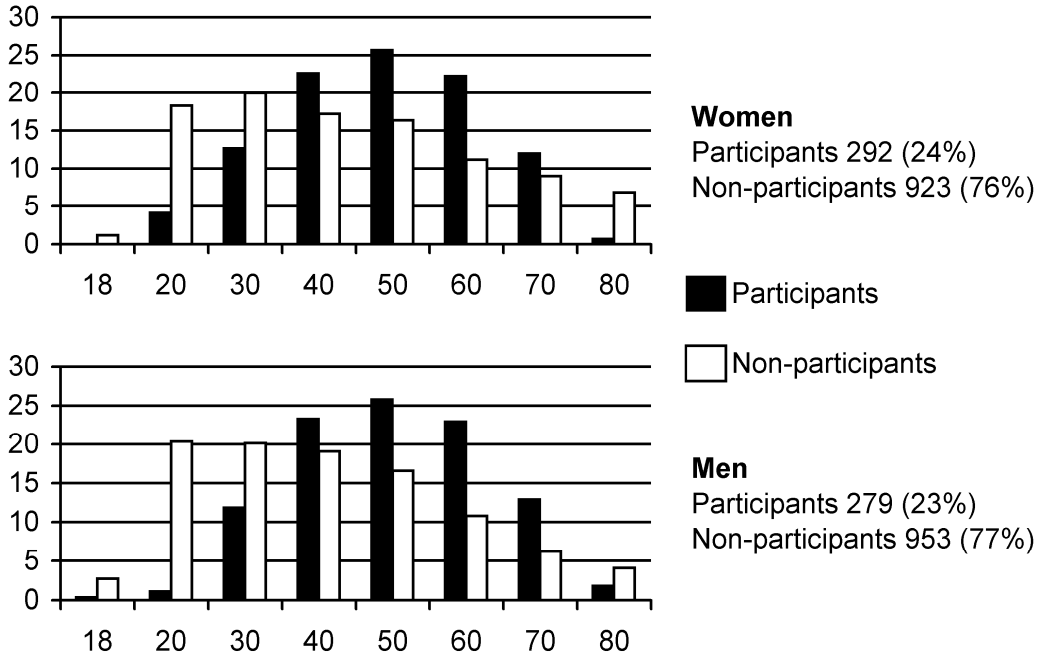


Figure 5. Age distribution (%) of participants and non-participants of the endoscopy examinations in 2004. Ten years intervals.



5.2.2.2. Information bias

If measurements of risk factors or outcome differ between comparison groups we encounter information bias [35]. Measurement error is a subtype of information bias. All analyses of stool samples were done by the same two persons using the same techniques for all participants. All histological examinations were done by one pathologist who also re-examined the histology slides from 1987. All endoscopy examinations in 2004 were done by this author. The questionnaire was the same for all participants. In the cross-sectional part of the study we have not found sources of information bias. In the follow-up study we have differential classification of *H. pylori,* as the diagnosis was done with different methods in 1987 and in 2004. We have considered this when comparing results from 1987 and 2004 (thoroughly discussed in Papers III and IV). Method of assessment of *H. pylori* should not bias the results in the analyses restricted to either 2004 or 1987. The questions on dyspepsia were the same at both times. Peptic ulcer was partly self-

reported and partly diagnosed at endoscopy. Self-reporting involves a risk of recall bias, as persons suffering the outcome (ulcer) tend to remember risk factors (dyspepsia, smoking) better than healthy persons do [36]. In our case risk factors were measured ahead of outcome, and the cohort design as used in our study, is thus more resistant to recall bias. When comparing findings at endoscopy between 1987 and 2004 we may be at risk of measurement bias as the examinations were performed by two physicians. The study of observer-variation reveals a high degree of disagreement in endoscopy, and in consequence of this we have simplified endoscopic findings in our analyses (dichotomized the findings of oesophagitis), and chosen distinct findings (absence or presence of peptic ulcer) as outcome variables.

5.2.3. Confounding and interaction

Confounding is present when a statistically significant association between a risk factor and outcome under study is causally explained by another factor that is also associated to the risk factor under study [35]. The causal factor is the confounder, and the apparent association between the risk factor and outcome under study is said to be confounded. The confounder can explain all or some of the observed association. In our study (Paper IV) we found a difficult financial situation to be associated with peptic ulcer in univariable analysis. Several other studies have also reported socioeconomic difficulties to be associated with peptic ulcer and/or dyspeptic symptoms [42-44] However, it is difficult to imagine a direct causal relationship. There are various strategies to deal with presumed confounding. We have used multivariable regression, in which the effects of the risk factors entered into the model are adjusted for the effect of the other risk factors or potentially confounders entered in the model[33]. In the multivariable regression model the apparent risk for peptic ulcer associated with a difficult financial situation disappeared. This was also the case for the use of antacids, which in univariable logistic regression analysis was positively associated with peptic ulcer, whereas it in multivariable logistic regression analysis was not. We thus have employed strategies to reveal confounding, but we can never know if we have considered all potential confounders. Regression models are limited to what one chooses to enter, a choice that should always be open for discussion.

Interaction is the case when two causal risk factors interact, in the way that the effect of one risk factor differs with different levels of the other [45]. We found interaction between *H. pylori* and gender in the analyses of risk of peptic ulcer in Paper IV. *H. pylori* was a much stronger risk factor for peptic ulcer in men than in women. If interaction is present, results should be presented stratified by one of the interacting risk factors, which is why we have presented the results stratified by gender. When we stratify, the groups and the number of outcomes get smaller which results in loss of power. In Paper IV, the number of peptic ulcers among women was as low as 6. The cumulative prevalence of peptic ulcer was 4.8% (n = 4) in women with *H. pylori* and 2.6% (n = 2) in women without *H. pylori*. Power calculations revealed that we would have needed 2000 women in the study to prove that the observed difference in prevalence was significant, with a power of 0.8 and an α level of 0.05.

5.2.4. Challenges in follow-up

For practical and formal reasons our follow-up could only include persons still living in the municipality of Sørreisa, the practical reason for this being the location of the endoscopy unit. This was only partly a limitation, as many of the 121 subjects that had moved had not moved far and could have been easily enrolled. The formal reason was that the license to register persons given to us by the Norwegian Data Inspectorate, was limited to persons living in Sørreisa.

5.3. *Helicobacter pylori* testing; feasibility

The assessment of *H. pylori* infection was essential to the study. We decided early on a cross-sectional design of testing for *H. pylori* linked to the questionnaire, and was thus challenged to use a non-invasive and accurate test. Serology is a sensitive diagnostic method with a too low specificity [46], and would also present logistic challenges in obtaining, storing, and transporting blood samples. Urea breath test using a C^{13} isotope was too costly, whereas using the C^{14} isotope, which at the time was the standard procedure at the University Hospital of North Norway, was not an option as this radioactive isotope could not be sent by mail.

Antigen testing in stool samples was a fairly new method in 2003. We thought this test could be useful in our study, and decided to do a local validation of a commercial kit, the Amplified IDEIA Hp StAR®. With this sub-study we hoped to assess the technical performance of the test, and to become familiar with the logistics of laboratory analysis. In addition, we wanted to learn how patients complied with taking and sending stool samples, which one could expect some to be reluctant to do. We could not systematically register if patients were not enrolled due to reluctance of sending stool samples, as the patients were not asked to give a reason for refusing enrolment for ethical reasons. This has implications for our appraisal of compliance with the test, but does not alter the analyses of test performance.

The major reasons for not enrolling intended patients in the validation study of the stool test was logistic, as the study was part of the daily routine, and some days in the outpatient department were too busy too enrol patients. All together 10 of 131 subjects enrolled in the study failed to send stool samples, a drop-out rate of 7.6% which is not more than expected in a clinical study. After validation, the test was taken into clinical use. The technical performance of the test was excellent, as presented in Paper I. Although compliance could not be quantified, our experience from the study and subsequent use of the test in clinical practice was that compliance was good. We therefore considered it feasible to take it into use in the population-based study.

Unfortunately the response rate was markedly lower than we had hoped for. Part of the explanation of this may be attributed to the stool test, as we heard comments about it in Sørreisa at the time of the study. The response rates were lowest in the youngest and the oldest age groups. The overall response rate of about 40% was low compared with another population-based study in the same region, the Tromsø VI study (ongoing 2007/2008) that has a response rate of somewhat more than 60%. However, a population-based study in Bristol, UK, detecting *H. pylori* using a C^{13} urea breath test, report similar response rates [47]. Taking into account the discomfort experienced by the responders, of taking and sending stool tests, we found the response rate acceptable.

5.4. Gastroscopy

As with most diagnostic procedures, endoscopy has been taken into clinical use in patient populations without a prior systematic validation of technical and diagnostic performance. When discussing management strategies of dyspepsia and *H. pylori*, endoscopy is one of the options, and for this reason it is appropriate to reflect upon the observer variation of endoscopy. OMED has addressed the issue of standardisation and documentation of endoscopy reports in an attempt to render possible exchange of information worldwide [29].

Our study revealed extensive, but not surprising, variation in the assessment of endoscopy images. Studies of observer variation in endoscopy and other diagnostic disciplines show similar results [24;25], though some are more optimistic regarding agreement [48;49]. When examining highly prevalent conditions as dyspepsia and the presence of *H. pylori*, it is important to be aware of the limitations of the diagnostic tools, and this should be considered when discussing management strategies.

The high degree of observer variation had implications for our study, as it made us cautious in the interpretations of endoscopy findings. We have chosen outcome parameters based on more distinct findings, such as the presence or absence of peptic ulcer and the presence or absence of oesophagitis, rather than non-distinct observations such as endoscopy features of gastric inflammation or grades of erosive oesophagitis

5.5. Risk factors

A risk factor in epidemiology is a condition or characteristic associated with, but not necessarily causing a disease. In our study the risk factor of main interest was *H. pylori*, with a prevalence of around 25 % in 2004 and 40% in 1987. There are many strains of this bacterium, and some strains are characterized by qualities connected to a higher degree of pathogenesis than others [50]. One may argue that *H. pylori* is part of the normal flora with a potential of pathogenesis. This view is supported by the fact that other mammals also host *Helicobacter* species [51;52].

There are indications that *H. pylori,* or its ancestors, have been with us since before we evolved as homo sapiens, and there is support for the view that it has both beneficial and harmful effects to humans [53]. Some beneficial effects believed to be associated with carrying *H. pylori* are a lower risk of asthma and diarrhoea, a positive modulation of the energy balance, and a lower risk of GORD, though the latter is controversial [54;55]. The recognised harmful effects are peptic ulcer disease [56], gastric adenoma [57] and mucosa-associated lymphoid tissue (MALT) lymphoma [58].

We found male gender to be associated with an increased risk of peptic ulcer as well as oesophagitis. When studying gender differences in health, differences in behaviour regarding presentation of symptoms and use of health services between men and women must be considered. This is a challenge in patient populations, as they are *a priori* selected on the basis of symptoms and behaviour. Gender specific symptom presentation and behaviour patterns are clinically important and studies of patients are of great value. In contrast, population-based studies add information which, to a certain extent, disregards such conditioned behaviour. Our finding of an increased risk of oesophagitis and peptic ulcer in men should thus reflect real gender differences (further discussed in Section 5.8).

The relationship between ASA and NSAID use and *H. pylori* as risk factors of peptic ulcer disease has been considered in many studies, with reviews and meta-analyses concluding that they are independent risk factors with a synergistic effect [56;59].

Smoking is a major challenge to public health, and the gastrointestinal tract is also a target for the harmful effects of smoking [11]. We found support for smoking being an independent risk factor for peptic ulcer, with an odds ratio of 2.19 (Paper IV). In a meta-analysis from 1997, Kurata and Nogowa reported smoking to have a relative risk of about 2.2 and *H. pylori* to have a relative risk of about 3.3 regarding peptic ulcer disease [60]. Our findings may reflect a decreasing role of *H. pylori*, relative to that of smoking. Whereas the prevalence of *H. pylori* seems to decrease spontaneously with improved hygienic standard, efforts are still needed for the prevalence of smoking to decrease.

5.6. Dyspepsia from a public health perspective

A major challenge in the discussion of dyspepsia is its definition. In the Sørreisa study we used a low threshold definition covering a long time span in both the 1987 and the 2004 surveys ("the Sørreisa definition"). In addition, a graded definition covering a short time span (the GSRS) was used. The GSRS is a validated questionnaire on gastrointestinal disorders, asking for symptoms during the last week. As such, the Sørreisa dyspepsia criteria are not easily translated into the GSRS score. We considered other validated questionnaires such as the Reflux Disease Questionnaire (RDQ) [61], the Quality of Life in Reflux and Dyspepsia (QOLRAD) [62] and the commonly used Rome Criteria (Rome II Criteria at the time of our planning) [63]. The Rome criteria cover a longer time span than does the GSRS, but a shorter time span than the Sørreisa definition. We chose the GSRS scale as it measures the point prevalence of dyspepsia within the last week, and thus complements the "life time" prevalence of the Sørreisa definition of dyspepsia. The overall score of the GSRS scale is an average of the score of the 15 questions included.

In Paper III, the GSRS questions were divided into five dimensions (abdominal pain, indigestion, reflux, constipation, and diarrhoea) and dichotomised. The prevalence's of the various dimensions were given. These dimensions were a composite of the GSRS questions included. A positive score was defined if at least one of the questions were equal to, or higher than 3. This is a somewhat different approach than used by others, as the GSRS dimensions are normally calculated by an average of the included questions. The GSRS questions about acid regurgitation and heartburn are somewhat similar and both measures of gastro-oesophageal reflux symptoms.

Our way of coding the GSRS reflux dimension, resembles the Sørreisa definition better, but makes comparison with other studies a little more obscure.

Table 1 shows the measured agreement between the Sørreisa question and the GSRS questions on reflux symptoms. "GSRS reflux syndrome" in the table is a combination of "acid reflux" and "heartburn", with a combined score equal to the higher of the two.

Table 1. Agreement between Sørreisa reflux symptoms and reflux syndrome on the gastrointestinal symptoms rating scale.

		GSRS reflux syndrome						
		1	2	3	4	5	6	7
Sørreisa Reflux	No	555	116	49	3	0	0	0
	Yes	122	78	113	34	3	5	0

When the GSRS categories 1-2 and 2-7 of the GSRS are pooled and dichotomised as described above and presented in table 2, we find moderate agreement ($\kappa = 0.40$) with the Sørreisa definition of reflux [32;33].

Table 2. Agreement between Sørreisa reflux symptoms and GSRS reflux syndrome on a dichotomous scale.

		GSRS Reflux Syndrome	
		No	Yes
Sørreisa Reflux	No	671	52
	Yes	200	155

The GSRS does not include questions on upper abdominal pain, and comparison with the Sørreisa question on this subset of symptoms is encumbered with too much uncertainty.
All assessment methods of dyspepsia have much of the same shortcomings, due to the heterogeneity of symptoms that is often seen in the same patient. Our low threshold questions in the Sørreisa definition cover a broad spectrum of upper abdominal symptoms. As the public health care consequences are much the same for all subgroups of patients with upper GI symptoms, i.e. referral to endoscopy or prescription of anti-secretory medication, we believe our definition to give a realistic measure of the burden of dyspepsia. Information on the use of health services and medications should also be taken into consideration, which is discussed below.

Other studies report prevalence of dyspepsia between 10 and 40% [13;64;65]. These numbers seem unaltered during the last decades, and the uniformity of the prevalence of dyspepsia with different definitions is more striking than the differences [64].

Trying to differentiate dyspeptic symptoms into ulcer-like and reflux-like is difficult as symptoms overlap, and are prone to change over time [66;67]. In addition, symptoms give a poor prediction of organic disease [68].

The high prevalence of dyspepsia makes it an important public health issue. At the same time it is important to remember that in the vast majority of patients, dyspepsia is a benign condition [64;69]. In our study, about 32% suffered dyspeptic symptoms using the Sørreisa definition. All together 37% of these had seen a specialist in gastroenterology due to their dyspeptic symptoms sometime during the follow-up period, and 31% had seen their general practitioner during the last year for the same reason (unpublished data).

Medications for dyspepsia have undergone an impressive development during the last 20 years. Antacids have been available for decades. In the eighties, the H2-receptor antagonists were introduced, and the latest contribution is the family of PPI. In Norway the use of PPIs is high and increasing, whereas the use of the other acid inhibiting drugs is quite stable (Table 3.).

Table 3. Sales of drugs for acid-related disorders and sales of ulcerogenic drugs.
DDD[a]/1000 inhabitants/day in Norway

Year	Antacids	H2-receptor antagonists	Proton-pump inhibitors	ASA[b]	NSAID
1995	4.9	6.7	4.5	45.4	24.6
2000	3.3	5.9	14.7	48.7	33.8
2005	2.1	5.5	24.5	66.5	43.9
2006	2.0	5.7	27.1	69.4	45.3
2007	1.9	5.8	29.8	72.9	46.4

[a]The Defined Daily Dose (DDD) is the assumed average maintenance dose per day for a drug used in its main indication in adults. http://www.whocc.no/atcddd/

[b]Including other platelet aggregation inhibitors, but not heparin

Extract from http://nomesco-da.nom-nos.dk/filer/publikationer/Helse%202006.pdf [70]

From the individual patient's view, it is reassuring that very efficient drugs for treating dyspepsia are available. From a public health view it is adequate to question if the most expensive and efficient drugs should be our first choice in cases of dyspepsia, or whether we can somehow reach our goal by the use of cheaper and less efficient drugs, which may be good enough.
Still, dyspepsia occupies a large amount of health resources, and there is an ongoing debate of how to manage dyspepsia rationally and cost-beneficially [71;72].

5.7. *Helicobacter pylori* from a public health perspective

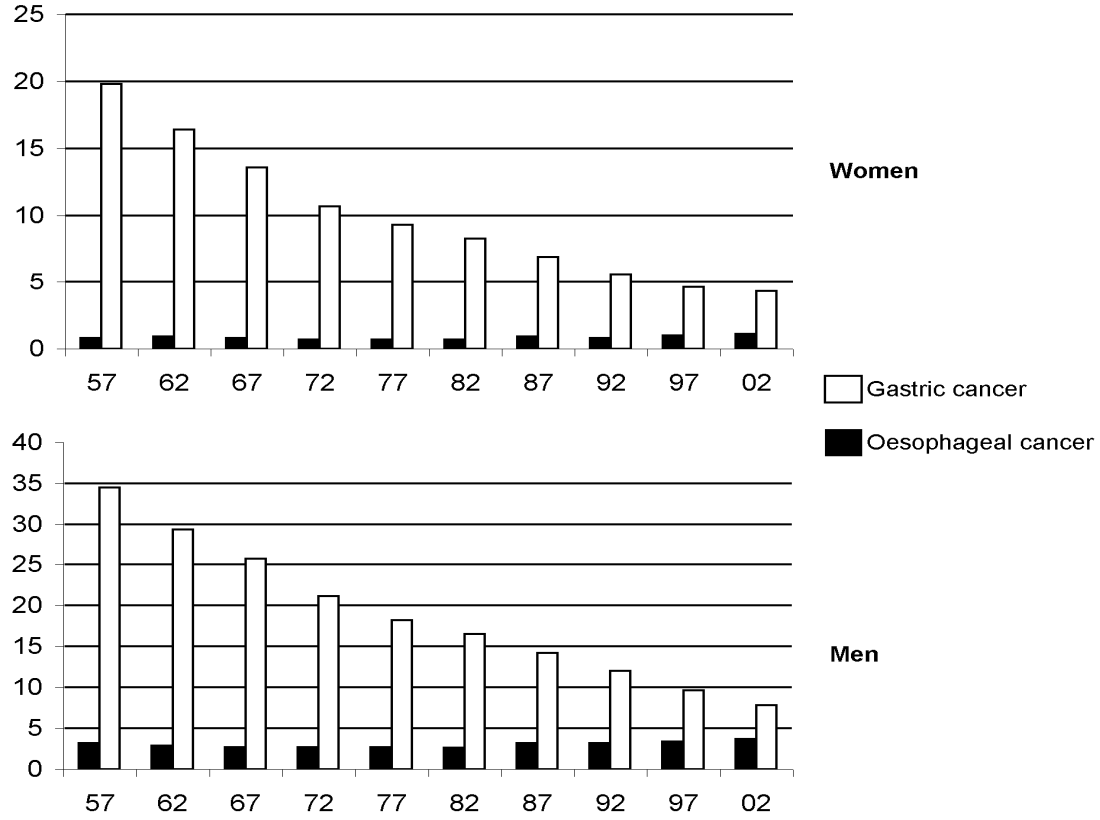
Most of the research on *H. pylori* infection has been done in patients suffering dyspepsia or peptic ulcer disease. Population-based studies are needed for a public health perspective on these issues. If every person hosting *H. pylori* should be considered infected, i.e. being a patient, then *H. pylori* infection, with a prevalence of 25%, is a major public health issue. However, the diseases linked to *H. pylori* are not common in our part of the world. The incidence of gastric cancer is decreasing (Figure 6). We do not have data from health registers on the incidence and severity of peptic ulcer disease in Norway, but a previous study from Northern Norway from 1984 reported incidence rates of duodenal and stomach ulcers of 1.4 and 0.8 per 1,000 per year [73], which corresponds very well with earlier Danish reports [74;75]. In Denmark, the incidence of duodenal ulcers is decreasing [76], a trend believed to apply to Norway as well, where a decreasing incidence of perforated peptic ulcers has been reported [77].
MALT lymphoma, which is strongly associated to *H. pylori*, is a very rare disease with 9.4 new cases in Norway every year (Incidence; 0.21/100 000/year) [78], and thus not a public health issue.

Treatment of *H. pylori* is a potentially important issue implicating the use of two or three different, broad spectrum antibiotics. The indigenous bacterial flora is also affected during such treatment, with the potential of selection and persistence of resistant strains [79], contributing to future problems of spread of infections with resistant bacteria. If we

do not apply strict clinical indications for antibiotic treatment, we could face a serious overuse, bearing in mind that 25% of the population host *H. pylori* and 32% suffer dyspeptic symptoms from time to time independent of this. In central parts of Europe and in the USA, a "test and treat" strategy is recommended [17]. We do not find any support for such a strategy in our study due to the lack of association between dyspeptic symptoms and *H. pylori*.

In other parts of the world the epidemiology of *H. pylori* and gastric cancer differs very much from here, and our results would apply for our region only. In Asia *H. pylori* is highly prevalent and gastric cancer far more common than in Europe and North America [80]. Japan and Korea have the highest incidence of gastric cancer with rates in the range of 50-80/100 000/year in men, and 20-30/100 000/year in women. Northern Europe have some of the lowest incidence rates worldwide; about 5/100 000/year in women and 11/ 100 000/ year in men [81]. As the premises differ, the strategies of dealing with *H. pylori* should be adapted to regional epidemiology.

Figure 6. Five-year age adjusted incidence (per 100 000) of gastric and oesophageal cancer in Norway.



From The Norwegian Cancer Registry. www.kreftregisteret.no

5.8. Endoscopy findings in a general population

5.8.1. Peptic ulcer

In 2004 we found 19 subjects with peptic ulcers at endoscopy (Table 4) compared with 15 subjects in 1987 (Table 5). The numbers of ulcers are too low to say something definite about changes in prevalence of peptic ulcer disease, especially considering the inter-observer variation in endoscopy. However, we can address the distribution between stomach and duodenal ulcers, the gender-specific distribution and the role of *H. pylori.*

In 2004 there were almost twice as many gastric as duodenal ulcers (Table 4), whereas in 1987 there was a more even distribution of stomach and duodenal ulcers (Table 5) (unpublished data). *H. pylori* was present in almost all cases of duodenal ulcers at both times, whereas in gastric ulcers, *H. pylori* was dominant in 1987 but only present in about

50% in 2004. This could imply that peptic ulcer disease is becoming more dominated by gastric ulcers, and that the role of *H. pylori* is on retreat. Other reports indicating that duodenal ulcers are strongly associated with *H. pylori*, whereas the association to gastric ulcers is not as close support this [82;83]. As discussed above, peptic ulcer disease is often reported as a predominantly male disease. In Sørreisa in 2004 we can confirm that the prevalence of peptic ulcer disease is higher in men than in women, as only 4 of 19 subjects with ulcer were women (p=0.01). In 1987 the gender distribution of peptic ulcer disease was more even.

Table 4. Localisation of peptic ulcers at endoscopy in 2004

		Duodenal ulcer		
		Yes	No	Total
Stomach ulcer	Yes	1	12	13[a]
	No	6	543	549
	Total	7[b]	555	562

[a] 6 Hp +ve, 5 Hp –ve (2 missing values of Hp) 7 men, 4 women. ¨

[b] All men, all Hp +ve

Table 5. Localisation of peptic ulcers at endoscopy in 1987

		Duodenal ulcer		
		Yes	No	Total
Stomach ulcer	Yes	0	8	8 [a]
	No	7	604	611
	Total	7 [b]	612	619

[a] 7 Hp +ve, 4 men, 4 women.

[b] 6 Hp +ve, 3 men, 4 women

5.8.2. Oesophagitis

The high inter-observer variation in assessing oesophagitis (Paper II) makes comparison between 1987 and 2004 difficult. In addition, oesophagitis was assessed with the Savary-Miller classification in 1987 [84] and with the Los Angeles Classification [48] in 2004.

However, it is interesting to see that at both times oesophagitis was more prevalent in men than in women. In 1987 the prevalence of oesophagitis was 13.4% (95% CI 9.8%-17.0%) in men, and 5.9% (95% CI 3.1%-8.8%) in women, whereas in 2004 the prevalence of oesophagitis was 30.6% in men (95% CI 25.2%-36.0%) in men, and 14.3% (95% CI 10.3%-18.3%) in women (the numbers are age adjusted using the joint study population at each time as standard population). A predominance of oesophagitis in men is also known from meta-analyses of patient populations [85]. There is accumulating evidence that increasing body mass index (BMI) is a risk factor of GORD [86;87], and some, but sparse, evidence that weight loss may improve gastro-oesophageal reflux symptoms [88]. In our follow-up analysis of the cohort of endoscopy participants from 1987 we have examined BMI as a possible risk factor for oesophagitis, without finding BMI in 1987 to affect the presence of oesophagitis in 2004. The relationship between oesophagitis and BMI is better addressed in a cross-sectional study, as a risk factor as high BMI should be present when measuring its effect.

5.8.3. Morphological changes in the gastric mucosa

In 1987 75% of the subjects had some pathological finding in the gastric mucosa (92% in *H. pylori* positive and 40% in *H. pylori* negative), compared with 66% in 2004 (95% and 59%, respectively) This is based on assessment by the same pathologist. The numbers are age adjusted using the joint study population at each time as standard population. Hosting *H. pylori* was followed by some degree of gastric inflammation in almost all cases. However, about half the subjects without *H. pylori* also showed some degree of morphological changes. The question of what features to be found in a "normal" gastric mucosa is still open for discussion [89]. Our most important finding regarding morphological changes in the gastric mucosa is probably that the most chronic lesions may be initiated by *H. pylori*, but that elimination of this infection does not result in regression of the lesions.

6. IMPLICATION FOR CLINICAL PRACTICE AND FURTHER RESEARCH

Detection of *H. pylori* in stool samples is a convenient and accurate diagnostic method, suitable for an outpatient setting. Its use in a population-based study will imply a trade off between the benefit of it being an accurate test, with the risk of low participation due to a reluctance to provide stool samples.

During the last decades, we have seen a decreasing prevalence of *H. pylori* parallel to a decreasing incidence of gastric cancer and peptic ulcer disease. At the same time we have seen a persistent high prevalence of dyspepsia.

From a public health view, *H. pylori* today plays a decreasing role in our part of the world, whereas dyspepsia is still a major burden of health, generating high expenditures and use of health services. We are in need of rational strategies for the management of dyspepsia. Such strategies should probably not include treating *H. pylori*, in the absence of other symptoms or findings than dyspepsia, as the association between dyspepsia and H. pylori is unclear in our region. We should rather balance costs of health care services associated to dyspepsia against its rather benign nature.

Further validation of the benefit of endoscopy, especially in patient populations with less severe symptoms, seems appropriate.

7. CONTRIBUTION TO THE PAPERS

I: Asfeldt AM, Løchen ML, Straume B, Steigen, SE, Florholmen J, Goll, R Nestegard, Paulssen EJ. Accuracy of a monoclonal antibody-based stool antigen test in the diagnosis of Helicobacter pylori infection. Scand J Gastroenterol 2004;39(11):1073-7.

*Full Responsibility for the integrity of the study***:** Asfeldt. *Study concept*; Asfeldt and Paulssen. *Study design*: Asfeldt, Paulssen, Straume, Løchen, Florholmen. *Handling ethical and legal aspects*[a]: Asfeldt. *Acquisition of Data*: Asfeldt, Paulssen, Goll, Nestegard, Florholmen (enrolment and endoscopy). *Morphologic assessment*: Steigen. *Analysis and interpretation of data:* Asfeldt, Paulssen, Løchen, Straume, *Statistical analysis:* Asfeldt. *Drafting of the manuscript:* Asfeldt. *Critical revision of the manuscript for important intellectual content:* Asfeldt, Løchen, Straume, Steigen, Florholmen, Goll, Nestegard, Paulssen. *Study supervision:* Løchen, Paulssen, Straume.

II. Asfeldt AM, Straume B, Paulssen EJ. Impact of observer variability on the usefulness of endoscopic images for the documentation of upper gastrointestinal endoscopy. Scand J Gastroenterol 2007;42(9):1106-12.

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III. Asfeldt AM, Straume B, Steigen SE, Løchen ML, Florholmen J, Bernersen B, Johnsen R, Paulssen EJ. Changes in the prevalence of dyspepsia and Helicobacter pylori infection after 17 years: The Sørreisa gastrointestinal disorder study. Eur J Epidemiol 2008;23(9):625-33.

*Full Responsibility for the integrity of the study***:** Asfeldt. *Overall study concept and design:* Asfeldt, Bernersen, Florholmen, Johnsen, Løchen, Paulssen, Straume. *Handling ethical and legal aspects*[a]: Asfeldt. *Planning, establishing and running endoscopy unit in Sørreisa*: Asfeldt. *Acquisition of Data:* Asfeldt (questionnaire survey, *H. pylori* testing and gastroscopy in 2004), Bernersen (questionnaire survey, *H. pylori* testing and gastroscopy in 1987), Johnsen (questionnaire survey 1987). *Morphologic assessment***:** Asfeldt, Paulssen (planning), Steigen (planning and carrying out). *Analysis and interpretation of data:* Asfeldt, Paulssen, Løchen, Straume. *Drafting of the manuscript:* Asfeldt. *Critical revision of the manuscript for important intellectual content:* Asfeldt, Bernersen, Florholmen, Johnsen, Løchen, Paulssen, Straume, Steigen. *Statistical analysis:* Asfeldt, Straume. *Obtaining funding:* Asfeldt, Florholmen, Løchen, Straume. *Administrative, technical or material support:* Florholmen, Straume. *Study supervision:* Løchen, Paulssen, Straume.

IV. Asfeldt AM, Steigen SE, Løchen ML, Straume B, Johnsen R, Bernersen B, Florholmen J, Paulssen EJ. The natural course of Helicobacter pylori in gastritis, peptic ulcer disease and reflux oesophagitis in a population-based prospective cohort: The Sørreisa Gastrointestinal disorder study. Submitted.

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[a]Seeking the Regional Committee for Medical Research Ethics. Seeking the Norwegian Data Inspectorate for license to register participants. Registering the biobank of the study. Additionally in Papers II and III corresponding with NPE among others, regarding the issue of health insurance of participants.

ERRATA

The numbers in Figure 1 differs slightly from the flowchart in Figure 1 of Paper III. Invited population in 1987 was 2391, and not 2385 as stated in the paper. The numbers of responders are correct, but include only subjects <70 years old, as only these were included in the original publications from the study in 1987.
In 2004 1145 subjects answered the questionnaire and not 1143 as stated, a difference due to misclassification of attendance.

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Appendix 1

Printed version of the questionnaire for observer agreement

(Follow the link below to view the web-page)

http://www.ism.uit.no/anne-mette/2/
Username: gastro Password: Tromso

Spørreskjema interobservatørstudie

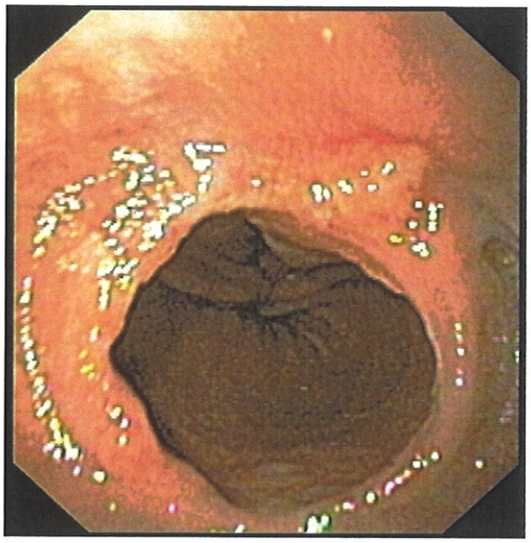
Legg inn dine svar nedenfor:

1/22

1 2 3
○ ○ ○ **Sp1:**
Hvor mange gastroskopier har du utført?
1 - Færre enn 200 skopier?
2 - 200-1000 skopier?
3 - Flere enn 1000 skopier?
(Svaralternativ: **1, 2, 3**)

Spiserør:

2/22

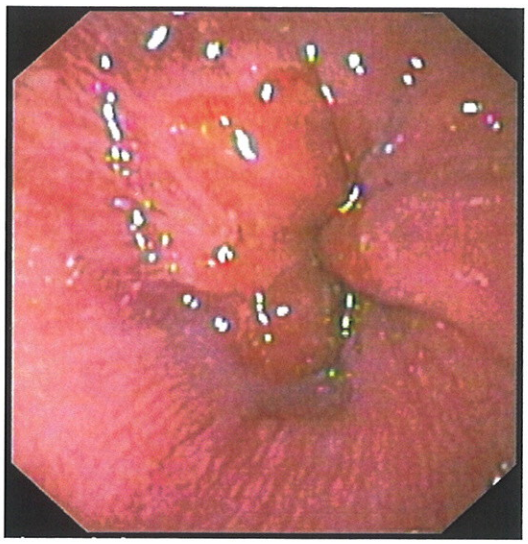


nei A B C D
○ ○ ○ ○ ○ **Sp3: Øsofagitt** bedømt ved Los Angeles klassifikasjon
(Svaralternativ: **nei, A, B, C, D)**

ja nei
○ ○ **Sp4: Mistanke om metaplasi?**
(Svaralternativ: **ja, nei**)

ja nei usikker
○ ○ ○ **Sp5: Hiatus Hernie?**
(Svaralternativ: **ja, nei, usikker**)

3/22

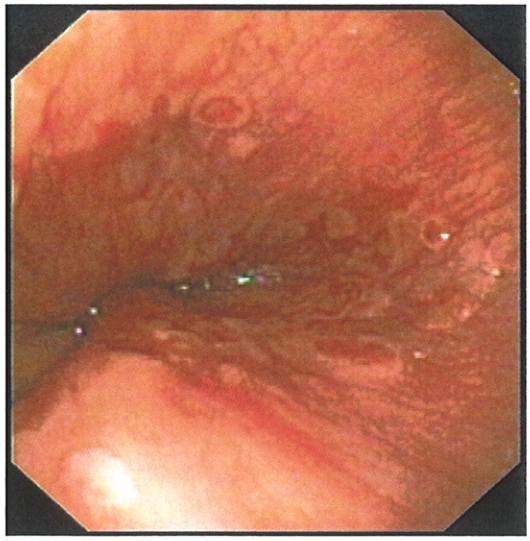


nei A B C D
○ ○ ○ ○ ○ **Sp7: Øsofagitt** bedømt ved Los Angeles klassifikasjon
(Svaralternativ: **nei, A, B, C, D)**

ja nei
○ ○ **Sp8: Mistanke om metaplasi?**
(Svaralternativ: **ja, nei**)

ja nei usikker
○ ○ ○ **Sp9: Hiatus Hernie?**
(Svaralternativ: **ja, nei, usikker**)

4/22



nei A B C D
○ ○ ○ ○ ○

Sp11: Øsofagitt bedømt ved Los Angeles klassifikasjon
(Svaralternativ: **nei, A, B, C, D)**

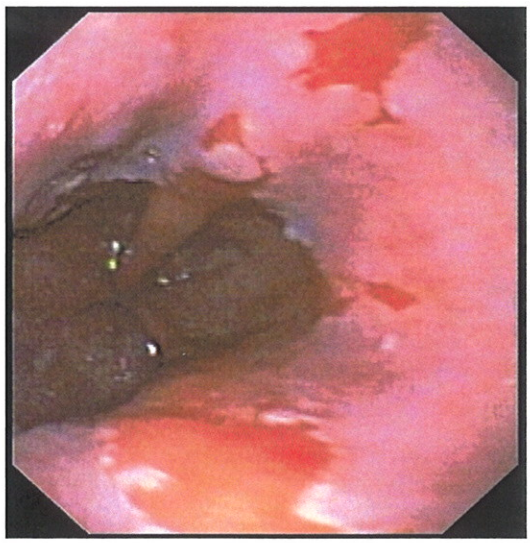
ja nei
○ ○

Sp12: Mistanke om metaplasi?
(Svaralternativ: **ja, nei**)

ja nei usikker
○ ○ ○

Sp13: Hiatus Hernie?
(Svaralternativ: **ja, nei, usikker**)

5/22



nei A B C D
○ ○ ○ ○ ○

Sp15: Øsofagitt bedømt ved Los Angeles klassifikasjon
(Svaralternativ: **nei, A, B, C, D)**

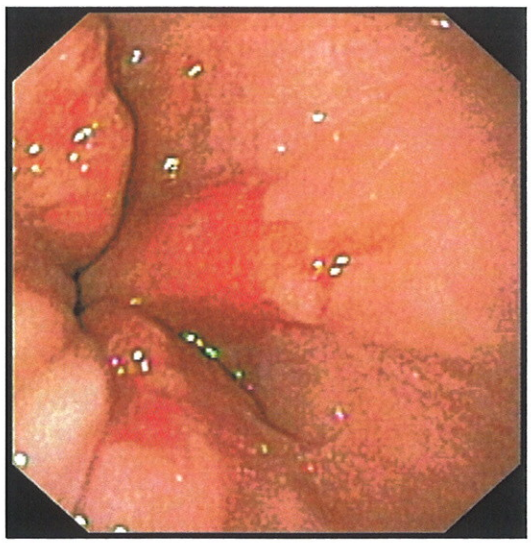
ja nei
○ ○

Sp16: Mistanke om metaplasi?
(Svaralternativ: **ja, nei**)

ja nei usikker
○ ○ ○

Sp17: Hiatus Hernie?
(Svaralternativ: **ja, nei, usikker**)

6/22



nei A B C D
○ ○ ○ ○ ○

Sp19: Øsofagitt bedømt ved Los Angeles klassifikasjon
(Svaralternativ: **nei, A, B, C, D)**

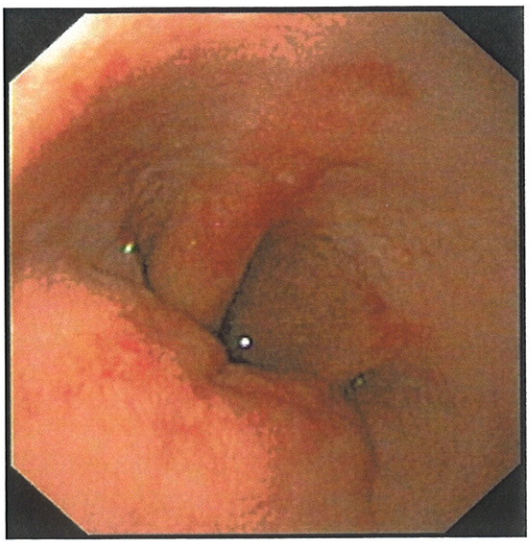
ja nei
○ ○

Sp20: Mistanke om metaplasi?
(Svaralternativ: **ja, nei**)

ja nei usikker
○ ○ ○

Sp21: Hiatus Hernie?
(Svaralternativ: **ja, nei, usikker**)

7/22



nei A B C D
○ ○ ○ ○ ○

Sp23: Øsofagitt bedømt ved Los Angeles klassifikasjon
(Svaralternativ: **nei, A, B, C, D)**

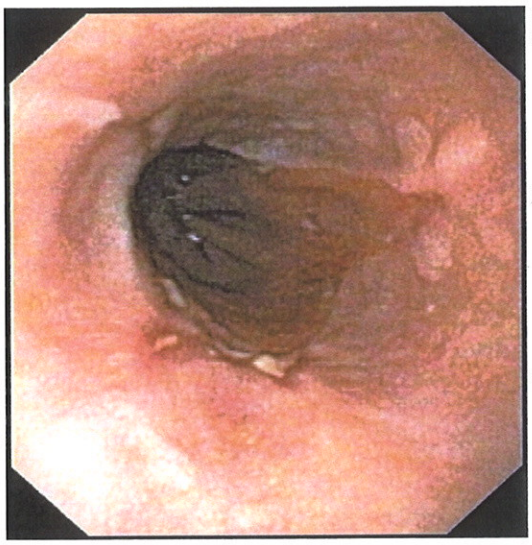
ja nei
○ ○

Sp24: Mistanke om metaplasi?
(Svaralternativ: **ja, nei**)

ja nei usikker
○ ○ ○

Sp25: Hiatus Hernie?
(Svaralternativ: **ja, nei, usikker**)

8/22



nei A B C D
○ ○ ○ ○ ○

Sp27: Øsofagitt bedømt ved Los Angeles klassifikasjon
(Svaralternativ: **nei, A, B, C, D)**

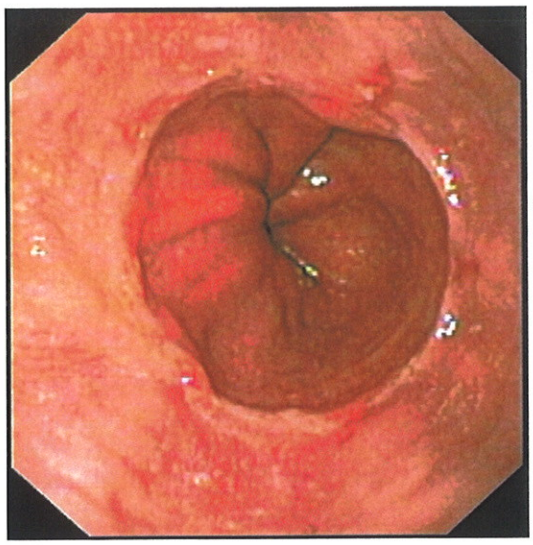
ja nei
○ ○

Sp28: Mistanke om metaplasi?
(Svaralternativ: **ja, nei**)

ja nei usikker
○ ○ ○

Sp29: Hiatus Hernie?
(Svaralternativ: **ja, nei, usikker**)

9/22



nei A B C D
○ ○ ○ ○ ○

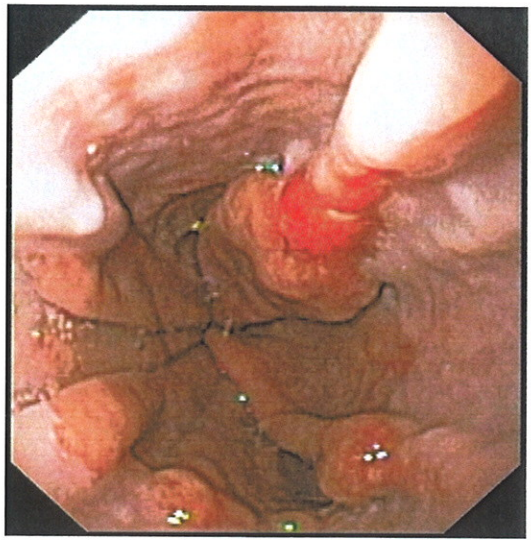
Sp31: Øsofagitt bedømt ved Los Angeles klassifikasjon
(Svaralternativ: **nei, A, B, C, D)**

ja nei
○ ○

Sp32: Mistanke om metaplasi?
(Svaralternativ: **ja, nei**)

ja nei usikker
○ ○ ○

Sp33: Hiatus Hernie?
(Svaralternativ: **ja, nei, usikker**)



10/22

nei A B C D
○ ○ ○ ○ ○

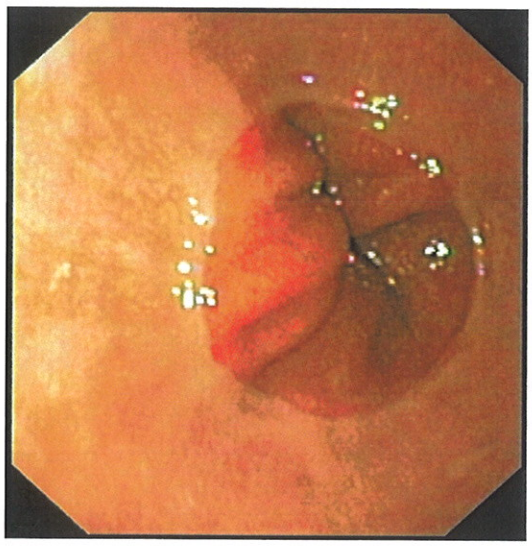
Sp35: Øsofagitt bedømt ved Los Angeles klassifikasjon
(Svaralternativ: **nei, A, B, C, D)**

ja nei
○ ○

Sp36: Mistanke om metaplasi?
(Svaralternativ: **ja, nei**)

ja nei usikker
○ ○ ○

Sp37: Hiatus Hernie?
(Svaralternativ: **ja, nei, usikker**)



11/22

nei A B C D
○ ○ ○ ○ ○

Sp39 Øsofagitt bedømt ved Los Angeles klassifikasjon
(Svaralternativ: **nei, A, B, C, D)**

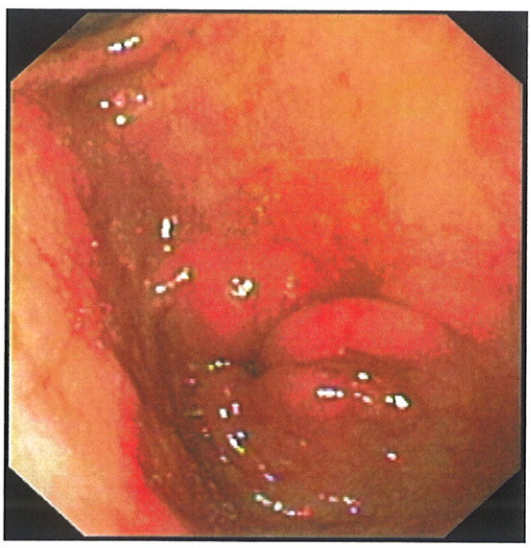
ja nei
○ ○

Sp40: Mistanke om metaplasi?
(Svaralternativ: **ja, nei**)

ja nei usikker
○ ○ ○

Sp41: Hiatus Hernie?
(Svaralternativ: **ja, nei, usikker**)

Magesekk:



12/22

ja nei
○ ○

Sp42: Normal slimhinne?
(Svaralternativ: **ja, nei**)

ja nei
○ ○

Sp43: Ødematøs slimhinne?
(Svaralternativ: **ja, nei**)

ja nei
○ ○

Sp44: Erytematøs slimhinne
(Svaralternativ: **ja, nei**)

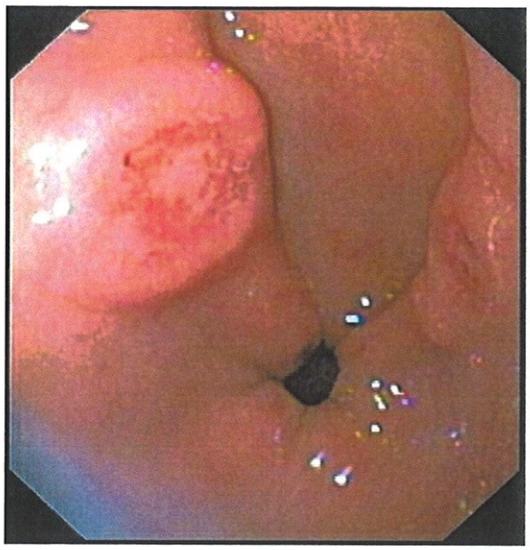
ja nei
○ ○

Sp45: Erosjon(er)?
(Svaralternativ: **ja, nei**)

ja nei
○ ○

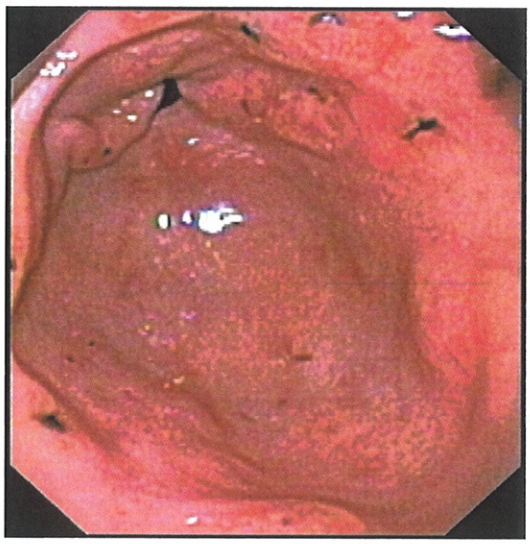
Sp46:Ulcus/Ulcera?
(Svaralternativ: **ja, nei**)

13/22



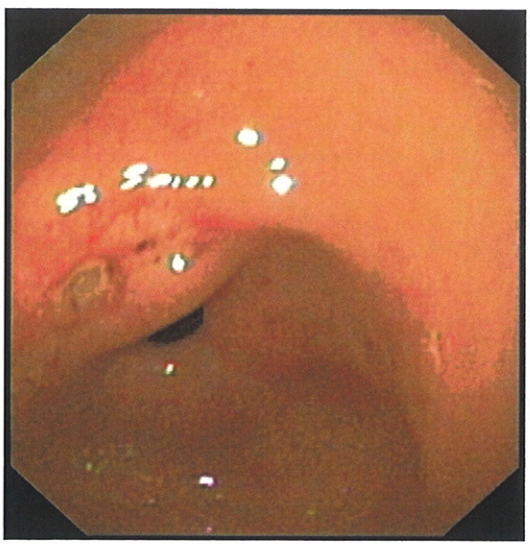
ja	nei	
○	○	**Sp47: Normal slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp48: Ødematøs slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp49: Erytematøs slimhinne** (Svaralternativ: **ja, nei**)
○	○	**Sp50: Erosjon(er)?** (Svaralternativ: **ja, nei**)
○	○	**Sp51:Ulcus/Ulcera?** (Svaralternativ: **ja, nei**)

14/22



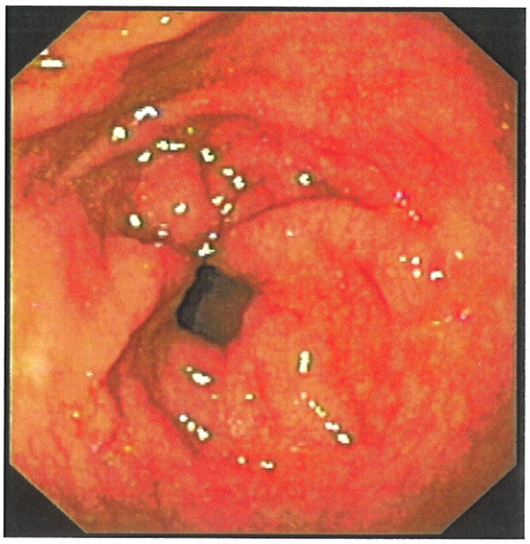
ja	nei	
○	○	**Sp52: Normal slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp53: Ødematøs slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp54: Erytematøs slimhinne** (Svaralternativ: **ja, nei**)
○	○	**Sp55: Erosjon(er)?** (Svaralternativ: **ja, nei**)
○	○	**Sp56:Ulcus/Ulcera?** (Svaralternativ: **ja, nei**)

15/22



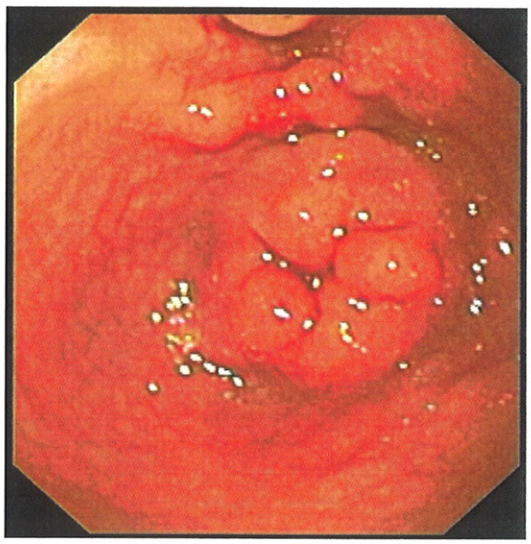
ja	nei	
○	○	**Sp57: Normal slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp58: Ødematøs slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp59: Erytematøs slimhinne** (Svaralternativ: **ja, nei**)
○	○	**Sp60: Erosjon(er)?** (Svaralternativ: **ja, nei**)
○	○	**Sp61:Ulcus/Ulcera?** (Svaralternativ: **ja, nei**)

16/22



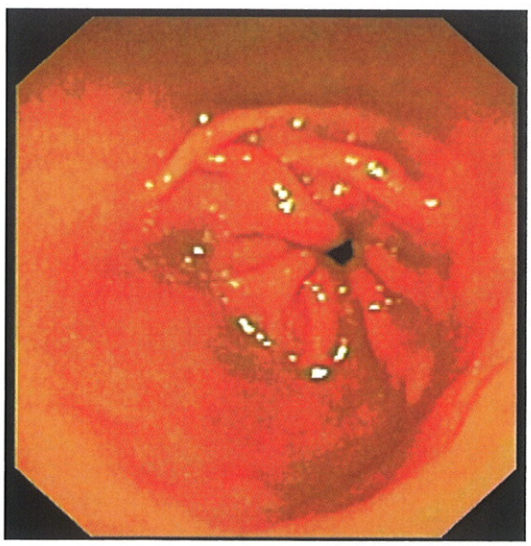
ja	nei	
○	○	**Sp62: Normal slimhinne?** (Svaralternativ: **ja, nei**)
ja	nei	**Sp63: Ødematøs slimhinne?**
○	○	(Svaralternativ: **ja, nei**)
ja	nei	**Sp64: Erytematøs slimhinne**
○	○	(Svaralternativ: **ja, nei**)
ja	nei	**Sp65: Erosjon(er)?**
○	○	(Svaralternativ: **ja, nei**)
ja	nei	**Sp66:Ulcus/Ulcera?**
○	○	(Svaralternativ: **ja, nei**)

17/22



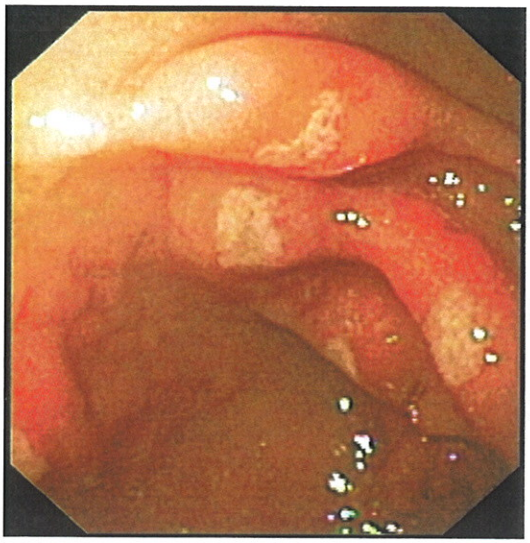
ja	nei	
○	○	**Sp67: Normal slimhinne?** (Svaralternativ: **ja, nei**)
ja	nei	**Sp68: Ødematøs slimhinne?**
○	○	(Svaralternativ: **ja, nei**)
ja	nei	**Sp69: Erytematøs slimhinne**
○	○	(Svaralternativ: **ja, nei**)
ja	nei	**Sp70: Erosjon(er)?**
○	○	(Svaralternativ: **ja, nei**)
ja	nei	**Sp71:Ulcus/Ulcera?**
○	○	(Svaralternativ: **ja, nei**)

18/22



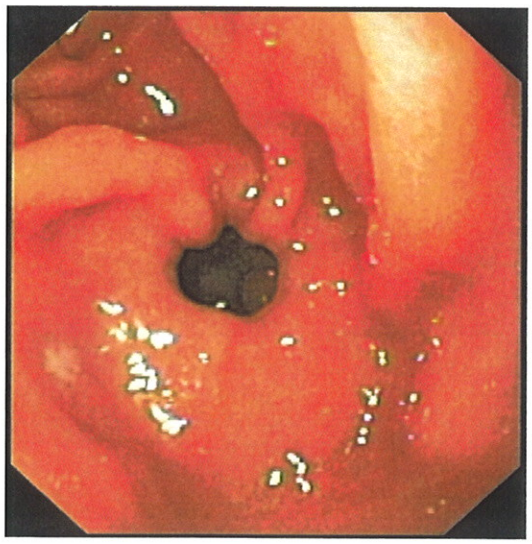
ja	nei	
○	○	**Sp72: Normal slimhinne?** (Svaralternativ: **ja, nei**)
ja	nei	**Sp73: Ødematøs slimhinne?**
○	○	(Svaralternativ: **ja, nei**)
ja	nei	**Sp74: Erytematøs slimhinne**
○	○	(Svaralternativ: **ja, nei**)
ja	nei	**Sp75: Erosjon(er)?**
○	○	(Svaralternativ: **ja, nei**)
ja	nei	**Sp76:Ulcus/Ulcera?**
○	○	(Svaralternativ: **ja, nei**)

19/22



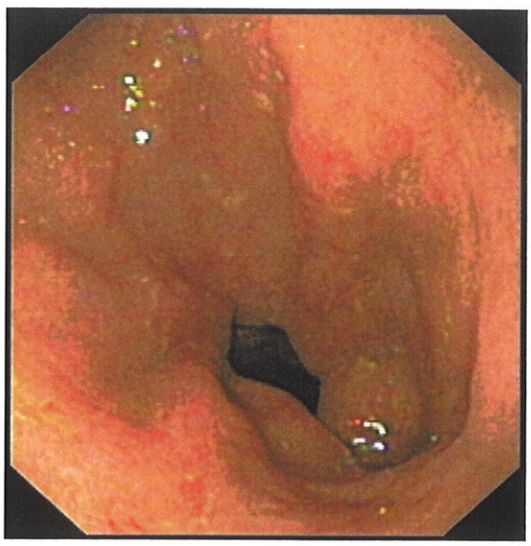
ja	nei	
○	○	**Sp77: Normal slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp78: Ødematøs slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp79: Erytematøs slimhinne** (Svaralternativ: **ja, nei**)
○	○	**Sp80: Erosjon(er)?** (Svaralternativ: **ja, nei**)
○	○	**Sp81:Ulcus/Ulcera?** (Svaralternativ: **ja, nei**)

20/22



ja	nei	
○	○	**Sp82: Normal slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp83: Ødematøs slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp84: Erytematøs slimhinne** (Svaralternativ: **ja, nei**)
○	○	**Sp85: Erosjon(er)?** (Svaralternativ: **ja, nei**)
○	○	**Sp86:Ulcus/Ulcera?** (Svaralternativ: **ja, nei**)

21/22



ja	nei	
○	○	**Sp87: Normal slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp88: Ødematøs slimhinne?** (Svaralternativ: **ja, nei**)
○	○	**Sp89: Erytematøs slimhinne** (Svaralternativ: **ja, nei**)
○	○	**Sp90: Erosjon(er)?** (Svaralternativ: **ja, nei**)
○	○	**Sp91:Ulcus/Ulcera?** (Svaralternativ: **ja, nei**)

22/22

Tenker du det samme om 3 måneder?

På et senere tidspunkt
ønsker vi å gjøre en intraobservatørstudie for å se om slik bildebedømming hos samme observatør er konsistent.
Vi vil da på nytt presentere deg for bildene du nå har sett.

Såfremt du kan tenke deg å være med på en slik intraobservatørstudie, må vi ha mulighet for å kontakte deg og vi må vite hvordan du har bedømt bildene første gang. Så snart vi har samlet data fra 2. gangs bedømming, blir all bedømming av bilder anonymisert.

Kan du tenke deg
å være med på dette ber vi deg fylle ut navn og E-post i feltene nedenfor.
Du kan naturligvis velge ikke å delta i intraobservatørstudien.
Da lar du bare nedenstående felter stå tomme.

Frivillig utfylling:

Fornavn: *
Etternavn: *
Telefon:
Mail:

---

* Systemet *godtar ikke blanke tegn* i feltene Fornavn og Etternavn. Dersom du skal registrere mellomnavn, må bindestrek (-) benyttes i stedet for mellomrom**!!** Eks**: Jarle Kristian**

må registreres som **Jarle-Kristian**

Send svarene

utviklet av: **Jarle Mathiassen, IT-ansvarlig, ISM**
Mail: jarle.mathiassen@ism.uit.no
Private web: http://home.no.net/jarmath
Private phone: +47 404 02 66 50 oppdatert 05.03.2009

Appendix 2

The questionnaire of

The Sørreisa Gastrointestinal Disorder Study - 1987

Sørreisa-undersøkelsen

Fordøyelsesbesvær eller magesårlignende plager er svært vanlig. Bare et fåtall av de som har magesårlignende plager har imidlertid magesår. Vi vet ikke hvor mange som har slike plager i en vanlig befolkning. Heller ikke vet vi årsaken til slike plager, eller om personer med slike plager vil utvikle magesår senere.

Det vil derfor være av stor betydning for forståelsen og dermed behandlingen av slike plager å kunne gjennomføre en undersøkelse over fordøyelsesbesvær eller magesårlignende plager i Sørreisa. Denne undersøkelsen er et samarbeidsprosjekt mellom Kommunehelsetjenesten i Sørreisa, Gastroenterologisk seksjon, Medisinsk avdeling, Regionsykehuset i Tromsø og Institutt for samfunnsmedisin, Universitetet i Tromsø.

Som det vil fremgå av vedlagte spørreskjema, ønsker vi å kartlegge følgende som kan være av betydning:

- Generelle forhold.
- Mageplager og beslektede forhold.
- Andre plager.
- Slektsforhold med tanke på mulig arvelighet.
- Spisevaner som kan virke utløsende og forverrende.
- Likeså forbruk av kaffe, te, tobakk, alkohol og medikamenter.
- Yrkesmessige og sosiale forhold.

De fleste som har eller har hatt fordøyelsesbesvær vil senere få tilbud om en nærmere undersøkelse av magen på kommunelegekontoret i Sørreisa ved overlege Bjørn Bernersen. Det er viktig at så mange som mulig møter opp til denne undersøkelsen.

Vi håper at alle som får tilsendt dette spørreskjemaet tar bryet med å fylle det ut og å returnere det så fort som mulig. All deltagelse er frivillig.

Innsendte spørreskjemaer vil bli gjennomgått av medisinsk personell og behandlet strengt konfidensielt på samme måte som legejournaler. Alle opplysninger blir lagret på EDB og gjort utilgjengelig for uvedkommende.

Vennlig hilsen

Per A. Stakkevold
kommunelege I

Bjørn Bernersen
overlege

Idar Elvemo
kommunelege II

GENERELT

1. Dato for utfylling av ditt skjema: ..... dag mnd. år _____ 001

2. Etternavn: _____ 002.1

   Fornavn: _____ .2

3. Fødselsdato: ..... dag mnd. år _____ 003

4. Kjønn: (sett kryss i den ruten som passer) ..... Kvinne: ☐ 004.1

   Mann: ☐ .2

5. Adresse: _____ 005

   Postnr.:_____ Poststed: _____

6. Sivilstand:

   Sett kryss i den ruten som passer best.

   - Ugift: ..... ☐ 006.1
   - Samboende: ..... ☐ .2
   - Gift: ..... ☐ .3
   - Separert: ..... ☐ .4
   - Skilt: ..... ☐ .5
   - Enke/enkemann: ..... ☐ .6

Mageplager

7. Har du noen gang hatt smerter eller «verk» i magen som har vart i minst to uker? (Omgangssyke («reksjuke») regnes ikke med) JA ☐ 007.1 NEI ☐ .2
   (Sett kryss i den ruten som passer)

   Hvis «NEI», gå direkte til spørsmål nr. 29.
   Hvis «JA», fortsett med spørsmål nr. 8.

8. Sitter smertene eller «verken» i

   Sett kryss i den ruten som passer best.

   - øvre del av magen? ..... ☐ 008.1
   - nedre del av magen? ..... ☐ .2
   - hele magen? ..... ☐ .3

9. Angi så nøyaktig som mulig hvilket årstall du første gang merket smertene eller «verken» i magen: ..... Årstall _____ 009

10. Har smertene eller «verken» i magen noen gang vært tilstede hver dag i mer enn to måneder? JA ☐ 010.1 NEI ☐ .2
    (Sett kryss i den ruten som passer)

11. Har du hatt smerter eller «verk» i magen de siste to ukene? ..... JA ☐ 011.1 NEI ☐ .2
    (Sett kryss i den ruten som passer)

12. Er smertene eller «verken» jevnt over tilstede

    Sett kryss i den ruten som passer best.

    - i perioder av ukers varighet? . ☐ 012.1
    - i perioder av måneders varighet? ☐ .2
    - bestandig? ..... ☐ .3

13. Hvilke måneder er smertene eller «verken» i magen vanligvis verst?

    Sett kryss i den eller de rutene som passer.

    - Januar–februar: ..... ☐ 013.1
    - Mars–april: ..... ☐ .2
    - Mai–juni: ..... ☐ .3
    - Juli–august: ..... ☐ .4
    - September–oktober: ..... ☐ .5
    - November–desember: ..... ☐ .6
    - Ingen forandring gjennom året: ☐ .7

14. Blir smertene eller «verken» i magen vanligvis

    Sett kryss i den ruten som passer best.

    - bedre når du spiser? ..... ☐ 014.1
    - verre når du spiser? ..... ☐ .2
    - upåvirket når du spiser?..... ☐ .3

15. Blir smertene eller «verken» i magen vanligvis

    Sett kryss i den ruten som passer best.

    - bedre ved fysiske anstrengelser? ..... ☐ 015.1
    - verre ved fysiske anstrengelser? ☐ .2
    - upåvirket ved fysiske anstrengelser? ..... ☐ .3

16. Hender det at du våkner om natten av smertene eller «verken» i magen? ..... JA ☐ NEI ☐ 016.1 .2
(Sett kryss i den ruten som passer)

17. Har du søkt lege på grunn av smertene eller «verken» i magen? ..... JA ☐ NEI ☐ 017.1 .2
(Sett kryss i den ruten som passer)

18. Hvis «JA», hvor mange ganger har du søkt lege siste året på grunn av smertene eller «verken» i magen? ..... Antall _____ 018

19. Har du vært henvist til, eller innlagt i sykehus på grunn av smertene eller «verken» i magen? JA ☐ NEI ☐ 019.1 .2
(Sett kryss i den ruten som passer)

20. Hvis «JA», angi hvilket sykehus.
(Skriv navnet her): _____ 020.1

Hvilket år ble du henvist eller undersøkt siste gang? ..... Årstall _____ .2

21. Har du vært sykemeldt for smertene eller «verken» i magen? JA ☐ NEI ☐ 021.1 .2
(Sett kryss i den ruten som passer)

22. Hvis «JA», angi hvor mange uker du har vært sykemeldt for smertene eller «verken» i magen i løpet av de siste 12 månedene: .... Antall uker _____ 022

23. Har du brukt syrenøytraliserende midler som Balancid, Link, Novaluzid, Alminox, Antacid, Titralac, Natron eller Wismutmixtur mot smertene eller «verken» i magen? ..... JA ☐ NEI ☐ 023.1 .2
(Sett kryss i den ruten som passer)

24. Hvis «JA», har disse midlene hjulpet mot smertene eller «verken» i magen? ..... JA ☐ NEI ☐ 024.1 .2
(Sett kryss i den ruten som passer)

25. Har du fått andre medikamenter på resept for smertene eller «verken» i magen? ..... JA ☐ NEI ☐ 025.1 .2
(Sett kryss i den ruten som passer)

Hvis «JA», kryss av for den gruppen under spørsmålene 26, 27 og 28, hvor du eventuelt finner navnet på det medikamentet du har fått. Om nødvendig se etter på resept, medisinglass eller pakning om du finner navnet. Svar også på om dette medikamentet har hjulpet eller ikke hjulpet mot smertene eller «verken» i magen.

26. Cimal, Cimetid, Gastrobitan, Tagamet, Ranacid eller Zantac? ..... JA ☐ NEI ☐ 026.1 .2
(Sett kryss i den ruten som passer)

Hvis «JA», har dette hjulpet mot smertene eller «verken» i magen? ..... JA ☐ NEI ☐ .3 .4
(Sett kryss i den ruten som passer)

27. Egazil Duretter, Daricon, Gastrozepin, Librax, Oximin, Ulcoban? ..... JA ☐ NEI ☐ 027.1 .2
(Sett kryss i den ruten som passer)

Hvis «JA», har dette hjulpet mot smertene eller «verken» i magen? ..... JA ☐ NEI ☐ .3 .4
(Sett kryss i den ruten som passer)

28. Surmontil? ..... JA ☐ NEI ☐ 028.1 .2
(Sett kryss i den ruten som passer)

Hvis «JA», har dette hjulpet mot smertene eller «verken» i magen? ..... JA ☐ NEI ☐ .3 .4
(Sett kryss i den ruten som passer)

29. Har du hatt sure oppstøt, halsbrann eller brystbrann nesten daglig i minst en uke? .. JA ☐ NEI ☐ 029.1 .2
(Sett kryss i den ruten som passer)

30. Er du ofte plaget av kvalme eller oppkast? .. JA ☐ NEI ☐ 030.1 .2
(Sett kryss i den ruten som passer)

31. Har du noen gang kastet opp blod? ..... JA ☐ NEI ☐ 031.1 .2
(Sett kryss i den ruten som passer)

32. Har du vansker med å svelge, eller følelse av at maten stopper opp i halsen eller brystet? JA ☐ NEI ☐ 032.1 .2
(Sett kryss i den ruten som passer)

33. Er du ofte plaget av oppblåsthet, rumling i magen eller rikelig luftavgang fra endetarmen? JA ☐ NEI ☐ 033.1 .2
(Sett kryss i den ruten som passer)

34. Hvis «JA», blir oppblåstheten eller rumlingen bedre etter avføring eller luftavgang fra endetarmen? ..... JA ☐ NEI ☐ 034.1 .2
(Sett kryss i den ruten som passer)

35. Er avføringen din vanligvis

Sett kryss i den ruten som passer best.

— normal? ..... ☐ 035.1
— løs? ..... ☐ .2
— hard og perlet? ..... ☐ .3
— vekslende løs og hard? ..... ☐ .4

36. Har du i perioder tre eller flere avføringer daglig? ..... JA ☐ NEI ☐ 036.1 .2
(Sett kryss i den ruten som passer)

37. Har du i perioder avføring sjeldnere enn hver tredje dag? ..... JA ☐ NEI ☐ 037.1 .2
(Sett kryss i den ruten som passer)

38. Har du ofte sett slim i avføringen? ..... JA ☐ NEI ☐ 038.1 .2
(Sett kryss i den ruten som passer)

39. Har du noen gang sett friskt, rødt blod i avføringen? ..... JA ☐ NEI ☐ 039.1 .2
(Sett kryss i den ruten som passer)

40. Har du noen gang hatt beksvart eller tjærelignende avføring? ..... JA ☐ NEI ☐ 040.1 .2
(Sett kryss i den ruten som passer)

41. Hvis «JA», brukte du forut for dette jerntabletter eller jernmikstur? ..... JA ☐ NEI ☐ 041.1 .2
(Sett kryss i den ruten som passer)

42. Har du noen gang hatt hemorroider eller sår/rifter i endetarmsåpningen? ..... JA ☐ NEI ☐ 042.1 .2
(Sett kryss i den ruten som passer)

43. Har du eller har du fått påvist magesår? ..... JA ☐ NEI ☐ 043.1 .2
(Sett kryss i den ruten som passer)

44. Er du operert for magesår? ..... JA ☐ NEI ☐ 044.1 .2
(Sett kryss i den ruten som passer)

45. Har du eller har du hatt gallestein? ..... JA ☐ NEI ☐ 045.1 .2
(Sett kryss i den ruten som passer)

46. Har du vært operert for noe annet i magen? .. JA ☐ NEI ☐ 046.1 .2
(Sett kryss i den ruten som passer)

47. Hvis du har vært operert i magen, angi da så nøyaktig som mulig når du ble operert i magen siste gang ..... Årstall _____ 047.1

— og angi også ved hvilket sykehus

(Skriv navnet på sykehuset her): _____ .2

Andre plager

48. Har du eller har du hatt angina pectoris (hjertekrampe)? ..... JA ☐ 048.1
(Sett kryss i den ruten som passer) NEI ☐ .2

49. Har du eller har du hatt hjerteinfarkt (sår på hjertet)? ..... JA ☐ 049.1
(Sett kryss i den ruten som passer) NEI ☐ .2

50. Har du eller har du hatt annen hjertesykdom? JA ☐ 050.1
(Sett kryss i den ruten som passer) NEI ☐ .2

51. Har du sukkersyke? ..... JA ☐ 051.1
(Sett kryss i den ruten som passer) NEI ☐ .2

Hvis «JA», bruker du

Sett kryss i den ruten som passer best.

- insulin? ..... ☐ .3
- tabletter for sukkersyke? ..... ☐ .4
- bare diett? ..... ☐ .5

52. Har du eller har du hatt nyrestein? ..... JA ☐ 052.1
(Sett kryss i den ruten som passer) NEI ☐ .2

53. Har du hatt allergiske reaksjoner i øyne/nese (høysnue e.l.)? ..... JA ☐ 053.1
(Sett kryss i den ruten som passer) NEI ☐ .2

54. Har du hatt allergiske reaksjoner i luftveier (astma)? ..... JA ☐ 054.1
(Sett kryss i den ruten som passer) NEI ☐ .2

55. Har du hatt allergiske reaksjoner i hud (utslett)? ..... JA ☐ 055.1
(Sett kryss i den ruten som passer) NEI ☐ .2

56. Har du hatt allergiske reaksjoner i mage-tarm? ..... JA ☐ 056.1
(Sett kryss i den ruten som passer) NEI ☐ .2

57. Har du noen gang reagert allergisk på medisiner? ..... JA ☐ 057.1
(Sett kryss i den ruten som passer) NEI ☐ .2

58. Har du ofte en eller flere av følgende plager?

Sett kryss i den eller de rutene som passer.

- Hodepine: ..... ☐ 058.1
- Svimmelhet: ..... ☐ .2
- Hjertebank: ..... ☐ .3
- Søvnvansker: ..... ☐ .4
- Menstruasjonsplager: ..... ☐ .5

59. Har du leddgikt eller ofte ledd- og muskelsmerter? ..... JA ☐ 059.1
(Sett kryss i den ruten som passer) NEI ☐ .2

60. Plages du med forkjølelsessår eller munnsår?

Sett kryss i den ruten som passer best.

- Aldri: ..... ☐ 060.1
- Sjelden: ..... ☐ .2
- Av og til: ..... ☐ .3
- Ofte: ..... ☐ .4

61. Hvordan synes du din helsetilstand er nå?

Sett kryss i den ruten som passer best.

- Meget bra: ..... ☐ 061.1
- Bra: ..... ☐ .2
- Midt i laget: ..... ☐ .3
- Dårlig: ..... ☐ .4
- Meget dårlig: ..... ☐ .5

62. Oppgi din egen høyde og vekt nå:
- Høyde (i cm): ..... _____ cm 062.1
- Vekt (i kg): ..... _____ kg .2

63. Angi, såfremt du kan, om du som spebarn fikk:

Sett kryss i den ruten som passer best.

- Brystmelk: ..... ☐ 063.1
- Kunstig ernæring (flaske): .... ☐ .2
- Begge deler: ..... ☐ .3
- Vet ikke: ..... ☐ .4

Slekt

64. Angi hvor mange nålevende søsken du har: .. Antall _____ 064

65. Angi hvor mange av dine søsken som er døde: ..... Antall _____ 065

66. Angi hvor mange barn du har: ..... Antall _____ 066

67. Har noen av disse i din familie hatt magesår?

Sett kryss i den eller de rutene som passer.

- Ektefelle/samboer: ..... ☐ 067.1
- Mor: ..... ☐ .2
- Far: ..... ☐ .3
- Søster: ..... ☐ .4
- Bror: ..... ☐ .5
- Barn: ..... ☐ .6
- Ingen: ..... ☐ .7

68. Har noen av disse i din familie hatt fordøyelsesplager uten å ha hatt magesår?

Sett kryss i den eller de rutene som passer.

- Ektefelle/samboer: ..... ☐ 068.1
- Mor: ..... ☐ .2
- Far: ..... ☐ .3
- Søster: ..... ☐ .4
- Bror: ..... ☐ .5
- Barn: ..... ☐ .6
- Ingen: ..... ☐ .7

Spisevaner

69. Spiser du til faste tider?

Sett kryss i den ruten som passer best.

- Alltid: ..... ☐ 069.1
- Vanligvis: ..... ☐ .2
- Av og til: ..... ☐ .3
- Så godt som aldri: ..... ☐ .4

70. Spiser du vanligvis frokost hver dag? ..... JA ☐ 070.1
(Sett kryss i den ruten som passer) NEI ☐ .2

71. Spiser du vanligvis middag hver dag? ..... JA ☐ 071.1
(Sett kryss i den ruten som passer) NEI ☐ .2

72. Spiser du vanligvis etter kl. 10 om kvelden? JA ☐ 072.1
(Sett kryss i den ruten som passer) NEI ☐ .2

73. Spiser du vanligvis mellom hovedmåltidene? JA ☐ 073.1
(Sett kryss i den ruten som passer) NEI ☐ .2

74. Har du for vane å salte maten ekstra? ..... JA ☐ 074.1
(Sett kryss i den ruten som passer) NEI ☐ .2

75. Har du for vane å bruke mye krydder? ..... JA ☐ 075.1
(Sett kryss i den ruten som passer) NEI ☐ .2

76. Har du for vane å bruke mye sennep? ..... JA ☐ 076.1
(Sett kryss i den ruten som passer) NEI ☐ .2

77. Har du for vane å bruke mye ketchup? ..... JA ☐ 077.1
(Sett kryss i den ruten som passer) NEI ☐ .2

Kosthold

78. Hva slags brød spiser du vanligvis?

Sett kryss i den ruten som passer best.

- Loff: ..... ☐ 078.1
- Fint (lyst) brød: ..... ☐ .2
- Grovt (mørkt) brød: ..... ☐ .3
- Klibrød: ..... ☐ .4

79. Hvor mange brødskiver spiser du vanligvis daglig?

Sett kryss i den ruten som passer best.

- Mindre enn 2 skiver: ☐ 079.1
- 2–4 skiver: ☐ .2
- 5–6 skiver: ☐ .3
- 7–12 skiver: ☐ .4
- 13 eller flere skiver: ☐ .5

80. Bruker du vanligvis fibertilskudd som kli, klibrød, klikavring, kliknekkebrød, Musli, frokostblanding o.l.? JA ☐ 080.1 NEI ☐ .2
(Sett kryss i den ruten som passer)

81. Hvor mange glass melk drikker du vanligvis daglig?

Sett kryss i den ruten som passer best.

- Drikker ikke melk: ☐ 081.1
- Mindre enn 1 glass: ☐ .2
- 1–2 glass: ☐ .3
- 3–4 glass: ☐ .4
- 5 glass eller flere: ☐ .5

82. Hvor ofte spiser du vanligvis grønnsaker til middag eller som egen rett? (Her menes både rå og kokte grønnsaker.)

Sett kryss i den ruten som passer best.

- Sjelden eller aldri: ☐ 082.1
- Omtrent en gang i uken: ☐ .2
- 2–3 ganger i uken: ☐ .3
- 4–5 ganger i uken: ☐ .4
- Omtrent daglig: ☐ .5

Fysisk aktivitet

83. Hvor ofte mosjonerer du eller deltar du i fysisk trening av minst 20 minutters varighet og slik at du blir svett eller andpusten?

Sett kryss i den ruten som passer best.

- Sjelden eller aldri: ☐ 083.1
- Ukentlig: ☐ .2
- Flere ganger i uken: ☐ .3
- Daglig: ☐ .4

84. Hvor lang tid bruker du til mosjon eller trening av den typen som er nevnt ovenfor?

Sett kryss i den ruten som passer best.

- Mindre enn 30 min i uken: ☐ 084.1
- Mellom 30 min og 1 time i uken: ☐ .2
- Mellom 1 og 2 timer i uken: ☐ .3
- Mer enn 2 timer i uken: ☐ .4

Kaffe/te

85. Hvor mange kopper kaffe drikker du vanligvis daglig?

Sett kryss i den ruten som passer best.

- Drikker ikke kaffe, eller mindre enn en kopp: ☐ 085.1
- 1–4 kopper: ☐ .2
- 5–8 kopper: ☐ .3
- Mer enn 9 kopper: ☐ .4

86. Hvis du drikker kaffe; har du minsket kaffeforbruket i løpet av de siste 5 år? JA ☐ 086.1 NEI ☐ .2
(Sett kryss i den ruten som passer)

87. Hvor mange kopper te drikker du vanligvis daglig?

Sett kryss i den ruten som passer best.

- Drikker ikke te, eller mindre enn en kopp: ☐ 087.1
- 1–4 kopper: ☐ .2
- 5–8 kopper: ☐ .3
- Mer enn 9 kopper: ☐ .4

Tobakk

88. Røker du sigaretter daglig (enten ferdige eller rullede)? JA ☐ 088.1 NEI ☐ .2
(Sett kryss i den ruten som passer)

89. Hvis «JA», røker du mindre nå enn for 5 år siden? JA ☐ 089.1 NEI ☐ .2
(Sett kryss i den ruten som passer)

90. Hvis «NEI», har du røkt sigaretter tidligere? JA ☐ 090.1 NEI ☐ .2
(Sett kryss i den ruten som passer)

91. Hvis du har røkt sigaretter tidligere; hvor lenge er det siden du sluttet?

Sett kryss i den ruten som passer best.

- Mindre enn 3 mnd.: ☐ 091.1
- Mellom 3 mnd. og 1 år: ☐ .2
- Mellom 1 og 5 år: ☐ .3
- Mer enn 5 år: ☐ .4

92. For alle som røker eller som har røkt sigaretter tidligere, angi hvor mange år du tilsammen har røkt sigaretter daglig? Antall år _____ 092

93. Angi hvor mange sigaretter du røker/eller du røkte tidligere daglig? Antall _____ 093

94. Røker du daglig annen tobakk som sigarer, sigarillos eller pipetobakk? JA ☐ 094.1 NEI ☐ .2
(Sett kryss i den ruten som passer)

95. Bruker du vanligvis snus eller skråtobakk daglig? JA ☐ 095.1 NEI ☐ .2
(Sett kryss i den ruten som passer)

96. Hvis «JA», angi hvor mange esker snus eller skråtobakk du bruker ukentlig: Antall _____ 096

Alkohol

97. Smaker du fra tid til annen alkoholholdige drikker som øl, vin eller brennevin? JA ☐ 097.1 NEI ☐ .2
(Sett kryss i den ruten som passer)

Hvis «JA»:

98. Hvor ofte pleier du å drikke øl?

Sett kryss i den ruten som passer best.

- Aldri, eller noen få ganger i året: ☐ 098.1
- 1–2 ganger i måneden: ☐ .2
- Omtrent 1 gang i uken: ☐ .3
- 2–3 ganger i uken: ☐ .4
- Omtrent hver dag: ☐ .5

99. Hvor ofte pleier du å drikke vin?

Sett kryss i den ruten som passer best.

- Aldri, eller noen få ganger i året: ☐ 099.1
- 1–2 ganger i måneden: ☐ .2
- Omtrent 1 gang i uken: ☐ .3
- 2–3 ganger i uken: ☐ .4
- Omtrent hver dag: ☐ .5

100. Hvor ofte pleier du å drikke brennevin?

Sett kryss i den ruten som passer best.

- Aldri, eller noen få ganger i året: ☐ 100.1
- 1–2 ganger i måneden: ☐ .2
- Omtrent 1 gang i uken: ☐ .3
- 2–3 ganger i uken: ☐ .4
- Omtrent hver dag: ☐ .5

Medikamenter

101. Bruker du ofte ett eller flere av følgende medikamenter?
— Albyl, Albyl-E, Alka-Seltzer, Antineuralgica, Dispril, Globentyl, Globoid, Paraflex eller Paraflex comp.: ..... JA ☐ NEI ☐ 101.1 .2
(Sett kryss i den ruten som passer)

102. Bruker du ofte ett eller flere av følgende medikamenter?
— Brufen, Clinoril, Confortid, Donobid, Felden, Indocid, Napren, Napren-E eller Naprosyn: ..... JA ☐ NEI ☐ 102.1 .2
(Sett kryss i den ruten som passer)

103. Bruker du ofte sovemedisiner?..... JA ☐ NEI ☐ 103.1 .2
(Sett kryss i den ruten som passer)

104. Bruker du ofte nervemedisiner?..... JA ☐ NEI ☐ 104.1 .2
(Sett kryss i den ruten som passer)

Yrke

105. Nåværende hovedyrke:

Sett kryss i den ruten som passer.

— Hjemmeværende husmor: ..... ☐ 105.1
— Skoleelev/student: ..... ☐ .2
— Industri/verksted/anleggs/bygnings/sprengnings/gruvearbeide: ..... ☐ .3
— Jordbruks/skogbruksarbeide: ..... ☐ .4
— Fisker/sjømann: ..... ☐ .5
— Kontor/handels/hotell/servicearbeide: ..... ☐ .6
— Helse/lærer/annet undervisningsarbeide: ..... ☐ .7
— Landtransport (sjåfør m.v.): ..... ☐ .8
— Arbeidsledig: ..... ☐ .9
— Under attføring: ..... ☐ .10
— Uføretrygdet/alderstrygdet/pensjonert: ..... ☐ .11
— Annet: ..... ☐ .12
— Angi evt. yrkesbetegnelse her:

_____

106. Har du skiftarbeide? ..... JA ☐ NEI ☐ 106.1 .2
(Sett kryss i den ruten som passer)

107. Angi antall år du har vært på din siste arbeidsplass: ..... Antall år _____ 107

108. Må du i forbindelse med arbeide/skolegang overnatte utenfor hjemmet? ..... JA ☐ NEI ☐ 108.1 .2
(Sett kryss i den ruten som passer)

109. Hvis «JA», hvordan overnatter du?

Sett kryss i den ruten som passer best.

— I ordinær bopel/leilighet: ..... ☐ 109.1
— På hybel: ..... ☐ .2
— På hotell/pensjonat: ..... ☐ .3
— I anleggsbrakke: ..... ☐ .4
— På annen måte: ..... ☐ .5

110. Hvordan trives du med yrket/arbeidet du har nå?

Sett kryss i den ruten som passer best.

— Meget godt:..... ☐ 110.1
— Godt: ..... ☐ .2
— Dårlig: ..... ☐ .3
— Trives ikke: ..... ☐ .4

111. Angi hvor mange års skolegang du har medregnet folkeskole og framhaldsskole eller 9-årig grunnskole? ..... Antall år _____ 111

Sosiale forhold

112. Angi antall familiemedlemmer (deg selv medregnet) som bor i din husstand: ..... Antall _____ 112

113. Er noen i din husstand 10 år eller yngre?.... JA ☐ NEI ☐ 113.1 .2
(Sett kryss i den ruten som passer)

114. Trenger noen i din husstand utenom barna spesielt tilsyn eller pleie? ..... JA ☐ NEI ☐ 114.1 .2
(Sett kryss i den ruten som passer)

115. Hvordan var de økonomiske forhold i familien under oppveksten din?

Sett kryss i den ruten som passer best.

— Meget gode: ..... ☐ 115.1
— Gode: ..... ☐ .2
— Vanskelige: ..... ☐ .3
— Meget vanskelige: ..... ☐ .4

116. Hvordan vil du beskrive din økonomiske situasjon nå?

Sett kryss i den ruten som passer best.

— Meget god: ..... ☐ 116.1
— God: ..... ☐ .2
— Vanskelig: ..... ☐ .3
— Meget vanskelig: ..... ☐ .4

117. Har du de siste to månedene følt deg ute av stand til å mestre dine vanskeligheter?

Sett kryss i den ruten som passer best.

— Aldri eller sjelden: ..... ☐ 117.1
— Av og til: ..... ☐ .2
— Ofte: ..... ☐ .3
— Nesten hele tiden: ..... ☐ .4

118. Har du de siste to månedene følt deg «nedfor»?

Sett kryss i den ruten som passer best.

— Aldri eller sjelden: ..... ☐ 118.1
— Av og til: ..... ☐ .2
— Ofte: ..... ☐ .3
— Nesten hele tiden: ..... ☐ .4

119. Føler du at du har dårlig tid, også når det gjelder daglige gjøremål?

Sett kryss i den ruten som passer best.

— Aldri eller sjelden: ..... ☐ 119.1
— Av og til: ..... ☐ .2
— Ofte: ..... ☐ .3
— Nesten hele tiden ..... ☐ .4

Denne undersøkelsen er støttet av firmaene
SEARLE NORGE A/S og SMITH KLINE & FRENCH

Appendix 3

The questionnaire of

The Sørreisa Gastrointestinal Disorder Study - 2004

Sørreisa II
En studie om mageplager i en befolkning
Forespørsel om deltakelse i forskningsprosjekt (voksen 18-85 år)

Fordøyelsesbesvær eller magesårsliknende plager er svært vanlig. I 1987 ble det gjort en stor undersøkelse om slike plager i Sørreisa kommune. Vi skal nå gjøre en ny undersøkelse for å studere utviklingen av mageplager siden 1987. Hovedformålet med denne undersøkelsen i Sørreisa er å skaffe ny kunnskap om mageplager for å kunne forbedre behandlingen av dem.

Helseundersøkelsen i Sørreisa er godkjent av Datatilsynet. Regional etisk komite for medisinsk forskningsetikk har vurdert studien og har ikke innvendinger mot gjennomføringen.

All deltakelse i forskningsprosjektet er frivillig, og du kan trekke deg fra undersøkelsen til enhver tid uten begrunnelse. Om du ikke ønsker å delta eller om du trekker deg vil det ikke få noen konsekvenser for forholdet til helsevesenet.

I tillegg til opplysningene om mageplager som du gir i spørreskjemaet ønsker vi å kunne hente opplysninger om mageplager som finnes i din journal på legekontorene i Sørreisa og i eventuell sykehusjournal. For de som deltok i Sørreisaundersøkelsen i 1987 ønsker vi å undersøke innsamlet materiale fra den gang på nytt, og sammenholde det med resultater fra Sørreisaundersøkelsen i 2003. For de som ikke samtykker til dette, vil tidligere data bli anonymisert. I prosjektet ønsker vi å undersøke avføringsprøver for å se på forekomsten av forskjellige bakterier og parasitter, deriblant magesårsbakterien Helicobacter pylori, og deres følsomhet for antibiotika. Til dette trenger vi en avføringsprøve slik det er angitt på vedlagte prøveglass.

En del personer vil også bli forespurt om å la seg undersøke med gastroskopi (kikkertundersøkelse av magesekken) og blodprøve i Sørreisa. Hvis du ikke ønsker å gjennomgå gastroskopi og gi vevsprøve og blodprøve, kan du likevel delta i spørreundersøkelsen.

Innsendte spørreskjemaer og avføringsprøver vil bli gjennomgått av prosjektleder eller medarbeidere, og vil bli behandlet strengt fortrolig. Alle innsamlete opplysninger og prøver oppbevares og analyseres i 15 år, hvor personidentifikasjon er erstattet med registreringsnummer. Dette nummeret viser til et personregister som oppbevares adskilt fra det øvrige materialet. Dataregistrering og oppbevaring er godkjent av datatilsynet. All bruk av opplysninger og prøver vil bare skje etter godkjenning fra Datatilsynet og såfremt Regional komite for medisinsk forskningsetikk ikke har innvendinger mot det. Du har innsynsrett i opplysninger som registreres om deg. Om du trekker deg fra undersøkelsen kan du få allerede innhentede data slettet.

Resultater av studien vil bli publisert i medisinske tidsskrift og et sammendrag vil bli presentert i lokale medier. Alle resultater presenteres på en slik måte at ingen enkeltpersoner kan kjennes igjen.

Vi ber deg om å bekrefte om du ønsker å delta i prosjektet ved å fylle ut og underskrive samtykkeerklæringen på neste side.

Universitetet i Tromsø

Vi bryr oss - sammen tar vi ansvar
UNN
Universitetssykehuset Nord-Norge HF

SAMTYKKEERKLÆRING

Spørreskjema og avføringsprøve:
Jeg har lest informasjonen i forespørselen og sender herved utfyltspørreskjema og avføringsprøve.

Ja ☐ Nei ☐

(Hvis du ikke ønsker å besvare spørreskjemaet, og vil unngå purring, kan du sette kryss i "Nei" ruten og sende skjemaet i retur)

Hvis du samtykker i å delta i spørreundersøkelsen, vil vi be deg om i tillegg å bekrefte eller avkrefte, om du ønsker å delta i de forskjellige delene av prosjektet, slik de er beskrevet nedenfor.

Journalopplysninger:
Jeg samtykker i at opplysninger om mageplager og undersøkelser/behandling for disse kan innhentes hos primær-/fastlege og hos sykehus.

Ja ☐ Nei ☐

Ny kontakt:
Jeg samtykker i å eventuelt bli kontaktet i fremtiden med forespørsel om nye opplysninger eller undersøkelser om mageplager, hjerte eller lungesykdommer, kreftsykdommer eller spørsmål om livsstil.

Ja ☐ Nei ☐

Kobling av data:
Jeg samtykker i at resultatene mine, etter godkjenning fra datatilsynet, kan settes sammen med opplysninger om meg i andre registre til bruk i medisinsk forskning om mageplager. Det kan være registre om helse, trygd og sykdom. Det kan også være registre om inntekt, utdanning og yrke. Eksempler på slike registre er Kreftregistret, Dødsårsaksregistret og folketellingene.
I disse tilfeller blir navnet og personnummeret mitt fjernet når dataene blir analysert.

Ja ☐ Nei ☐

Sørreisa I:
Jeg deltok i Sørreisaundersøkelsen i 1987 og samtykker i, at resultatene mine og innsamlet prøvemateriale fra den gang undersøkes på nytt.

Ja ☐ Nei ☐

Sted: ..... Dato:.....

Navn (blokkbokstaver): .....

Underskrift: .....

Avføringsprøven tatt: Dag ..... /Måned ..... /År .....

Sendes inn snarest mulig i vedlagte konvolutt av hensyn til holdbarhet. Portoen er betalt.

Skjemaetleses maskinelt. Vennligst skriv innenfor rutene.

Du kan ta vare på den løse kopien av dette skrivet som ditt eget.

Har du spørsmål kan du ringe tl. 99 40 63 83.

Med vennlig hilsen

Anne Mette Asfeldt	Eyvind Paulssen	Bjørn Straume
Lege	Overlege	1. amanuensis
Institutt for klinisk med.	Gastromedisinsk avd.	Institutt for samfunnsmedisin
UiTø	UNN	UiTø

Den første del av spørreskjemaet handler om livsstil, levekår og helse generelt.

1. Hvor er du født?

1 ☐ Norge 2 ☐ Europa
3 ☐ Nordamerika 4 ☐ Resten av verden

2. Hvor er dine foreldre født?

1 ☐ Norge 2 ☐ Europa
3 ☐ Nordamerika 4 ☐ Resten av verden

3. Bodde du i Sørreisa kommune i 1987?

1 ☐ Ja 2 ☐ Nei

4. Deltok du i Sørreisaundersøkelsen i 1987? **(Sett evt. flere kryss)**

0 ☐ Ja, besvarte spørreskjema
1 ☐ Ja, ble undersøkt med gastroskopi
2 ☐ Nei, deltok ikke

5. Har du vært i utlandet siste månenden?

1 ☐ Ja 2 ☐ Nei

Andre helseforhold

6. Har du eller har du hatt kreftsykdom?

1 ☐ Ja 2 ☐ Nei

Hvis "Ja" Hvor i kroppen _____

Hvilket år ble den oppdaget _____

Ved hvilken institusjon ble den påvist _____

7. Er du operert i magen?

1 ☐ Ja 2 ☐ Nei

Hvis "Ja" Av hvilken årsak _____

Ved hvilket sykehus _____

I hvilket årstall _____

9. Hvordan er helsen din nå? **(Sett ett kryss)**

1 ☐ Dårlig
2 ☐ Ikke helt god
3 ☐ God
4 ☐ Svært god

10. Oppgi din høyde og vekt nå

Høyde uten sko ☐☐☐ cm

Vekt uten klær ☐☐☐ kg

11. Hvilket nummer er du i rekken av søsken? **(Eksempel; Hvis søskenflokken består av 2 storebrødre, deg og lillesøster blir du nummer 3 av 4. Tell også med søsken som er døde)**

Nummer ☐☐ av ☐☐

12. Hvor mange nålevende søsken har du?

Antall ☐☐

13. Har noen av disse i din familie hatt magesår?

1 ☐ Ektefelle/samboer 5 ☐ Bror
2 ☐ Mor 6 ☐ Barn
3 ☐ Far 7 ☐ Ingen
4 ☐ Søster 8 ☐ Vet ikke

14. Angi, såfremt du kan, om du som barn fikk: **(Sett bare ett kryss)**

1 ☐ Brystmelk
2 ☐ Kunstig ernæring (flaske)
3 ☐ Begge deler
4 ☐ Vet ikke

15. Hvor ofte har du mosjonert eller deltatt i fysisk trening av minst 20 minutters varighet og slik at du blir svett eller andpusten? **(sett kryss for hver alder)**

	1 Sjelden eller aldri	2 Ukentlig	3 Flere gang-er i uken	4 Daglig
15.1 Som 15 åring	☐	☐	☐	☐
15.2 For 5 år siden	☐	☐	☐	☐
15.3 For tiden	☐	☐	☐	☐

Alkohol

17. Hvor ofte drikker du øl, vin eller brennevin?

1 ☐ Sjeldent eller aldri
2 ☐ Omtrent 1 gang i måneden
3 ☐ 2-3 ganger i måneden
4 ☐ Omtrent 1 gang i uka
5 ☐ 2-3 ganger i uka
6 ☐ Omtrent daglig

18. Hvor mange gjenstander drikker du i gjennomsnitt på en dag hvor du drikker? (gjenstander defineres som: glass øl på 0.33 l, vanlig glass vin på 1.4 dl eller vanlig glass brennevin på 40 cl. Skriv samlet antall gjenstander)

Antall gjenstander ☐☐

19. Omtrent hvor mange ganger i løpet av det siste året har du drukket så mye som minst 5 glass eller drinker i løpet av et døgn?

Antall ganger ☐☐

Tobakk

20. Hvor mange sigaretter (filtersigaretter og/eller rullings) røyker du daglig?

Skriv 0 hvis du ikke røyker sigaretter

Antall ☐☐

21. Hvor mange esker snus eller skråtobakk bruker du ukentlig? Skriv 0 hvis du ikke bruker noe

Antall ☐☐

22. Hvor mange piper røyker du daglig?

Antall ☐☐

Medisin

23. Bruker du flere ganger i uken en eller flere av følgende medisiner: Albyl E, Plavix, Asasantin, Aspirin, Dispril, Globoid?

1 ☐ Ja 2 ☐ Nei

24. Bruker du flere ganger i uken en eller flere av følgende medisiner: Confortid, Indocid, Clinoril, Cataflam, Diclofenac, Modifenac, Otriflu, Voltaren, Toradol, Barcan, Arthrotec, Brexidol, Felden, Pirox, Piroxicam, Tetram, Mobic, Brufen, Ibumetin, Ibuprofen, Ibux, Alpoxen, Ledox, Napren, Napren-E, Naprosyn, Naprosyn Entero, Naproxen, Naproxen-E, Ketoprofen, Orudis, Migea, Celebra, Vioxx?

1 ☐ Ja 2 ☐ Nei

25. Har du i løpet av de siste 3 måneder brukt penicillin eller andre antibiotika

1 ☐ Ja 2 ☐ Nei

Hvis ja, angi dato

fra _____ **til** _____ **navn** _____

fra _____ **til** _____ **navn** _____

fra _____ **til** _____ **navn** _____

Sosiale forhold

26. Hvor mange familiemedlemmer (deg selv medregnet) bor i din husstand?

Antall ☐☐

27. Er noen i din husstand 11 år eller yngre?

1 ☐ Ja 2 ☐ Nei

28. Hvor mange års utdanning har du medregnet folkeskole/ grunnskole?

Angi år ☐☐

Drikkevannskilde

29. Hvilken drikkevannskilde hadde du som barn? (sett evt. flere kryss)

1 ☐ Egen brønn
2 ☐ Privat vannverk
3 ☐ Kommunalt vannverk
4 ☐ Vet ikke

30. Hvilken drikkevannskilde har du nå? (sett bare ett kryss)

1 ☐ Egen brønn
2 ☐ Privat vannverk
3 ☐ Kommunalt vannverk
4 ☐ Vet ikke

Toalettforhold

31. Hvilken type toalett hadde du som barn? (sett evt flere kryss)

1 ☐ Utedo
2 ☐ Vannklosett
3 ☐ Tørrklosett

32. Hvilken type toalett har du nå (sett bare ett kryss)

1 ☐ Utedo
2 ☐ Vannklosett
3 ☐ Tørrklosett

Økonomiske forhold

33. Hvordan var den økonomiske situasjon i familien under oppveksten din? (sett bare ett kryss)

1 ☐ Meget god
2 ☐ God
3 ☐ Vanskelig
4 ☐ Meget vanskelig

34. Hvordan er din økonomiske situasjon nå? (sett bare ett kryss)

1 ☐ Meget god
2 ☐ God
3 ☐ Vanskelig
4 ☐ Meget vanskelig

"Stress"

35. Har du de siste 2 måneder følt deg ute av stand til å mestre dine vanskeligheter? (sett bare ett kryss)

1 ☐ Aldri eller sjelden
2 ☐ Av og til
3 ☐ Ofte
4 ☐ Nesten Alltid

36. Har du de siste 2 måneder følt deg "nedfor"? (sett bare ett kryss)

1 ☐ Aldri eller sjelden
2 ☐ Av og til
3 ☐ Ofte
4 ☐ Nesten Alltid

37. Føler du at du har dårlig tid også når det gjelder daglige gjøremål? (sett bare ett kryss)

1 ☐ Aldri eller sjelden
2 ☐ Av og til
3 ☐ Ofte
4 ☐ Nesten Alltid

Dyrehold

38. Har du/din familie hatt noen form for husdyr/kjæledyr?
(Hvis Nei, gå til pkt. 40)

1 ☐ Ja 2 ☐ Nei

39. Hvis ja i spørsmål 38 angi da hvilket dyr og i hvilken periode i forhold til din egen alder

f.eks Husdyr SAU fra jeg var 5 til 8 år

Husdyr _____ fra jeg var _____ til _____år

Husdyr _____ fra jeg var _____ til _____år

Husdyr _____ fra jeg var _____ til _____år

Husdyr _____ fra jeg var _____ til _____år

Husdyr _____ fra jeg var _____ til _____år

Husdyr _____ fra jeg var _____ til _____år

f.eks Kjæledyr KATT fra jeg var 6 til 12 år

Kjæledyr _____ fra jeg var _____ til _____år

Kjæledyr _____ fra jeg var _____ til _____år

Kjæledyr _____ fra jeg var _____ til _____år

Kjæledyr _____ fra jeg var _____ til _____år

Kjæledyr _____ fra jeg var _____ til _____år

I denne delen av spørreskjemaet omtales Sørreisa I-undersøkelsen i 1987 flere ganger. Vi ber deg svare på alle spørsmålene uavhengig av om du deltok Sørreisa I-undersøkelsen i 1987 eller ikke

Mageplager

40. Har du siden 1987 hatt smerter eller "verk" i magen som har vart i minst 2 uker? (omgangssyke (ræksjuke) regnes ikke med).

1 ☐ Ja 2 ☐ Nei

Hvis "Ja", hvor ofte har du hatt disse smertene?
(sett bare ett kryss)

3 ☐ Ukentlig
4 ☐ Månedlig
5 ☐ Årlig eller sjeldnere

hvor satt smertene eller "verken" ? (sett bare ett kryss)

6 ☐ i øvre del av magen
7 ☐ i nedre del av magen
8 ☐ i hele magen

41. Har du siden 1987 hatt sure oppstøt, halsbrann eller brystbrann nesten daglig i minst en uke?

1 ☐ Ja 2 ☐ Nei

Hvis "Ja", hvor ofte har du hatt disse smertene?
(sett bare ett kryss)

3 ☐ Ukentlig
4 ☐ Månedlig
5 ☐ Årlig eller sjeldnere

42. Har du hatt diaré siste måneden

1 ☐ Ja 2 ☐ Nei

Bruk av helsetjenester

43. Søkte du i løpet av første året etter Sørreisa I undersøkelsen i 1987 primærlege på grunn av sure oppstøt, halsbrann, brystbrann, smerter eller "verk" i magen?

1 ☐ Ja 2 ☐ Nei

Hvis "Ja", hvor ofte? (sett bare ett kryss)

Antall legebesøk første år ☐☐

44. Har du i løpet av det siste året søkt primærlege på grunn av sure oppstøt, halsbrann, brystbrann, smerter eller "verk" i magen?

1 ☐ Ja 2 ☐ Nei

Hvis "Ja", hvor ofte? (sett bare ett kryss)

Antall legebesøk siste år ☐☐

45. Har du siden Sørreisa I undersøkelsen i 1987 vært henvist til, eller innlagt i sykehus på grunn av sure oppstøt, halsbrann, brystbrann, smerter eller "verk" i magen?

1 ☐ Ja 2 ☐ Nei

Hvis "Ja"

Hvilket sykehus? _____

Hvilket årstall? _____

46. Har du siden 1987 brukt syrenøytraliserende eller syrehemmende medisin, daglig eller av og til?

1 ☐ Ja 2 ☐ Nei

Hvis "Ja", hvor ofte? (sett bare ett kryss)

3 ☐ Månedlig
5 ☐ Ukentlig
6 ☐ Daglig

Har du fått ett eller flere av medisinene på resept? (sett ett eller flere kryss)

7 ☐ Ja, vanlig resept
8 ☐ Ja, blå resept
9 ☐ Nei

47. Har du siden 1987 fått påvist noen av følgende sykdommer? (Sett ett eller flere kryss)

1 ☐ Magekatarr
2 ☐ Magesår
3 ☐ Sår på tolvfingertarmen
4 ☐ Betennelse i spiserøret
5 ☐ Kreft i magesekken
6 ☐ Kreft i spiserøret
7 ☐ Mellomgulvsbrokk
8 ☐ Ingen

Hvordan ble sykdommen påvist?

9 ☐ Gastroskopi
10 ☐ Annet _____

Hvor ble du undersøkt?

11 ☐ RiTø/UNN
12 ☐ Kommunelegen i Sørreisa
13 ☐ Dr. Stakkevold
14 ☐ Annet sted _____

48. Har du siden 1987 fått påvist magesårsbakterien Helicobacter pylori?

1 ☐ Ja 2 ☐ Nei

Hvis "Ja", hvordan ble den påvist? (sett ett eller flere kryss)

1 ☐ Gastroskopi
2 ☐ Blodprøve
3 ☐ Pusteprøve

Hvor ble du undersøkt?

11 ☐ RiTø/UNN
12 ☐ Kommunelegen i Sørreisa
13 ☐ Dr. Stakkevold
14 ☐ Annet sted _____

49. Har du siden 1987 fått behandling for å fjerne magesårsbakterien Helicobacter pylori? (såkalt trippelkur; tre forskjellige medisiner daglig i en uke eller mer)

1 ☐ Ja 2 ☐ Nei

50. Har du noen gang vært nødt til å skifte jobb, omskolere deg eller forlate arbeidsmarkedet på grunn av smerter eller "verk" i mangen.

1 ☐ Ja 2 ☐ Nei

I siste del av spørreskjemaet vil vi be deg svare på noen spørsmål om betydningen av forskjellige mageplager i hverdagen. Spørsmålene er formulert på en slik måte, at de kan sammenliknes med andre spørreundersøkelser fra Norge og utlandet.

51. Har du i løpet av den siste uken hatt plager med magen? (Med mageplager menes all slags smerte eller knip i magen) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt
2 ☐ Ubetydelige plager
3 ☐ Beskjedne plager
4 ☐ Ganske alvorlige plager
5 ☐ Alvorlige plager
6 ☐ Meget alvorlige plager
7 ☐ Verst tenkelige plager

52. Har du i løpet av den siste uken vært plaget av halsbrann? (Med halsbrann menes en sviende eller brennende følelse av ubehag bak brystbeinet) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt
2 ☐ Ubetydelige plager
3 ☐ Beskjedne plager
4 ☐ Ganske alvorlige plager
5 ☐ Alvorlige plager
6 ☐ Meget alvorlige plager
7 ☐ Verst tenkelige plager

53. Har du i løpet av den siste uken vært plaget av sure oppstøt? (med sure oppstøt menes plutselige oppstøt av surt mageinnhold) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt
2 ☐ Ubetydelige plager
3 ☐ Beskjedne plager
4 ☐ Ganske alvorlige plager
5 ☐ Alvorlige plager
6 ☐ Meget alvorlige plager
7 ☐ Verst tenkelige plager

54. Har du i løpet av den siste uken vært plaget av sug i magen? (med sug i magen menes her en følelse i magen av behov for å spise mellom måltidene) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt
2 ☐ Ubetydelige plager
3 ☐ Beskjedne plager
4 ☐ Ganske alvorlige plager
5 ☐ Alvorlige plager
6 ☐ Meget alvorlige plager
7 ☐ Verst tenkelige plager

55. Har du i løpet av den siste uken følt deg uvel? (Med å føle seg uvel menes ubehagsfølelse som kan gå over i kvalme og brekninger/oppkast) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt
2 ☐ Ubetydelige plager
3 ☐ Beskjedne plager
4 ☐ Ganske alvorlige plager
5 ☐ Alvorlige plager
6 ☐ Meget alvorlige plager
7 ☐ Verst tenkelige plager

56. Har du i løpet av den siste uken vært plaget av rumling i magen? (Med rumling menes vibrasjoner eller "buldring" i magen) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt
2 ☐ Ubetydelige plager
3 ☐ Beskjedne plager
4 ☐ Ganske alvorlige plager
5 ☐ Alvorlige plager
6 ☐ Meget alvorlige plager
7 ☐ Verst tenkelige plager

57. Har du i løpet av den siste uken vært plaget av oppblåsthet? (med oppblåsthet menes utspiling, ofte forbundet med en følelse av luft i magen) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt
2 ☐ Ubetydelige plager
3 ☐ Beskjedne plager
4 ☐ Ganske alvorlige plager
5 ☐ Alvorlige plager
6 ☐ Meget alvorlige plager
7 ☐ Verst tenkelige plager

58. Har du i løpet av den siste uken vært plaget av raping? (med raping menes behov for "utlufting", ofte forbundet med lindring av følelse av oppblåsthet) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt
2 ☐ Ubetydelige plager
3 ☐ Beskjedne plager
4 ☐ Ganske alvorlige plager
5 ☐ Alvorlige plager

6 ☐ Meget alvorlige plager

7 ☐ Verst tenkelige plager

59. Har du i løpet av den siste uken vært plaget av luftavgang? (Med luftavgang menes her behovet for å slippe seg, ofte forbundet med lindring av følelse av oppblåsthet) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt

2 ☐ Ubetydelige plager

3 ☐ Beskjedne plager

4 ☐ Ganske alvorlige plager

5 ☐ Alvorlige plager

6 ☐ Meget alvorlige plager

7 ☐ Verst tenkelige plager

60. Har du i løpet av den siste uken vært plaget av forstoppelse? (Med forstoppelse menes minsket avføringshyppighet) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt

2 ☐ Ubetydelige plager

3 ☐ Beskjedne plager

4 ☐ Ganske alvorlige plager

5 ☐ Alvorlige plager

6 ☐ Meget alvorlige plager

7 ☐ Verst tenkelige plager

61. Har du i løpet av den siste uken vært plaget av diaré? (Med diaré menes økt avføringshyppighet) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt

2 ☐ Ubetydelige plager

3 ☐ Beskjedne plager

4 ☐ Ganske alvorlige plager

5 ☐ Alvorlige plager

6 ☐ Meget alvorlige plager

7 ☐ Verst tenkelige plager

62. Har du i løpet av den siste uken vært plaget av løs avføring? (Hvis du har hatt vekslende hard og løs avføring, gjelder dette spørsmålet bare i hvilken utstrekning du har følt deg plaget av at avføringen har vært løs) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt

2 ☐ Ubetydelige plager

3 ☐ Beskjedne plager

4 ☐ Ganske alvorlige plager

5 ☐ Alvorlige plager

6 ☐ Meget alvorlige plager

7 ☐ Verst tenkelige plager

63. Har du i løpet av den siste uken vært plaget av hard avføring? (Hvis du har hatt vekslende hard og løs avføring, gjelder dette spørsmålet bare i hvilken utstrekning du har følt deg plaget av at avføringen har vært hard) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt

2 ☐ Ubetydelige plager

3 ☐ Beskjedne plager

4 ☐ Ganske alvorlige plager

5 ☐ Alvorlige plager

6 ☐ Meget alvorlige plager

7 ☐ Verst tenkelige plager

64. Har du i løpet av den siste uken vært plaget av tvingende avføringsbehov? (Med tvingende avføringsbehov menes raskt oppståtte behov for å gå på toalettet, ofte forbundet med en følelse av mangelfull kontroll) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt

2 ☐ Ubetydelige plager

3 ☐ Beskjedne plager

4 ☐ Ganske alvorlige plager

5 ☐ Alvorlige plager

6 ☐ Meget alvorlige plager

7 ☐ Verst tenkelige plager

65. Har du i løpet av den siste uken i forbindelse med avføring hatt en følelse av ufullstendig tømming av tarmen? (Med ufullstendig tømming av tarmen menes at det trass i anstrengelser i forbindelse med avføring gjenstår en følelse av ufullstendig tømming) (sett bare ett kryss)

1 ☐ Ingen plager i det hele tatt

2 ☐ Ubetydelige plager

3 ☐ Beskjedne plager

4 ☐ Ganske alvorlige plager

5 ☐ Alvorlige plager

6 ☐ Meget alvorlige plager

7 ☐ Verst tenkelige plager

Paper I

Paper II

Paper III

Paper IV