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Quality deviations in cancer diagnosis:

prevalence and time to diagnosis in general practice

Abstract

Background
High quality in every phase of cancer diagnosis is important to optimise the prognosis for the patient. General practice plays an important role in this phase.

Aim
The aim was to describe the prevalence and the types of quality deviations (QDs) that arise during the diagnostic pathway in general practice as assessed by GPs and to analyse the association between these QDs, the cancer type, and the GP's interpretation of presenting symptoms as well as the influence on the diagnostic interval.

Design and setting
A Danish retrospective cohort study based on questionnaire data from 1466 GPs on 5711 incident patients with cancer identified in the Danish National Patient Registry (response rate = 71.4%). The GP was involved in diagnosing in 4036 cases.

Method
Predefined QDs were prompted with the possibility for free text. QD prevalence was estimated as was the association between QDs and diagnosis, the GP's symptom interpretation, and time to diagnosis.

Results
QDs were present for 30.4% (95% confidence interval [CI] = 29.0 to 31.9) of cancer patients. The most prevalent QD was 'retrospectively, one or more of my clinical decisions were less optimal'. QDs were most prevalent among patients with vague symptoms (24.1% for alarm symptoms versus 39.5% for vague symptoms [P<0.001]). QD presence implied a 41-day (95% CI = 38.4 to 43.6) longer median diagnostic interval.

Conclusion
GPs noted at least one QD, which often involved clinical decisions, for one-third of all cancer patients. QDs were more likely among patients with vague symptoms and increased the diagnostic interval considerably.

Keywords
delayed diagnosis; general practice; healthcare; neoplasms; quality assessment, risk management.

INTRODUCTION

Identifying patients with cancer is a challenging and extremely important task in general practice. Most patients will contact their GP with symptoms,[1,2] but only half will present known alarm symptoms of cancer.[3] Delay in the time to cancer diagnosis may worsen the prognosis and require more intensive treatment, which may have more adverse effects and a negative impact on quality of life.[4–7] Therefore, it is vital to limit delay and ensure high quality at every step of the diagnostic pathway.

Unnecessary wait (delay) in cancer diagnosis increases the patient's time to diagnosis.[8] Delay may be caused by, for example, low levels of symptom awareness among patients,[9] postponed consultation,[9,10] delayed initiation of diagnostic procedures,[11] inappropriate tests and procedures, failure to initiate follow-up on inconclusive test results,[9,10,12] symptomatic treatment, erroneous assessment of symptom origin by the GP,[10] inappropriate organisation of the healthcare system, perceived role and accessibility of the GP,[9] and GP access to further investigation.[10]

A quality deviation (QD) can, in general practice, functionally be defined as 'an event that should not have happened and that you do not want to happen again',[11] as no harm to the patient is reported in up to 60% of QDs in general practice.[13,14]

Most studies on QDs in cancer diagnosis are based on retrospective audits of clinical data[15,16] or patient questionnaires[17] and show diverse findings. To the authors' knowledge, no studies have investigated QDs in the pre-diagnostic phase and the impact on the time to diagnosis.

The aim of this study was to describe the prevalence and types of QDs that arose during the diagnostic pathway for Danish patients with cancer as assessed by the GPs. Further, the aim was to analyse the associations between QDs and the type of cancer and also between QDs and the GP interpretation of presenting symptoms as well as the impact of QDs on diagnostic interval length.

METHOD

The study was a population-based nationwide retrospective cohort study of incident cancer patients, where the GP was involved in the diagnostic pathway.

Setting

The study took place in 2010 in Denmark, where the incidence of cancer is 326 per 100 000 compared to 267 per 100 000 in the UK.[18] The Danish publicly-funded healthcare system ensures free access to diagnostics and treatment for all citizens of which 99% are listed with a general practice. People must contact the GP for medical advice, unless in emergencies, as the GP initiates diagnostic investigations and acts as a gatekeeper to the specialised healthcare system. All Danish GPs are legally obliged to keep detailed medical records of all their patients.

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How this fits in

The frequency of quality deviations (QD) in general practice and their implications for the diagnostic interval for patients with cancer have so far been unknown. It was found that QDs, especially false-negative tests, are common in general practice. Vague symptoms increased the risk of QDs and implied a much longer diagnostic interval. More emphasis should be given to patients with vague symptoms and negative tests. There is a need for systematic collection of these experiences and communication of the findings back to general practice.

Study population

All newly-diagnosed patients aged ≥18 years with a cancer diagnosis coded as C00.0–C99.9 (except non-melanoma skin cancer [C44.*]) according to the tenth edition of the International Classification of Diseases (ICD-10) during the period from 1 May 2010 to 31 August 2010 (8223 patients) were identified. A total of 227 (2.8%) patients were excluded due to: missing civil registration number (two patients), pilot test (nine patients), not registered with a GP (155 patients), and registered with a GP who had retired just after diagnosis (61 patients).

Identification of patients

Patients were identified in the Danish National Patient Registry (NPR), which contains information on all patient contacts with Danish hospitals (except psychiatric hospitals), emergency rooms, and outpatient clinics.[19] Incident cancer was defined as having a cancer diagnosis as the primary diagnosis and no prior history of cancer recorded in the Danish Cancer Registry (DCR).[20]

Data collection

A questionnaire for each individual patient was sent 4 months after diagnosis to the patient's GP, who was asked to complete the questionnaire on the basis of the patient's medical record. The GP received no remuneration. Non-responders were sent a reminder, including a new questionnaire, after 5–6 weeks.

The questionnaire was based on previously used and tested measures of the diagnostic pathway, including whether or not the GP had been involved (for example, breast-cancer screening or emergency admission).[2] Part of the questionnaire addressed whether the diagnostic pathway had given rise to QDs, and if so, what types of QDs had been raised. The definition of QDs was based on the initial work of Dovey *et al*[11] as 'events that should not have happened and that you do not want to happen again' for that specific patient.

The GP could choose from 10 categories of QDs (including one free-text option). The categories were based on level 1.1 (office administration), 1.2 (investigations), 1.4 (communication), and 2 (knowledge and skills errors) in the preliminary taxonomy proposed by Dovey *et al*.[11] The free-text coding created two new categories ('waiting time in secondary care' and 'patient wanted to postpone diagnostics') as these were most often mentioned by the GPs.

On the basis of previously developed items,[3] the questionnaire requested information on GP's interpretation of the patient's presenting symptoms as either 'alarm symptoms suggestive of cancer', 'symptoms suggestive of any serious illness', or 'vague symptoms not directly suggestive of cancer or other serious illness'.

Finally, the questionnaire included specific dates encompassing the diagnostic interval. The diagnostic interval was defined as the time from the patient's first presentation of symptoms of cancer to a doctor until the time of diagnosis,[8] while the date of diagnosis was defined according to DCR.[20]

Non-responders

Patients listed with non-responding GPs were compared with patients listed with responding GPs regarding sex, age, region of residence, marital status, and diagnosis.

Analysis

The prevalence, including 95% confidence intervals (CIs), of specific QDs among patients with QDs and the prevalence among all patients with cancer was calculated.

The associations between GP symptom interpretation and QD risk and between cancer type and QD risk were analysed using prevalence rate ratios (Poisson distribution[21]) adjusted for patient clusters at GP level. Breast cancer was chosen as the reference diagnosis since suspected breast cancer best represented an optimised route to diagnosis. The adjusted median difference in diagnostic interval was estimated between patients with and without one or more QDs using quantile regression.[22]

The statistical significance level was 0.05 or less. No alteration was made regarding missing data on presence or no presence of QDs. All analyses were done using Stata (version 11.2).

RESULTS

Of the mailed 7996 questionnaires, a total of 5711 (71.4%) were returned from 1466 GPs. More responses were received for younger patients ($P = 0.043$), female patients in total ($P<0.001$) and female patients diagnosed with neoplasm of ill-defined sites ($P = 0.024$). No other differences were observed. A total of 1517 (26.6%) patients were excluded as the GP was not involved in the diagnosis (for example, screening or emergencies) and 158 (2.8%) patients due to missing information. In total, 6 patients were included in the analyses.

GPs reported that QDs were present in 1228 (30.4% [95% CI = 29.0 to 31.9]) cases and not present in 2621 (65.0% [95%CI = 63.4 to 66.4]) cases. In 187 (4.6% [95% CI = 4.0 to 5.3]) cases, the GP was unable to state whether or not a QD occurred. Totally, 1620 QDs were reported, with a median of 1 (interquartile interval [IQI] = 1–2) (range = 1–5) QDs per case with a reported QD. There were no sex ($P = 0.380$) or age-related ($P = 0.076$) differences in the distribution of QDs.

The most frequent QD was 'retrospectively, one or more of my clinical decisions were less optimal', which occurred for 23.5% of patients with QDs, often combined with another QD (Table 1). The QD combinations most often encompassed false-negative clinical examination, laboratory tests and/or less optimal clinical decision making by the GP (Table 1).

Uterus cancer had the lowest QD prevalence and bladder cancer the highest (Table 2). Compared to breast cancer, GPs

Table 1. GP-reported prevalence of specific quality deviations (QDs) for 4034[a] Danish patients with cancer of whom 1228 had a minimum of one QD (1620 QDs in total)

Quality deviations	Total number of QDs	Prevalence[b] *n* = 1228 patients with QD % (95% CI)	Prevalence[c] *n* = 4034 patients % (95% CI)
Type of QD present (1228 cases with 1620 QDs)			
• Patient did not show up for examination/follow-up	198	16.1 (14.1 to 18.3)	4.9 (4.3 to 5.6)
• Patient wanted prolonged diagnostics	54	4.4 (3.3 to 5.7)	1.3 (1.0 to 1.8)
• GPs medical record lacked information regarding symptoms/prior examinations	33	2.7 (1.8 to 3.8)	0.8 (0.5 to 1.2)
• Communication between GP and patient was not optimal	126	10.3 (8.6 to 12.1)	3.1 (2.6 to 3.7)
• Communication internally in practice was not optimal	19	1.5 (0.9 to 2.4)	0.5 (0.2 to 0.8)
• Communication between GP and specialist care/hospital was not optimal	184	15.0 (13.0 to 17.1)	4.6 (3.9 to 5.3)
• False-negative clinical examination	159	12.9 (11.1 to 15.0)	3.9 (3.3 to 4.6)
• False-negative laboratory test	157	12.8 (10.9 to 14.8)	3.9 (3.3 to 4.6)
• Relevant test not performed/ordered	105	8.6 (7.0 to 10.3)	2.6 (2.1 to 3.2)
• Retrospectively, one or more of my clinical decisions were less optimal	289	23.5 (21.1 to 26.0)	7.2 (6.3 to 8.0)
• Waiting time in secondary care	102	8.3 (6.8 to 10.0)	2.5 (2.0 to 3.1)
• Other	194	15.8 (13.8 to 18.0)	4.8 (4.1 to 5.6)
Type of combinations when two QDs were present (229 cases with 458 QDs)			
• False-negative clinical examination and false-negative laboratory test	25	10.9 (7.1 to 15.7)	0.6 (0.4 to 1.0)
• Relevant test not performed/ordered and retrospectively, one or more of my clinical decisions were less optimal	16	7.0 (4.0 to 11.1)	0.4 (0.2 to 0.7)
• False-negative clinical examination and retrospectively, one or more of my clinical decisions were less optimal	16	7.0 (4.0 to 11.1)	0.4 (0.2 to 0.7)
Type of combinations when three or more QDs were present (76 patients with 249 QDs)			
• False-negative clinical examination and relevant test not performed/ordered and one or more of my clinical decisions were less optimal	4	5.3 (1.4 to 12.9)	0.1 (0.0 to 0.3)
• False-negative laboratory examination and relevant test not performed/ordered and one or more of my clinical decisions were less optimal	4	5.3 (1.4 to 12.9)	0.1 (0.0 to 0.3)
• Communication between GP and patient was not optimal and communication between GP and specialist care/hospital was not optimal and one or more of my clinical decisions were less optimal	4	5.3 (1.4 to 12.9)	0.1 (0.0 to 0.3)

[a] Two patients had no information on the type of QD. [b] Prevalence of type of QD among patients with QD present. [c] Prevalence of type of QD among all patients (including those without a QD present.

Table 2. 1228 cases with quality deviations (QDs) present stratified by sex, age groups, and nine specific cancer diagnoses among 4036 Danish patients with cancer as reported by their GPs

	Cases	Quality issue present			
	n	*n*	% (95%CI)	PRR – unadjusted	PRR – adjusted[a]
Male	2176	650	29.9 (27.9 to 31.9)	1 (reference)	1 (reference)
Female	1860	578	31.1 (28.9 to 33.3)	1.04 (0.94 to 1.15)	1.05 (0.96 to 1.17)
Age groups, years					
<39	178	56	31.5 (24.7 to 38.9)	1 (reference)	1 (reference)
40–49	318	104	32.7 (27.6 to 38.2)	1.04 (0.79 to 1.36)	1.04 (0.79 to 1.35)
50–59	618	206	33.3 (29.6 to 37.2)	1.06 (0.82 to 1.36)	1.07 (0.83 to 1.37)
60–69	1185	345	29.1 (26.5 to 31.8)	0.93 (0.73 to 1.18)	0.93 (0.73 to 1.19)
70–79	1099	342	31.1 (28.3 to 34.0)	0.99 (0.78 to 1.25)	1.01 (0.80 to 1.28)
80–89	565	155	27.4 (23.7 to 31.4)	0.87 (0.67 to 1.13)	0.89 (0.68 to 1.15)
≥90	73	20	27.4 (17.6 to 39.1)	0.87 (0.56 to 1.35)	0.88 (0.56 to 1.36)
Cancer					
Breast	522	127	24.3[b] (20.7 to 28.3)	1 (reference)	1 (reference)
Uterus	105	23	21.9[b] (14.4 to 31.1)	0.91 (0.61 to 1.35)	0.93 (0.62 to 1.37)
Malignant melanoma	223	62	27.8 (22.0 to 34.2)	1.15 (0.88 to 1.50)	1.19 (0.91 to 1.56)
Prostate	604	158	26.2[b] (22.6 to 29.9)	1.07 (0.87 to 1.33)	1.25 (0.99 to 1.59)
Lung	426	140	32.9 (28.4 to 37.6)	**1.33 (1.07 to 1.64)**	**1.44 (1.16 to 1.80)**
Rectal	206	66	32.0 (25.7 to 38.9)	**1.34 (1.04 to 1.73)**	**1.48 (1.13 to 1.92)**
Colon	365	130	35.6 (30.7 to 40.8)	**1.46 (1.17 to 1.81)**	**1.57 (1.26 to 1.96)**
Others	1224	447	36.6[b] (33.8 to 39.4)	**1.48 (1.24 to 1.76)**	**1.59 (1.33 to 1.91)**
Ovarian	54	22	40.7 (27.6 to 55.0)	**1.71 (1.20 to 2.45)**	**1.73 (1.21 to 2.46)**
Bladder	121	53	43.8[b] (34.8 to 53.2)	**1.76 (1.35 to 2.29)**	**2.02 (1.53 to 2.67)**
Total	4036	1228	31.9 (30.4 to 33.4)		

[a]Adjusted for sex, age, diagnosis, and geographical region (the five regions in Denmark). [b]Statistically significant different (P≤0.05, Wilcoxon rank-sum) from all others combined. ***Bold*** *= Statistically significant at P≤0.05.*

were more likely to report a QD for colon, rectal, lung, ovarian, bladder, or other cancers.

The risk of QDs was higher when the patient symptoms were interpreted as less serious (Table 3).

Table 3. Prevalence of quality deviations (QDs) by GP's symptom interpretation of the patient's presenting symptoms and prevalence rate ratios (PRR) for one or more QDs. Information on symptom interpretation was missing for 128 patients and hence not used in this analysis

GP's symptom interpretation	Cases	Quality issue present		PRR – unadjusted	PRR – adjusted[a]
	n	*n*	%		
• Alarm symptoms suggestive of cancer	1857	447	24.1	1 (reference)	1 (reference)
• Serious symptoms	751	238	31.7	**1.32 (1.14 to 1.51)**	**1.23 (1.07 to 1.42)**
• Vague or ill-defined symptoms	1300	513	39.5	**1.64 (1.47 to 1.83)**	**1.59 (1.42 to 1.78)**
Total	3908	1198	30.7		

[a]Adjusted for sex, age, diagnosis and geographical region. ***Bold*** *= Statistically significant at P<0.05.*

Overall, the diagnostic interval was 69 (IQI = 33–152) days for patients with QDs compared to 25 (13–49) days for patients without QDs (*P*<0.001). The adjusted median diagnostic interval was 41 days longer (95% CI = 38.4 to 43.6) for patients with one or more QDs compared to patients with no QD (Figure 1). QDs relating to examinations and tests were statistically significantly associated with longer diagnostic interval (Figure 1). The presence of one or more QDs showed stronger associations with the diagnostic interval among the 20% who waited the longest (Figure 2).

DISCUSSION

GPs reported that at least one QD had taken place for nearly one-third of their patients with cancer. Patients with bladder and ovarian cancer had the highest likelihood of QDs. The likelihood of a QD increased if the GP regarded the presenting symptom as less serious than alarm symptoms. For patients with GP-identified QDs, the diagnostic interval was increased by a median of 41 days providing a strong influence on time to diagnosis.

Strengths and limitations

A major strength of this study was its considerable size ensuring high statistical precision. Furthermore, the study population was well-defined and complete with minimal selection bias since the NPR was used, wherein 98% of all patients with cancer in Denmark are registered,[20] to identify all consecutive cancer patients. Yet, due to delay in NPR registrations, some patients may have been missed. However, this is expected to be negligible as the sample was repeated on two consecutive months including late-registered patients.

The high response rate of 71.4% minimises the risk of selection bias. The small differences in age and sex for patients between responding and non-responding GPs should not affect the outcome as stratified analysis showed no differences in the prevalence of QDs. However, patients who were not included due to GP non-response may differ from patients of responding GPs in respect to QDs.

Information bias could exist due to GP recall bias when filling in the questionnaires. Yet, the recall bias was reduced as GPs were asked to complete the questionnaire on the basis of their contemporaneously updated electronic medical records. Even so, the retrospective nature of the study holds the risk that the GPs may erroneously ascribe circumstances to a specific case, and hence overestimate the prevalence of QDs. Yet,

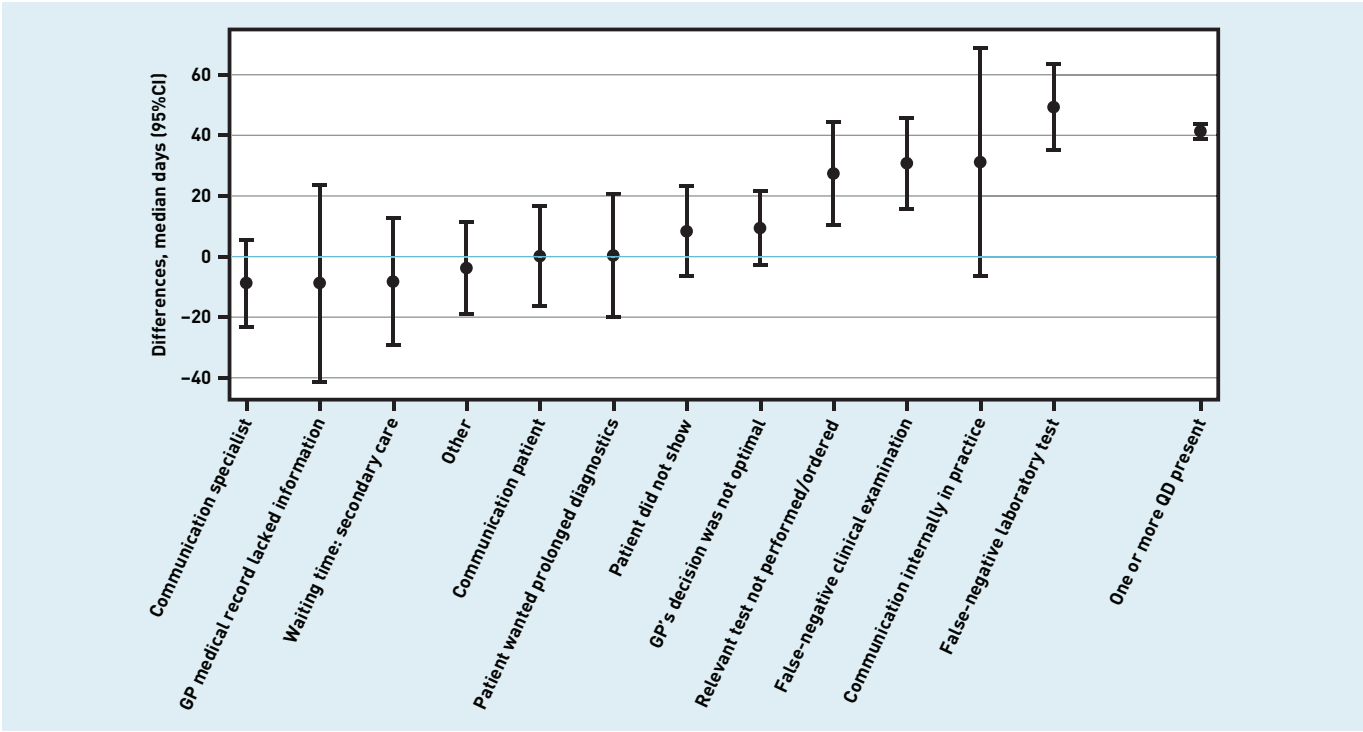
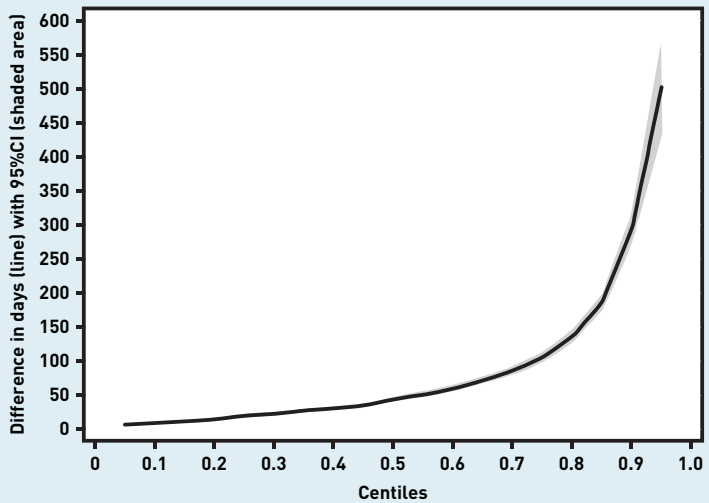


Figure 1. Difference in median diagnostic interval (dots) for cases with one or more quality deviations (QDs) compared to cases without QD presence; overall QD presence (far right) and broken down by type of QD (ranked from low to high). Shown estimates are adjusted for sex, age, diagnosis, and region of residence. Note, no information on diagnostic interval was given for 591 cases and hence they were not included in this analysis.

Figure 2. For increasing quantiles of the diagnostic interval in days, the black line shows the additional diagnostic interval for cases with one or more quality deviations (QDs) compared to cases without QD presence. Shown estimates are adjusted for sex, age, diagnosis, and region of residence.



this possibility alone cannot explain the high prevalence observed.

The method used for data collection resembles the method of employing an audit of patients with cancer in general practice described by Rubin *et al*, which showed to be a valid method for collecting data on individual cancer cases.[23] Furthermore, the use of case reviews is favoured by GPs as a learning method and tends to initiate reflective processes about real-life cases,[24] and this method is also considered useful to identify and report incidents.[25]

Comparison with existing literature

This study's QD frequency of 30.4% is slightly lower than the 37% of missed abnormal test results found by Wahls and Cram.[26] Furthermore, the median of 1 QD per patient is slightly lower than the median of 2 QDs per patient reported by Cooke.[25] This may be explained by the design of these studies and Cooke's inclusion of some incidents reported more than once. This study is the first to quantify the association between QDs and the diagnostic interval. The results show an increased diagnostic interval for QD presence, with a stronger association for patients waiting the longest. These findings illustrate that part of the diagnostic interval must be attributed to a delay caused by QDs, even though the entire diagnostic interval cannot be taken as a delay. This is in accordance with delay being the most often reported consequence of a QD.[13] This is of clinical importance as longer diagnostic intervals are associated with higher mortality.[4,27]

A recent study from the UK, also based on GP-collected data, reported differences in the number of pre-referral consultations for different cancers, but the study did not investigate why.[28] This study adds important new knowledge to possible reasons why these differences exist.

The high prevalence of the QD on less optimal clinical decisions (that is, 'retrospectively, one or more of my clinical decisions were less optimal') seems intuitive

as it was often reported together with false-negative results of clinical examination or laboratory test. Furthermore, this overlap may also partly explain why QDs related to less optimal clinical decisions did not have a statistically significant association with the median time to diagnosis.

The findings of higher risk of QDs when the patient had vague symptoms may imply that alarm symptoms (aka 'red flags') make it easier to confirm the diagnosis. Yet, as cancer alarm symptoms have a low prevalence,[29] this study's findings also suggest that more focus is needed on patients with non-alarming symptoms.

The QDs in this study fall into three main categories. The first category (15% of all QDs) is related to the patient; that is, the patient failed to attend a scheduled consultation or postponed the diagnostic investigation. Patient non-attendance has formerly been reported to vary from 6.5% to 42%.[30–32] this study was not designed to explore the reasons for patient non-attendance.

A second category (20% of all QDs) contains QDs related to communication issues, which have previously been investigated in other studies.[12,14,33,34] It is especially noteworthy that doctor–patient communication problems were reported in 10% of the cases in this study, which is similar to the results of a Danish national patient survey, where 10% of all patients reported communication problems.[35] However, no elaboration was given by the GPs.

The third category (45% of all QDs) related to the clinical investigations and decisions. The magnitude of this category is in the high range compared to previous reports.[33]

In accordance with other findings[15–17] it was found that the diagnostic pathway is suboptimal for some patients in general practice, which suggests that more focus is needed on patients with negative test results.

Implications for research and practice

Methods should be developed and tested to direct the attention towards patients who are at risk of experiencing QDs. As indicated by these findings, this group may include patients with vague or unspecific symptoms and negative tests and examinations. Lately, it has been shown that attendance rates for patients who are later diagnosed with cancer tend to rise months before a cancer diagnosis.[36–38] These results support earlier findings that diagnostic delay in general practice may be reduced by optimised history taking, explanations of the rationale for ruling out non-cancer causes, and adoption of an 'open-door' policy for patients with persisting symptoms.[15]

To conclude, for nearly one-third of all patients with cancer in Denmark involving the GP in the diagnostic pathway, the GP noted that at least one QD had taken place in the diagnostic phase. The QD presence was strongly and inversely associated with the severity of the patient's symptoms as interpreted by the GP. QD presence contributed considerably to the length of the diagnostic pathway, introducing a median delay of 41 days in cases with QDs present. It is recommend that it be tested whether such QDs in general practice can be avoided and thereby have a positive impact on the diagnostic interval.

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Ethical approval

The study was approved by the Danish Data Protection Agency (record number: 2009-41-3471). The Danish National Board of Health (today: the Danish Health and Medicines Authority) granted legal permission to obtain information from the GPs' medical records without asking the patients for permission. According to the research ethics committee of the Central Denmark Region, the Danish acts on research ethics review of health research projects (s. 8(3) of Act No. 402 of 28 May 2003) did not apply to this project.

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Competing interests

The authors have declared no competing interests.

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