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Classifying Patients' Complaints for Regulatory Purposes: A Pilot Study

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Objectives: It is assumed that classifying and aggregated reporting of patients' complaints by regulators helps to identify problem areas, to respond better to patients and increase public accountability. This pilot study addresses what a classification of complaints in a regulatory setting contributes to the various goals.
Methods: A taxonomy with a clinical, management, and relationship domain was used to systematically analyze 364 patients' complaints received by the Dutch regulator.

Results: Most complaints were about hospital care, mental health care, and elder care. About certain sectors such as emergency care, little numbers of complaints were received. The largest proportion of complaints concerned the clinical domain (51%), followed by the management domain (47%) and the relationship domain (42%).

Clinical domain complaints were more prevalent in elder care (65%) than in hospital care (56%) and mental health care (41%). In complaints about mental health care, the relationship domain was the most important (65%). The management domain was most prevalent in elder care (49%) compared with the other sectors.

Conclusions: Problem areas within different health-care sectors could be identified by classifying the complaints. It provided insight in the regulator's own practices, which are aimed at public accountability. However, there are several limitations. Aggregated analyses were not possible in sectors with low numbers of complaints. Furthermore, the information remains rather superficial, and a standardized detailed system of reporting among agencies is needed. To assess which complaints need regulatory action, an in-depth analysis, using standardized methodology and criteria, of specific complaints is needed.

Improving responses to patients requires more than merely aggregated reporting of complaints.

In research, it is argued that current approaches to health-care quality regulation tend to reflect a narrow clinical perspective that excludes the patients' perspective.¹⁻⁶ In addition, some largescale incidents in several countries, such as the Mid Staffordshire NHS trust scandal, where patients signals were ignored, have further inflamed this debate.^{7,8} Regulators in various countries have therefore expressed a greater commitment to use patients' complaints.⁹⁻¹⁵ There are differences between countries in what role complaints currently have in regulation. In Finland, for example, patients can file complaints to the regulator who then judges the legitimacy of the complaint,^{16,17} whereas in other countries such as the UK and The Netherlands, individual complaint handling is not the primary task of the regulator. Signals derived from individual complaints are often used to monitor the performance of individual care providers.^{9,10,18} Internationally, researchers agree that aggregated analysis and reporting of adverse events, including complaints of patients, by care providers and regulators is required.¹⁹⁻²⁴ Organizations could treat patient complaints similar to adverse events, by early detection, systematic analysis, learning, and prevention of, for instance, malpractice risks.^{20,25-27} A recent study by Reader et al therefore attempted to develop a taxonomy with the aim of classifying and reporting on patients' complaints at the hospital level.¹⁹ According to the authors and other scholars, such aggregated analyses and classification of complaints would serve various goals. First, aggregated complaint analysis would give a chance to proactively identify (system-wide) problem areas that point to poor care and risk areas.^{19,23,28} Second, it could help respond more effectively to individual patients and their complaints and give them a voice in regulation.^{19,20,22,28,29} Third, it could increase accountability of care providers and regulators to the government and the public for their actions.^{9,23,29} Systematically classifying and analyzing complaints by regulators is not common yet,^{9,20,29} although it would provide a first step toward using patients' complaints for regulatory purposes.

This pilot study therefore aimed to classify one sample of complaints about all health-care sectors received by the Dutch Healthcare Inspectorate using a taxonomy. We aimed to explore what information can be extracted from a classification of complaints and to what extent this information contributes to the various goals. The following study questions were formulated: Can problem areas be identified by classifying and aggregated reporting of a sample of complaints? Can classifying complaints help to respond more effectively to patients and their complaints and provide them a voice? · How could classifying complaints contribute to public accountability of regulators? The Dutch situation is used as a case study (more information Box 1).

METHODS

Complaints Selection

Complaints received by the Inspectorate between August 2012 and November 2012 were selected, resulting in a total sample of 364 complaints. Complaints made by professionals, about a sector other than health care, or written in a language other

than Dutch were excluded. Complaints were received by letter or email or through a digital form on the Inspectorate's Web site.

[Box 1]

Systematic Complaints Analysis

A taxonomy was used to conduct a systematic content analysis and quantification of complaints. This taxonomy is based on the original taxonomy of Reader et al.¹⁹ This taxonomy was adapted to the Dutch regulatory setting, and reliability was analyzed in another study (Bouwman et al, submitted). Several reasons can be given for the adaptations made. Some main and subcategories were combined because they overlapped. Some domain and (sub) category names were reformulated or extended to make them clearer and to reflect the underlying subcategories. Furthermore, several subcategories were added, making the taxonomy applicable to care sectors other than hospitals, such as mental health care and covering specific legislation that the Inspectorate supervises.

For instance, the Inspectorate supervises compliance with the clients' right to complain act that obliges care providers to provide an accessible complaints procedure for patients. The taxonomy differentiates between the clinical (+ care, cure), management (+ organization, logistics, planning), and relationship (patient-care provider, communication) domains, which are grouped into 6 main categories (quality and safety, communication, human rights, organizational and institutional problems, timing and accessibility, complex complaints) and 29 subcategories. We tested the reliability of the taxonomy because the aim was that the taxonomy should be used in practice by the Inspectorate's employees to encode complaints homogeneously. The complaints were categorized and assigned into various taxonomy codes by 2 raters. The average reliability of the taxonomy at the level of main categories was considered substantial ($\kappa = 0.64$). The mean kappa at the level of subcategories was moderate ($\kappa = 0.56$).

Our goal of using the taxonomy was to create an aggregated overview of the subjects of complaints and workable system for complaint handlers for reviewing complaints from 18 healthcare sectors (ie, hospital care, mental health, and elder care). Complaints from these sectors were classified into the 3 domains of clinical, relationship, and management. Each domain was divided into main and subcategories of complaint themes (see Table 1).

The content and themes in each complaint were analyzed and classified into a complaint subcategory in the appropriate domain.

It was therefore determined that a maximum of 3 themes per complaint could be coded. Montini et al found that patient complaints averaged 1.5 themes, ranging from 1 to 9 themes per complaint.²¹ Similarly, Reader et al found an average of 1.49 issues per complaint, with a range of 1.05 to 3.19.¹⁹ The maximum of 3 therefore seemed justified. In addition, if it was not possible to assign a maximum of 3 themes to one complaint, it was encoded solely as a "complex complaint." Other information that was available to be extracted from the data was whether the complaint was investigated further by the Inspectorate, the type of care provider involved, and whether the complainant was the patient or someone else.

Statistical Analyses

Statistical analyses were conducted using the software program STATA version 13. New variables were created to determine the frequencies (at least once) of the domains, the main categories, and the subcategories within the complaints. To determine the frequency, occurring categories that were agreed upon in complaints were counted as 1 (ie, a category is applicable to a complaint according to both raters), non-occurring categories that were agreed upon were counted as 0, and categories that were not agreed upon were counted as 0.5. A Venn diagram was constructed to assess the overlap of the 3 domains.

Types of care provider involved in the complaint classified by the 2 raters were compared. Only if differences were found, it was compared with the care provider type as initially classified by the Inspectorate itself. If one of the raters matched the classification of the Inspectorate, that type of care provider was chosen. If all 3 classifications mismatched, it was classified as “unclear.” The same applies for whether the complainant was the patient or someone else.

[TABLE 1]

Chi-squared tests were carried out to explore differences between numbers of complaints investigated further within healthcare sectors. Results were considered significant if $P < 0.05$.

Privacy

The complaint letters were encoded in the offices of the Inspectorate to prevent further distribution of personal information of complainants. The raters signed a confidentiality agreement.

Personal information about the complainants was not used.

RESULTS

To explore what types of information can be extracted from classifying the complaints and what this contributes to the various goals, we analyzed the complaints at different levels. We first analyzed numbers of complaints per care sector. We then analyzed the complaints at the domain, main category, and subcategory levels of the taxonomy. For the 3 health-care sectors with the highest number of complaints (hospital care, mental health, and elder care), we conducted some more detailed analyses. In the discussion section, we will address how this information contributes to the various goals described in the introduction.

To illustrate the content of complaints patients reported to the Inspectorate, some text fragments from the complaints in the various care sectors are shown in Box 2. As can be seen, complaints are often complex and multifactorial and contain detailed information.

On average, complaint themes were categorized into 2 complaint subcategories.

Complaints Per Care Sector

Most complaints were about hospital care (22%), mental health care (17%), and elder care (12%) (Table 2). In half the complaints, the complaint was issued by the patient themselves. In 56% of the complaints about hospital care, the complaints were issued by the patient. In mental health care, this was 67%. In elder care and care for disabled patients, almost all complaints (98% and 92%) were about someone else,

who was mostly a relative. In total, 31% of complaints were investigated further by the Inspectorate.

[BOX 2]

[TABLE 2]

Complaints on Domain Level

Figure 1 shows a Venn diagram of the overlap between the 3 domains of the taxonomy. The clinical and relationship domains have the greatest overlap (14%), followed by the clinical and management domains (13%). All 3 domains overlap in 8%. Furthermore, the relationship domain occurs alone least often (9%) in the complaints.

To gain insights into the regulator's decisions about complaints, we analyzed the number of complaints investigated for each domain of the taxonomy (Fig. 2). More information about the current process for determining which complaints to investigate can be found in Box 1. Within the clinical domain, significantly more complaints were investigated (37%, $P = 0.02$) by the regulator compared with the other categories (26%-30%).

Complaints at the Main Category and Subcategory Levels

Figure 3 shows the distribution of the complaints over the 6 main categories and 29 subcategories. Of the 364 complaints, the largest proportion concerned the main category "quality and safety" (187, 51%). Within this main category, the subcategories that were most prevalent were "quality of care, skills and performance, improper or unprofessional behavior or clinical treatment," and "safety incidents." Almost 4 (138, 38%) of 10 complaints concerned the main category "organizational and institutional problems." Within this main category, the most prevalent subcategories were "inappropriate/ incorrect behavior of the organization or individuals within the organization," and "unhealthy, poor or unsafe environment/ building or supporting services." Only a small proportion within the management domain concerned the main category "timing and accessibility" (34, 9%).

Communication issues were present in about a quarter of the complaints, of which, the most were about "incorrect/incomplete/ missing information/shared decision making" and "not listening, not taking patient seriously, rude attitude." Within the category "human rights" (77, 21%), "coercion and compulsory submission" was the most prevalent subcategory, followed by "abuse/sexual misconduct."

Complaints issued by the patients themselves were significantly more often about human rights compared with complaints issued by someone else. For the other main categories, no significant differences were found.

[FIGURE 1]

[FIGURE 2]

Complaints on Domain Level in 3 Sectors With Most Complaints

For the 3 health-care sectors with the highest number of complaints (hospital care, elder care, and mental health), differences in the occurrence of the domains were analyzed (Fig. 4). The clinical domain occurred in all sectors, but significant differences were found ($P = 0.006$). In elderly care, it was more prevalent (65%) than in hospital care (56%) and mental health care (41%). In mental health care, the relationship domain occurred significantly more often (65%, $P < 0.008$) than in the other sectors. These complaints mostly concerned human rights issues. The management domain was most prevalent (49%) in elder care; this was not significantly different from the other health-care sectors. In Figure 5, absolute numbers of complaints for each domain in the 3 healthcare sectors are shown. It is also shown how many of those complaints were investigated further by the Inspectorate to see in detail what decisions were made by the Inspectorate. In mental health care, in total, fewer complaints (18%) were investigated than in hospitals (24%) and elder care (36%), but this did not differ significantly. In general, relatively more complaints within the clinical domain were investigated, and these mostly concerned safety and abuse or sexual misconduct (not in Figure).

[FIGURE 3]

DISCUSSION

In this pilot study, a sample of patients' complaints received by the Dutch Healthcare Inspectorate was classified using a taxonomy that was adapted from Reader et al to the regulatory setting.

From a regulatory perspective, we examined what information can be extracted by classifying and quantifying the complaints and whether this information meets the goals that were set in the literature.

The results are discussed with reference to those goals.^{9,19,20,22,29}

Identify Problem Areas and Quality and Safety Issues

Classifying complaints makes it possible to structure and document the often complex and unstructured complaints into interpretable and easy-to-report categories. The analysis provided information at a national level and care sector level. This pilot study was confined to one sample of complaints received by the Dutch Healthcare Inspectorate within 3 months, providing a first step toward creating a central overview of complaints.

[FIGURE 4]

At the national and care sector level, it was possible to identify problem areas. Slight shifts of patterns were seen in the problems that patients reported in different health-care sectors. The patterns were quite clear for characteristics of the care and care sectors. For instance, in elder care, patients point to organizational problems more often than in other sectors. However, identifying problem areas and patterns is only possible if sufficient numbers of complaints are received for each sector. For

instance, in home care and emergency care, too few complaints were received for this analysis. Moreover, assuming that complaints reported by patients are only a “tip of an iceberg,” we cannot be sure that the complaints reported are representative for all patients’ experiences in health care.

Furthermore, the classification supports basic analyses but does not accurately explain and map the complex reality behind a complaint. The information that the analysis provided remains rather superficial. This makes it difficult to assess which complaints need regulatory action. Important details and contextual information described in the complaints are crucial for determining the severity of a complaint. The same phenomenon has already been described in the case of incident reporting; although the main principle of reporting incidents was to identify and prioritize significant risks, in practice, incidents are only counted to monitor performance of care providers, removing the opportunity for broader learning.^{30,31} Classification of complaints can be seen as a first step, helping to set priorities. The second step would be analyses of the content of complaints that were selected in the first step in greater depth. Furthermore, helping the learning processes requires not only classifying and quantifying but also social processes involving the regulators, complaint investigative agencies, and care providers.

Giving Patients a Voice

The analysis gives insights into what aspects of health care are relevant for improving health-care quality, according to the patients.

It provides contextual information, allowing further consideration of how to incorporate patients’ perspectives into healthcare quality regulation. Formally, the Inspectorate further investigates patients’ complaints if they point to severe or structural problems.³² The results show that only a selection of complaints, often including a clinical component, are investigated further by the Inspectorate.

However, other research has shown that patients have different perceptions of the relevance of their complaint for health-care quality.²⁹ Furthermore, as observed in other studies, patients have differing views about factors relating to health-care quality and safety.^{33,34} Patients often assess the care received on a broad spectrum of aspects going beyond exclusively clinical markers, such as the interpersonal skills of the care provider³⁵ and how care is organized.³⁶ If regulators want to give patients a voice and use complaints in their work, they may therefore need to broaden their perspective of the factors that contribute to health-care quality.

Responding to Complaints

Patients’ dissatisfaction with responses to their complaints is often associated with an expectation gap.^{29,37-39} Other research shows that patients find it important to prevent the problem from recurring by reporting their complaint to a regulator. They want to be kept informed about the effect of their complaints on quality of care. However, they lack confidence in the effects their complaints have.²⁹ It would therefore seem that mere aggregated reporting of complaint data is insufficient to meet the patients’ expectations.

The aggregated overview of complaints could be used for publicly reporting what effects complaints have on the health-care system.

^{20,29,40} However, a clearer understanding of the expectation gaps that arise between complainants and regulators is still needed to achieve solutions that improve responses to complaints and patient satisfaction.

Increasing Public Accountability

This study provided an opportunity to gain insight in the regulator's own practices and recognize its own blind spots. It creates a bigger picture of which complaints are selected by the Inspectorate for further investigation and which not. Quality issues were investigated more often by the Dutch regulator, which is in line with its statutory task.³² However, differences are seen between the health-care sectors in the numbers of complaints investigated. Furthermore, some themes and subjects that patients reported, such as safety incidents and abuse, are addressed more frequently than others. This information could help in making evaluation procedures and decisions more homogenous and consistent and improve public accountability. The Inspectorate could consider whether it is desirable that certain subjects are not addressed.

It is also interesting to consider the results in the context of other complaint investigative agencies and organizations. One interesting finding is that the Inspectorate received complaints about elder care, whereas other research has shown that patients in elder care hardly ever lodge complaints.^{22,41} They do not want to be seen as "difficult."⁴¹ The Inspectorate is, thus, perceived to be more accessible by patients in elder care than other complaint options.

[FIGURE 5]

There will still be an important challenge, as clarification is needed about the most appropriate roles for care providers, complaint investigative agencies and regulators regarding the monitoring of and responding to complaints.

Future Research

With our relatively small study sample, we were not able to conduct more complex analyses. A further study should examine whether future follow-up samples of complaints allow for comparisons over time that point to emerging problems as experienced by patients. Furthermore, it is recommended that other information sources are linked to the aggregated complaint data, such as numbers of incidents reported by care providers. This will allow patterns of nonreporting to be detected and more precise comparisons between the performance of different care providers to be made. In other research, it has been shown that different reporting systems, such as incident reporting, risk management reports, patient complaints, and malpractice claims, all produce substantially different, incomplete but complementary pictures of patient safety.

Underreporting is a major issue, as sometimes 95% of adverse events are not reported.⁴² Systems for achieving a detailed understanding of the full range of things that go wrong at the population level are largely undeveloped.²³ Additionally, the predictive value of complaints could be further studied to clarify the value of using complaints for regulatory purposes.^{25,27} Examples: the relationship between complaints and mortality rates, incidents, patient satisfaction, or regulatory measures against care providers could be analyzed.⁴³

Strengths and Weaknesses

A unique aspect of this study is that it includes complaints about various health-care sectors, whereas other studies on complaints often focus on one sector, which is mostly the hospital sector.^{19,39,44} A strength of this study is that an evidence-based and substantially reliable taxonomy was used.

No basic characteristics such as age, sex, and ethnicity of the complainants were available because they were hard to extract from the often unstructured complaint data.

It should be noted that classifying complaints is a labor intensive activity.

Furthermore, future analyses using the taxonomy require extensive rater preparation and practice because this is widely acknowledged to be an important precondition for a valid assessment process in content analysis.⁴⁵

CONCLUSIONS

This pilot study reveals that a complaints classification makes it possible to structure and document the often unstructured complaints into interpretable and easy-to-report categories. If complaint numbers are sufficient, the classification allows problem areas within different health-care sectors to be identified. It also gives insights into the regulator's own practices and blind spots, which could help the regulator's public accountability. The overview of complaints could also be used for publicly reporting what effects complaints have on the health-care system.

However, there are several limitations on meeting the goals that are targeted by a complaints classification. Because the classification reduces the complexity of the complaints, the information remains rather superficial. To assess if the complaints need regulatory action, an in-depth analysis of emerging issues is still needed. All complaints should have detailed standardized information.

Detailed information about the severity of the complaints may show a severe lapse in safety, which may be enough to initiate a policy change. Associated to this, criteria for which complaints are eligible for investigation should be clearly set. However, without some form of standardized reporting of complaints, there is no way to monitor what patients experience in health care and give them a more consolidated voice in the regulatory practice. Standardization of detailed complaint information should promote sharing between complaint investigative agencies and stimulate learning processes.

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TABLES AND FIGURES

TABLE 1. List of the Domains (**bold**), Main Categories (*italic*), and Subcategories of the Taxonomy

Clinical, care and cure domain
<i>Quality and safety</i>
Safety incidents
Medication/medication errors/preference policy
Errors in diagnosis/triage/diagnostic assessment/ medical judgement/assessing urgency
Inadequate record keeping
Failing equipment/material
Title misuse
Quality of care, skill and performance/improper or unprofessional behavior/clinical treatment
Coordination/alignment problems
Other, viz
Relationship patient-care provider domain
<i>Communication</i>
Incorrect/incomplete/missing information/shared decision making
Unprofessional response to complaint
Not listening, not taking patient seriously, rude attitude
<i>Human rights</i>
Abuse/sexual misconduct
Confidentiality
Consent
Discrimination
Coersion and compulsory admission
Other patient's and human rights
Other, viz
Management, organization, logistics, planning domain
<i>Organisational and institutional problems</i>
Inappropriate/incorrect behavior of the organization or individuals within the organization
Unhealthy, poor, or unsafe environment/building or supporting services
Finances, invoicing, billing, costs, patient's own contribution
Insufficient/unqualified personnel or (supporting) resources present
Insufficient compliance with legislation/regulations/protocols/ guidelines and insufficient safeguarding of patients' rights
Inadequate organization/logistics/bureaucracy/governance
<i>Timing and accessibility</i>
People are not able to access or get admission to care or the care provider (or cannot do so in time)
Discharge
Referral
Other, viz
<i>Very complex problems</i>

Box 2: Fragments of complaints in different care sectors

“In the nursing home where my mother lived, the conditions are unhygienic. My mother's room smelled of urine, there was dust under the beds and the bathroom was filthy. [...] My mother's pressure sore was taken care of in this dirty room, on the dirty bedding. The care providers wore gloves but no aprons and they wore their hair loose. After 2 weeks, the wound was infected.” (elderly care)

“While they were busy with the preparations, my wife was asked to sign a declaration (...). Under the circumstances, she had no knowledge of the content of this declaration and had not been informed about possible complications. She signed the declaration in good faith. In the subsequent visit (...) I asked about the possible complications. They could not give us an answer.” (private clinic, minor medical procedure on the face)

“My mum [...] slipped off the toilet. She pushed the alarm button and then had to wait for 15 minutes before someone came.[...] She broke her hip. It was decided (without consulting me) that X-rays were not needed. An operation is not seen as important because she cannot walk anyway.” (elderly care)

“Tuesday-Wednesday-Thursday night: night shift staff are deployed who cannot assist with artificial respiration of a patient.” (care for handicapped patients)

“I've heard that a fellow patient of mine has been in isolation for 5 months now. He is a vulnerable man who gets confused quickly. I blame it on clinic negligence because [...] the man was confused because of medication intoxication” (mental health care)

TABLE 2. Care Sectors the Complaints Were About, Numbers of Complaints That Were Investigated Further by the Inspectorate, and Number of Complex Complaints for Each Care Provider

Care Sector:	No. Complaints (%)	No. Further Investigated	No. Complex
Total	364 (100)	113	57
Medical specialist somatic care/hospital care	79 (22)	19	13
Mental health care	62 (17)	11	10
Inpatient elderly care	44 (12)	16	9
Other	28 (8)	11	7
Care for disabled persons	27 (7)	18	10
Pharmacist	24 (7)	8	0
Dental care	18 (5)	3	1
General practitioner	17 (5)	5	2
Private clinic/independent medical centre	12 (3)	5	2
Unclear	12 (3)	2	0
Alternative care	7 (2)	5	0
Associated care professions/rehabilitation	7 (2)	1	1
Home care	7 (2)	3	2
Child welfare care	7 (2)	3	2
Forensic health care	6 (2)	0	0
Emergency care	2 (1)	1	0
Manufacturer/medical technology company	2 (1)	2	0
Public health care	2 (1)	0	0
Integrated care (cross-sectoral)	1 (0)	0	0
Manufacturer of medicines/pharmaceutical company	0	0	0

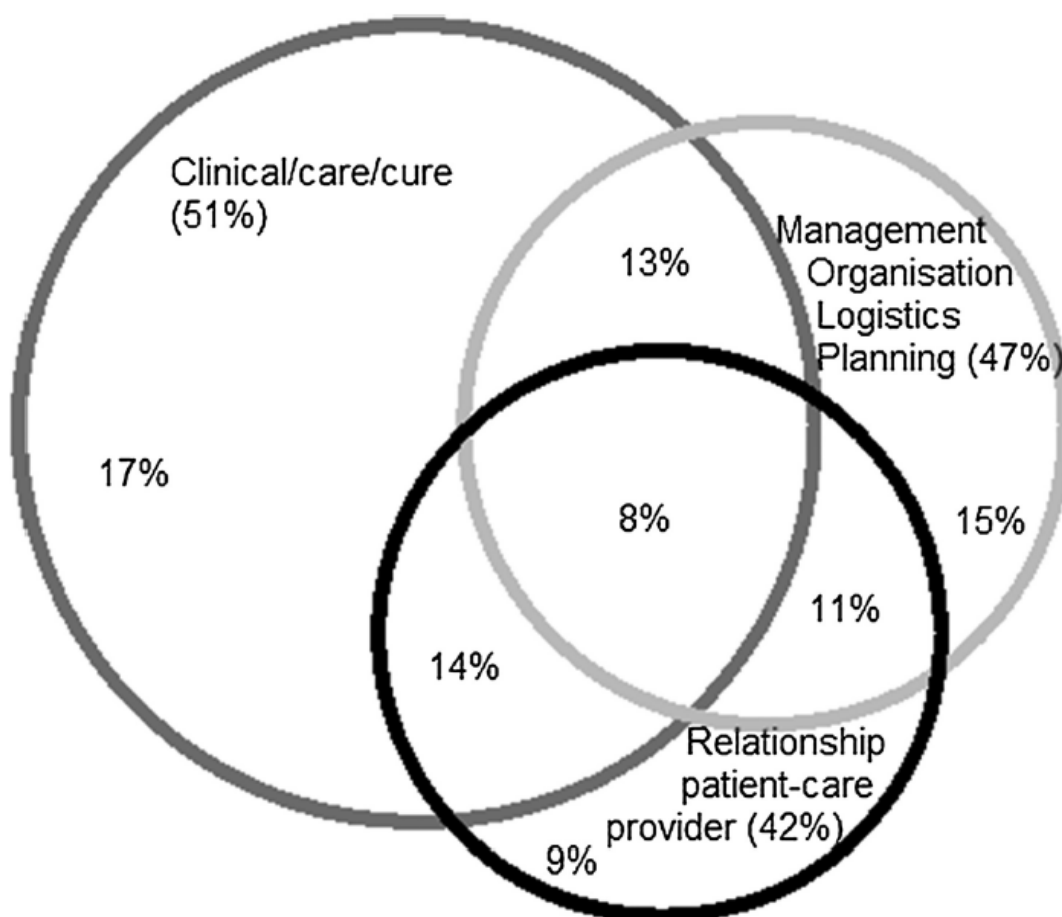


FIGURE 1. Venn diagram of the overlap of the 3 domains.

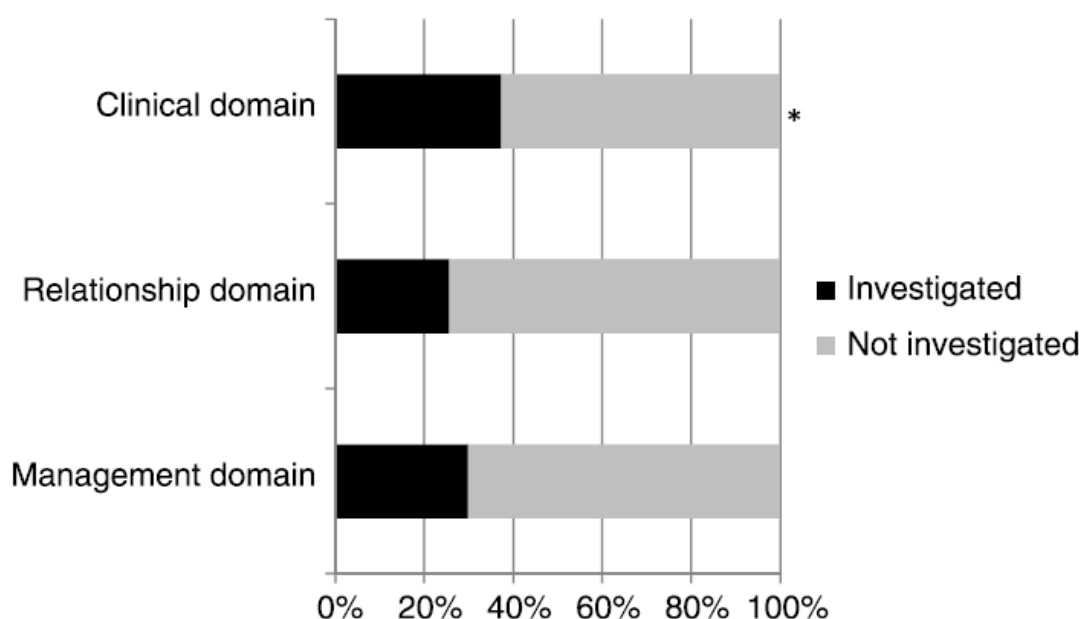


FIGURE 2. Percentages of complaints investigated and not investigated per domain.*Significant difference between complaints that concern the specific domain compared with the complaints that concern the other domains, $P < 0.05$ (far right column).

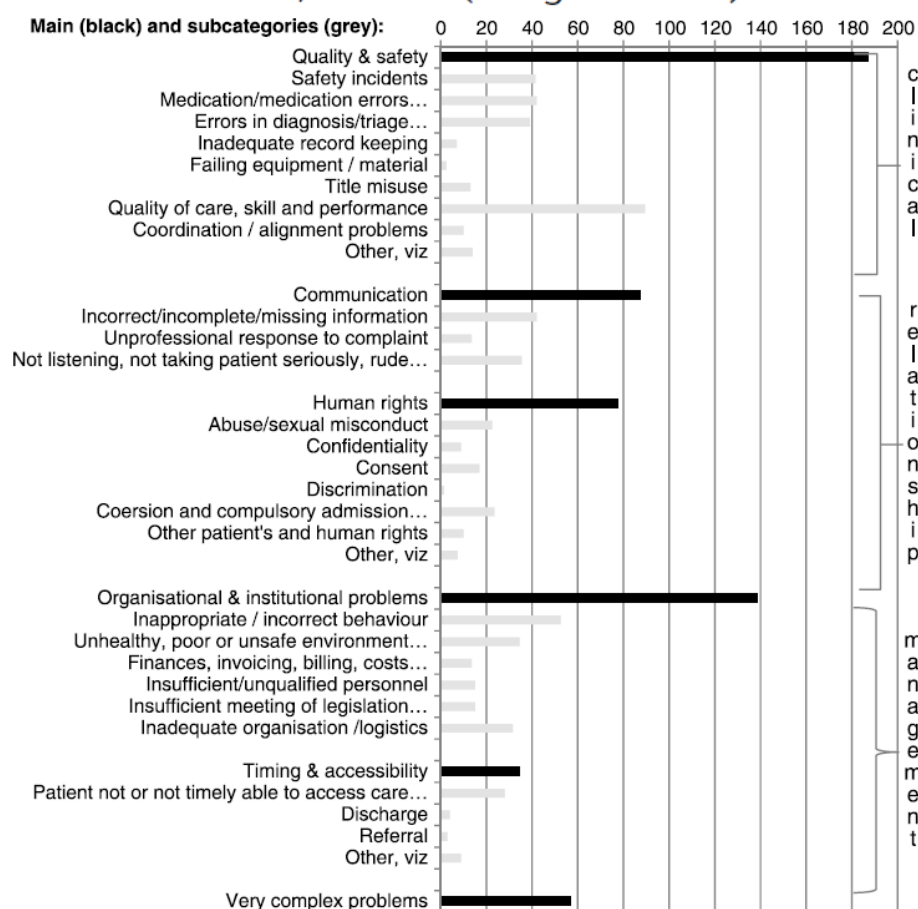


FIGURE 3. Absolute numbers of occurrences of main categories and subcategories within the complaints, divided into the 3 domains.

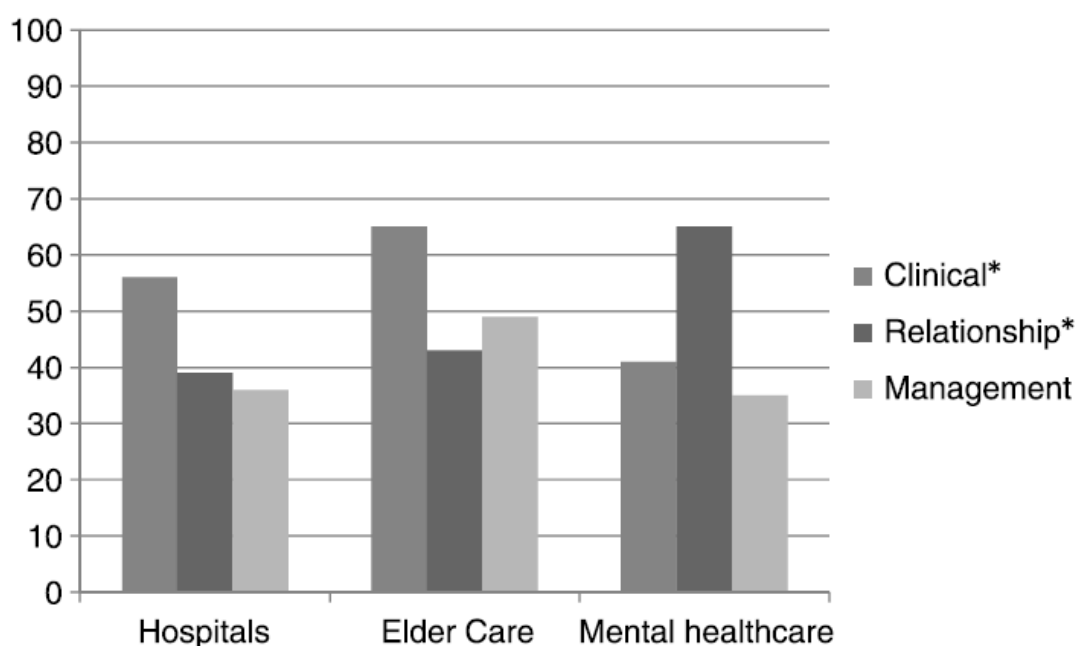


FIGURE 4. Percentages of occurrence of domains within the complaints in 3 sectors with most complaints. *Significant difference ($P < 0.05$) between the 3 domains (far right column).

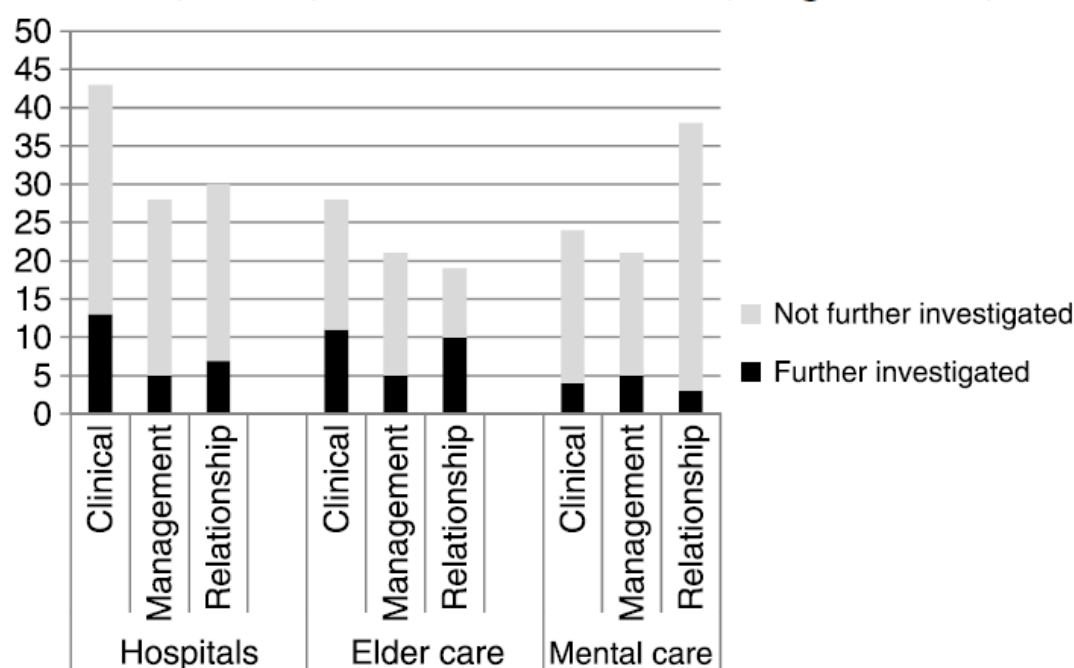


FIGURE 5. Absolute numbers of complaints in each domain for each health-care sector and numbers of further investigated complaints.