Patients’ Silence towards the Health Care System after Ethical Transgressions by Staff: Associations with Patient Characteristics in a Cross-Sectional Study among Swedish Female Patients

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TITLE: Patients’ Silence towards the Health Care System after Ethical Transgressions by Staff: Associations with Patient Characteristics in a Cross-Sectional Study among Swedish Female Patients

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KEY WORDS: abuse in health care, patient action, TEP, principle-based ethics, quality of care, patient satisfaction

WORD COUNT: 3510
ABSTRACT

Objectives: To identify which patient characteristics are associated with silence towards the health care system after experience of abusive or ethically wrongful transgressive behaviour by healthcare staff.

Design: Cross-sectional questionnaire study using the Transgressions of Ethical Principles in Health Care Questionnaire (TEP).

Setting: A women’s clinic in the south of Sweden

Participants: Selection criteria were: consecutive female patients coming for an outpatient appointment, >18 years old, with the ability to speak and understand the Swedish language, and a known address. Questionnaires were answered by 534 women (60%) who had visited the clinic.

Primary outcome measure: How many times the respondent remained silent relative to the number of times the respondent spoke up.

Results: Associations were found between patients’ silence and young age as well as lower self-rated knowledge of patient rights. Both variables showed independent effects on patients’ silence in a multivariate model. No associations were found with social status, country of birth, health, or other abuse.

Conclusions: The results offer opportunities for designing interventions to stimulate patients to speak up and open up the clinical climate, for which the responsibility lies in the hands of staff; but more research is needed.
INTRODUCTION

In a recent volume of BMJ Quality and Safety, focus was on patients’ “bad experiences in the hospital”.[1] These experiences, illustrated in two patient stories, highlighted inhumane aspects of care, beyond or despite technically correct treatment.[2, 3] Similar experiences have also been labelled abuse in health care (AHC) [4] and high numbers have been reported. AHC has been described as patients’ subjective experiences characterized by a lack of care, which implies suffering and the feeling of losing one’s value as a human being [4]. These events are most often of unintentional nature. Studies in the Nordic countries showed that lifetime prevalence of AHC ranged between 13 and 28 per cent in female patients.[5] Current suffering was reported by eight to 20 per cent of all women.[5] The approximate prevalence of AHC among Swedish men was seven per cent, and four per cent of the male sample reported current suffering.[6] Qualitative studies have shown that female patients who experienced AHC felt powerless and ignored, and experienced carelessness and non-empathy, resulting in the core category “being nullified”. [7] A related study among male patients showed that men had similar experiences, but instead of turning their emotions inwards, they wanted to express their emotions and felt hindered in doing so, resulting in the core category “mentally pinioned”. [8]

It may be assumed that face-to-face incidents of violence never exist in isolation. Johan Galtung’s theory of violence views these incidents of direct violence as part of a complex environment, consisting of possible violent structures and cultural norms and taboos, which feed and legitimize direct violence.[9-12] If health care providers want to understand and change these structures and cultures it is of importance to structurally include patients in health care processes, as some have suggested for the prevention of medical errors and quality improvement.[13, 14] According to sociologist Anthony Giddens,
structures are the rules and routines that at the same time enable and limit individuals’
behaviour.[15] Each time individuals act according to existing routines, these routines are
reproduced and confirmed. These routines, however, can be changed through different
feedback mechanisms inherent to the process of reproducing structures. A first step in that
direction could be to examine and consider patients’ feedback to the health care system.

One branch of research that aims to include patients’ evaluations in health care
processes are studies of formal patient complaints.[16, 17] However, it has been shown that
formal complaints are strongly biased and only represent specific patients and events, for
example those events that patients feel competent to complain about, e.g. hotel
services.[18] In a study on the expression of dissatisfaction, a British research group found
that only a small number of incidents were filed as formal complaints; the majority of
expressions was done verbally, and the patient did not label this as “complaining”.[18] This
suggests it could be more accurate and preferable to also concentrate on other forms of
feedback, such as directly speaking up to staff: so-called “informal complaints”. [19]

In a recent study based on the Transgressions of Ethical Principles in Health
Care Questionnaire (TEP), AHC was operationalized as patients’ experiences of staff’s ethical
transgressions and it was examined to what extent patients speak up or remain silent
towards the health care system after experiencing such events.[20] In the study (N=530) it
was found that the vast majority of female patients had experienced such events, and many
patients experienced these events as abusive and wrongful. More than two-thirds of these
patients had ever remained silent towards the health care system about at least one event.
For some transgressions, more than 80 per cent of the patients had kept silent, despite
feeling abused by the event or judging it as wrongful. Patients’ silence about abusive events
is alarming as it is not only directly harmful to patients, but a lack of patient feedback also hampers structural improvements.

Knowledge about which patient characteristics are associated with silence about abusive events within the health care system could shed light on which patients’ voices are heard less than others. The overarching aim was to gain knowledge that could contribute to more effective clinical interventions that ultimately decrease the prevalence of AHC, for which health care staff is responsible. Therefore the current study, also based on TEP, aimed to identify which patient characteristics are associated with silence towards the health care system after having experienced abusive or wrongful transgressions of ethical principles by health care staff.

Hypotheses

We hypothesized that patients’ silence towards the health care system was related to older age, lower social status, and being “ethnic” (not born in Sweden), all of which have shown to be associated with low levels of assertiveness in medical settings, or with lower rates of informal complaining.[19, 21-23] It was also hypothesized that patients with a history of other kinds of abuse remained silent to a higher degree, as they may have felt more guilt and shame caused by fear of negative reactions and blame by others.[12] Furthermore, we hypothesized that remaining silent could be related to poor health and little knowledge of patient rights.

METHOD

Subjects and procedure
Over the period between September 2009 and May 2010, TEP was sent to 890 female patients.[20] These patients were recruited at a women’s clinic at a county hospital in the south of Sweden. The sample was selected according to the following criteria: participants must 1. be a consecutive female patient coming for an outpatient appointment, 2. be >18 years old, 3. speak and understand the Swedish language, and 4. have a known address. Patients first received an information letter from a secretary at the clinic and had the option to decline participation. Patients who did not decline participation received a second information letter, TEP, and a pre-paid return envelope. Two reminders were sent out with two-week intervals. The study was approved by the regional ethical review board (reg.no. M116-09).

**Measurements**

TEP describes 23 events that operationalize transgressions of ethical principles in health care. The events were distributed between the principles as follows: autonomy 5; justice 2; physical non-maleficence 4; integrity 4; sexual non-maleficence 8 (box 1).
Have you ever experienced in Swedish health care that...

<table>
<thead>
<tr>
<th>Autonomy principle</th>
<th>Justice principle</th>
</tr>
</thead>
<tbody>
<tr>
<td>you were not adequately informed?</td>
<td>another patient was allowed to pass you in the queue without having a reason?</td>
</tr>
<tr>
<td>you did not get enough time to consider (e.g. options)</td>
<td>you did not get the care you think you have the right to get?</td>
</tr>
<tr>
<td>your opinion was not taken notice of?</td>
<td></td>
</tr>
<tr>
<td>you were not listened to?</td>
<td></td>
</tr>
<tr>
<td>you felt forced to accept a treatment or a sampling against your will because of fear for maltreatment if you did not?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical nonmaleficence principle</th>
<th>Integrity principle</th>
</tr>
</thead>
<tbody>
<tr>
<td>held you firmly against your will?</td>
<td>exposed you to mockery?</td>
</tr>
<tr>
<td>performed an examination/treatment in a too rough way?</td>
<td>humiliated you?</td>
</tr>
<tr>
<td>continued an examination in spite of your protests?</td>
<td>made you feel forgotten or neglected?</td>
</tr>
<tr>
<td>hit you or threatened to hit you?</td>
<td>violated his/her professional secrecy concerning you?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sexual nonmaleficence principle</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>explained you undress or dress instead of offering you to do it in private?</td>
<td>performed an examination in a way that you perceived as having an undertone of sex?</td>
</tr>
<tr>
<td>commented or criticized with a sexual undertone, your underwear or your body?</td>
<td>performed an examination in a way that you perceived as having an undertone of sex?</td>
</tr>
<tr>
<td>flirted or talked to you in a seductive way?</td>
<td></td>
</tr>
<tr>
<td>told you about his/her own sexual preferences, problems or fantasies?</td>
<td></td>
</tr>
<tr>
<td>performed an examination in a way that you perceived as having an undertone of sex?</td>
<td></td>
</tr>
<tr>
<td>exposed you to a sexual way your breasts, external genitals or other parts of your body?</td>
<td></td>
</tr>
<tr>
<td>encouraged you to masturbate or made you watch him/her masturbate?</td>
<td></td>
</tr>
<tr>
<td>wished to start a sexual relationship with you?</td>
<td></td>
</tr>
</tbody>
</table>

**Box 1: Operationalizations of ethical principles in the Transgressions of Ethical Principles in Health Care Questionnaire**

-Patients report whether they experienced such events, whether they experienced them as abusive, whether they judged the event as wrongful, and whether they acted upon it or spoke up (box 24). “Remaining silent” was defined as patients refraining from giving direct feedback to the health care system, despite experiencing an event as abusive or wrongful.
Have you ever experienced in Swedish health care that...

<table>
<thead>
<tr>
<th></th>
<th>A Did you perceive what happened as abusive?</th>
<th>B Did you judge what happened as wrongful?</th>
<th>C Have you talked about what happened with the health care staff, complained, or made clear in any other way that you experienced what happened in this way?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
</tr>
</tbody>
</table>

Example cases of transgression

Box 2: Transgression and silence questions in the Transgressions of Ethical Principles in Health Care Questionnaire

The face validity of the silence construction was judged to be good.[20] Patients’ reports of abusive transgressions in TEP also showed satisfactory convergent validity with patients’ reports to the AHC questions from the validated Norvold Abuse Questionnaire (NorAQ; validated in a Swedish female sample).[24] The silence operationalization in TEP has a starting point in James Rest’s four component model of moral behaviour.[25] This model identifies four components that are necessary for moral action to come about: moral sensitivity, moral judgment, moral motivation, and moral character. These components were then transformed into questions concerning patients’ experiences of and actions after staff’s transgressions. More detailed information about TEP and its underlying theoretical assumptions have been described elsewhere.[20]

TEP also includes questions about socio-demography, history of abuse, self-rated health, and knowledge of patient rights.

Questions about socio-demography included year-of-birth (age recoded into two categories: < 30, ≥ 30 years; fit line in scatterplot with age and the dependent variable showed a clear cut-off at age 30), education (recoded into three categories: < 10, 10-12, > 12 years), country of birth (recoded into four categories: Sweden, other Nordic country, other...
European country, outside Europe), occupation (recoded into two categories: [self] employed or other, which included: studied, unemployed, parental leave, sick leave/retired/social welfare, homemaker), income (original alternatives: < 7000, 7-14900, 15-24900, 25-34900, 35-44900, 45-54900, 55-65000, > 65000 SEK), and subjective social status, based on the idea of how one sees oneself in relation to others in society, considering money, job, and education.[26] The MacArthur Scale of Subjective Social Status (a 10 point ladder rank) is a well-established instrument of which we used a Swedish translation.[27] This measure was expected to better explain variance in silence than the objective measures of income, education, and occupation. Objective measures are useful for the guidance of effective interventions, since they are more concrete than subjective social status,[27] and were therefore included as well.

The patients' history of other kinds of abuse, i.e. emotional, physical, and sexual, was measured using the abuse questions from NorAQ.[28] The questionnaire identifies different levels of abuse: mild, moderate, and severe. The abuse questions in NorAQ have shown good reliability and validity, with an interview as the gold standard in a sample of Swedish women (n=64).[24] A full version of the abuse questions in NorAQ can be found in Swahnberg et al. [5]. Respondents who answered yes to at least one of the three questions for each type of abuse were regarded as having experienced that type of abuse, regardless of severity. The exception to this was mild physical abuse, which was shown to be rather unspecific,[24] and which was included in the “no lifetime physical abuse” category.

Self-rated health was measured on a seven point Likert item (1=very bad, 7=very good).

Lastly, knowledge of patient rights was operationalized as self-rated knowledge of these rights on an 11-point item (original coding: 0=none, 10=to a high degree).
As it has been suggested that non-response can be seen as an extrapolation of late response, we included “days to respond” (based on 30 days to 12 months).[29] Any association between this variable and an outcome could point at a possible response bias in the data set.

Study design

From the abovementioned silence operationalization in TEP we developed a dependent variable indicating how many times the respondent remained silent relative to the number of times the respondent spoke up, expressed as a percentage of the total number of opportunities to remain silent and speak up (continuous variable, 0–100, where 100 per cent indicated remained silent after all events and 0 per cent meant acted after all events). As this variable showed a U-distribution, which was hard to use as a dependent variable, it was chosen to trichotomize the variable (ordinal: 1=0%, 2=1-99%, 3=100%). Associations with silence were first tested univariately, using Cramer’s V (nominal by ordinal) and Kruskal’s Gamma (ordinal by ordinal, and interval by ordinal). Accordingly, all variables that tested significantly were included in an ordinal logistic regression model (through a Generalized Linear Model) testing for the main effect of these variables on the ordinal dependent variable. Knowledge of patient rights was entered as a covariate, assuming a continuous scale.

Statistical analyses were performed using the IBM Statistical Package of the Social Sciences 19.0. Test results with a p-value of <0.05 were considered significant.
RESULTS

Sixty per cent (534/891) of female patients answered and returned TEP and 530 were included in our final dataset, as four respondents were excluded (one male patient, and three patients because of invalid answers or more than half of the answers missing). Fifty-five per cent of the sample (293/530) reported at least one transgression that they judged abusive or wrongful and were included in the present study sample. Background data are shown in table 1 and more detailed information about the total sample is described elsewhere.[20]

Univariate analyses showed no associations between remaining silent and the patients' social status, country of birth, their background of abuse, or their health status. Associations were found with age and knowledge of patient rights (table 1). This result did not differ when only looking at abusive events or wrongful events in health care (data not shown). Considering age, the youngest age group reported a higher rate of remaining silent. Knowledge of patient rights was negatively correlated with remaining silent, implying that a higher reported knowledge was associated with a lower rate of remaining silent. The regression model including both of these variables showed that both age and knowledge of patient rights had an effect on remaining silent (table 2). Age and knowledge of patient rights were not associated with each other.

Further examination showed that knowledge of patient rights did not correlate with the number of events experienced, nor with the number of events that were perceived as abusive or wrongful (table 3).
n=293*  Remained silent

<table>
<thead>
<tr>
<th>Age (range 19-85, mean 42.5 ± 14.0)</th>
<th>0%</th>
<th>1-99%</th>
<th>100%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 30</td>
<td>8 (14.0)</td>
<td>17 (29.8)</td>
<td>32 (56.1)</td>
<td>0.03</td>
</tr>
<tr>
<td>≥ 30</td>
<td>68 (29.1)</td>
<td>74 (31.6)</td>
<td>92 (39.3)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education (years)</th>
<th>0.84</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10</td>
<td>9 (24.3)</td>
</tr>
<tr>
<td>10-12</td>
<td>30 (24.8)</td>
</tr>
<tr>
<td>&gt;12</td>
<td>36 (27.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country of birth</th>
<th>0.91</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden</td>
<td>63 (24.4)</td>
</tr>
<tr>
<td>Other Nordic country</td>
<td>1 (20.0)</td>
</tr>
<tr>
<td>Other European country</td>
<td>4 (40.0)</td>
</tr>
<tr>
<td>Outside Europe</td>
<td>5 (33.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Occupation (latest 12 months)</th>
<th>0.93</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Self) employed</td>
<td>61 (26.6)</td>
</tr>
<tr>
<td>Other</td>
<td>14 (24.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Any lifetime emotional abuse**</th>
<th>0.30</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>55 (29.6)</td>
</tr>
<tr>
<td>Yes</td>
<td>19 (18.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Any lifetime physical abuse**</th>
<th>0.33</th>
</tr>
</thead>
<tbody>
<tr>
<td>No (including mild abuse)</td>
<td>57 (26.9)</td>
</tr>
<tr>
<td>Yes</td>
<td>18 (22.6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Any lifetime sexual abuse**</th>
<th>0.08</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>66 (29.9)</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (12.9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Self-rated health</th>
<th>0.13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range 1-7 (7 being very good)</td>
<td>5 (1-7)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Household income (SEK/month before taxes)</th>
<th>0.09</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range &lt;7 000 - &gt;66 000</td>
<td>35 -44 900 (&lt;7 000 - &gt;65 000)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Subjective social status</th>
<th>0.17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range 1-10 (10 being the highest)</td>
<td>6 (1-10)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Knowledge of patient rights</th>
<th>&lt;0.01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range 0-10 (0=mone, 10=to a high degree)</td>
<td>4 (0-10)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Days to respond</th>
<th>0.49</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on 12 months to 30 days</td>
<td>18 (0-273)</td>
</tr>
</tbody>
</table>

* deviations in percentages exist due to item non-response
** according to questions from the Norvold Abuse Questionnaire
1 tested with Cramer's V
2 tested with Kruskal's Gamma

Table 1: Univariate analyses of predictor variables with the continuous dependent variable (number of times remained silent as a percentage of the total number of opportunities)
Table 2: Ordinal Logistic Regression (through a Generalized Linear Model) with study variables and ordinal dependent variable. Beta coefficients (B) and Confidence Intervals (CI) for regressions with patients’ silence towards the health care system after experiencing staff’s abusive or wrongful transgressions

Table 3: Correlation coefficients (Spearman’s rho) for knowledge of patient rights and four study variables

DISCUSSION

Despite extensive research on formal complaints and a growing interest in patients’ behaviour concerning informal complaints,[18, 19] little is known about patients’ behaviour after abusive or ethically wrongful events in health care. In the present study we investigated which patient characteristics are associated with remaining silent after such events. It was shown that this silence was negatively associated with patients’ knowledge of their rights and with their ages. However, we could not confirm associations with patients’ social status, country of birth, their backgrounds of abuse, or their health status.
A negative association was found between patients’ knowledge of patient rights and patients remaining silent. It was surprising to see that knowledge of rights were not associated with the number of experienced events, nor with the number of events perceived as abusive or wrongful. One explanation for this could be that patients’ own common sense beliefs highly converge with what is included in patient right and ethical documents. Many of these documents and guidelines are built on Beauchamp and Childress’ principles of biomedical ethics, which in its turn is based on “common-morality”.[30] For that reason, knowledge of patient rights would not change patients’ judgments of the events described in TEP. When it comes to acting after an abusive or wrongful situation, this knowledge could increase patients’ moral motivation or moral identity, feeling legitimized to act when they know ethical or legal rules had been transgressed, although no causal explanations can be made based on the current material. The fact that this knowledge was self-reported in this study may suggest the importance of patients’ beliefs that they know their rights.

In spite of the small scale and cross-sectional character of the current study, this result could suggest two entrances for future interventions. First, to aim to increase patients’ actual knowledge of their rights, for example by making information about rights more accessible. Second, to strengthen patients’ beliefs that they know what is right and wrong when staff transgresses ethical principles. The latter may be strongly related to patients’ self-efficacy, or the fact that patients believe in their capacities; which, according to Bandura, may also affect their level of motivation for a certain behavioural path.[31] Besides trying to increase patients’ knowledge of their rights through persuasive communication, Bandura defined three other sources for increasing self-efficacy.[32] The first source is ‘performance accomplishments’, which are experiences of successful outcomes after
performing certain tasks. Second, ‘vicarious experiences’, which have their starting point in
the identification with a role model. Third, ‘physiological state’, which concerns information
from one’s own bodily state. Future interventions could focus on strengthening any of these
sources, but as Bandura pointed out, mere persuasive communication is a very weak source
to increase self-efficacy, and could therefore be combined with any of the other three
sources. We believe that any patient education intervention should not only focus on
behavioural change in patients; the intervention should be sensitively embedded in clinical
practice, including the engagement of staff.[33] In the end, staff is responsible for not acting
in an abusive way towards patients.

Patients’ silence was also associated with age, but contrary to our
expectations, the youngest age group tended to remain silent slightly more often. It should
be noted, however, that this group was compared to a group of patients over 30 years of age
with relatively few respondents over the age of 65. A sample including patients > 65 years of
age could give contrary results. We may also question the initial assumption on which this
hypothesis is based, namely that patients speaking up after and abusive event is convergent
with their assertiveness. Galtung’s structuralist theory of violence [10] would suggest that
which patient characteristics are associated with silence depends on existing structures,
rather than patients’ assertiveness. For example, in a study on cancer communication
patterns, it was suggested that certain patient characteristics, such as race, strongly
influenced the physicians’ communication style, which in its turn could affect patients’
behaviour.[21] The fact that younger patients remain silent to a higher degree could,
according to this reasoning, depend on how well health care structures and staff are
prepared to motivate younger patients to speak up. Following this theoretical reasoning,
such a structural bias or prejudice could jeopardize the treatment of younger patients and
hinder these patients in becoming involved in feedback processes.

Some of our hypotheses could not be confirmed. One general explanation for
this is that the area has hardly been studied, and that our hypotheses were based on
knowledge from related fields. Also, some methodological limitations may have affected
these results. First, considering country of birth, there was a problem with small group sizes,
as in total only ten per cent of all patients were born outside Sweden. Larger groups could
have shown different results, more in line with our hypothesis. Second, the self-rated health
item we used concerned the last twelve months, while our silence operationalization
covered lifetime experiences. It would have been more accurate to estimate patients’ health
at the time of the event. Questions about other kinds of abuse also covered lifetime
experiences and hence could have happened after transgressions in health care. Besides
these methodological limitations, other explanations for the fact that we hardly found any
associations with patient characteristics could be that we missed relevant variables, or that
remaining silent is, for the most part, dependent on the structural conditions present in the
actual health care situation. It may be a sign that structural conditions, such as health care
norms and taboos, are powerful enough to outweigh the bulk of differences between
individual patients. For example, differences in patients’ social status can still imply
differences in assertiveness but they are irrelevant if all patients feel equally powerless to
act after abusive events.

As we know that male and female patients experience AHC in different
ways,[28, 30] it should be taken into account that the current study only included female
patients. A qualitative study on how Latino American women dealt with dissatisfying health
care experiences found that these women mostly avoided confrontation.[34] Instead of
confronting a physician, the women chose indirect strategies such as switching health care providers. In the study it is suggested that these strategies may reflect traditional gender norms, where women tend to avoid confrontation with authority figures.[34] In TEP, such actions are not included in the silence operationalization as they were not expected to function as direct feedback to the health care system.[20] This means that we only capture a part of women’s strategies, and also that if men apply more direct strategies, we would expect to find less silence in TEP in male patients. On the other hand, a qualitative study with male patients about their experiences of AHC showed they felt “mentally pinned”, which included their frustration after the powerlessness of not being able to act according to their interests. Hence, it could very well be that male patients also feel forced to avoid conflicts within a health care setting, deviating from a traditional male norm. Male patients’ silence should be a subject for future studies.

CONCLUSION

Remaining silent after experiencing health care staff’s abusive or wrongful transgressions was negatively associated with patients’ knowledge of their rights and patients’ ages. Both variables could offer opportunities for designing patient education interventions that stimulate patients to speak up and open up the clinical climate, but more research is needed. It should be emphasized that it is not the responsibility of patients to speak up to staff to decrease the prevalence of AHC; staff carries the responsibility for this.
ACKNOWLEDGEMENTS

The NorVold Abuse Questionnaire (NorAQ) was developed by NorVold, a research network established in 1997 to explore the prevalence of violence against women and its effects on women’s health. The NorVold research network was supported by grants from the Nordic Council of Ministers. Principal investigators: Barbro Wijma, Berit Schei. Coordinator: Katarina Swahnberg. Local investigators: Denmark: Katrine Sidenius, Malene Hilden, Finland: Erja Halmesmäki, Ulla Pikkarinen, Iceland: Tora Steingrimsdottir, Norway: Berit Schei, Hildegunn Stoum-Hinsverk, Kristin Offerdal, Sweden: Barbro Wijma, Katarina Swahnberg.

COMPETING INTERESTS

The authors declare there are no competing interests.

FUNDING

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DATA SHARING

Extra data is available by emailing A. Jelmer Brüggemann (jelmer.bruggemann@liu.se)
REFERENCES


14. Unruh KT, Pratt W. Patients as actors: The patient's role in detecting, preventing, and recovering from medical errors. *Int J Med Inform 2007;76*:S236-S244.


28. Wijma B, Schei B, Swahnberg K. NorAQ. The NorVold Abuse Questionnaire. Linköping: Division of Gender and Medicine, Faculty of Health Sciences, Linköping University 2004.


Patients’ Silence towards the Health Care System after Ethical Transgressions by Staff: Associations with Patient Characteristics in a Cross-Sectional Study among Swedish Female Patients

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</table>
TITLE: Patients’ Silence towards the Health Care System after Ethical Transgressions by Staff: Associations with Patient Characteristics in a Cross-Sectional Study among Swedish Female Patients

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KEY WORDS: abuse in health care, patient action, TEP, principle-based ethics, quality of care, patient satisfaction

WORD COUNT: 3918
ABSTRACT

Objectives: To identify which patient characteristics are associated with silence towards the health care system after experiences of abusive or ethically wrongful transgressive behaviour by healthcare staff.

Design: Cross-sectional questionnaire study using the Transgressions of Ethical Principles in Health Care Questionnaire.

Setting: A women’s clinic in the south of Sweden

Participants: Selection criteria were: consecutive female patients coming for an outpatient appointment, >18 years old, with the ability to speak and understand the Swedish language, and a known address. Questionnaires were answered by 534 women (60%) who had visited the clinic, of which 293 were included in the present study sample.

Primary outcome measure: How many times the respondent remained silent towards the health care system relative to the number of times the respondent spoke up.

Results: Associations were found between patients’ silence towards the health care system and young age as well as lower self-rated knowledge of patient rights. Both variables showed independent effects on patients’ silence in a multivariate model. No associations were found with social status, country of birth, health, or other abuse.

Conclusions: The results offer opportunities for designing interventions to stimulate patients to speak up and open up the clinical climate, for which the responsibility lies in the hands of staff; but more research is needed.
ARTICLE SUMMARY

Article focus

- Many patients remain silent towards the health care system after experiencing abusive or wrongful ethical transgressions by staff, in this article it is examined which patient characteristics influence whether or not to speak up about such events

Key messages

- It was shown that remaining silent towards the health care system was negatively associated with the knowledge that patients have of their rights and with the patients’ ages
- Associations between remaining silent towards the health care system and patients’ social status, country of birth, their backgrounds of abuse, or their health status could not be confirmed
- The results could inform patient education interventions that stimulate and enable patients to speak up

Strengths and limitations of this study

- This study is the first to examine which patient characteristics associate with remaining silent to the health care system after experiencing abusive or wrongful ethical transgressions
- Due measurement problems, including small group sizes, not all hypotheses could be tested with equal statistical rigidity
INTRODUCTION

A recent volume of BMJ Quality and Safety focused on patients’ “bad experiences in the hospital”.[1] These experiences, illustrated in two patient stories, highlighted inhumane aspects of care, beyond or despite technically correct treatment.[2, 3] Similar experiences have also been labelled abuse in health care (AHC) and high numbers have been reported. AHC has been described as patients’ subjective experiences characterized by a lack of care, which implies suffering and the feeling of losing one’s value as a human being.[4] These events are most often of unintentional nature. Studies in the Nordic countries showed that lifetime prevalence of AHC ranged between 13 and 28 per cent in female patients.[5] Current suffering was reported by eight to 20 per cent of all women.[5] The approximate prevalence of AHC among Swedish men was seven per cent, and four per cent of the male sample reported current suffering.[6] Qualitative studies have shown that female patients who experienced AHC felt powerless and ignored, and experienced carelessness and non-empathy, resulting in the core category “being nullified”.[7] A related study among male patients showed that men had similar experiences, but instead of turning their emotions inwards, they wanted to express their emotions and felt hindered in doing so, resulting in the core category “being mentally pinioned”.[8]

It can be assumed that face-to-face incidents of violence never exist in isolation. Johan Galtung’s theory of violence views these incidents of direct violence as part of a complex environment, consisting of possible violent structures and cultural norms and taboos, which feed and legitimize direct.[9-12] If health care providers want to understand and change these structures and cultures it is important to structurally include patients in health care processes, as some have suggested for the prevention of medical errors and quality improvement.[13, 14] According to sociologist Anthony Giddens, structures are the
rules and routines that at the same time enable and limit individuals’ behaviour.[15] Each
time individuals act according to existing routines, these routines are reproduced and
confirmed. These routines, however, can be changed through different feedback
mechanisms inherent to the process of reproducing structures. A first step in that direction
could be to examine and consider patients’ feedback to the health care system.

One branch of research that aims to include patients’ evaluations in health care
processes are studies of formal patient complaints.[16, 17] However, it has been shown that
formal complaints are strongly biased and only represent specific patients and events, for
example those events that patients feel competent to complain about, such as a hospital’s
“hotel” services.[18] In a study on the expression of dissatisfaction, a British research group
found that only a small number of incidents were filed as formal complaints; the majority of
expressions was done verbally, and the patient did not label this as “complaining”. [18] This
suggests it could be more accurate and preferable to also concentrate on other forms of
feedback, such as directly speaking up to staff: so-called “informal complaints”. [19]

In a recent study based on the Transgressions of Ethical Principles in Health
Care Questionnaire (TEP), AHC was operationalized as patients’ experiences of staff’s ethical
transgressions and it was examined to what extent patients speak up or remain silent
towards the health care system after experiencing such events. [20] In the study (N=530) it
was found that the vast majority of female patients had experienced such events, and many
patients experienced these events as abusive and wrongful. More than two-thirds of these
patients had remained silent towards the health care system about at least one experienced
event. For some transgressions, more than 80 per cent of the patients had kept silent,
despite feeling abused by the event or judging it as wrongful. Patients’ silence about abusive
events is alarming as it is not only directly harmful to patients, but a lack of patient feedback also hampers structural improvements.

Patients might have certain characteristics that determine whether or not they speak up about abuse they may have experienced within the health care system. The overarching aim of this study, also based on TEP, was to gain knowledge about these characteristics, which could contribute to more effective clinical interventions that ultimately decrease the prevalence of AHC, for which health care staff is responsible.

**Hypotheses**

We hypothesized that patients’ silence towards the health care system was related to their older age, lower social status, and foreign birth (outside of Sweden). Each of these characteristics has shown to be associated with low levels of assertiveness in medical settings, and with lower rates of informal complaining.[19, 21-23] It was also hypothesized that patients with a history of other kinds of abuse were more likely to remain silent towards the health care, as they may have felt more guilt and shame caused by fear of negative reactions and blame by others.[12] Furthermore, we hypothesized that the occurrence of patients remaining silent towards the health care system could be related to their poor health and little knowledge of patient rights.

**METHOD**

**Subjects and procedure**

Over the period between September 2009 and May 2010, TEP was sent to 890 female patients [20]. These patients were recruited at a women’s clinic at a county hospital in the south of Sweden. This clinic was chosen because of an ongoing collaboration between the
clinic and our research group, and because of the clinic’s great variety of patients, including those coming for routine screening procedures. Also, female patients have reported AHC to a much higher degree than men, which was another reason to explore these questions in a female sample. The sample was selected according to the following criteria: participants must 1. be a consecutive female patient coming for an outpatient appointment, 2. be ≥18 years old, 3. speak and understand the Swedish language, and 4. have a known address. Patients first received an information letter from a secretary at the clinic and had the option to decline participation. Patients who did not decline participation received a second information letter, TEP, and a pre-paid return envelope at home. Two reminders were sent out with two-week intervals. The study was approved by the regional ethical review board (reg.no. M116-09).

Measurements

TEP describes 23 events that operationalize transgressions of ethical principles in health care. Five categories of transgressed ethical principles were identified, and the events were distributed over these categories as follows: autonomy 5; justice 2; physical non-maleficence 4; integrity 4; sexual non-maleficence 8 (Box 1).
Have you ever experienced in Swedish health care that...

**Autonomy principle**
you were not adequately informed?
you did not get enough time to consider (e.g. options)
your opinion was not taken notice of?
you were not listened to?
you felt forced to accept a treatment or a sampling against your will because of fear for maltreatment if you did not?

**Justice principle**
another patient was allowed to pass you in the queue without having a reason?
you did not get the care you think you have the right to get?

Have you ever experienced in Swedish health care that staff...

**Physical nonmaleficence principle**
held you firmly against your will?
performed an examination/treatment in a too rough way?
continued an examination in spite of your protests?
hit you or threatened to hit you?

**Integrity principle**
exposed you to mockery?
humiliated you?
made you feel forgotten or neglected?
violated his/her professional secrecy concerning you?

**Sexual nonmaleficence principle**
watched you undress or dress instead of offering you to do it in private?
commented or criticized with a sexual undertone, your underwear or your body?
flirted or talked to you in a seductive way?
told you about his/her own sexual preferences, problems or fantasies?
performed an examination in a way that you perceived as having an undertone of sex?
touched in a sexual way your breasts, external genitals or other parts of your body?
encourages you to masturbate or made you watch him/her masturbate?
wished to start a sexual relationship with you?

Box 1: Operationalizations of ethical principles in the Transgressions of Ethical Principles in Health Care Questionnaire

Patients report whether they experienced such events, whether they experienced them as abusive, whether they judged the event as wrongful, and whether they acted upon it or spoke up (Box 2). ‘Remaining silent’ was defined as patients refraining from giving direct feedback to the health care system, despite experiencing an event as abusive or wrongful.

The face validity of this ‘silence construction’, based on a qualitative judgment, was considered to be good.[20] Patients’ reports of abusive transgressions in TEP also showed satisfactory convergent validity with patients’ reports to the AHC questions from the
validated Norvold Abuse Questionnaire (NorAQ; validated in a Swedish female sample)[24]; sensitivity and specificity were found to be 82% and 80% respectively.

The way ‘remaining silent’ was operationalized in TEP has a starting point in James Rest’s four component model of moral behaviour.[25] This model identifies four components that are necessary for moral action to come about: moral sensitivity, moral judgment, moral motivation, and moral character. In TEP, these components were transformed into questions concerning patients’ experiences of and actions after staff’s transgressions. More detailed information about TEP and its underlying theoretical assumptions have been described elsewhere.[20]

**Box 2: Transgression and silence questions in the Transgressions of Ethical Principles in Health Care Questionnaire**

<table>
<thead>
<tr>
<th>Have you ever experienced in Swedish health care that...</th>
<th>A Did you perceive what happened as abusive?</th>
<th>B Did you judge what happened as wrongful?</th>
<th>C Have you talked about what happened with the health care staff, complained, or made clear in any other way that you experienced what happened in this way?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example cases of transgression</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
</tr>
</tbody>
</table>

TEP also includes questions about socio-demography, history of abuse, self-rated health, and knowledge of patient rights.

Questions about socio-demography included ‘year-of-birth’ (age recoded into two categories: < 30, ≥ 30 years; fit line in scatterplot with age and the dependent variable showed a clear cut-off at age 30), ‘education’ (recoded into three categories: < 10, 10-12, > 12 years), ‘country of birth’ (recoded into four categories: Sweden, other Nordic country, other European country, outside Europe), ‘occupation’ (recoded into two categories: [self]
employed or other, which included: studying, unemployed, parental leave, sick leave, 
retired, social welfare, homemaker), ‘income’ (original alternatives: < 7000, 7-14900, 15-
24900, 25-34900, 35-44900, 45-54900, 55-65000, > 65000 SEK), and ‘subjective social 
status’, based on the idea of how one sees oneself in relation to others in society, 
considering money, job, and education.[26] The MacArthur Scale of Subjective Social Status 
(a 10 point ladder rank) is a well-established instrument of which we used a Swedish 
translation [27]. This measurement was expected to better explain variance in silence than 
the objective measurements of ‘income’, ‘education’, and ‘occupation’. Objective 
measurements are useful for the guidance of effective interventions, since they are more 
concrete than ‘subjective social status’[27], and they were therefore included as well.

The patients’ history of other kinds of abuse, i.e. emotional, physical, and 
sexual, was measured using the abuse questions from NorAQ.[28] The questionnaire 
identifies different levels of abuse: mild, moderate, and severe. The abuse questions in 
NorAQ have shown good reliability and validity, with an interview as the gold standard in a 
sample of Swedish women [n=64; 24]. A full version of the abuse questions in NorAQ can be 
found in Swahnberg et al.[5] Respondents who answered yes to at least one of the three 
questions for each type of abuse were regarded as having experienced that type of abuse, 
regardless of severity. The exception to this was ‘mild physical abuse’, which was shown to 
be rather unspecific,[24] and which was included in the category ‘no lifetime physical abuse’.

‘Self-rated health’ was measured on a seven point Likert item (1=very bad, 7=very good). 
Lastly, knowledge of patient rights was operationalized as self-rated knowledge of these 
rights, asking respondents to rate their knowledge level on an 11-point item (original coding: 
0=none, 10=to a high degree).
As it has been suggested that non-response can be seen as an extrapolation of late response, we included the variable ‘days to respond’, based on 30 days to 12 months.[29] Any association between this variable and an outcome variable could point at a possible response bias in the data set.

Study design

From the abovementioned silence operationalization in TEP, we developed a dependent variable that indicates how many times the respondent remained silent relative to the number of times the respondent spoke up, expressed as a percentage of the total number of opportunities to remain silent and speak up (continuous variable, 0–100, where 100 per cent indicated ‘remained silent after all events’ and 0 per cent meant ‘acted after all events’). As this variable showed a U-distribution, which was hard to model as a dependent variable, it was chosen to trichotomize the variable (ordinal: 1=0%, 2=1-99%, 3=100%; Figure 1).

Associations with silence were first tested univariately, using Cramer’s V (nominal by ordinal) and Kruskal’s Gamma (ordinal by ordinal, and interval by ordinal). Accordingly, all variables that tested significantly were included in an ordinal logistic regression model (through a Generalized Linear Model) testing for the main effect of these variables on the ordinal dependent variable. ‘Knowledge of patient rights’ was entered as a covariate, assuming a continuous scale. Missing values due to item non-response were excluded from the analyses.

Statistical analyses were performed using the IBM Statistical Package of the Social Sciences 19.0. Test results with a p-value of <0.05 were considered significant.

*** Figure 1 near here***
RESULTS

Sixty per cent (534/891) of female patients answered and returned TEP and 530 were included in our final dataset, as four respondents were excluded (one male patient, and three patients because of invalid answers or more than half of the answers missing). Fifty-five per cent of the sample (293/530) reported at least one transgression that they judged abusive or wrongful and were included in the present study sample (see Figure 2). Background data are shown in Table 1 and more detailed information about the total sample is described elsewhere [20]. For all variables shown in Table 1, the number of participants with missing values ranged between two and eleven.

Univariate analyses showed no associations between ‘remaining silent’ and the patients’ social status, country of birth, their background of abuse, or their health status. Associations were found with ‘age’ and ‘knowledge of patient rights’ (Table 1). Considering ‘age’, the youngest age group reported a higher rate of silence towards the health care system (Figure 3). ‘Knowledge of patient rights’ was negatively correlated with ‘remaining silent’, implying that a higher reported knowledge was associated with a lower rate of silence towards the health care system (Figure 4).

The regression model that included both of these variables showed that both ‘age’ and ‘knowledge of patient rights’ had an effect on ‘remaining silent’ (Table 2). ‘Age’ and ‘knowledge of patient rights’ were not associated with each other.

This result did not change when only looking at abusive or wrongful events, although the association between ‘remaining silent’ after abusive events and ‘knowledge of patient rights’ was only significant if ‘remaining silent’ was used as a dichotomous variable (1=0%, 2=1-100%) in a binary regression model (data not shown).
Further examination showed that ‘knowledge of patient rights’ did not correlate with the number of events experienced, nor with the number of events that were perceived as abusive or wrongful (Table 3).

***Figure 2, 3, and 4 near here***
Table 1: Univariate analyses of predictor variables with the ordinal dependent variable (expressed as the number of times remained silent as a percentage of the total number of opportunities)

<table>
<thead>
<tr>
<th>n=293*</th>
<th>Remained silent</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0%</td>
<td>1-99%</td>
</tr>
<tr>
<td>Age (range 19-85, mean 42.5 ± 14.0)</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>&lt; 30</td>
<td>8 (14.0)</td>
<td>17 (29.8)</td>
</tr>
<tr>
<td>≥ 30</td>
<td>68 (29.1)</td>
<td>74 (31.6)</td>
</tr>
<tr>
<td>Education (years)</td>
<td>0.84</td>
<td></td>
</tr>
<tr>
<td>&lt;10</td>
<td>9 (24.3)</td>
<td>13 (35.1)</td>
</tr>
<tr>
<td>10-12</td>
<td>30 (24.8)</td>
<td>37 (30.6)</td>
</tr>
<tr>
<td>&gt;12</td>
<td>36 (27.1)</td>
<td>40 (30.1)</td>
</tr>
<tr>
<td>Country of birth</td>
<td>0.91</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>63 (24.4)</td>
<td>82 (31.8)</td>
</tr>
<tr>
<td>Other Nordic country</td>
<td>1 (20.0)</td>
<td>2 (40.0)</td>
</tr>
<tr>
<td>Other European country</td>
<td>4 (40.0)</td>
<td>3 (30.0)</td>
</tr>
<tr>
<td>Outside Europe</td>
<td>5 (33.3)</td>
<td>4 (26.7)</td>
</tr>
<tr>
<td>Occupation (latest 12 months)</td>
<td>0.93</td>
<td></td>
</tr>
<tr>
<td>(Self) employed</td>
<td>61 (26.6)</td>
<td>69 (30.1)</td>
</tr>
<tr>
<td>Other</td>
<td>14 (24.1)</td>
<td>18 (31.0)</td>
</tr>
<tr>
<td>Any lifetime emotional abuse**</td>
<td>0.30</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>55 (29.6)</td>
<td>51 (27.4)</td>
</tr>
<tr>
<td>Yes</td>
<td>19 (18.3)</td>
<td>40 (38.5)</td>
</tr>
<tr>
<td>Any lifetime physical abuse**</td>
<td>0.33</td>
<td></td>
</tr>
<tr>
<td>No (including mild abuse)</td>
<td>57 (26.9)</td>
<td>57 (26.9)</td>
</tr>
<tr>
<td>Yes</td>
<td>18 (22.8)</td>
<td>34 (34.0)</td>
</tr>
<tr>
<td>Any lifetime sexual abuse**</td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>66 (29.9)</td>
<td>61 (27.6)</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (12.9)</td>
<td>29 (41.4)</td>
</tr>
</tbody>
</table>

| Median (range) | 0.13 |
| Self-rated health | 5 (1-7) |
| Household income (SEK/month before taxes) | 0.09 |
| Range <7000 - >65000 | 35-44900 (<7000 - >65000) |
| Subjective social status | 0.17 |
| Range 1-10 (10 being the highest) | 6 (1-10) |
| Knowledge of patient rights | <0.01 |
| Range 0-10 (0=none, 10=to a high degree) | 4 (0-10) |
| Days to respond | 0.49 |
| Based on 12 months to 30 days | 18 (0-273) |

* deviations in percentages exist due to item non-response
** according to questions from the Norvold Abuse Questionnaire
1 tested with Cramer’s V
2 tested with Kruskal’s Gamma
Table 2: Ordinal Logistic Regression (through a Generalized Linear Model) with study variables and ordinal dependent variable. Beta coefficients (B) and Confidence Intervals (CI) for regressions with patients’ silence towards the health care system after experiencing staff’s abusive or wrongful transgressions

<table>
<thead>
<tr>
<th>Threshold</th>
<th>B</th>
<th>SE</th>
<th>lower</th>
<th>upper</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remained silent 0%</td>
<td>-2.07</td>
<td>0.34</td>
<td>2.74</td>
<td>1.40</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Remained silent 1-99%</td>
<td>-0.82</td>
<td>0.32</td>
<td>1.45</td>
<td>-0.18</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Age

<table>
<thead>
<tr>
<th>Age</th>
<th>B</th>
<th>SE</th>
<th>lower</th>
<th>upper</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 30</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 30</td>
<td>-0.71</td>
<td>0.29</td>
<td>-1.29</td>
<td>-0.14</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Knowledge of patient rights

<table>
<thead>
<tr>
<th>Knowledge of patient rights</th>
<th>B</th>
<th>SE</th>
<th>lower</th>
<th>upper</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-0.11</td>
<td>0.04</td>
<td>-0.19</td>
<td>-0.03</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Likelihood Ratio Chi-Square: 13.60, p<0.01 (fitted model against thresholds-only model)

* n=18 excluded due to item non-response

Table 3: Correlation coefficients (Spearman’s rho) for ‘knowledge of patient rights’ and four study variables (on a continuous scale)

<table>
<thead>
<tr>
<th>Knowledge of patient rights</th>
<th>n=288*</th>
<th>n=288</th>
<th>n=288</th>
<th>n=277</th>
</tr>
</thead>
<tbody>
<tr>
<td>number of experienced events</td>
<td>&lt;0.01</td>
<td>-0.20</td>
<td>&lt;0.01</td>
<td>-0.19 **</td>
</tr>
<tr>
<td>number of events perceived as abusive</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>number of events judged as wrongful</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>remained silent relative to opportunities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* deviations in sample size exist due to item non-response

** p<0.01
DISCUSSION

Despite extensive research on formal complaints and a growing interest in patient behaviour concerning informal complaints,[18, 19] little is known about patient behaviour after abusive or ethically wrongful events in health care. In the present study, we investigated which patient characteristics are associated with remaining silent after such events. It was shown that this silence was negatively associated with the knowledge that patients have of their rights and with the patients’ ages. However, we could not confirm associations with patients’ social status, country of birth, their backgrounds of abuse, or their health status.

A negative association was found between the knowledge that patients have of their rights and patients remaining silent towards the health care system. It was surprising to see that knowledge of patient rights was not associated with the number of experienced events, nor with the number of events perceived as abusive or wrongful. One explanation for this could be that patients’ “common sense” beliefs highly converge with what is included in patient right and ethical documents, and that more knowledge about these rights not necessarily leads to more experiences of transgressions. Many of the ethical documents and guidelines are based on Beauchamp and Childress’ principles of biomedical ethics, which in its turn is based on “common-morality”. [30] For that reason, knowledge of patient rights would not change patients’ judgments of the events described in TEP. However, when it comes to acting after an abusive or wrongful situation, this knowledge could increase a patient’s moral motivation or moral identity, and help her to feel legitimized to act when she knows ethical or legal rules have been transgressed, although no conclusions about causality can be made based on the current material. The fact that this
patients’ knowledge was self-reported in this study may suggest the importance of patients believing that they know their rights, rather than patients actually knowing their rights.

In spite of the small-scale and cross-sectional character of the current study, this result could suggest two entrances for future interventions. The first entrance could be to increase the actual knowledge patients have of their rights, for example by making information about rights more accessible. The second could be to strengthen the belief that patients know what is right and wrong when a staff member transgresses ethical principles. The latter may be strongly related to patients’ self-efficacy, or the fact that patients believe in their capacities; which, according to Bandura, may also affect their level of motivation for a certain behavioural path.[31] Besides trying to increase the knowledge patients have of their rights through persuasive communication, Bandura defined three other sources for increasing self-efficacy.[32] The first source is ‘performance accomplishments’, which are experiences of successful outcomes after performing certain tasks. The second source is ‘vicarious experiences’, which have a starting point in the identification with a role model. Third, we see a ‘physiological state’, which concerns information from a patient’s own bodily state. Future interventions could focus on strengthening any of these sources, but as Bandura pointed out, mere persuasive communication is a very weak source for increasing self-efficacy, and could therefore better be combined with any of the other three sources.

More importantly, we believe that any patient education intervention should not only focus on behavioural change in patients; the intervention should be sensitively embedded in clinical practice, including the engagement of staff.[33] In the end, staff is responsible for not acting in an abusive way towards patients.

Patients’ silence towards the health care system was also associated with age, but contrary to our expectations, the youngest age group tended to remain silent slightly
more often. It should be noted, however, that this group was compared to a group of patients over 30 years of age with relatively few respondents over the age of 65. A sample including patients > 65 years of age could give contrary results. We could also discuss the initial assumption on which this hypothesis is based, namely that patients speaking up after and abusive event is convergent with their assertiveness. Galtung’s structuralist theory of violence [10] would suggest that which patient characteristics are associated with silence depends on existing structures, rather than patients’ assertiveness. For example, in a study on cancer communication patterns, it was suggested that certain patient characteristics, such as race, strongly influenced the physicians’ communication style, which in its turn could affect patient behaviour.[21] The fact that younger patients remain silent to a higher degree could, according to this reasoning, depend on how well health care structures and staff are prepared to motivate younger patients to speak up. Following this theoretical reasoning, such a structural bias or prejudice could jeopardize the treatment of younger patients and hinder these patients in becoming involved in feedback processes.

Some of our hypotheses could not be confirmed. One general explanation for this is that the area has hardly been studied, and that our hypotheses were based on knowledge from related fields. Also, some methodological limitations may have affected these results. First, considering country of birth, the small group sizes posed a problem, as in total only ten per cent of all patients were born outside Sweden. Larger groups could have shown different results, more in line with our hypothesis. Second, the self-rated health item we used concerned the last twelve months, while our silence operationalization covered lifetime experiences. It would have been more accurate to estimate patients’ health at the time of the event. Questions about other kinds of abuse also covered lifetime experiences and hence could have happened after transgressions in health care. Besides these
methodological limitations, other explanations for the fact that we found only two associations with patient characteristics could be that we missed relevant variables, or that remaining silent is, for the most part, dependent on the structural conditions present in the actual health care situation. It may be a sign that structural conditions, such as health care norms and taboos, are powerful enough to outweigh the bulk of differences between individual patients. For example, differences in patients’ social status can still imply differences in assertiveness but they are irrelevant if all patients feel equally powerless to act after abusive events.

As we know that male and female patients experience AHC in different ways,[28, 30] it should be taken into account that the current study only included female patients. A qualitative study on how Latino American women dealt with dissatisfying health care experiences found that these women mostly avoided confrontation.[34] Instead of confronting a physician, the women chose indirect strategies such as switching health care providers. In that study it is suggested that these strategies may reflect traditional gender norms, where women tend to avoid confrontation with authority figures.[34] In TEP, such actions are not included in the silence operationalization as they were not expected to function as direct feedback to the health care system.[20] This means that we only capture a part of women’s strategies, and also that if men apply more direct strategies, we would expect to find less silence in TEP in male patients. On the other hand, a qualitative study with male patients about their experiences of AHC showed that they felt “mentally pinioned”, which included their frustration after the powerlessness of not being able to act according to their interests. Hence, it could very well be that male patients also feel forced to avoid conflicts within a health care setting, deviating from a traditional male norm. Male patients’ silence could be a subject for future studies.
CONCLUSION

Remaining silent after experiencing health care staff’s abusive or wrongful transgressions was negatively associated with the knowledge that patients have of their rights and with their ages. Both these variables could offer opportunities for designing patient education interventions that stimulate patients to speak up and open up the clinical climate, but more research is needed. It should be emphasized that it is not the responsibility of patients to speak up to staff to decrease the prevalence of AHC; staff carries the responsibility for this.

ACKNOWLEDGEMENTS

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COMPETING INTERESTS

The authors declare there are no competing interests.

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DATA SHARING

Extra data is available by emailing A. Jelmer Brüggemann (jelmer.bruggemann@liu.se)

CONTRIBUTORSHIP

A. Jelmer Brüggemann: study conception/design, data collection and analysis, drafting of manuscript, critical revisions for important intellectual content.

K. Swahnberg: study conception/design, data collection/analysis, critical revisions for important intellectual content, supervision

REFERENCES


28. Wijma B, Schei B, Swahnberg K. NorAQ. The NorVold Abuse Questionnaire. Linköping: Division of Gender and Medicine, Faculty of Health Sciences, Linköping University 2004.


TITLE: Patients’ Silence towards the Health Care System after Ethical Transgressions by Staff: Associations with Patient Characteristics in a Cross-Sectional Study among Swedish Female Patients

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KEY WORDS: abuse in health care, patient action, TEP, principle-based ethics, quality of care, patient satisfaction

WORD COUNT: 35103918
ABSTRACT

Objectives: To identify which patient characteristics are associated with silence towards the health care system after having experienced experiences of abusive or ethically wrongful transgressions of ethical principles by healthcare staff.

Design: Cross-sectional questionnaire study using the Transgressions of Ethical Principles in Health Care Questionnaire (TEP).

Setting: A women’s clinic in the south of Sweden.

Participants: The sample was selected according to the following criteria: participants must 1. be consecutive female patients coming for an outpatient appointment, 2. be >18 years old, 3. have the ability to speak and understand the Swedish language, and 4. have a known address. Questionnaires were answered by 534 women (60%) who had visited the clinic, of which 293 were included in the present study sample.

Primary outcome measure: how many times the respondent remained silent towards the health care system relative to the number of times the respondent spoke up.

Results: Associations were found between patients’ silence after abusive or wrongful transgressions towards the health care system and young age as well as lower self-rated knowledge of patient rights. Both variables showed independent effects on patients’ silence in a multivariate model. No associations were found with social status, country of birth, health, or other abuse.

Conclusions: Patients’ silence towards the health care system after abusive or wrongful ethical transgressions in health care was associated with young ages and less knowledge of patient rights. Both variables offer opportunities for designing interventions to stimulate patients to speak up and open up the clinical climate, for which the responsibility lies in the hands of staff; but more research is needed.
ARTICLE SUMMARY

Article focus

- Many patients remain silent towards the health care system after experiencing abusive or wrongful ethical transgressions by staff, in this article it is examined which patient characteristics influence whether or not to speak up about such events.

Key messages

- It was shown that remaining silent towards the health care system was negatively associated with the knowledge that patients have of their rights and with the patients’ ages.
- Associations between remaining silent towards the health care system and patients’ social status, country of birth, their backgrounds of abuse, or their health status could not be confirmed.
- The results could inform patient education interventions that stimulate and enable patients to speak up.

Strengths and limitations of this study

- This study is the first to examine which patient characteristics associate with remaining silent to the health care system after experiencing abusive or wrongful ethical transgressions.
- Due measurement problems, including small group sizes, not all hypotheses could be tested with equal statistical rigidity.
INTRODUCTION

In a recent volume of BMJ Quality and Safety, focus was focused on patients’ “bad experiences in the hospital”. These experiences, illustrated in two patient stories, highlighted inhumane aspects of care, beyond or despite technically correct treatment. Similar experiences have also been labelled abuse in health care (AHC), and high numbers have been reported. AHC has been described as patients’ subjective experiences characterized by a lack of care, which implies suffering and the feeling of losing one’s value as a human being. These events are most often of unintentional nature. Studies in the Nordic countries showed that lifetime prevalence of AHC ranged between 13 and 28 per cent in female patients. Current suffering was reported by eight to 20 per cent of all women. The approximate prevalence of AHC among Swedish men was seven per cent, and four per cent of the male sample reported current suffering. Qualitative studies have shown that female patients who experienced AHC felt powerless and ignored, and experienced carelessness and non-empathy, resulting in the core category “being nullified”. A related study among male patients showed that men had similar experiences, but instead of turning their emotions inwards, they wanted to express their emotions and felt hindered in doing so, resulting in the core category “being mentally pinned”. It may be assumed that face-to-face incidents of violence never exist in isolation. Johan Galtung’s theory of violence views these incidents of direct violence as part of a complex environment, consisting of possible violent structures and cultural norms and taboos, which feed and legitimize direct violence. If health care providers want to understand and change these structures and cultures it is important to structurally include patients in health care processes, as some have suggested for the prevention of medical errors and quality improvement. According
to sociologist Anthony Giddens, structures are the rules and routines that at the same time enable and limit individuals' behaviour.[15] Each time individuals act according to existing routines, these routines are reproduced and confirmed. These routines, however, can be changed through different feedback mechanisms inherent to the process of reproducing structures. A first step in that direction could be to examine and consider patients’ feedback to the health care system.

One branch of research that aims to include patients’ evaluations in health care processes are studies of formal patient complaints.[16, 17] However, it has been shown that formal complaints are strongly biased and only represent specific patients and events, for example those events that patients feel competent to complain about, e.g., such as a hospital’s “hotel” services.[18] In a study on the expression of dissatisfaction, a British research group found that only a small number of incidents were filed as formal complaints; the majority of expressions was done verbally, and the patient did not label this as “complaining”.[18] This suggests it could be more accurate and preferable to also concentrate on other forms of feedback, such as directly speaking up to staff: so-called “informal complaints”.[19]

In a recent study based on the Transgressions of Ethical Principles in Health Care Questionnaire (TEP), AHC was operationalized as patients’ experiences of staff’s ethical transgressions and it was examined to what extent patients speak up or remain silent towards the health care system after experiencing such events.[20][20] In the study (N=530) it was found that the vast majority of female patients had experienced such events, and many patients experienced these events as abusive and wrongful. More than two-thirds of these patients had ever remained silent towards the health care system about at least one experienced event. For some transgressions, more than 80 per cent of the patients had kept
silent, despite feeling abused by the event or judging it as wrongful. Patients’ silence about abusive events is alarming as it is not only directly harmful to patients, but a lack of patient feedback also hampers structural improvements.

Knowledge about which patient characteristics are associated with silence about abusive events that determine whether or not they speak up about abuse they may have experienced within the healthcare system could shed light on which patients’ voices are heard less than others. The overarching aim of this study, also based on TEP, was to gain knowledge about these characteristics, which could contribute to more effective clinical interventions that ultimately decrease the prevalence of AHC, for which healthcare staff is responsible. Therefore the current study, also based on TEP, aimed to identify which patient characteristics are associated with silence towards the healthcare system after having experienced abusive or wrongful transgressions of ethical principles by healthcare staff.

Hypotheses

We hypothesized that patients’ silence towards the healthcare system was related to their older age, lower social status, and being “ethnic” (not born in foreign birth (outside of Sweden), all of which have shown to be associated with low levels of assertiveness in medical settings, and with lower rates of informal complaining.[19, 21-23] It was also hypothesized that patients with a history of other kinds of abuse remained more likely to remain silent to a higher degree towards the healthcare, as they may have felt more guilt and shame caused by fear of negative reactions and blame by others.[12] Furthermore, we hypothesized that the occurrence of patients
remaining silent towards the health care system could be related to their poor health and little knowledge of patient rights.

**METHOD**

**Subjects and procedure**

Over the period between September 2009 and May 2010, TEP was sent to 890 female patients. These patients were recruited at a women’s clinic at a county hospital in the south of Sweden. This clinic was chosen because of an ongoing collaboration between the clinic and our research group, and because of the clinic’s great variety of patients, including those coming for routine screening procedures. Also, female patients have reported AHC to a much higher degree than men, which was another reason to explore these questions in a female sample. The sample was selected according to the following criteria: participants must 1. be a consecutive female patient coming for an outpatient appointment, 2. be >18 years old, 3. speak and understand the Swedish language, and 4. have a known address. Patients first received an information letter from a secretary at the clinic and had the option to decline participation. Patients who did not decline participation received a second information letter, TEP, and a pre-paid return envelope at home. Two reminders were sent out with two-week intervals. The study was approved by the regional ethical review board (reg.no. M116-09).

**Measurements**

TEP describes 23 events that operationalize transgressions of ethical principles in health care. The five categories of transgressed ethical principles were identified, and the events...
were distributed between the principles over these categories as follows: autonomy 5; justice 2; physical non-maleficence 4; integrity 4; sexual non-maleficence 8 (Box 1).

Have you ever experienced in Swedish health care that...

**Autonomy principle**
- you were not adequately informed?
- you did not get enough time to consider (e.g. options)
- your opinion was not taken notice of?
- you were not listened to?
- you felt forced to accept a treatment or a sampling against your will because of fear for maltreatment if you did not?

**Justice principle**
- another patient was allowed to pass you in the queue without having a reason?
- you did not get the care you think you have the right to get?

Have you ever experienced in Swedish health care that staff...

**Physical nonmaleficence principle**
- held you firmly against your will?
- performed an examination/treatment in a too rough way?
- continued an examination in spite of your protests?
- hit you or threatened to hit you?

**Integrity principle**
- exposed you to mockery?
- humiliated you?
- made you feel forgotten or neglected?
- violated his/her professional secrecy concerning you?

**Sexual nonmaleficence principle**
- watched you undress or dress instead of offering you to do it in private?
- commented or criticized with a sexual undertone, your underwear or your body?
- flirted or talked to you in a seductive way?
- told you about his/her own sexual preferences, problems or fantasies?
- performed an examination in a way that you perceived as having an undertone of sex?
- touched in a sexual way your breasts, external genitals or other parts of your body?
- encouraged you to masturbate or made you watch him/her masturbate?
- wished to start a sexual relationship with you?

---

**Box 1: Operationalizations of ethical principles in the Transgressions of Ethical Principles in Health Care Questionnaire**

Patients report whether they experienced such events, whether they experienced them as abusive, whether they judged the event as wrongful, and whether they acted upon it or spoke up (Box 2). "Remaining silent" was defined as patients refraining from giving...
direct feedback to the health care system, despite experiencing an event as abusive or wrongful.

<table>
<thead>
<tr>
<th>Have you ever experienced in Swedish health care that...</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you perceive what happened as abusive?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you judge what happened as wrongful?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you talked about what happened with the health care staff, complained, or made clear in any other way that you experienced what happened in this way?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Box 2: Transgression and silence questions in the Transgressions of Ethical Principles in Health Care Questionnaire**

The face validity of the silence construction, based on a qualitative judgment, was judged to be good. Patients’ reports of abusive transgressions in TEP also showed satisfactory convergent validity with patients’ reports to the AHC questions from the validated Norvold Abuse Questionnaire (NorAQ; validated in a Swedish female sample). The silence operationalization; sensitivity and specificity were found to be 82% and 80% respectively.

The way ‘remaining silent’ was operationalized in TEP has a starting point in James Rest’s four component model of moral behaviour. This model identifies four components that are necessary for moral action to come about: moral sensitivity, moral judgment, moral motivation, and moral character. These components were then transformed into questions concerning patients’ experiences of and actions after staff’s transgressions. More detailed information about TEP and its underlying theoretical assumptions have been described elsewhere.
Box 2: Transgression and silence questions in the Transgressions of Ethical Principles in Health Care Questionnaire

<table>
<thead>
<tr>
<th>A</th>
<th>Did you perceive what happened as abusive?</th>
<th>B</th>
<th>Did you judge what happened as wrongful?</th>
<th>C</th>
<th>Have you talked about what happened with the health care staff, complained, or made clear in any other way that you experienced what happened in this way?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Example cases of transgression:

- Yes / No
- Yes / No
- Yes / No
- Yes / No

TEP also includes questions about socio-demography, history of abuse, self-rated health, and knowledge of patient rights.

Questions about socio-demography included 'year-of-birth' (age recoded into two categories: < 30, ≥ 30 years; fit line in scatterplot with age and the dependent variable showed a clear cut-off at age 30), 'education' (recoded into three categories: < 10, 10-12, > 12 years), 'country of birth' (recoded into four categories: Sweden, other Nordic country, other European country, outside Europe), 'occupation' (recoded into two categories: [self] employed or other, which included: studying, unemployed, parental leave, sick leave, retired, social welfare, homemaker), 'income' (original alternatives: < 7000, 7-14900, 15-24900, 25-34900, 35-44900, 45-54900, 55-65000, > 65000 SEK), and 'subjective social status', based on the idea of how one sees oneself in relation to others in society, considering money, job, and education.[26] The MacArthur Scale of Subjective Social Status (a 10 point ladder rank) is a well-established instrument of which we used a Swedish translation.[27] This measure was expected to better explain variance in silence than the objective measures of income, education, and occupation. Objective measures are useful for the guidance of effective interventions, since they are more concrete than subjective social status.[27] and [27]. This
measurement was expected to better explain variance in silence than the objective measurements of ‘income’, ‘education’, and ‘occupation’. Objective measurements are useful for the guidance of effective interventions, since they are more concrete than ‘subjective social status’[27], and they were therefore included as well.

The patients’ history of other kinds of abuse, i.e. emotional, physical, and sexual, was measured using the abuse questions from NorAQ.[28] The questionnaire identifies different levels of abuse: mild, moderate, and severe. The abuse questions in NorAQ have shown good reliability and validity, with an interview as the gold standard in a sample of Swedish women (n=64).[24] A full version of the abuse questions in NorAQ can be found in Swahnberg et al.[5] Respondents who answered yes to at least one of the three questions for each type of abuse were regarded as having experienced that type of abuse, regardless of severity. The exception to this was ‘mild physical abuse’, which was shown to be rather unspecific[24] and which was included in the “category ‘no lifetime physical abuse’ category.

Self-rated health was measured on a seven point Likert item (1=very bad, 7=very good).

Lastly, knowledge of patient rights was operationalized as self-rated knowledge of these rights, asking respondents to rate their knowledge level on an 11-point item (original coding: 0=none, 10=to a high degree).

As it has been suggested that non-response can be seen as an extrapolation of late response, we included “the variable ‘days to respond’” based on 30 days to 12 months).[29][29] Any association between this variable and an outcome variable could point at a possible response bias in the data set.
Study design

From the abovementioned silence operationalization in TEP, we developed a dependent variable indicating how many times the respondent remained silent relative to the number of times the respondent spoke up, expressed as a percentage of the total number of opportunities to remain silent and speak up (continuous variable, 0–100, where 100 per cent indicated ‘remained silent after all events’ and 0 per cent meant ‘acted after all events’). As this variable showed a U-distribution, which was hard to use as a dependent variable, it was chosen to trichotomize the variable (ordinal: 1=0%, 2=1-99%, 3=100%: Figure 1). Associations with silence were first tested univariately, using Cramer’s V (nominal by ordinal) and Kruskal’s Gamma (ordinal by ordinal, and interval by ordinal). Accordingly, all variables that tested significantly were included in an ordinal logistic regression model (through a Generalized Linear Model) testing for the main effect of these variables on the ordinal dependent variable. Knowledge of patient rights was entered as a covariate, assuming a continuous scale.

Missing values due to item non-response were excluded from the analyses.

Statistical analyses were performed using the IBM Statistical Package of the Social Sciences 19.0. Test results with a p-value of <0.05 were considered significant.

*** Figure 1 near here***
RESULTS

Sixty per cent (534/891) of female patients answered and returned TEP and 530 were included in our final dataset, as four respondents were excluded (one male patient, and three patients because of invalid answers or more than half of the answers missing). Fifty-five per cent of the sample (293/530) reported at least one transgression that they judged abusive or wrongful and were included in the present study sample. Background data are shown in Table 1 and more detailed information about the total sample is described elsewhere [20] (see Figure 2). Background data are shown in Table 1 and more detailed information about the total sample is described elsewhere [20]. For all variables shown in Table 1, the number of participants with missing values ranged between two and eleven.

Univariate analyses showed no associations between ‘remaining silent’ and the patients’ social status, country of birth, their background of abuse, or their health status. Associations were found with age and knowledge of patient rights (Table 1). This result did not differ when only looking at abusive events or wrongful events in health care (data not shown). Considering age, the youngest age group reported a higher rate of remaining silent—silence towards the health care system (Figure 3). Knowledge of patient rights was negatively correlated with ‘remaining silent’, implying that a higher reported knowledge was associated with a lower rate of remaining silent—silence towards the health care system (Figure 4).

The regression model including both of these variables showed that both age and ‘knowledge of patient rights’ had an effect on ‘remaining silent’ (Table 2). Age and ‘knowledge of patient rights’ were not associated with each other.
This result did not change when only looking at abusive or wrongful events, although the association between ‘remaining silent’ after abusive events and ‘knowledge of patient rights’ was only significant if ‘remaining silent’ was used as a dichotomous variable (1=0%, 2=1-100%) in a binary regression model (data not shown).

Further examination showed that ‘knowledge of patient rights’ did not correlate with the number of events experienced, nor with the number of events that were perceived as abusive or wrongful (Table 3).

***Figure 2, 3, and 4 near here***
Table 1: Univariate analyses of predictor variables with the ordinal dependent variable (expressed as the number of times remained silent as a percentage of the total number of opportunities)

<table>
<thead>
<tr>
<th>Predictor Variable</th>
<th>0%</th>
<th>1-99%</th>
<th>100%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (range 19-85, mean 42.5 ± 14.0)</td>
<td>8 (14.0)</td>
<td>17 (29.8)</td>
<td>32 (56.1)</td>
<td>0.03</td>
</tr>
<tr>
<td>&lt;30</td>
<td>68 (29.1)</td>
<td>74 (31.6)</td>
<td>92 (39.3)</td>
<td>0.84</td>
</tr>
<tr>
<td>&gt;30</td>
<td>9 (24.3)</td>
<td>13 (35.1)</td>
<td>15 (40.5)</td>
<td></td>
</tr>
<tr>
<td>Education (years)</td>
<td>30 (24.8)</td>
<td>37 (30.6)</td>
<td>54 (44.6)</td>
<td>0.84</td>
</tr>
<tr>
<td>&lt;10</td>
<td>63 (24.4)</td>
<td>82 (31.8)</td>
<td>113 (43.8)</td>
<td>0.91</td>
</tr>
<tr>
<td>10-12</td>
<td>30 (24.8)</td>
<td>37 (30.6)</td>
<td>54 (44.6)</td>
<td></td>
</tr>
<tr>
<td>&gt;12</td>
<td>36 (27.1)</td>
<td>40 (30.1)</td>
<td>57 (42.9)</td>
<td></td>
</tr>
<tr>
<td>Country of birth</td>
<td>9 (24.3)</td>
<td>13 (35.1)</td>
<td>15 (40.5)</td>
<td>0.93</td>
</tr>
<tr>
<td>Sweden</td>
<td>63 (24.4)</td>
<td>82 (31.8)</td>
<td>113 (43.8)</td>
<td></td>
</tr>
<tr>
<td>Other Nordic country</td>
<td>1 (20.0)</td>
<td>2 (40.0)</td>
<td>2 (40.0)</td>
<td></td>
</tr>
<tr>
<td>Other European country</td>
<td>4 (24.8)</td>
<td>37 (30.6)</td>
<td>54 (44.6)</td>
<td></td>
</tr>
<tr>
<td>Outside Europe</td>
<td>5 (13.3)</td>
<td>4 (26.7)</td>
<td>6 (40.0)</td>
<td></td>
</tr>
<tr>
<td>Occupation (latest 12 months)</td>
<td>61 (26.6)</td>
<td>69 (30.1)</td>
<td>99 (43.2)</td>
<td>0.93</td>
</tr>
<tr>
<td>Self-employed</td>
<td>34 (24.1)</td>
<td>18 (31.0)</td>
<td>26 (44.8)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>55 (29.6)</td>
<td>51 (27.4)</td>
<td>80 (43.0)</td>
<td>0.30</td>
</tr>
<tr>
<td>Any lifetime emotional abuse**</td>
<td>19 (18.3)</td>
<td>40 (38.5)</td>
<td>45 (43.3)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>3 (1-10)</td>
<td>4 (0-10)</td>
<td>6 (0-10)</td>
<td>0.08</td>
</tr>
<tr>
<td>Yes</td>
<td>18 (22.8)</td>
<td>34 (43.0)</td>
<td>27 (34.2)</td>
<td></td>
</tr>
<tr>
<td>Any lifetime physical abuse**</td>
<td>66 (29.9)</td>
<td>61 (27.6)</td>
<td>94 (42.5)</td>
<td>0.33</td>
</tr>
<tr>
<td>No (including mild abuse)</td>
<td>9 (12.9)</td>
<td>29 (41.4)</td>
<td>32 (45.7)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>55 (29.6)</td>
<td>51 (27.4)</td>
<td>80 (43.0)</td>
<td></td>
</tr>
<tr>
<td>Any lifetime sexual abuse**</td>
<td>63 (24.4)</td>
<td>82 (31.8)</td>
<td>113 (43.8)</td>
<td>0.30</td>
</tr>
<tr>
<td>No</td>
<td>18 (22.8)</td>
<td>34 (43.0)</td>
<td>27 (34.2)</td>
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</tr>
<tr>
<td>Yes</td>
<td>4 (0-10)</td>
<td>6 (0-10)</td>
<td>8 (0-10)</td>
<td></td>
</tr>
<tr>
<td>Self-rated health</td>
<td>5 (1-7)</td>
<td>5 (1-7)</td>
<td>5 (1-7)</td>
<td>0.71</td>
</tr>
<tr>
<td>Household income (SEK/month before taxes)</td>
<td>5 (1-7)</td>
<td>5 (1-7)</td>
<td>5 (1-7)</td>
<td>0.99</td>
</tr>
<tr>
<td>Subjective social status</td>
<td>5 (1-7)</td>
<td>5 (1-7)</td>
<td>5 (1-7)</td>
<td>0.17</td>
</tr>
<tr>
<td>Knowledge of patient rights</td>
<td>5 (1-7)</td>
<td>5 (1-7)</td>
<td>5 (1-7)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

* deviations in percentages exist due to item non-response.
** according to questions from the Norvold Abuse Questionnaire
1 tested with Cramer’s V
2 tested with Kruskal’s Gamma

Note: The data in the table is presented in a tabular format with columns for the predictor variable, categories, and corresponding percentages or counts. The table also includes p-values for statistical significance, with some variables tested using Cramer’s V (indicated by ‘%’) and others using Kruskal’s Gamma (indicated by ‘±’). The table provides a comprehensive analysis of how different factors related to silence during conversations are distributed across the population.
<table>
<thead>
<tr>
<th>n=286</th>
<th>-</th>
<th>-</th>
<th>-</th>
<th>95% Wald Confidence Interval</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>-</td>
<td>B</td>
<td>SE-B</td>
<td>lower</td>
<td>upper</td>
</tr>
<tr>
<td><strong>Threshold</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remained silent 0%</td>
<td>-2.09</td>
<td>0.34</td>
<td>-2.75</td>
<td>-1.44</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Remained silent 1-99%</td>
<td>-7.17</td>
<td>0.33</td>
<td>-1.33</td>
<td>-0.1</td>
<td>0.02</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 30</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 30</td>
<td>-0.69</td>
<td>0.39</td>
<td>-1.25</td>
<td>-0.13</td>
<td>0.02</td>
</tr>
<tr>
<td><strong>Knowledge of patient rights</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-0.11</td>
<td>0.04</td>
<td>-0.19</td>
<td>-0.03</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Likelihood Ratio Chi-Square: 13.50, p<0.01 (fitted model against thresholds-only model)

* n=7 excluded due to item non-response
Table 2: Ordinal Logistic Regression (through a Generalized Linear Model) with study variables and ordinal dependent variable. Beta coefficients (B) and Confidence Intervals (CI) for regressions with patients’ silence towards the health care system after experiencing staff’s abusive or wrongful transgressions.

<table>
<thead>
<tr>
<th>Threshold</th>
<th>Remained silent 0%</th>
<th>Amount of events</th>
<th>Amount of events judged as wrongful relative to opportunities</th>
<th>Remained silent 1-99%</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=288</td>
<td>-2.10</td>
<td>0.94</td>
<td>-2.07</td>
<td>0.82</td>
</tr>
<tr>
<td>n=288</td>
<td></td>
<td>0.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=288</td>
<td></td>
<td>-2.74</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=277</td>
<td></td>
<td>-1.40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% Wald Confidence Interval</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Likelihood Ratio Chi-Square: 13.60, p<0.01 (fitted model against thresholds-only model)

* n=18 excluded due to item non-response

Table 3: Correlation coefficients (Spearman’s rho) for ‘knowledge of patient rights’ and four study variables (on a continuous scale)

<table>
<thead>
<tr>
<th>Knowledge of patient rights</th>
<th>n=288*</th>
<th>n=288</th>
<th>n=288</th>
<th>n=277</th>
</tr>
</thead>
<tbody>
<tr>
<td>number of experienced events</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>number of events perceived as abusive</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>number of events judged as wrongful relative to opportunities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* deviations in sample size exist due to item non-response

** p<0.01
DISCUSSION

Despite extensive research on formal complaints and a growing interest in patients’ behaviour concerning informal complaints, little is known about patients’ behaviour after abusive or ethically wrongful events in health care. In the present study, we investigated which patient characteristics are associated with remaining silent after such events. It was shown that this silence was negatively associated with patients’ knowledge that patients have of their rights and with their ages. However, we could not confirm associations with patients’ social status, country of birth, their backgrounds of abuse, or their health status.

A negative association was found between patients’ knowledge that patients have of patient rights and patients remaining silent towards the health care system. It was surprising to see that knowledge of patient rights was not associated with the number of experienced events, nor with the number of events perceived as abusive or wrongful. One explanation for this could be that patients’ own “common sense” beliefs highly converge with what is included in patient right and ethical documents, and that more knowledge about these rights not necessarily leads to more experiences of transgressions. Many of these ethical documents and guidelines are built on Beauchamp and Childress’ principles of biomedical ethics, which in its turn is based on “common-morality”. For that reason, knowledge of patient rights would not change patients’ judgments of the events described in TEP. However, when it comes to acting after an abusive or wrongful situation, this knowledge could increase patients’ moral motivation or moral identity, helping her to feel legitimized to act when they know ethical or legal rules had been transgressed, although no causal conclusions about causality can be made based on the current material. The
fact that this patients' knowledge was self-reported in this study may suggest the
importance of patients' beliefs that they know their rights, rather than patients actually knowing their rights.

In spite of the small-scale and cross-sectional character of the current study, this result could suggest two entrances for future interventions. First, to aim The first entrance could be to increase patients' actual knowledge patients have of their rights, for example by making information about rights more accessible. Second, The second could be to strengthen patients' beliefs that they know what is right and wrong when a staff member transgresses ethical principles. The latter may be strongly related to patients' self-efficacy, or the fact that patients believe in their capacities; which, according to Bandura, may also affect their level of motivation for a certain behavioural path. [31] Besides trying to increase patients' knowledge patients have of their rights through persuasive communication, Bandura defined three other sources for increasing self-efficacy. [32] The first source is 'performance accomplishments', which are experiences of successful outcomes after performing certain tasks. Second, The second source is 'vicarious experiences', which have their starting point in the identification with a role model. Third, we see a 'physiological state', which concerns information from one's own bodily state. Future interventions could focus on strengthening any of these sources, but as Bandura pointed out, mere persuasive communication is a very weak source to increase for increasing self-efficacy, and could therefore better be combined with any of the other three sources. We

More importantly, we believe that any patient education intervention should not only focus on behavioural change in patients; the intervention should be sensitively

...
embedded in clinical practice, including the engagement of staff.[33] In the end, staff is responsible for not acting in an abusive way towards patients.

Patients’ silence towards the health care system was also associated with age, but contrary to our expectations, the youngest age group tended to remain silent slightly more often. It should be noted, however, that this group was compared to a group of patients over 30 years of age with relatively few respondents over the age of 65. A sample including patients > 65 years of age could give contrary results. We could also question the initial assumption on which this hypothesis is based, namely that patients speaking up after an abusive event is convergent with their assertiveness. Galtung’s structuralist theory of violence [10] would suggest that which patient characteristics are associated with silence depends on existing structures, rather than patients’ assertiveness. For example, in a study on cancer communication patterns, it was suggested that certain patient characteristics, such as race, strongly influenced the physicians’ communication style, which in its turn could affect patients’ behaviour.[21] The fact that younger patients remain silent to a higher degree could, according to this reasoning, depend on how well health care structures and staff are prepared to motivate younger patients to speak up. Following this theoretical reasoning, such a structural bias or prejudice could jeopardize the treatment of younger patients and hinder these patients in becoming involved in feedback processes.

Some of our hypotheses could not be confirmed. One general explanation for this is that the area has hardly been studied, and that our hypotheses were based on knowledge from related fields. Also, some methodological limitations may have affected these results. First, considering country of birth, there was a problem with the small group sizes posed a problem, as in total only ten per cent of all patients were born outside.
Sweden. Larger groups could have shown different results, more in line with our hypothesis.

Second, the self-rated health item we used concerned the last twelve months, while our silence operationalization covered lifetime experiences. It would have been more accurate to estimate patients’ health at the time of the event. Questions about other kinds of abuse also covered lifetime experiences and hence could have happened after transgressions in health care. Besides these methodological limitations, other explanations for the fact that we hardly found any only two associations with patient characteristics could be that we missed relevant variables, or that remaining silent is, for the most part, dependent on the structural conditions present in the actual health care situation. It may be a sign that structural conditions, such as health care norms and taboos, are powerful enough to outweigh the bulk of differences between individual patients. For example, differences in patients’ social status can still imply differences in assertiveness but they are irrelevant if all patients feel equally powerless to act after abusive events.

As we know that male and female patients experience AHC in different ways,[28, 30] it should be taken into account that the current study only included female patients. A qualitative study on how Latino American women dealt with dissatisfying health care experiences found that these women mostly avoided confrontation.[34] Instead of confronting a physician, the women chose indirect strategies such as switching health care providers. In that study it is suggested that these strategies may reflect traditional gender norms, where women tend to avoid confrontation with authority figures.[34] In TEP, such actions are not included in the silence operationalization as they were not expected to function as direct feedback to the health care system.[20][20] This means that we only capture a part of women’s strategies, and also that if men apply more direct strategies, we would expect to find less silence in TEP in male patients. On the other hand, a qualitative
study with male patients about their experiences of AHC showed that they felt “mentally pinioned”, which included their frustration after the powerlessness of not being able to act according to their interests. Hence, it could very well be that male patients also feel forced to avoid conflicts within a health care setting, deviating from a traditional male norm. Male patients’ silence should be a subject for future studies.

CONCLUSION

Remaining silent after experiencing health care staff’s abusive or wrongful transgressions was negatively associated with patients’ knowledge that patients have of their rights and patients’ ages. Both these variables could offer opportunities for designing patient education interventions that stimulate patients to speak up and open up the clinical climate, but more research is needed. It should be emphasized that it is not the responsibility of patients to speak up to staff to decrease the prevalence of AHC; staff carries the responsibility for this.
ACKNOWLEDGEMENTS

The NorVold Abuse Questionnaire (NorAQ) was developed by NorVold, a research network established in 1997 to explore the prevalence of violence against women and its effects on women’s health. The NorVold research network was supported by grants from the Nordic Council of Ministers. Principal investigators: Barbro Wijma, Berit Schei. Coordinator: Katarina Swahnberg. Local investigators: Denmark: Katrine Sidenius, Malene Hilden, Finland: Erja Halmesmäki, Ulla Pikkarinen, Iceland: Tora Steingrimsdottir, Norway: Berit Schei, Hildegunn Stoum-Hinsverk, Kristin Offerdal, Sweden: Barbro Wijma, Katarina Swahnberg.

COMPETING INTERESTS

The authors declare there are no competing interests.

FUNDING

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DATA SHARING

Extra data is available by emailing A. Jelmer Brüggemann (jelmer.bruggemann@liu.se)
REFERENCES


28. Wijma B, Schei B, Swahnberg K. NorAQ. The NorVold Abuse Questionnaire. Linköping: Division of Gender and Medicine, Faculty of Health Sciences, Linköping University 2004.


Figure 1: Histogram of the continuous variable "remaining silent" and the three groups derived from this variable.
Figure 2: Flow diagram showing the numbers of individuals at each stage of study

Study population
All unique outpatients visiting clinic Sep 09 - Apr 10
N = unknown

Declined participation
Communication problems
Under 18 yrs old
N = unknown

Included by clinic
N = 900

Under 18 yrs old
N = 5

Deceased
N = 1

Study sample
Received questionnaire
N = 894

Moved to unknown address
N = 3

Complete non-response
N = 357

Answered questionnaire
N = 534

Male patient
N = 1

>50% item non-response
N = 2

Invalid answers on part IV
N = 1

Final dataset
N = 530

Did not report any abusive/wrongful transgressions
N = 237

Study sample
N = 293
Figure 2: Distribution of patients' relative silence after abusive and/or wrongful ethical transgressions within two age categories.
Figure 4: Distribution of patients’ relative silence after abusive and/or wrongful ethical transgressions within patients’ self-rated level of knowledge of their rights

Self-rated level of knowledge of patient rights (10 being the highest)

90x103mm (300 x 300 DPI)
### STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item #</th>
<th>Item</th>
<th>Recommendation</th>
<th>Reported on page #</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td>1</td>
<td>(a)</td>
<td>Indicate the study’s design with a commonly used term in the title or the abstract</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b)</td>
<td>Provide in the abstract an informative and balanced summary of what was done and what was found</td>
<td>2</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td>2</td>
<td></td>
<td>Explain the scientific background and rationale for the investigation being reported</td>
<td>5-6</td>
</tr>
<tr>
<td><strong>Objectives</strong></td>
<td>3</td>
<td></td>
<td>State specific objectives, including any prespecified hypotheses</td>
<td>6</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td>4</td>
<td></td>
<td>Present key elements of study design early in the paper</td>
<td>6</td>
</tr>
<tr>
<td>Study design</td>
<td>5</td>
<td></td>
<td>Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection</td>
<td>6-7</td>
</tr>
<tr>
<td>Setting</td>
<td>6</td>
<td>(a)</td>
<td>Give the eligibility criteria, and the sources and methods of selection of participants</td>
<td>6-7</td>
</tr>
<tr>
<td>Participants</td>
<td>7</td>
<td></td>
<td>Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable</td>
<td>8-11</td>
</tr>
<tr>
<td>Variables</td>
<td>8*</td>
<td></td>
<td>For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group</td>
<td>8-11, Figure 1</td>
</tr>
<tr>
<td>Data sources/measurement</td>
<td>9</td>
<td></td>
<td>Describe any efforts to address potential sources of bias</td>
<td>11</td>
</tr>
<tr>
<td>Bias</td>
<td>10</td>
<td></td>
<td>Explain how the study size was arrived at</td>
<td>Figure 2</td>
</tr>
<tr>
<td>Study size</td>
<td>11</td>
<td></td>
<td>Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why</td>
<td>8-11, Figure 1</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>12</td>
<td>(a)</td>
<td>Describe all statistical methods, including those used to control for confounding</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b)</td>
<td>Describe any methods used to examine subgroups and interactions</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(c)</td>
<td>Explain how missing data were addressed</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(d)</td>
<td>If applicable, describe analytical methods taking account of sampling strategy</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(e)</td>
<td>Describe any sensitivity analyses</td>
<td>-</td>
</tr>
</tbody>
</table>

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Participants
(a) Report numbers of individuals at each stage of study—e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
(b) Give reasons for non-participation at each stage
(c) Consider use of a flow diagram

Descriptive data
(a) Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders
(b) Indicate number of participants with missing data for each variable of interest

Outcome data
Report numbers of outcome events or summary measures

Main results
(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included
(b) Report category boundaries when continuous variables were categorized
(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses
Report other analyses done—e.g. analyses of subgroups and interactions, and sensitivity analyses

Discussion
Key results
Summarise key results with reference to study objectives

Limitations
Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias

Interpretation
Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence

Generalisability
Discuss the generalisability (external validity) of the study results

Other information
Funding
Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.