Mitigating risk in Norwegian psychiatric care: Identifying triggers of adverse events through Global Trigger Tool for psychiatric care

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Abstract

BACKGROUND: Patients treated in psychiatric care are exposed to the risk of adverse events, similar to patients treated in somatic health care.

OBJECTIVES: In this article we report the findings of triggers associated with adverse events (AEs) identified by a version of GTT-P (Global Trigger Tool – Psychiatry) adapted for Norwegian hospital-based psychiatric treatment.

METHODS: The design was a retrospective analysis of a random sample of 240 patient records from a psychiatric clinic in one Norwegian hospital. Patient records were sampled from both inpatient and outpatient psychiatric clinics in hospitals serving the northern part of the county of Trøndelag, Norway.

RESULTS: Our analysis was based on the identification of 32 potential triggers of adverse events. Eighteen of the triggers were significantly related to adverse events. No adverse events were identified in patient records that did not also contain triggers included in the Global Trigger Tool.

CONCLUSIONS: There is a clear relationship between the presence of triggers in a patient record and the likelihood of adverse events. Particularly relevant for psychiatric patients is 'suffering' as a trigger and this may also be relevant to somatic care and has implications for inclusion in the GTT-P.

Keywords: Adverse events, Mental health, Patient safety, Precipitating factors, Psychiatry

Introduction

Adverse events (AEs) in somatic care are relatively common [1-7]. Based on several studies [1,2,8,9], the WHO estimates that about 10% of patients are harmed during hospital care in Western countries [10]. In a U.S. study AE reporting methods commonly used to track patient safety fared very poorly compared to other methods and missed 90% of occurrences [4]. In 2011 the Norwegian Government launched a national patient safety campaign to reduce risk of AE and improve patient safety as a part of a systematic approach to quality and reinforcing a patient safety culture[7].

In Norway more than 13% of hospital admissions in somatic care contribute to an AE of lesser or greater severity [7]. To reduce harm, methods for measuring and characterizing patient safety have been developed [11]. By tracking the occurrence of AEs over time it is possible to determine if changes in how health care services are organized and facilitated increase the safety of treatment [12]. The Global Trigger Tool (GTT) was designed to review medical records generating data on the frequency and types of AEs in somatic care [12]. A number of studies show that AEs detected with the GTT in somatic care are underreported by other AE reporting systems [12-14]. The application of the GTT has become an internationally recognized and standardized procedure for measuring AEs among adult patients in non-psychiatric hospital admissions [15]. The GTT is based on a list of potential triggers that are used to identify specific issues in patient records that suggest a higher probability of the patient experiencing an adverse event. This approach was chosen as the way to promote a patient safety culture through continuous reviews of medical record in all acute care hospitals in Norway [16]. The GTT adopts a particular definition of adverse events (AEs): "unintended physical injury resulting from or contributed to by medical care

that requires additional monitoring, treatment or hospitalization, or that results in death" [17].

Patients treated in psychiatric care are also exposed to the risk of experiencing AEs, just as patients treated in somatic health care [18-22]. For those with serious mental illness, AEs were positively associated with physical harm and 30-day mortality in non-psychiatric hospitalizations [23]. In mental health care the use of a review team has been suggested as a method for detecting and reporting medication errors [19]. In 2008 generic screening criteria were developed to identify what constitutes an AE, but there was no agreement on their application to psychiatry [24]. Jayaram (2008) considers a range of criteria to assess the quality of care including: re-hospitalization within a month of discharge, unexpected prolongation of hospital stay, adverse

drug reactions, medical complications, suicide, unexpected transfer to a medical service and cardiac complications. Martens et al. [25] demonstrate that physicians and nurses working in inpatient psychiatric care were at risk of being confronted with an AE at some point in their career, for instance incidences of patient suicide.

To our knowledge, Sweden is the only country where the GTT has been adapted to measure AEs in psychiatric care. There is also some ambition to introduce the GTT in psychiatric care in Singapore and Denmark [26]. In 2013 a Swedish report was published based on the results of applying the GTT to 110 psychiatric patient records [27]. A Swedish manual for reviewing patient records in adult and forensic psychiatry was produced in 2015 [26]. In September 2018 a new report based on the GTT review of 2 552 records of general adult patients in psychiatric care was published [28].

The aim of the study reported in this article was apply the modified version of GTT-P (Global Trigger Tool – Psychiatry) adapted for Norwegian hospital - based psychiatric

treatment to evaluate its efficacy in identifying triggers associated with adverse events (AEs).

Methods

In January 2017 we initiated the development of the GTT for psychiatric care: the GTT-P. We translated the Swedish psychiatric GTT tool and methodological appendix and adapted the tool to the Norwegian context, including defining AEs in Norwegian psychiatric care [29]. The Norwegian manual differs from the Swedish by not including conditions that are very specific to forensic psychiatry. In the Norwegian version, we also chose to include relevant conditions for the treatment of drug misuse. The process of adapting and validating the tool to a Norwegian context is reported in Tritter, Okkenhaug and Landstad [30]. We engaged with patients throughout the research and gathered data on both triggers and adverse events using one focus group interview with patients, two focus groups with health care personnel. To validate the revised GTT-P we convened a dialog conference that brought together both patients and health care professionals. We define an AE as an accidental or unintended incident that occurs in health care or services which requires further monitoring, treatment or hospitalization or leads to a fatal outcome which is not a consequence of the patient's illness [29]. In psychiatric care AEs include both physical and mental harm. This definition is in accordance with the Swedish version of the psychiatric GTT [26]. Mental harm can be a consequence of, or independent of, physical harm. An AE will usually be an accidental incident that has occurred during treatment in health care services, or due to the absence of treatment. An AE might have a fatal outcome that is not a consequence of the patient's illness.

Neuroleptica malignant syndrome, circulation and heart failure and suicide are examples of possible fatal outcomes. Unnecessary deprivation of liberty, sexual harassment, experiencing violence during hospitalization are examples of AEs that patients may be subjected to when undergoing psychiatric care [29].

As in the Swedish version of the psychiatric GTT, we distinguish between avoidable an unavoidable AEs [28]. An AE that could be avoided is defined as a physical or mental injury, illness or death which is not a consequence of the patient's illness, that could have been avoided if adequate measures had been initiated when the patient was in contact with the health care system. Examples of avoidable AEs include inappropriate care due to a lack of a treatment plan and unknown diseases because of inappropriate or inadequate tests. We categorized AEs using a four-point severity scale: little (discomfort or negligible injury), moderate (temporary impairment), considerable (persistent moderate impairment) and catastrophic (persistent major disability or death) [29]. This four-point severity scale is aligned with the approach to risk analysis used in both Norwegian and Swedish health services [31].

In the GTT-P a 'trigger' is an indicator identified during the review of a patient record as the basis for identifying potential AEs but is not considered an AE in itself. Examples of triggers of potential AEs include readmission within 30 days [32] and lack of documentation [33], for instance the absence of a treatment plan. The GTT-P provides a list of triggers that may be apparent in patient records and potentially indicate a higher probability of an AE [29].

Thirty-two triggers were translated and adapted for the Norwegian GTT-P [29,30]. They were divided into five domains; Treatment (14 triggers), Drugs (1 trigger), Coercive Treatment (4 triggers), Medicine (7 triggers) and Continuity and transitions (6

triggers) (see Table 3). The Swedish psychiatric GTT has 36 triggers [26] and is consistent with the Norwegian GTT-P across three of the five domains; Coercive Treatment, Medicine, and Continuity and transitions. We have merged the four Swedish triggers related to drug addiction into one trigger and specific triggers for forensic psychiatry have been removed [29]. In addition, we include "Undesired effect of ECT" as a specific trigger in our tool. The AEs identified in the Norwegian GTT-P are the same as in the Swedish psychiatric GTT.

Sample and Data Collection

In total we examined 240 patient records from the inpatient and outpatient psychiatric department in Nord-Trøndelag Hospital Trust. The majority of psychiatric patients in Norway receive outpatient treatment. Therefore, in order to identify AEs for all Norwegian patients receiving hospital treatment we validated the GTT-P for both in- and outpatients [30]. Psychiatric care includes the Interdisciplinary Specialized Treatment for Drug Abuse and therefore the data relates to patients treated for drug misuse as well as psychiatric patients.

Every month from May 2017 to January 2018 (except July due to public holidays), 30 patient records for discharged patients were randomly selected for review; 12% of all the patients treated during the period.

Each month, a secretary conducted a random extraction of 15 patient records from discharged inpatients and a further 15 from discharged outpatients. The records were analysed using the GTT-P by project teams composed of a physician and two nurses in each of the three different psychiatric clinic sites in the hospital trust; each team analysed five inpatient and five outpatient records per month. The patients were not

anonymous to the project teams but they were unknown to the investigators as they worked at a different location from where the patients were treated.

Those who were part of the project teams were experienced health professionals that had previous experience of quality assurance work. Prior to the analysis, all members of the project team undertook training under the direction of the authors of the Swedish psychiatric GTT handbook [26]. Drawing on the Swedish experience this was followed by a calibration exercise where the team members reviewed the same five records [27]. Following a discussion and comparison of these results it was necessary to repeat the procedure on three more patient records before the teams were consistent. In addition to these two rounds of calibration, we had two additional joint meetings with all three teams to ensure a common understanding of the research procedures.

On a monthly basis the two nurses within each project team, reviewed the records independently before comparing their results and then validating their finding with the physician on their project team. Through discussion, they usually reached a common understanding of the various coding challenges. In the event of a disagreement, the doctor had the last word.

Since the teams started out as "beginners", they spent more time in the beginning than the set time limit (20 min) to review a patient record; within three months they were averaging 20 minutes to review each record. The identified AEs were classified by type and rated on the four-point severity scale [31]. The teams also had the opportunity for clarification with a departmental superior if necessary.

Table 1 about here

The demographic characteristics of the sample (see Table 1) suggest that the patients studied are similar to the national population [34]. The northern part of the county where the patients come from has a relatively constant population of about

130,000 inhabitants. The county is mostly rural, without large cities, but still fairly representative of Norway in terms of geography, economy, types of employment, age distribution, morbidity and mortality [35]. There are differences apparent in educational attainment; attainment in the sample is lower than the national average.

The analysis of the patient records also documented the primary diagnosis for each patient consultation or treatment [34]. The distribution of patient diagnoses in the study sample was consistent with the pattern at national level (see Table 2). Across the hospital trust there are fewer patients with diagnoses coded as F20-, F30-, F40-, but more with the F60 spectrum compared with the National Patient Registry data [36] and this is reflected in our study sample.

Table 2 about here

Analysis

In this study we analyzed 'triggers' of a potential AE as a consequence of treatment at a hospital psychiatric clinic. In addition, we identified demographic data, a measure of the severity of identified AE and evaluated whether the AEs could be avoided.

Descriptive statistics are presented using frequencies and relative frequencies for categorical variables, and using means and standard deviations for continuous variables. Differences in relative frequencies were tested using Fisher's exact test. To analyse factors associated with AEs we used multivariate logistic regression with AE (yes/no) as the dependent variable. For completeness we also estimated univariate logistic regressions for each covariate in order to show how the importance of each covariate changed when taking into account all other covariates. A significance level of 5% was chosen. We recorded data in an Excel summary sheet and analyses were performed using SPSS v23 and Stata 15.0.

Results

The results of our analysis identified at least one AE in 19 (7.9%) of the 240 patient records in the study sample. In total these 19 records included 29 AEs. Of these, 13 records included evidence of one AE while six records had 2-4 AE. No AEs were detected without accompanying triggers included in the GTT-P.

The AE recognized in the analysis were: suffering (five cases), disease worsening (three cases), suicide attempt (three cases), self-harm (three cases), other drug-related AEs (three cases), measures without support in law (three cases), insult (two cases), interrupted treatment (two cases), other AEs (two cases), insufficient effect of treatment (one case), metabolic influence (one case), and falls (one case). Of the 29 AEs identified in the 240 patient records in the study sample, 17 were categorized as minor and 12 as moderate. Thirteen AEs identified were associated with treatment in the outpatient unit and four of these were potentially avoidable. Sixteen AEs were found in treatment delivered to patients in the inpatient units and 11 of these were avoidable. In total 832 triggers were identified in the study sample. The number of triggers in records with a detected AE was 7.28 vs. 2.81 in records in those cases without an identified AE (Mean diff. = -4.5; CI = -5.3 - -3.6; p-value = .000). Table 3 shows the distribution of the triggers in the sample. Nine triggers were statistically significant in relation to potentially avoidable AEs across four domains; Treatment (B5, B7, B8, B10, B11), Coercion (T2), Medicine (L3) and Continuity (K1, K3).

Table 3 about here

In the study sample 22% of the patients were diagnosed with mood disorders (see table 4) and 53% of the AEs were found in this group. More than a fifth (21%) of all AEs identified in the analysis related to patients with psychotic disorders (11% of the sample).

Table 4 about here

Table 5 presents the triggers and AEs in relation to the demographic characteristics of the patients. Triggers related to compulsory treatment, drugs and continuity of care were associated with a significant increase in the likelihood of experiencing an AE. Being treated solely as an outpatient, significantly reduced the odds of an AE compared to patients who were also treated as inpatients care. There was no association between the likelihood of an AE and age, sex or triggers related to treatment. Triggers related to drugs were associated with a significant reduction in the likelihood of experiencing an AE.

Table 5 about here

Discussion

Statement of the principal findings

The aim of this study was to analyse and report AEs and the associated triggers identified using a modified version of GTT-P on a random sample of psychiatric patients treated in one Norwegian hospital trust. Our findings show that AEs occurred in nine outpatients (of a total of 119) and in 10 inpatients (of a total of 121). This

equates to approximately 8% of the patients treated in the hospital. This level of AEs is consistent with some studies [23,27] while a more recent study reported approximately 20% patients experienced a patient safety event [28,37].

In a study reviewing patient records in somatic care, between 4% and 17% of hospital admissions were associated with an AE and a significant proportion of these (1/3 – 2/3) were preventable [6]. Many AEs are traditionally considered inevitable complications of treatment, but certain AEs can be defined as avoidable. AE that can be clearly attributed to failure, ie assessment, activity or treatment delays or the absence of such, should be considered as avoidable [29]. Our results show that 15 of the 29 identified AEs could have been avoided if adequate measures had been initiated when the patient was in contact with the health care system.

We found AEs in 19 of the 240 patient records analysed and in terms of severity these were categorised as minor and moderate. The most common AE was "suffering" (five cases, three avoidable) followed by "disease worsening" (three cases, one avoidable), "suicide attempt" (three cases, zero avoidable), "self-harm" (three cases, one avoidable), "other drug-related AE" (three cases, zero avoidable), and "measures without support in law" (three cases, three avoidable).

We also included an AE that we labeled *suffering* [29]. Patients in the focus groups that refined the translated GTT-P for the Norwegian context considered *suffering* as one of the most important AEs [30] and identified stigma as a possible cause of suffering. Stigma relates to a group of people with common characteristics being exposed to a form of discrimination that is rooted in prejudice and ignorance [38]. Stigmatization associated with mental illness is common [39] and stigma can act as a formidable

barrier to active recovery [40]. If healthcare professionals expose patients to stigmatizing treatment, we suggest that it should be considered as an AE [29].

The most frequent triggers identified in this study were the lack of a treatment plan, followed by the lack of contact with relatives, change of treatment unit and unplanned inpatient treatment or contact with the psychiatric acute unit. Swedish studies reported similar patterns [27], with the lack of a treatment plan as the most common identified trigger [28]. This contrasts with other patient safety surveys in somatic care where different events are more common. In Marcus`s survey [37] the most frequent events were medication errors (delayed and missed doses, 17.2%), followed by adverse drug events (4.1%), falls (2.8%), and assaults (1.0%). Most reported patient safety events (94.9%) resulted in little or no harm although more than half of the events (56.6%) were deemed preventable [37].

Our study also shows a correlation between the number of identified triggers and AEs. The number of triggers in records with a detected AE was 7.28 vs. 2.81 in records in those cases without an identified AE. The more triggers we found in a patient record, the greater the risk that the patient would have experienced an AE. This is in accordance with research in somatic care [3,50]. As far as we know this has not previously been discussed in relation to psychiatric care.

In the Swedish study [28] both in- and outpatients were included – and they identified considerable more AEs than we found in our study (17% vs. 8%). The Swedish researchers found (as we did) more AEs in inpatients than outpatients. Studies in somatic care only included inpatients and their analysis identified higher numbers of AEs (13%) [7]. This might indicate that there are more AE in inpatient than in outpatient care.

To our knowledge, our study is the first time the results of the GTT being applied to psychiatric care have been published in the scientific literature; although the Sveriges Kommuner och Landsting have produced two reports in Swedish on the application of the GTT to psychiatric care in Sweden [27,28]. This means that there are no other studies to directly compare our results with. Nevertheless, there are some studies that have focused on AEs or patient safety events in psychiatric care but these accounts provide little agreement on what constitutes an AE in a psychiatric environment [18,24] and most studies have focused on the frequency of specific AE such as suicide [33,41], assaults [42], violence [43], medication errors [21,44-46] or falls [18,37].

Strengths and weaknesses of the study

The Department of Psychiatry in Nord-Trøndelag Hospital Trust were certified according to the ISO-standard in 2005. This included systematic control of records by unit leads and revision teams [47]. This is not commonplace in Norwegian psychiatric clinics, thus our department might not be comparable to other psychiatric departments regarding quality systems. This could be a strength as well as a weakness. It is possible that we have identified fewer AEs and less serious harm than would be expected in most Norwegian psychiatric clinics.

The clinical sample in the present study was relatively small thus increasing the risk of reduced external validity and generalizability. This article reports the results of a dataset drawn from one hospital trust with few AEs.

With 32 different triggers we applied some data reduction techniques in order to postulate a model that was possible to estimate and replicate more widely within Norway. Ideally cluster analysis techniques should be applied when analyzing these data. The rationale behind this is that it might not be the grouping we have applied that best predicts AEs. It may be that certain combinations of different triggers together create a better prediction. Our initial idea was therefore to apply cluster analysis or similar data reduction techniques that would enable us to detect such groups. However, the number of observations and the number of AEs in this dataset is too small compared to the number of triggers, so such an analysis could not be done. We would need the project to be scaled up in order for this to be achievable.

Implications for clinicians and policymakers

GTT is a widespread and accepted patient safety tool in somatic care [4,15]. When developing the tool for psychiatric care it is natural to think that there might be synergies with the approach to delivering care. Triggers such as "lack of a treatment plan" or "the undesired effect of treatment" that we identified in our study as important in psychiatric care may be relevant for the somatic GTT. If an examination of a patient record reveals that a patient in need of rest has become insecure and afraid because of sharing the room with an aggressive elderly demented person and the nurses in the unit know about it, but do not respond - does this constitute an AE we could label "suffering"?

Simply applying the GTT to hospital-based psychiatric care might help identify processes that need to be changed in order to promote patient safety. But, embedding the application of the GTT-P through a process of engaging with

stakeholders, patients, relatives and different health care professionals, will help to create and promote a safety culture and improve the quality of inpatient psychiatric care [48].

Physicians and nurses working in inpatient psychiatric care are at high risk of encountering adverse events at some point in their career [25]. Working with staff and other stakeholders using the GTT-P can help to prevent AEs through the identification of potential triggers and aspects of care that can be improved and generate benefits for patients, families and staff.

Conclusions and need of further research

Our study demonstrates a relationship between specific triggers and AEs in hospital-based psychiatric care. It also reveals that patient records with more triggers are associated with an increased likelihood of an AE. In addition, this study suggests that suffering is an important trigger that may be associated with AEs.

Mental illness implies a risk of AEs. Mental health conditions can be very severe, but also engender a significant risk of AEs during hospitalization and treatment. Health professionals should provide the best possible treatment for their patients and should therefore acknowledge that many AEs can be avoided with appropriate models of care delivery. Attention to detecting AEs creates the basis for redesigning processes to help ensure they are avoided in the future.

To our knowledge, this is the first research study in this field. Further refinement of the GTT in psychiatric care and the application to a larger patient cohort is needed. The clinical sample in the present study was relatively small. To extend the validity

and generalizability of our findings and further develop the GTT-P there is a need to investigate a larger number of records from more hospitals. Systematic identification of triggers associated with AEs can help to prevent injury, increase knowledge about the causes of AEs and promote a patient safety culture in psychiatric care benefitting patients, relatives and staff.

Authors` contributions

AO, JT, ED, KM and BJL designed and conducted the study. AO and BJL drafted and finalised the protocol. TÅM statistically analysed the data. AO, BJL and JQT undertook the initial interpretation of the data, which was followed by discussions with all the authors. AO drafted the initial version of the manuscript, which was followed by a critical revision process of the intellectual content involving all the authors. All authors have read and approved the final manuscript.

Conflict of interests

The authors declare that they have no competing interest.

Ethics approval

The study was considered by the Regional Ethics Committee which concluded that it did not require formal ethical approval (2017/1779 REK Midt) and was therefore considered by the Data Protection Officer (DPO) at Nord-Trøndelag Hospital Trust who approved the study (2017/39 - 2369/2017).

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Table 1. Characteristics of study participants compared to national patient data; gender, age and treatment unit, are from Indergård et al. (2018) and data on education and civil status are from Ose et al. (2014)

	Study Cases	National Data
Patients in total	240 (100%)	150 440†/23 124‡ (100%)
Gender†		
- Men	100 (42%)	61 680 (41%)
- Women	140 (58%)	88 760 (59%)
Age†		
- < 17	0 (0)	1 149 (1%)
- 18-29	95 (39%)	49 725 (33%)
- 30-29	29 (12%)	33 159 (22%)
- 40-49	47 (20%)	27 170 (18%)
- 50-59	33 (14%)	18 738 (13%)
- 60-69	19 (8%)	9 586 (6%)
- > 70	17 (7%)	10 913 (7%)
Education‡		
- Not finished compulsory school	2 (1%)	541 (2%)

-	High school	95 (40%)	6 759 (30%)
-	Upper secondary school	84 (35%)	10 510 (46%)
-	University colleges/ University	35 (14%)	4 977 (21%)
-	Missing	23 (10%)	337 (1%)

Civil status[2]

-	Married/cohabiting	99 (42%)	9 209 (39%)
-	Single	139 (57%)	13 806 (60%)
-	Missing	2 (1%)	109 (1%)

Treatment unit

-	Inpatient	37 (15%)
-	In- and outpatient	84 (35%)
-	Outpatient	119 (50%)

† National data = 150 440 (100%) [34]. ‡ National data = 23 124 (100%) [49]. The data are from outpatient units only.

Table 2. Diagnoses of study participants (ICD-10 codes) vs national statistics.

	Diagnoses	Study data % Total	Study data % (n) Inpatient†	National data % Inpatient	Study data % (n) Outpatient	National data % Outpatient
F01-09	Mental disorders due to known physiological condition	2	3 (4)	2	0	1
F10–19	Mental and behavioral disorders due to psychoactive substance use	9	12 (15)	11	5 (6)	2
F20–29	Schizophrenia, schizotypal, delusional, and other non-mood psychotic disorders	11	22 (27)	26	1 (1)	16
F30–39	Mood [affective] disorders	22	22 (27)	25	22 (26)	24
F40–49	Area of anxiety, dissociative, stress-related, somatoform and other non-psychotic mental disorders (with PTSD)	21	14 (17)	17	28 (33)	24

F50–59	Behavioral syndromes associated with physiological disturbances and physical factors	3	3 (3)	2	2 (3)	3
F60–69	Disorders of adult personality and behavior	14	19 (23)	9	10 (12)	8
F80–89	Pervasive and specific developmental disorders	1	0	1	2 (3)	1
F90–98	Behavioral and emotional disorders with onset usually occurring in childhood and adolescence	5	3 (3)	1	8 (9)	4
F70-79, 99	Others	12	2 (2)	1	22 (26)	1
G00-99, R00-99, Others	Diseases of the nervous system. Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified.	0	0	3	0	15
Sum		100	100 (121)	98	100 (119)	99

† The study group consists of both inpatient and outpatients.

Table 3. Relationship between examined records with adverse events (AE) and triggers, and examined records with no adverse events (NAE) and triggers. Total of examined records: N = 240. Triggers as defined in the handbook (Okkenhaug et al, 2017).

Triggers		Number of triggers identified in patient records with no associated AE (n=221)	% of records with triggers and no AE	Number of triggers found with a specific AE (n=29)	% of records with the trigger and AE	p-value
Treatment						
B1	Absence of treatment plan	110	50	20	69	.074 (ns)
B2	Absence of individual plan	39	17	4	14	.795 (ns)
B3	Lack of review of suicide risk	24	11	8	28	.018*
B4	Documentation of failure	5	2	5	17	.002**
B5	Consultation with a physician on call / doctor from another specialty	37	17	18	62	.000**
B6	Change of diagnosis	17	8	7	24	.012*
B7	Self-harm	14	6	10	34	.000***

B8	Undesired effect of treatment	11	5	12	41	.000***
B9	Undesired effect of ECT	0	0	1	3	na[1]
B10	Threats, violence and inappropriate behavior	10	5	9	31	.000***
B11	Increased surveillance	8	4	15	52	.000***
B12	Lack of somatic status	29	13	2	7	.548 (ns)
B13	Absence of contact with relatives	50	23	10	34	.169 (ns)
B14	Others	16	7	7	24	.009**
Drugs						
R1	Lack of examination of substance abuse	43	19	2	7	.124 (ns)
Coercive treatment						
T1	Coercion	15	7	8	28	.002**
T2	Coercion treatment – administrative failure	2	1	6	21	.000***
T3	Conversion from voluntary treatment to coercion (emergency law)	2	1	4	14	.002**
T4	Police assistance	4	2	0	0	na
Medicine						
L1	Use of three or more different antipsychotic medicine	3	1	0	0	na
L2	Treatment with anticholinergics	0	0	0	0	na
L3	More than four different psychofarmaca	0	0	5	17	.000***
L4	Two or more benzodiazepine or treatment more than 3 month	11	5	2	7	.652 (ns)
L5	Metabolic risk factors	7	3	6	21	.001***
L6	Guidelines not followed when medicine require regular tests	6	3	2	7	.234 (ns)
L7	Others	25	11	6	21	.224 (ns)
Continuity and transition						
K1	Unplanned inpatient treatment or contact with psychiatric acute unit	42	19	24	83	.000***
K2	Reinstatement within 30 days	21	10	10	34	.001***
K3	Change of treatment unit	49	22	21	72	.000***
K4	Unplanned discharge or ending outpatient treatment	42	19	2	7	.126 (ns)
K5	Lack of doctor`s round during the last 12 months	14	6	1	3	1.0 (ns)
K6	Lack of responsible doctor or coordinator	30	14	9	31	.026*

Table 4. Diagnoses presented as ICD-10 codes vs records without adverse events (WAE) and with adverse events (AE). Total of records examined: 240.

ICD-10 codes	Diagnoses	Total of Records %	Records with AE %	Records with AE N	Records Without AE N
F01-09	Mental disorders due to known physiological condition	2	0	0	4
F10–19	Mental and behavioral disorders due to psychoactive substance use	9	5	1	20
F20–29	Schizophrenia, schizotypal, delusional, and other non-mood psychotic disorders	11	21	4	24
F30–39	Mood [affective] disorders	22	53	10	43
F40–49	Area of anxiety, dissociative, stress-related, somatoform and other nonpsychotic mental disorders (without PTSD)	14	5	1	33
F43	PTSD	7	0	0	16

F50–59	Behavioral syndromes associated with physiological disturbances and physical factors	3	0	0	6
F60–69	Disorders of adult personality and behavior	14	16	3	32
F80–89	Pervasive and specific developmental disorders	1	0	0	3
F90–98	Behavioral and emotional disorders with onset usually occurring in childhood and adolescence	5	0	0	12
F99, F70-79	Others	12	0	0	28
Sum		100	100	19	221

Table 5. Factors associated with adverse events. Multivariable logistic regression with adverse event (yes/no) as dependent variable. Estimated univariable logistic regressions for each covariate in order to show how the importance of each covariate changed when taking into account all other covariates. P-value < 0.05*, < 0.01**, < 0.001***.

Variables	Univarible OR (95% CI)	Multivariable OR (95% CI)	P-value from multivariable regression
Treatment	2.1 (0.21-20.4)	1.4 (0.14 - 13.44)	.774
Drugs	0.24 (0.04 - 1.35)	0.12 (0.02 - 0.79)	.027*
Compulsory treatment	5.5 (1.77 - 16.79)	5.5 (1.67 - 18.2)	.005**
Medication	6.3 (2.1 - 19.18)	4.15 (1.29 - 13.4)	.017*
Continuity	10.6 (1.06 - 105)	13.2 (1.17 - 148.4)	.037*
Sex			
Female (reference)	1	1	
Male	1.13 (0.42 - 3.05)	1.15 (0.40 - 3.28)	.793
Age group			
0-29 (reference)	1	1	
30-49	0.29 (0.08 - 1.07)	0.46 (0.12 - 1.77)	.258
50-59	3.07 (0.65 - 14.6)	3.47 (0.68 - 17.8)	.136

60+	0.25 (0.05 - 1.32)	0.24 (0.04 - 1.43)	.119
Clinic			
Inpatient + in- and outpatient	1	1	
Outpatient only	0.09 (0.01 - 0.77)	0.08 (0.01 - 0.68)	.02*