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# BMJ Open Ethnic minority patients not at increased risk of adverse events during hospitalisation in urban hospitals in the Netherlands: results of a prospective observational study

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### **ABSTRACT**

**Objectives:** We analysed potential differences in incidence, type, nature, impact and preventability of adverse events (AEs) during hospitalisation between ethnic Dutch and ethnic minority patients, and the role of patient-related determinants. We hypothesised an increased AE incidence for ethnic minority patients.

**Setting:** We conducted a prospective cohort study in four urban hospitals.

Participants: 763 Dutch patients and 576 ethnic minority patients aged between 45 and 75, admitted for at least one night, were included in the study. All patients completed a questionnaire on patient-related determinants (eg. language proficiency).

Outcome measures: Incidence, type (eg., diagnostic AEs), impact and nature of AEs were assessed with a two-stage medical record review. Logistic regression analysis was used to adjust for patient and admission characteristics, and to investigate the contribution of patient-related determinants to AE risk.

**Results:** There was no significant difference in the incidence of AEs: 11% (95% CI 9% to 14%) in Dutch patients and 10% (95% CI 7% to 12%) in ethnic minority patients. Also, there was no significant difference in the incidence of preventable AEs: 3% (95% CI 1% to 4%) in Dutch patients and 1% (95% CI 0% to 2%) in ethnic minority patients. Low language proficiency, inadequate health literacy and low educational level did not increase the risk of an AE. **Conclusions:** Compared with Dutch patients, ethnic minority patients were not at increased risk of AEs while receiving care in Dutch hospitals. Healthcare providers seem to have responded effectively to specific patient care needs, but we do not know whether this occurred in an ad hoc or in a systematic way.

### INTRODUCTION

Patient safety, which is defined as the lack of preventable injury resulting from medical care, is the minimum prerequisite for good

### Strengths and limitations of this study

- Two-stage record review to investigate adverse events (AEs).
- Much effort in high-quality data collection (eg, bilingual researchers).
- Study was only carried out in hospitals that are used to care for ethnic minority patients.
- Blinding record reviewers for ethnic background of patients was not possible.

quality of care. Care should be equally safe for all people who use healthcare, independent of their ethnic origins or other contextual characteristics such as cultural practices. Of the current population in the Netherlands, 11% is of non-Western ethnic origin, and this percentage is steadily increasing, similar to other European countries.<sup>1</sup>

Various factors that are known to complicate the care process (such as low proficiency in the majority language and low health literacy) are more prevalent among ethnic minority groups. Although the currently available evidence suggests an increased risk of adverse events (AEs) during hospitalisation in ethnic minority patients, <sup>2–13</sup> there is a lack of valid clinical epidemiological evidence for the situation outside the USA and New Zealand. Since the American healthcare system is different from healthcare systems in the Netherlands and other European countries, results cannot easily be generalised. In the Netherlands (as elsewhere in Europe), access to healthcare is universal, which is not the case in the USA. Also, in the USA results, differences in hospital quality often explain ethnic differences in quality of care, because ethnic minorities more often tend to receive care lower quality hospitals.8

exploratory study in the Netherlands showed ethnic inequalities in excess length of stay (LOS) and unplanned readmission rates. Although excess LOS and readmission can possibly be interpreted as distal indicators of lower quality of hospital care, other interpretations (such as a difference in hospital care needs) are possible.

The patient's ethnic origin itself is a distal cause of a potentially increased patient safety risk. Ethnicity acts through characteristics that are often linked to ethnic minority status, such as a low proficiency in the majority language, a lower educational level and religious and cultural practices that differ from the majority population.<sup>5</sup> <sup>7</sup> <sup>11</sup> We proposed a conceptual model for understanding the relationship between ethnic origin and AEs during hospitalisation. Determinants of an increased risk of AEs were grouped into patient characteristics (such as language proficiency and health literacy) and healthcare (and healthcare provider) characteristics (such as use of an interpreter and cultural competence). If the healthcare provider inadequately adapts his or her service provision to the characteristics of ethnic minority patients (and vice versa), this may result in an increased risk of AEs. We designed an empirical study to compare AE incidence between ethnic Dutch (hereafter referred to as Dutch) and ethnic minority patients during hospitalisation, and to explain potential ethnic inequalities in AE incidence using healthcare-related and patientrelated determinants. 15

This study had the following objectives:

- 1. To compare incidence, type, nature, impact and preventability of AEs during hospitalisation of Dutch patients with those of ethnic minority patients.
- 2. To assess the extent to which patient-related determinants (language proficiency, health literacy, education and religion) are related to the incidence of AEs among Dutch and ethnic minority patients.

### **METHODS**

An extensive description of the methods used in this study (including background information on ethnic minorities living in the Netherlands and a sample size calculation) has been published elsewhere. A short description of the methods is provided below.

### Study population

We included patients of Dutch or ethnic minority origin between 45 and 75 years of age who had been admitted to the hospital for at least 1 night in one of the 30 participating wards (internal medicine, surgery, neurology, cardiology, pulmonology or orthopaedic surgery). These 30 wards were selected from two teaching hospitals and two university hospitals in three Dutch cities with highly ethnically diverse populations.

We used definitions of Statistic Netherlands to distinguish Dutch and ethnic minority patients. <sup>16</sup> We included patients of non-Western origin (as defined by Statistics

Netherlands) in the ethnic minority study group (non-Western countries of origin include Turkey and all countries in Africa, South America and Asia, except for Japan and Indonesia). The use of country of birth criteria is common in continental Europe and has a high correlation with self-assessed ethnic origin. Non-Dutch patients of Western origin were excluded from the study to maximise the contrast between the study groups with respect to potential explanatory variables (such as language proficiency). For the same reason, we excluded patients younger than 45, because in the Netherlands, ethnic minority patients aged 45 and older are mainly first-generation migrants.

### **Patient recruitment**

Patient recruitment took place between December 2010 and October 2012. Patients were recruited during their hospital stay by a researcher or research assistant. Each ward was visited once or twice a week, depending on patient turnover. During each visit, the researchers used each ward's admission information to assess the presence of patients who met the inclusion criteria. A senior nurse verified whether the eligible patients could approached. The senior nurse only advised against approach because of medical conditions, not because of language barriers. To avoid selection bias, we approached the eligible patients using chronological order of admission dates (ie, we approached the most recently admitted patient first). On most wards, there were more eligible Dutch patients than ethnic minority patients. Therefore, to maintain the comparability of study groups, the difference in numbers of Dutch and ethnic minority patients included in our cohort was not allowed to exceed 10 per ward.

Each research assistant was requested to monitor eligibility, availability to be approached, response and reasons for non-response. In one hospital and on one ward of another hospital, response monitoring was unintentionally incomplete. Therefore, we estimated the response rate using the complete response data of the other hospitals/wards.

All patients who were willing to participate gave informed consent. Informational letters, informed consent forms and questionnaires were available in different languages, and in each hospital we recruited bilingual research assistants to provide patients with oral translations.

### **Data collection**

### Patient and admission characteristics

At recruitment, a questionnaire was used to collect data on the patient's ethnic origin, language proficiency, health literacy, education and religion. Language proficiency was measured by asking about the patient's ability to understand, speak, write and read the Dutch language; health literacy was measured with Chew's Set of Brief Screening Questions (SBSQ); 18 education was measured by the total number of years of education from the age of 6 and the highest education completed;

religion was measured by asking whether the patient was religious, and if they answered yes, which religion the patient practised and how often they attended a religious service. The researcher also recorded his or her perception of the patient's language proficiency and health literacy. More details about the questionnaire have been published elsewhere. <sup>15</sup>

Further patient and admission characteristics were collected from the patient record, including age, sex, LOS, admission status (eg, elective, urgent), admission and discharge diagnosis, admission specialty, surgery during admission (yes/no) and intensive or intermediate care stay during admission.

### AE assessment

Around 4 months after the patient's discharge, independent record reviewers screened the patient record for the presence of AEs. Patient records were reviewed in a twostage review process based on the Harvard Medical Practice Study (HMPS)<sup>19</sup> and Dutch patient safety studies. <sup>20</sup> <sup>21</sup> In the first stage, a nurse screened the record for the presence of 1 or more of the 16 triggers known to be sensitive to the presence of an AE (such as an unexpected transfer to an intensive care unit or a hospital-acquired infection). 15 If one or more triggers were found, the record was forwarded to the second stage of the review procedure. The nurse decided which specialist would review the record in the second phase: a specialist in internal medicine, a surgeon or a neurologist. The specialist determined whether an AE had occurred. Seven nurses and five specialists participated in the record review. Since nurses and specialists were recruited from other Dutch record review studies, 20 21 they were trained and highly experienced record reviewers. They never reviewed records in hospitals where they currently worked or had worked in the past. During data collection, reflection meetings were organised on a regular basis. To avoid bias, all reviewers reviewed equal numbers of records from both study groups.

Three criteria were used to determine AEs. First, the specialist determined whether unintended injury had occurred. Second, the specialist determined whether this injury had resulted in temporary or permanent disability, a prolonged hospital stay or death. Third, the specialist used a 6-point scale to determine whether the injury was caused by healthcare management rather than by the patient's disease. Causation scores of 4–6 were classified as AEs and analysed further. If an AE was detected, the review was continued with questions about the nature, impact, location, classification, preventability and causes of the AE (box 1).

### Inter-rater reliability

To assess the reliability of the screening for triggers assessed by nurses, an independent nurse screened 5% of the records a second time. To assess the reliability of AE determination, a second specialist independently reviewed 10% of the second-stage records. In the first

stage, there was a positive agreement of 75% and a negative agreement of 73% for nurses finding one or more triggers. In the second stage, physicians showed a positive agreement of 61% and a negative agreement of 84% for determination of AEs. The numbers of double-checked records with preventable AEs were too small to calculate agreements. We showed positive and negative agreements, as these are absolute measures that are the most informative, specific and transparent compared with a relative measure such as a  $\kappa$  statistic.<sup>22</sup>

#### **Data analysis**

Data were analysed using SPSS V.20.0 for Windows. Descriptive statistics were used to assess patient and admission characteristics at baseline for the Dutch and ethnic minority patients. Differences at baseline between both groups were tested with a t test, median test, or  $\chi^2$  test, whichever was applicable. Crude AE incidences (%) were calculated for both groups with 95% CIs. Subsequently, we performed stepwise multiple logistic regression.

In the first model, only study group (Dutch or non-Western ethnic origin) was taken into account. In the second model, patient mix and admission characteristics were added. We selected patient mix and admission

## Box 1 Definition of an adverse event<sup>20</sup> <sup>21</sup>

### Adverse event (AE)

An unintended injury\* that results in temporary or permanent disability, death, or a prolonged hospital stay and is caused by healthcare management rather than by the patient's underlying disease process.

\*Unintended injury: Any disadvantage for the patient that leads to prolonged or additional treatment, temporary or permanent (physical and/or mental) impairment, or death.

In our study, determination of the *presence* of an AE was based on three criteria:

- 1. An unintended (physical and/or mental) injury that;
- Resulted in a prolonged hospital stay, temporary or permanent disability or death, and was;
- Caused by healthcare management rather than by the patient's disease.

### Preventable adverse event

An AE resulting from an error in management due to failure to follow accepted practice at an individual or system level. Accepted practice is the "current level of expected performance for the average practitioner or system that manages the condition in question."

In our study, the six levels of *preventability* of AEs were classified into two categories during data analysis:

- No preventability or low preventability: (Virtually) no evidence for preventability/slight to modest evidence for preventability/preventability not quite likely (less than 50/50 but 'close call')
- Potentially preventable AEs:
   Preventability more likely than not (more than 50/50, but 'close call')/Strong evidence of preventability/(Virtually) certain evidence of preventability

characteristics for the second model based on the bivariate analyses with study group and the variable of interest in the model (age, gender and all admission characteristics that could potentially have caused the outcome such as LOS, urgent admission, intensive/intermediate care stay and surgery during admission). Variables showing a p value of <0.2 after bivariate regression analysis were selected for the multivariate regression model. In the third model, we added the possible explanatory variables language proficiency, health literacy, education and religion. ORs, p values and 95% CIs were assessed for each model.

### Missing data

There were no missing data in outcome variables. In admission characteristics, certain missing data were identified (varying from 0 in surgery yes/no to 34 (2%) in intensive/intermediate care stay). Most missing data could be imputed with the help of other record data (eg, main diagnostic code could be determined from admission and discharge descriptions). In patient characteristics, the number of missing data varied from 18 (1%) in Dutch proficiency to 49 (4%) in highest education completed. Most of the time, they could be imputed with other data such as the reviewer's perception of the patient's language proficiency and health literacy, or by using the number of years of education completed to estimate the highest education completed. We chose to impute only missing data we considered valid (eg, when a researcher had clearly reported the patient's language proficiency based on the interview), leaving us with 21 cases with at least one missing value in the most extensive multiple regression model and thus a complete case analysis with 1318 cases.

#### **Privacy**

In this study, privacy of patients, healthcare providers and hospitals was considered to be of the utmost importance. Researchers and record reviewers signed a confidentiality agreement to maintain the confidentiality of the information. Each admission received a unique study number. Patient identifiers were kept in a data set separate from the research database. Record review data were entered directly into a secure electronic database.

### **RESULTS**

Initially, 1474 patients were willing to participate, of whom 98 did not meet the inclusion criteria (mainly because of a non-Dutch Western rather than a non-Western ethnic origin). Figure 1 shows a flow chart of the recruitment and record review process. A total of 1376 patients were included in our cohort: 785 Dutch

<sup>i</sup>Owing to incomplete inclusion and exclusion data from one hospital and one ward within another hospital, we used the complete data from all other wards to estimate numbers and percentages for these.

and 591 ethnic minority patients (table 1, demographics; figure 1, flow chart).

Occasionally, patients were not approached following the advice of the senior nurse (about 25 per hospital). These were mostly patients with severe neurological conditions, patients in strict isolation or patients who had recently heard bad news. We were able to include some of these patients later on. There was no difference between Dutch and ethnic minority patients in the number of such negative recommendations.

Some eligible patients could not be approached because of a language barrier (range: 7–20 patients per hospital). In the hospital with the highest number (20), we were not able to approach some Moroccan patients because a Moroccan research assistant was not always available. Most of the other patients who could not be approached spoke languages we were not able to cover.

Response rates did not differ between Dutch and ethnic minority patients, and varied from 73% to 87% between hospitals in Dutch patients, and from 77% to 82% in ethnic minority patients. Reasons given for refusal to participate varied from "too sick to participate" to "opposed to record review." More than 50% of the patients who refused did not provide an explicit reason for their refusal. During the record review, another 37 patients had to be excluded (eg, because their records were not available or because the patient appeared to have been admitted as a day patient; figure 1).

The final cohort consisted of 763 Dutch patients and 576 ethnic minority patients. Table 1 shows that the largest ethnic minority patient subgroup consisted of Surinamese patients, followed by Turkish and Moroccan patients, and smaller groups of patients of Ghanaian and Antillean origin. The 'other' group consisted mainly of patients originating from Iran, Iraq, Pakistan and Egypt. Fifty-seven per cent of ethnic minorities lived in the Netherlands for more than 30 years, while 3% lived in the Netherlands for less than 10 years. Dutch patients were on average 3.3 years older than ethnic minority patients. There was no significant difference in median LOS between Dutch and ethnic minority patients, although Dutch patients had more outliers, and thus a larger SD. Excluding LOS >40 days, or LOS >20 days did not materially change the results. There was a significantly higher rate of endocrine diseases as the main International Classification of Diseases (ICD) diagnosis among ethnic minority patients. These were mostly patients with diabetes mellitus. Also, ethnic minority patients had significantly more urgent admissions. The difference in intensive/intermediate care stay was non-significant. The patient's primary treating physician was a specialist in internal medicine more often for ethnic minority patients than for Dutch patients. Language proficiency, health literacy, education and religion differed significantly between Dutch and ethnic minority patients: nearly 39% of ethnic minority patients were not proficient in the Dutch language, 50% had inadequate health literacy and 31% had had no

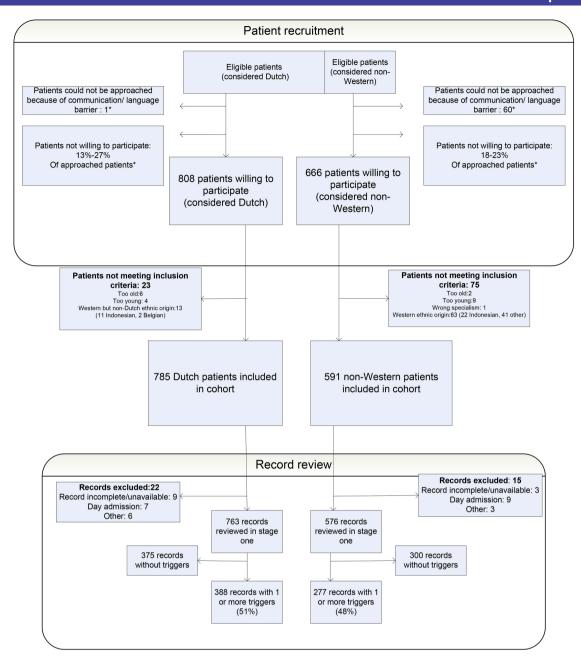


Figure 1 Flow chart of study.

education after the age of 6. More than 90% of ethnic minority patients considered themselves to be religious, compared with under 40% of Dutch patients.

Fifty-one per cent of the records of Dutch patients and 48% of the records of ethnic minority patients had one or more triggers. This was a non-significant difference. The pattern of distribution of specific screening criteria was the same in the two study groups.

As shown in table 2, we found an AE incidence of 11% in Dutch patients and 10% in ethnic minority patients (non-significant difference). There was no significant difference for preventable AE incidence, although the rate tended to be higher among Dutch patients. In both groups, most AEs were surgery-related. We did not find significant differences in type of AEs, although ethnic

minority patients tended to have more medical procedure-related AEs (eg, central catheters, endoscopies, pacemakers, intervention radiology) than Dutch patients (p value, 2-sided Fisher's exact test: 0.072). We found no significant differences in the impact of AEs (such as temporary or permanent disability).

Bivariate regression analysis with ethnic minority background and all of the patients' mix and admission variables shown in table 1 resulted in four variables for the multivariate model (p<0.2): endocrine disease, urgent admission, intensive/intermediate care stay and surgery during admission. Surgery and intensive/intermediate care stay increased the risk of AEs, while endocrine disease and urgent admissions decreased the risk.

|                                       | Dutch patients (N=763)              | Ethnic minority patients (N=576)      | Test,<br>p Value                 |
|---------------------------------------|-------------------------------------|---------------------------------------|----------------------------------|
| Ethnic origin (by                     | Dutch: 763 (100%)                   | Surinamese: 227 (39%)                 | Not                              |
| country of birth criteria)            |                                     | Moroccan: 100 (17%)                   | applicable                       |
| N (%)                                 |                                     | Turkish: 107 (18%)                    |                                  |
|                                       |                                     | Ghanaian: 21 (4%)                     |                                  |
|                                       |                                     | Dutch Antillean/Aruban: 27 (5%)       |                                  |
|                                       |                                     | Other: 94 (16%)                       |                                  |
| N (%) male                            | 438 (57%)                           | 337 (59%)                             | $\chi^2$ , >0.2                  |
| Age (mean, SD)*                       | 62.1, 8.1                           | 58.9, 8.3                             | t test, 0.000                    |
| LOS (median, SD)                      | 7.1, 25.1                           | 7.0, 12.9                             | Median test                      |
| Main ICD diagnosis                    | Infectious diseases: 23 (3%)        | Infectious diseases: 17 (3%)          | $\chi^2$ , >0.2                  |
| group                                 | Neoplasms: 89 (12%)                 | Neoplasms: 52 (9%)                    | $\chi^2$ , >0.2                  |
| N (%)                                 | Endocrine*: 20 (3%)                 | Endocrine*: 38 (7%)                   | $\chi^2$ , 0.023                 |
|                                       | Circulatory: 158 (21%)              | Circulatory: 127 (22%)                | $\chi^2$ , 0.023 $\chi^2$ , >0.2 |
|                                       | Respiratory: 67 (9%)                | Respiratory: 42 (7%)                  | $\chi^2$ , >0.2                  |
|                                       | Digestive: 92 (12%)                 | Digestive: 63 (11%)                   | $\chi^2$ , >0.2                  |
|                                       | Musculoskeletal: 104 (14%)          | Musculoskeletal: 81 (14%)             | $\chi^2$ , >0.2                  |
|                                       | Injury: 68 (9%)                     | Injury: 39 (7%)                       | $\chi^2$ , >0.2                  |
|                                       | Other: 142 (19%)                    | Other: 117 (20%)                      | $\chi^2$ , >0.2                  |
| Urgent admission N (%)*               | 454 (60%)                           | 384 (67%)                             | $\chi^2$ , 0.009                 |
| Intensive or                          | 115 (15%)                           | 77 (13%)                              | $\chi^2$ , >0.2                  |
| intermediate care stay N (%)          |                                     | ,                                     | <b>~</b> ·                       |
| Specialty of primary                  | Cardiology: 83 (11%)                | Cardiology: 76 (13%)                  | $\chi^2$ , >0.2                  |
| treating physician                    | Surgery: 134 (18%)                  | Surgery: 85 (15%)                     | $\chi^2$ , >0.2                  |
|                                       | Internal medicine*: 225 (30%)       | Internal medicine*: 208 (36%)         | $\chi^2$ , 0.010                 |
|                                       | Pulmonology: 89 (12%)               | Pulmonology: 52 (9%)                  | $\chi^2$ , >0.2                  |
|                                       | Neurology: 97 (13%)                 | Neurology: 64 (11%)                   | $\chi^2$ , >0.2                  |
|                                       | Orthopaedic surgery: 98 (13%)       | Orthopaedic surgery: 63 (11%)         | $\chi^2$ , >0.2                  |
|                                       | Other: 37 (5%)                      | Other: 28 (5%)                        | $\chi^2$ , >0.2                  |
| Reason for admission                  | Diagnosis: 241 (32%)                | Diagnosis: 195 (34%)                  | $\chi^2$ , >0.2                  |
|                                       | Observation: 72 (9%)                | Observation: 62 (11%)                 | $\chi^2$ , >0.2                  |
|                                       | Treatment: 432 (57%)                | Treatment: 306 (53%)                  | $\chi^2$ , >0.2                  |
|                                       | Other: 18 (2%)                      | Other: 13 (2%)                        | $\chi^2$ , >0.2                  |
| Surgery during admission (yes) N (%)* | 274 (36%)                           | 183 (32%)                             | $\chi^2$ , 0.116                 |
| Dutch proficiency†                    | Good: 677 (89%)                     | Good: 216 (38%)                       | $\chi^2$ , 0.000                 |
| N (%)*                                | Moderate: 78 (10%)                  | Moderate: 138 (24%)                   |                                  |
| 4 missing values                      | Low/none: 6 (1%)                    | Low/none: 220 (38%)                   |                                  |
| Health literacy N (%)*                | Adequate: 675 (89%)                 | Adequate: 282 (50%)                   | $\chi^2$ , 0.000                 |
| 8 missing values                      | Inadequate: 82 (11%)                | Inadequate: 292 (50%)                 |                                  |
| Educational level‡                    | Low/none: 260 (34%)                 | Low/none: 282 (48%)                   | $\chi^2$ , 0.000                 |
| N (%)*                                | Intermediate: 320 (42%)             | Intermediate: 227 (40%)               |                                  |
| 14 missing values                     | High: 180 (24%)                     | High: 69 (12%)                        |                                  |
| Religion                              | Not religious: 62%                  | Not religious: 8%                     | $\chi^2$ , 0.000                 |
| N (%)*                                | Religious: 38% (N=284) Christian:   | Religious: 92% (N=525) Christian:     |                                  |
|                                       | 78% Muslim: 1% Hindu: 0% Other: 21% | 19% Muslim: 55% Hindu: 15% Other: 11% |                                  |
|                                       | Not/rarely practising: 90.4%        | Not/rarely practising: 60%            |                                  |
|                                       | Practising: 9.6%                    | Practising: 40%                       |                                  |

<sup>\*</sup>Differs significantly between Dutch and ethnic minority patients (p<0.2).
†Proficiency in understanding, speaking, reading and writing Dutch.
‡ No educational level=no education after age 6; low educational level=primary school and/or lower secondary school level or no more than 6 years of education after age 6.
ICD, International Classification of Diseases; LOS, length of stay.

Table 2 Number of AEs, AE rates, preventable AE rates and responsible specialty, clinical process and impact within AEs for Dutch and ethnic minority patients

|   | Dutch                 | Ethnic minority      |
|---|-----------------------|----------------------|
| N records available for analysis  | 763                   | 576                  |
| N records forwarded to stage 2 (%)  | 388 (51%)             | 277 (48%)            |
| N records with at least 1 AE (crude)  | 87                    | 57                   |
| Percentage of patients with at least 1 AE during hospital stay (95% CI)       | 11.4% (9.14 to 13.66) | 9.9% (7.46 to 12.34) |
| (Potentially) preventable AEs (N), and incidence within unique cases (95% CI) | 20 preventable AEs    | 6 preventable AEs    |
|   | 2.6% (1.49 to 3.75)   | 1.0% (0.21 to 1.87)  |
| N AEs total (crude) (including 2nd and 3rd AEs per patient)                   | 93                    | 64                   |
| Responsible specialty (within AEs) N (%)                                      |                       |                      |
| Surgical  | 55 (59%)              | 35 (55%)             |
| Non-surgical  | 38 (41%)              | 29 (45%)             |
| Clinical process (within AEs) N (%)   | , ,                   | ` ,                  |
| Diagnosis   | 6 (7%)                | 1 (2%)               |
| Surgery   | 52 (56%)              | 31 (48%)             |
| Medical procedure   | 10 (11%)              | 14 (22%)             |
| Medication  | 21 (23%)              | 15 (23%)             |
| Other   | 4 (3%)                | 3 (5%)               |
| Impact of AEs   |                       |                      |
| No impact   | 24 (26%)              | 17 (27%)             |
| Injury, full recovery <1 year   | 48 (52%)              | 41 (64%)             |
| Severe, permanent disability or death   | 10 (11%)              | 4 (6%)               |
| Not known*  | 11 (12%)              | 2 (3%)               |

The three multivariate regression models are presented in table 3. The first model shows the crude OR for ethnic minority patients who experienced an AE compared with Dutch patients. The second model was adjusted for patient mix and admission characteristics, and shows a non-significant OR of 0.923 for ethnic minority patients. In the third model, we added the patient-related explanatory variables: health literacy, language proficiency, education and religion. The ORs

show that these factors did not significantly influence the odds of experiencing an AE during hospitalisation.

We performed several sensitivity analyses, such as univariate analyses with patient characteristics and subgroup analyses within groups with good versus inadequate proficiency in Dutch. In these analyses, the results remained the same. We read case descriptions of AEs to check whether the causal relationship between patient-related factors and AEs had been judged in a standardised way.

| Admission characteristics  Endocrine disease 0.40 (0.09 to 1.68) 0.45 (0.11 to 1 Urgent admission 1.10 (0.73 to 1.67) 1.05 (0.69 to 1 Intensive/intermediate care stay 1.05 (0.69 to 1 Intensive/intermediate 1.05 (0.45 to 1 Intensive/intermediate 1.05 (0.59 to 1 Intensive/intermediate 1.08 (0.64 to 1 Intensive/intensive/intermediate 1.08 (0.64 to 1 Intensive/intensive |                                  | Model 1          | Model 2             | Model 3            |
|--|----------------------------------|------------------|---------------------|--------------------|
| Endocrine disease 0.40 (0.09 to 1.68) 0.45 (0.11 to 1 Urgent admission 1.10 (0.73 to 1.67) 1.05 (0.69 to 1 Intensive/intermediate care stay 2.49 (1.67 to 3.87) 2.55 (1.66 to 3 Surgery 3.46 (2.29 to 5.22) 3.38 (2.23 to 5 Inadequate health literacy 0.79 (0.45 to 1 Dutch proficiency* moderate 1.05 (0.59 to 1 Dutch proficiency low/none 1.61 (0.79 to 3 Education† intermediate 1.08 (0.64 to 1 Education none/low 1.40 (0.81 to 2 Index to 1 Inde | Ethnic minority origin           | 0.85 (0.60-1.21) | 0.94 (0.65 to 1.35) | 0.89 (0.53 to 1.50 |
| Urgent admission       1.10 (0.73 to 1.67)       1.05 (0.69 to 1.67)         Intensive/intermediate care stay       2.49 (1.67 to 3.87)       2.55 (1.66 to 3.87)         Surgery       3.46 (2.29 to 5.22)       3.38 (2.23 to 5.22)         Patient characteristics       0.79 (0.45 to 1.67)         Inadequate health literacy       0.79 (0.45 to 1.67)         Dutch proficiency* moderate       1.05 (0.59 to 1.67)         Dutch proficiency low/none       1.61 (0.79 to 3.87)         Education† intermediate       1.08 (0.64 to 1.67)         Education none/low       1.40 (0.81 to 2.27)   | Admission characteristics        |                  |                     |                    |
| Intensive/intermediate care stay       2.49 (1.67 to 3.87)       2.55 (1.66 to 3.87)         Surgery       3.46 (2.29 to 5.22)       3.38 (2.23 to 5.22)         Patient characteristics       0.79 (0.45 to 1.22)         Inadequate health literacy       0.79 (0.45 to 1.22)         Dutch proficiency* moderate       1.05 (0.59 to 1.22)         Dutch proficiency low/none       1.61 (0.79 to 3.22)         Education† intermediate       1.08 (0.64 to 1.22)         Education none/low       1.40 (0.81 to 2.22)  | Endocrine disease                |                  | 0.40 (0.09 to 1.68) | 0.45 (0.11 to 1.79 |
| Surgery       3.46 (2.29 to 5.22)       3.38 (2.23 to 5.22)         Patient characteristics       0.79 (0.45 to 1.22)         Inadequate health literacy       0.79 (0.45 to 1.22)         Dutch proficiency* moderate       1.05 (0.59 to 1.22)         Dutch proficiency low/none       1.61 (0.79 to 3.22)         Education† intermediate       1.08 (0.64 to 1.22)         Education none/low       1.40 (0.81 to 2.23)   | Urgent admission                 |                  | 1.10 (0.73 to 1.67) | 1.05 (0.69 to 1.59 |
| Patient characteristics Inadequate health literacy Dutch proficiency* moderate Dutch proficiency low/none Education† intermediate Education none/low  O.79 (0.45 to 1 1.05 (0.59 to 1 1.01 (0.79 to 3 1.08 (0.64 to 1 1.08 (0.64 to 1 1.40 (0.81 to 2 1.40 (0. | Intensive/intermediate care stay |                  | 2.49 (1.67 to 3.87) | 2.55 (1.66 to 3.92 |
| Inadequate health literacy  Dutch proficiency* moderate  Dutch proficiency low/none  Education† intermediate  Education none/low  0.79 (0.45 to 1 1.05 (0.59 to 1 1.07 to 3 1.61 (0.79 to 3 1.08 (0.64 to 1 1.40 (0.81 to 2  | Surgery                          |                  | 3.46 (2.29 to 5.22) | 3.38 (2.23 to 5.14 |
| Dutch proficiency* moderate1.05 (0.59 to 1Dutch proficiency low/none1.61 (0.79 to 3Education† intermediate1.08 (0.64 to 1Education none/low1.40 (0.81 to 2   | Patient characteristics          |                  |                     |                    |
| Dutch proficiency low/none 1.61 (0.79 to 3 Education† intermediate 1.08 (0.64 to 1 Education none/low 1.40 (0.81 to 2  | Inadequate health literacy       |                  |                     | 0.79 (0.45 to 1.37 |
| Education† intermediate 1.08 (0.64 to 1 Education none/low 1.40 (0.81 to 2   | Dutch proficiency* moderate      |                  |                     | 1.05 (0.59 to 1.87 |
| Education none/low 1.40 (0.81 to 2   | Dutch proficiency low/none       |                  |                     | 1.61 (0.79 to 3.30 |
|  | Education† intermediate          |                  |                     | 1.08 (0.64 to 1.81 |
| Religious, practising 0.82 (0.51 to 1  | Education none/low               |                  |                     | 1.40 (0.81 to 2.41 |
|  | Religious, practising            |                  |                     | 0.82 (0.51 to 1.32 |
| Model 1: All cases included (N=1339).  Model 2: 1 case with missing value(s), analysis of 1338 cases.  |                                  |                  |                     |                    |

\*Good Dutch proficiency is the reference category. †High educational level is the reference category.

AE, adverse events.

We found no differences in judgement between Dutch and ethnic minority patients, or between language proficiency groups.

### DISCUSSION Summary results

This is the first empirical study on ethnic inequalities in patient safety during hospitalisation in a European country. In our study, we found that incidence rates of AEs and preventable AEs were not increased for ethnic minority patients when compared with Dutch patients. This result remained when we adjusted for admission characteristics. Patients with low language proficiency, low health literacy and low educational level were not at significantly increased risk of experiencing AEs while receiving care in Dutch hospitals.

### Strengths and limitations

The combination of patient questionnaires and record review provided us with high-quality data on ethnic origin, language proficiency, health literacy and education, which are rarely found in patient records. By using informational materials and measurement instruments in several languages as well as bilingual research assistants, we were able to include patients with low proficiency in the majority language. However, approximately 60 patients were not approached because of a language barrier, which is a potential selection bias because those are the patients who are also not able to communicate with healthcare providers. Nevertheless, we have still managed to include many of these potentially vulnerable patients (40% of the patients had low or no Dutch proficiency), and the selection was random. The patients not included were not more vulnerable to AEs than the patients who were included, this was dependent on the presence of research assistants or other interpreters at the time of inclusion. However, the patients who were more often accompanied by relatives might have had a slightly higher chance to be included in the study.

Despite the high response rate among this group, we did not include more than 600 ethnic minority patients. We do not believe that a larger sample of ethnic minority patients would have changed our results, because the AE rates of the study groups were almost the same and did not tend to differ. However, our study might have been underpowered for comparing *preventable* AE rates.

In designing the present study, our goal was to generate two comparable groups rather than a representative sample of the Dutch hospital population. Compared with the most recent national reference data on AEs in hospitalised patients 1 year of age and older across all wards except obstetrics and psychiatry, we found slightly (but not significantly) higher AE rates and equal preventable AE rates. We also found the same pattern in distribution of clinical processes within AEs. Hence, our results seem to be quite comparable to national data. However, the AE rate in ethnic minority patients may

not be generalisable to all ethnic minority patients in Dutch hospitals because this study was conducted in hospitals with a relatively high percentage of patients from ethnic minority backgrounds. In these hospitals, health-care providers are used to working with patients of ethnic minority origin. We can speculate that hospitals with a low percentage of ethnic minority patients may be less used to adapting their care provision to provide appropriate care for patients of ethnic minority origin.

Although we did not mention the patient's ethnic background to record reviewers, it was not possible to blind them entirely to the study groups. Surnames, photos and notes in the records often provided indications of the patient's ethnic background. This may have influenced the reviewers, as it may have affected the way they interpreted what they found. This potential observer bias is a limitation of the study. To avoid this potential observer bias, we made sure that individual reviewers reviewed equal numbers of records of Dutch as well as ethnic minority patients, and we addressed observer bias issues on reflection days. In addition, the structured and highly standardised review procedure reduced the risk of bias.

A weakness of record review is hindsight bias. Knowing the outcome and its severity may influence the judgement of causation and preventability. However, this will affect both groups equally, suggesting that comparability between them is unaffected.

Although record review is currently the most valid measure for assessing frequency and types of AEs, and has high face validity with healthcare workers, <sup>23</sup> it may be inadequate for assessing underlying causes related to patient-provider interaction. Detailed descriptions of patient-provider interaction were often absent from the records. We checked the descriptions of harm that had been judged to be 'patient-related' rather than 'healthcare-related,' and found no differences between Dutch and ethnic minority patients. Most often, patientrelated harm was caused by the patient's disease (eg, delirium because of pancreatitis). We identified only a few cases in both groups where patient behaviour had been the cause of patient-related harm (eg, noncompliance, alcohol abuse, no-show in outpatient clinic). Record reviewers used accepted practice (ie, 'the current level of expected performance for the average practitioner or system that manages the condition in question') to determine preventability of AEs. However, the extent to which a healthcare provider may be held responsible for patient non-compliance with regard to therapy or recommendations is still an area of debate.

#### **Comparison with other studies**

We found baseline differences between ethnic minority and Dutch patients in patient and admission characteristics potentially related to AEs. We found higher age and higher surgery rates during hospitalisation among Dutch patients. The international literature also reports less surgery among ethnic minority patients (eg, in orthopaedic surgery<sup>24</sup>). Although this might hint at informal access problems to orthopaedic care for ethnic minority patients, we cannot draw this conclusion because our data cover only the patients' hospital stays and not primary care, which is where patients are referred for orthopaedic surgery.

Three American studies that showed ethnic inequalities in patient safety used patient safety indicators (PSIs) as outcome measures, <sup>2</sup> <sup>4</sup> <sup>8</sup> which is not directly comparable to our outcome measure. However, PSIs are to some extent similar to the triggers in the first stage of the record review. Unlike the American studies, we found no differences between Dutch and ethnic minority patients in occurrence of triggers. In the American studies, ethnic inequalities in PSIs were explained (in full or in part) by differences in overall quality of care between hospitals, with lower overall quality in what are known as 'minority-serving hospitals'. In the Dutch healthcare system, all patients have equal access to a wide range of hospital care through their mandatory basic healthcare insurance. Although patient populations may differ between hospitals, there are no typically minority-serving hospitals in the Netherlands.

A study in New Zealand, <sup>10</sup> which had a study design quite comparable to our own, showed higher AE rates for the minority population when compared with the majority population, something the authors attributed to suboptimal care. The study also showed a marginally lower *preventable* AE rate for the minority population.

Although the international literature has shown that patient factors including low language proficiency and low health literacy influence the care process and AE risks, the present study did not show an increase in the risk of AEs. A study by Divi et  $al^7$  in the USA showed that low language proficiency increased the risk of AEs. This study analysed incident reports, and detected more failures in communication than we did using our method of record review. However, their results cannot easily be compared with our own because of different definitions for AEs and differences in study design. Another American study that focused particularly on language barriers used a case-control design to analyse 'serious medical events.'5 This study also used a different definition of outcome than we did, namely 'events that led to unintended or potentially adverse outcomes.' In addition, it was performed in a paediatric setting with children and their families, which cannot easily be compared with the adult study population in the present paper.

Our results might be explained by the adequate adaptation of hospitals and healthcare providers in the Netherlands to ethnically diverse patient populations. In the final meeting, the record reviewers said the records had left them with the impression that healthcare providers indeed made extra efforts for patients with low literacy and low Dutch proficiency. From observations and chats with care providers during the patient inclusion period, we also got the strong impression that care providers were highly motivated to provide high-quality care to

all patients including ethnic minorities, but that the way this care was provided highly depended on personal beliefs and interests, and was not based on systematic education or guidelines. Research has shown that 'diversity of patients' is not a structural part of medical education in the Netherlands.<sup>25</sup> Reviewers also felt that care was equally safe in both groups, although it did not proceed as smoothly for ethnic minority patients. Standard care suited Dutch patients better than ethnic minority patients. The results of the Dutch study on excess LOS and readmission also point towards this by showing excess LOS in ethnic minorities. 14 In the present study, excess LOS could not be assessed. Our results might also be explained in part by the fact that ethnic minority patients themselves, and their relatives, played a role in maintaining safety. We observed that ethnic minority patients were more often accompanied by relatives than Dutch patients, and that these relatives played a major role in the care process (eg, by providing translations). Although the use of interpretation services provided by untrained relatives is not in line with international standards such as those of the Joint Commission International (ICI), it might be considered to be better than no interpretation at all. The role of relatives in diversity-responsive care is a topic for future research.

#### Implications/conclusion

We found no difference in incidence of AEs between ethnic minority and Dutch hospitalised patients, although the groups clearly differed by patient profile. The hypothesised effects of variables such as low Dutch proficiency in increasing patient safety risks were not substantiated. Hospitals and healthcare providers seem to have handled the additional risks associated with ethnic minority patients (such as language barriers and low educational level) quite well. Relatives of patients may also have had a protective role. Although healthcare providers seem to have responded effectively to specific patient care needs, we do not know whether this occurred in an ad hoc or in a systematic way.

The minimum prerequisite for good quality of care, patient safety, is guaranteed for ethnic minorities in the Dutch Healthcare system. This is an unexpected finding that needs to be confirmed by replication studies in similar healthcare systems.

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Contributors FvR was responsible for study design, data collection, data analysis and drafted the paper. MdB codesigned the study, performed data interpretation and critically revised the paper. M-LE-B codesigned the study, performed data interpretation and critically revised the paper. KS and CW codesigned the study and critically revised the paper.

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