Do inter-hospital comparisons of in-hospital, acute myocardial infarction case-fatality rates serve the purpose of fostering quality improvement? An evaluative study

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5   **Background**

Acute Myocardial Infarction (AMI) is a health problem of paramount importance in terms of frequency, seriousness, social and economic costs, amenability to medical intervention and priority-ranking by policy makers and the community [1,2]. Although guidelines that effectively reduce AMI in-hospital case-fatality rates (AMI-CFRs) exist,

10   they are not uniformly applied [3-7]. Conversely, reports of AMI-CFRs were thought to favorably affect quality initiatives [8]. The relationship between better care and lower AMI-CFRs led several countries, national and international agencies, and consumer's organizations to select AMI-CFR as a quality indicator and to publish individual providers' rates[3,9-11].

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To organize the care of AMI patients in Belgium, a three-level structure has been set up. It consists of community hospitals (labeled A) having no catheterization facility, intermediary hospitals (labeled B1) providing coronary angiography but no Percutaneous Coronary Intervention (PCI), and tertiary hospitals (labeled B2-B3) offering PCI and/or

20   Coronary Artery Bypass Graft. A recent study, however, showed unable to establish better outcomes for patients treated in services with catheterization facilities.[12]

Current professional knowledge at the time of our study (2002-5) included the need to distinguish between ST-segment elevation myocardial infarction (STEMI) and non-ST-segment elevation myocardial infarction (NSTEMI), because of their different prognosis; the need for reperfusion as quick as possible, by PCI where possible or by thrombolysis

5   otherwise; and, the safety of transport of patients from community to tertiary hospitals [13-15].

Changes in definition and the diversity of the various cardiac troponin assays may have heavily affected AMI incidence rates and AMI-CFRs [16-20].

At the time the study data were registered and coded by the hospitals, the International

10   Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) did not distinguish between STEMI and NSTEMI, but as from October 2005 new ICD-9-CM regulations provide guidance to do so[21]. Herein STEMI is coded as 410.0-6, 410.8; NSTEMI as 410.7; and AMI "Not Otherwise Specified" (AMI-NOS) as 410.9. It became then possible for one of the authors (NT) to recode a posteriori the data in terms of

15   STEMI or NSTEMI.

According to the OECD "Case-fatality rates measure the proportion of patients with a given diagnosis, here acute myocardial infarction (AMI), who die within a specified time period, here 30 days[11]. Ideally, the case-fatality rates would be based on each

20   individual patient who would be tracked for at least 30 days. However, as most countries do not have unique patient identifiers and the ability to track patients after hospital discharge, the indicator is based on unique hospital admissions and restricted to mortality within the hospital. Thus, differences in practices in discharging and transferring patients

may influence the findings.[11]" Due to the specifics of our administrative data and in alignment with the Agency for Healthcare Research and Quality (AHRQ) definition of the Acute Myocardial Infarction Mortality Rate, our definition of AMI-CFR is exclusively based on hospitalized cases and fatalities within the hospital regardless of any time constraint [9,22].

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A fair inter-hospital comparison requires high-quality data[23,24]. Indeed, they have to be sufficiently detailed to allow fair comparison between a hospitals' practices and the then professional knowledge but also to assess the hospitals' organizational performance, especially its transfer policy and the symptom-onset-to-balloon time[25]. Risk-adjustment constitutes a constant threat to the fairness of the comparisons and widely used proprietary risk-adjustment systems may lead to erroneous conclusions[26,27].

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Accountability of caregivers and health authorities to the community is internationally considered of paramount importance[28]. In spite of known limitations, public reporting of comparative information about the quality of health care, often derived from administrative data, is frequently put forward as an important quality improvement tool, which attempts to stimulate caregivers to grade up the rendering of services and to reassure patients by demonstrating accountability[29-31]. In this context, ensuring data quality is a continuous challenge especially if the same data are used for reimbursement and for measuring quality[31,32].

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Desiring to encourage the hospital system to assume responsibility, the Belgian Ministry of Public Health decided to stimulate initiatives of quality improvement. Hereto a limited set of indicators was selected from the AHRQ Inpatient Quality Indicators, including the AMI-CFR[33]. These indicators were to be routinely analyzed, using routinely collected, Belgian hospital discharge records that are known to differ across institutions in quality of data[34].

In this study we explore the AMI-CFRs' potential as a quality-improving tool. More precisely we aimed (1) to evaluate to which extent Belgian discharge records allow the assessment of quality of care in the field of AMI, (2) to determine the existence of inter-hospital differences in AMI-CFR and (3) to compare outcomes according to type of hospital.

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Methods

Data source

Belgian hospitals are required to register discharge data on each sojourn, which are processed and stored in a dataset called the Minimal Clinical Data (MCD). The MCD

5 contains patient data (among which year of birth, gender, residence, and anonymous hospital and patient identifiers) and stay data (among which year, month and day of the week but, due to privacy restrictions, not the precise date of admission and discharge; length of stay; transfer to another hospital with specification of the type of hospital). It further includes an unbounded number of ICD-9-CM coded diagnoses and procedures but

10 neither results of laboratory investigations, such as cardiac enzymes, nor of technical examinations such as electrocardiograms. Due to privacy regulations a unique identifier, allowing for follow-up of a transferred patient, is lacking. Nonetheless, these data allow for the identification of a cardiogenic shock, the most feared complication of AMI, as well as for the computation of the Charlson co-morbidity index (CCI) (see additional file

15 1: Charlson), particularly well suited to study AMI-CFRs[2,20,35-37].

Incompleteness and inaccuracy are well-known drawbacks of administrative data; therefore, we compared our data with those from the Ghent and Bruges registries for acute coronary events, which are collected according to the protocol that was originally

20 developed in the WHO Multinational **Moni**toring of Trends and Determinants in **Ca**rdiovascular Diseases (MONICA) project[16,38] (see additional file 2: MONICA definitions). In this project the record form is intentionally kept as simple as possible[38]. It consists of (1) items characterizing the person (date of registration, sex, date of birth

and data of onset of the acute attack) and of (2) medical and diagnostic data (whether it

was an hospital case or managed elsewhere; whether the victim survived at 28 days or

not; determination of the diagnostic category based on symptoms, electrocardiograms,

serum enzymes and necropsy findings). In addition, the registries of Ghent (covering the

5   city of Ghent (about 250,000 inhabitants)) and Bruges (covering the district of Bruges

(about 260,000 inhabitants)) record whether or not a revascularization procedure (PTCA

or thrombolysis) was carried out. Coding of all items is checked by both external and

internal quality control[38].

In the light of these uniform registration practices and the quality control carried out, we

10   consider the MONICA registries the standard against which we evaluated the MCD.

For the years 2002-2004, we compared the MONICA hospitalized fatalities (fatal definite

(F1) + fatal possible (F2)) and MONICA hospitalized cases (non-fatal "definite" (NFl) +

"possible" (NF2) + fatal "definite" (F1) + "possible" (F2)), aged 25-74 years, with

respectively the AMI fatalities and cases in the same age groups of the MCD. Unlike the

15   AHRQ definition, a case fatality in MONICA is defined as death within 28 days after the

occurrence of the first symptoms[38]. Due to privacy regulations and according to the

agreement with the hospitals not to perform any analysis on hospital level, we were not

able to compare both databases neither on a hospital nor on an individual level.

20   **Definition of the study population**

Building on the work of the Agency for Healthcare Research and Quality (AHRQ)[9] we

selected, for the years 2002-2005, from the MCD all stays having AMI as principal

diagnosis (ICD-9-CM code 410.*1, the fifth digit indicating an initial episode of care).

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Cases with no information regarding vital status at discharge or aged less than 18 years or, to avoid double counting of patients when computing rates, transferring-out to another short-term hospital were excluded. We also excluded short-term hospitals registering less than 20 cases a year. Applying these criteria we obtained our study population consisting

5   of 46,287 cases (30,271 males and 16,016 females) and 7,099 fatalities (3,841 males and 3,285 females), registered in 109 short-term hospitals.

Design

Our aim was to identify, at the same time, hospitals with higher quality of care, for

10   benchmark and exemplary function purposes, and hospitals with lower quality, to help them improve their performance. To this effect, the AMI-CFR of each individual hospital was compared with the corresponding rate of the whole of the other Belgian hospitals. To assess hospital-specific rates of AMI-CFR a cohort study of all hospitalized AMI cases of the years 2002 to 2005 was carried out. Hereby, two types of analyses were

15   performed: a global one focusing on the AMI-CFRs of the entire time span of the study (the "period") and a temporal one (the "trend"), focusing on its per-semester evolution and intended to refine the initial, global assessment by taking temporal evolution into account.

It has been suggested that in analyses, founded on administrative databases, confounding

20   effects of unmeasured or mismeasured variables can be equivalent in magnitude to the effect of the association of interest and cannot be ruled out as an explanation of rather small, yet statistically significant effect sizes, such as a relative risk (RR) of, say, 0.75 to 1.35, which are roughly each other's inverses [39]. To take this caution against over-

interpretation into account, we defined a inconclusive zone, where the AMI-CF rate or

AMI-CFR trend of a hospital, compared with these of the other hospitals, should not be

interpreted as being "higher" or "lower," but rather be considered "inconclusive." First,

we computed a hospital's relative risk (RR) of having a higher/lower period or trend

5   AMI-CFR than those of the other hospitals. Subsequently, this RR allowed us to calculate

a "departure," equaling (RR -1) x 100, which we used to define an "inconclusive zone."

Regarding the period, we fixed the lower and upper boundaries of the inconclusive zone

at a departure of – 25% and of + 35%, respectively, in line with the aforementioned

relative risks. In the absence of literature regarding important departures of the trend, we

10   arbitrarily fixed these boundaries at – 5% and + 5%, allowing for a maximal increase of +

41% or for a maximal decrease of -30 %, respectively, of the AMI-CFR during the entire

time span of the study. The technical details of our approach are described in the

paragraph devoted to the statistical analysis.

15   The results of the analyses regarding hospitals outside the inconclusive zone, were

interpreted according to the degree of statistical evidence. We labeled th

is evidence as: 1) "strong," if the probability of finding a departure, as important or

bigger than that of the hospital under consideration, was smaller than or equal to 0.05

divided by the number of hospitals to be compared (the so-called Bonferroni correction

20   for multiple comparisons); 2) "moderate," if this probability was smaller than or equal to

0.05 but greater than 0.05 divided by the number of hospitals to be compared; 3) "weak,"

otherwise [34]. For both the period and the trend analyses, two AMI-CFRs were

computed: a first one in which transferring-out cases are excluded, so as not to compute

national rates with duplicate observations [9], and a second one in which all transferred

cases are excluded, to allow for a comparison between hospitals in the subset of cases

they treated from uptake to discharge.

5   We also aimed at identifying transferred patients using composite keys consisting of a

patient's year of birth; gender; residence; year and month of admission and discharge;

and day of the week of discharge ("discharge" facility's data) or admission ("intake"

hospital's data). In these patients, we intended to compare the CCI distributions before

and after transfer to evaluate the comparability across hospitals regarding the coding of

10 co-morbidity, a component of the risk-adjustment in our regression analyses. From the

viewpoint of quality of care, we also compared in these patients the time span between

admission and transfer with the then prevailing guidelines.

Statistical methods

15 For our analyses, we used so-called fixed-effects models, motivated by the fact that the

entire population of Belgian hospitals is considered, rather than sampling from them. We

performed multivariable logistic regressions [40], aiming to identify outlying hospitals,

i.e. characterized by an important and statistically significant, Bonferroni-corrected [24]

departure from the other hospitals' AMI-CF rate or AMI-CFR evolution over time. Given

20 that we cover the short time span of only eight semesters, we merely fitted models with a

linear time trend, which for brevity we called "trend". By incorporating an interaction

term in the logistic regression between a linear time trend, expressed in semesters, and

individual hospitals, those hospitals with an abnormal evolution in time were identified.

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Precisely, we compared the slope of each hospital's time trend with that of the other hospitals using linear contrasts.

When the outcome of interest, such as the percentage of fatal cases in the AMI case fatality rate, exceeds 10 %, or if the odds ratio is greater than 2.5 or less than 0.5, the estimation of the relative risk by the adjusted odds ratios, derived from the logistic regression no longer adequately approximates the relative risk, which may become heavily biased. Indeed, the more frequently that outcome occurs, the more the odds ratio overestimates the relative risk when it is greater than 1 or underestimates the relative risk when the odds ratio is less than one [41]. To reduce this bias, we used the approximation of the RR by Zhang [41], which has been used to compute the aforementioned departure. The relation between RR_Z and the odds ratio is given by $RR_Z = OR/((1-P0)+(P0 *OR))$, where P0 indicates the incidence of the outcome of interest in the non-exposed group[41].

Following the AHRQ model [22], we carried out two types of main analyses: a first one wherein transferred-out cases were excluded and a second one with exclusion of all transferred cases. In each analysis, adjustment was made for five-year age groups, gender, per-semester evolution of the AMI-CFRs, and shock.

To account for correlation within the data, rescaling techniques were used [42]. To study a possible national upward trend we used so-called Generalized Estimating Equations (GEE), a refinement of the logistic regression that corrects for within-hospital, generally within-unit, correlation [43].

Study goals

The results of the analysis serves two purposes: feedback to the hospitals to enable

improvement of care, and feedback to the Belgian College of Physicians to identify

5 hospitals with "strong" evidence of either superior or inferior quality.

The feedback to the hospitals consists mainly of (1) a graphical display of the "departure"

of each of the hospitals from the rate and trend of the other hospitals, and (2) an

anonymous and tabular representation of these departures as well as of an indication of

the level of statistical evidence. An aid in the interpretation, combining the information of

10 both the period and trend analyses, is provided alongside. Its decision tree is given in the

Appendix of the Supplementary Materials (see additional file 3: decision tree).

In the feedback to the Belgian College of Physicians, we present an "Average" and two

"Outlying" categories of hospitals. For the period analysis, a first, outlying category, the

'high AMI-CFR' group, consists of those hospitals with a departure of > +35 and

15 statistically significant (Bonferroni-corrected). A second, outlying category, the 'low

AMI-CFR' group, consists of those hospitals with a departure of < -25 and statistically

significant (Bonferroni-corrected). The other hospitals are grouped into the 'average

AMI-CFR' group. A similar approach is followed regarding the trend. The decision tree is

identical to that for the hospitals, except that hospitals recommended for an external audit

20 are now divided in "high AMI-CFR" and "low AMI-CFR" groups and that the other

hospitals are regrouped in an "average AMI-CFR" group.

Sensitivity analyses

Due to the prognostic differences, related to the type of AMI, its complications and treatment modalities, several sensitivity analyses were carried out. After an initial analysis, modeling AMI-CFR adjusted for age, gender, CCI and time (period as well as

5   trend), subsequent analyses were carried out, consecutively introducing a variable mentioning whether shock was present at admission or not, and a variable indicating whether or not an angioplasty had been performed. We repeated the subsequent analyses, this time replacing shock by a variable describing the type of AMI i.e. STEMI, NSTEMI or AMI NOS. We performed these analyses both after exclusion of the transfer-out stays

10   and of all stays mentioning a transfer. In the trend analyses, we additionally modeled an interaction term between trend and individual hospitals. To summarize the effect of including additional explanatory variables into the model, we classified for each model the hospitals into seven categories, ranging from strong, then moderate, to weak evidence of finding themselves above or below the inconclusive zone.

15   A last category consisted of hospitals showing no interpretable departure.

In so doing, we were able to compare between the hospitals their changes of category due to the modeling process.   Because differences in hospitals' discharge policy may influence their AMI-CFRs we also compared the hospitals' cumulative AMI-CFR at five points in time, namely at the 7th, 14th, 21st, and 28th day of hospitalization, and at the

20   latest day of discharge of any AMI-case[11]. Given the changing numerators of the rate over time, we based our comparison on the hospitals' change in deciles of AMI-CFR. To this end, we computed a maximum change in relation to the initial AMI-CFR. We further determined for each hospital the maximum length of stay (LOS) of any patient whether

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deceased or not, and the maximum LOS of any deceased patient, both after exclusion of the transfer-out stays and after exclusion of all stays mentioning a transfer.

To provide an idea of the variability of some major covariates we determined across hospitals and by level of care, averages of the lower quartile, mean, median and upper

5   quartile of the CCI, LOS and rate of shock. In the same way we computed the average 95th CCI-percentile and the ranges of the LOS.

The study being (1) of a retrospective, non-interventional type and (2) anonymous with respect to both hospitals and patients, no approval by an ethics committee is required

10   under the Belgian law.

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Results

Patient and hospital characteristics by level of care

The MCD dataset consisted of 46,287 cases and 7,099 fatalities [AMI-CFR: 15.34 (95%

CI: 15.01;15.67) from 109 hospitals. The majority of cases (65,4%) and of the fatalities

5   (54.1%) were males. In females the AMI-CFR was higher than in males [age-adjusted

OR: 1.13 (95% CI: 1.04; 1.22)]. In tertiary hospitals, younger age groups (Pearson chi-

square with 10 df = 794.7; p <0.0001) , males (Pearson chi-square with 2 df = 214.5; p

<0.0001) and shock(Pearson chi-square with 2 df = 6.29; p = 0.043) are over-represented

(Table 1).

10   The age-adjusted mortality was higher in Type A [OR:1.17; 95%CI(1.09;1.26)] hospitals

than in Type B2-B3 hospitals. However, we were unable to establish a significant

difference in age-adjusted mortality between Type A en Type B1, and between Type B1

and Type B2B3 hospitals (Table 1). Males had lower mortality figures than females

[OR:0.58; 95%CI(0.55;0.61)] . The sex-adjusted mortality was higher in Type A

15   [OR:1.37; 95%CI(1.30;1.45)].and Type B1[OR:1.18; 95%CI(1.10;1.27)] hospitals than in

Type B2-B3 hospitals. Type A hospitals also displayed a higher sex-adjusted odds ratio

[OR:1.16; 95%CI(1.08;1.26)] than Type B1 (Table 1).

Type B2B3 hospitals had a lower CFRs in case of cardiogenic shock {($OR_A vs_{B2B3}$:1.14

[95%CI(1.23;1.67)] and $OR_{B1} vs_{B2B3}$:1.89 [95%CI(1.51;2.21)])}, and Type A hospitals

20   also had a lower CFR than Type B1 ($OR_A vs_{B1}$:0.76 [95%CI(0.60;0.96)]). Type B2B3

hospitals had also a lower CFRs in case of absence of cardiogenic shock {$OR_A vs_{B2B3}$:1.70

[95%CI(1.58;1.82)] and $OR_{B1} vs_{B2B3}$:1.32 [95%CI(1.20;1.45)] }, but now Type A

hospitals had a higher CFR than Type B1 ($OR_A vs_{B1}$: 1.29 [95%CI(1.17;1.41)]). With

respect to STEMI cases we observed higher AMI-CFRs of Type A and B1 versus Type B2B3 hospitals $\{$(OR$_{A}$vs$_{B2B3}$:1.36 [95%CI (1.27;1.47)] and OR$_{B1}$vs$_{B2B3}$:1.22 [95%CI (1.12;1.34)])$\}$ and of Type A versus Type B1 hospitals (OR$_{A}$vs$_{B1}$: 1.11 [95%CI (1.01;1.22)]). In NSTEMI cases we observed substantially lower AMI-CFRs in Tyoe

5   B2B3 hospitals $\{$(OR$_{A}$vs$_{B2B3}$:2.01[95%CI (1.79;2.26)] and OR$_{B1}$vs$_{B2B3}$:1.84 [95%CI (1.55;2.18)])$\}$. In contrast we were unable to demonstrate either a difference in AMI-CFR between Type A and Type B1 hospitals or evidence of   any deviating AMI-CFR in cases of AMI-NOS. The proportions of cardiogenic shock were very high, viz 9.9 % in STEMI, 4.2% in non-STEMI infarctions and even 12.7% in the AMI NOS group.

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On the hospital level we noticed huge variability across institutions ==of the same type== regarding CCI, length of stay and to a lesser extent shock (expressed in %). However the distribution of these variables was very similar in the three types of hospitals (data not shown).

15   We also observe a huge variability in volume, i.e the number of cases, within and between types of hospital (Table 1). Based on the volumes of the lower quartile, the median and the upper quartile of the Type B1 hospitals in the data, transfers out excluded, we grouped the hospitals in four classes. We observed a huge variability in volume between and within Types of hospital (Pearson chi-square of 300019 with 6 df;p

20   <0.0001) with excesses of low volume hospitals in Type A hospitals (41 out of the 61 of these hospitals found themselves in the lowest class) and of high volumes in Type B2B3 hospitals (26 out of the 29 of these hospitals found themselves in the highest class). The

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Type B1 hospitals were almost equally distributed over the four classes. Similar findings were encountered in the analysis on the data with exclusion of all transfers.

Completeness and accuracy of the data

5 The comparison of the MCD with MONICA (Ghent and Bruges) shows important differences between both datasets (Table 2), characterized by more fatalities and significant higher case-fatality rates in the MONICA registry. Notice that in the MONICA registry 54 out of the 190 fatal cases occurred within the first hour after hospitalization. At that moment these patients probably found themselves in the

10 emergency services, where in Belgium as yet no specific ICD codes are systematically registered. To formally assess the completeness of the data we compared the number of cases by gender and place in both registries. Using log-linear models, we firstly modeled number of cases as dependent variable and gender place and registry as covariates, and subsequently left out registry from the explanatory variables to assess the need to include

15 registry as a covariate. Since the difference in the Pearson chi-squared statistics of these models was not significant ($p = 0.19$), we were unable to determine a significant difference in number of cases between both registries. Fitting log-binomial regression models[44] we observed a significant difference in risk ratio implying an important underestimation of case-fatality rates by the MCD (RR:0.39[95%CI:0.31;0.51]).

20 However in the absence of a significant interaction term between registry and place ($p=0.82$) we were unable to establish a differential underestimation according to place. Leaving out the fatalities occurring within one hour after admission led to similar results

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Notice that the number of (mortality) cases registered in the MCD alternately was larger or smaller than those of MONICA.

We were also able to compare PTCA figures between MONICA and MCD. For the years 2002-4 MONICA-Ghent registered 83 PTCAs in males and 19 in females versus

5 respectively 102 and 20 PTCAs in the MCD. For Bruges these numbers amounted to 87 and 20 in MONICA versus 149 and 30 in the MCD. Apart from the numbers for females in Ghent, the MCD numbers of PTCA exceeded significantly those of MONICA.

For the same years we also compared the recurrent events registered in MONICA with the AMI cases in the MCD mentioning in addition an "old myocardial infarction" (ICD-

10 9-CM code: 412) as a secondary diagnosis. This exercise also showed substantial differences between MONICA and MCD. In Ghent MONICA totaled 53 recurrent events in males and 11 in females, versus 22 and 3 respectively in the MCD. For Bruges these numbers amounted to 76 and 14 in MONICA versus 49 and 6 in Bruges. Each time the MONICA figures significantly outnumbered those of the MCD.

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Transfers

From our data, before the exclusion of transfer cases, we identified 6,555 stays mentioning only a transfer-in from another hospital, and 12,409 stays mentioning only a transfer-out to another hospital. We only succeeded to pair 2,524 transfers in which we

20 assessed the accuracy of our co-morbidity data. The first quartile, median and third quartile of the distribution of the CCI amounted to 0, 0 and 2 in the "discharging" and to 0,1 and 2 in the "intake" facilities respectively. We also determined the time of referral, which in over 50% of the cases exceeded 24 hours.

Sensitivity analyses

In 27 hospitals neither the adjustments used nor the stays excluded according to type of transfer, altered the category of evidence to which they belonged. In 45 hospitals the change did not exceed 2 categories; in 31 hospitals the change equaled 3 categories,

5 without crossing the overall rate; and, in 5 tertiary hospitals the change amounted at least to 3 categories and crossed the overall rate. In the latter cases poorer AMI-CFRs were found when adjustment was made for shock or STEMI and for carrying out an angioplasty.

The range of the point estimators of the departures was considerable and varied

10 substantially across the fitted models (see supplementary material: Range of the point estimators).

In a first series of analyses, wherein transferred-out cases, were excluded, the cumulative AMI-CFR, adjusted for age, gender, CCI and shock, showed a huge inter-hospital variability in AMI-CFR over time. The maximum change in deciles amounted to 0, 1, 2,

15 3 and 4 or 5 deciles in 21, 49, 25, 12 and 2 hospitals respectively. Analogously, after exclusion of all transferred cases, a maximum change in deciles of 0, 1, 2, 3, 4 or 5 was observed in 24, 58, 15, 11 and 1 hospitals, respectively.

Similarly, excluding the transferred-out cases, we observed across hospitals ranges of the maximum LOS of any patient from 36 to 337 days and from 12 to 233 days in deceased

20 patients. Very similar ranges from 36 to 243 days and from 12 to 232, respectively, were obtained after exclusion of all transferred cases.

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These findings reveal important inter-hospital differences in medical practices but seem not to indicate a systematic, early discharge practice in any hospital intended to diminish its AMI-CFR.

5   *Determinants and evolution of the national AMI-CFR*

Shock proved to be by far the strongest determinant of AMI-CFR in all the models, followed by age, and severe co-morbidity (a CCI > 3) (Table 3). All the models had a C-index, a measure of the discriminative performance of the models, between 0.74 and 0.85. The odds ratios of gender and trend, although statistically significant, found

10   themselves in the inconclusive zone.

Inter-hospital comparison

We observed substantial and statistically significant inter-hospital differences in AMI-CFRs, both in the period and the temporal analysis, based on a model with age, gender,

15   CCI and shock as explanatory variables. These differences arose in both the models with exclusion of transferred-out cases and those wherein all transferred cases were excluded. From the model wherein all transferred cases were excluded, we represented in Figure 1 the Bonferroni-corrected, outlying hospitals by green diamonds ("high") or blue circles ("low") and the other hospitals by red squares ("average"). Departures ranged from – 65

20   % up to + 196% in the period, and from – 47% up to + 39% in the trend analysis, resulting in seven "high AMI-CFR" and nine "low AMI-CFR" outlying hospitals in the period and one "high AMI-CFR" and three "low AMI-CFR" outlying hospital in the trend analysis. For the model with exclusion of transferred-out cases, we observed

departures ranging from -60% to +185% in the period and from -45% to +30% in the

trend analysis, resulting in four "high AMI-CFR" and eight "low AMI-CFR" outlying

hospitals in the period and one "high AMI-CFR" and one "low AMI-CFR" outlying

hospital in the trend analysis.

5   The same analyses, performed on the subset of tertiary level hospitals, also showed

marked and statistically significant inter-hospital differences in AMI-CFRs in both

models.

According to type of cardiac care provided, we found important, i.e. beyond the

10   inconclusive zone, and statistically significant differences between community and

tertiary level hospitals, except for "Initial 1 model" (Table 3). But for the "Shock 2"

model, the differences between intermediary and tertiary level hospitals fell outside the

inconclusive zone.

The fitted models showed very good discrimination properties reflected by areas under

15   the receiver operating characteristic (ROC) curves of about 0.84 [45].

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Discussion

Quality of the data

Our results suggested numerous quality-of-data-related problems and prompted a very cautious interpretation of the quality-of-care-related findings. At first, AMI is characterized by diagnostic uncertainty, manifesting itself in marked differences in sensitivity and specificity of the measurement of myocardial proteins, ECG recordings and imaging modalities[18,46]. This may be reflected by the denominator differences of the AMI-CFR we found between the MCD and MONICA data. Part of these differences is probably due to the absence of national guidelines leaving the choice of the diagnostic criteria to the individual clinicians, whereas in MONICA univocal diagnostic criteria were used. In a German study[47], similar to ours, the hospital's AMI-CFR amounted to 13.5% versus the 28% derived from the German MONICA data, whereas in ours these rates amounted to 7.5% and 19,0%, respectively.

The comparison between MONICA and the MCD, unfortunately very limited, due to privacy and agreement regulations, shed light on other quality-of-data problems. The outnumbering in PTCA of the MCD may illustrate the need of univocal definitions of AMI and coding practices and may reflect the propensity of administrative data for maximizing coding. By contrast the deficient registering of old myocardial infarctions, which is financially not rewarding in our prospective payment based reimbursement of the hospitals, comes as no surprise.

We also tried to assess as much as possible the quality-of-data through internal comparisons. Thus and contrary to the findings in a recent publication stressing the sensitivity of the CCI to coding practices[27], our comparison of the CCI distribution in

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transferred patients did not suggest too large before-after transfer differences. However, our sensitivity analyses seemed to indicate a sizable inter-hospital variability in the accuracy of the data.

5   The completeness of the data also was a cause for concern. Since about 50% of the fatal STEMI cases occur in the first two hours after the onset of the symptoms, the under-registration of fatalities may be due to the lack of ICD-coding of the pathologies during a stay in an emergency department[4]. Important information such as symptom-onset to needle-time, the time lag between the onset of symptoms and the initiation of the

10   treatment, is lacking in our data, as well as pharmacological treatment details, which are essential with respect to quality assessment, especially in primary hospitals. Also, although low socio-economic status (SES) is related with lesser AMI-outcomes, we have no information regarding SES[48].

15   Further, one has to take the basic tension into account that exists between using the same data for reimbursement of the hospitals and for quality improvement purposes. Indeed, in the former case the purpose is to maximize the coding of complications and co-morbidities (e.g., CCI), while in the latter it is to restrict it to conditions really affecting care [32]. Our shock data may well illustrate this phenomenon. For example, we observed

20   rates of 9.9 % and 4,2% in STEMI and non-STEMI infarctions, respectively, which are substantially higher than the 5 to 8.6% and 2.5% in the literature, respectively, and to which, in addition, the 12.73% of the AMI-NOS are to be added [20,37]. The doubling of the reimbursement rate in these cases reflects the possible financial gains through

maximization, but the high CFRs in case of cardiogenic shock seem not to indicate important efforts of maximization

Whereas in Belgium it is impossible to routinely obtain 30-day mortality data of

5   discharged patients, they are very well comparable to the in-hospital mortality data[12]. By contrast, the comparison with MONICA revealed a substantial proportion of probably early fatalities not registered in the MCD. As a result, the in-hospital AMI-CFR may chiefly be biased in the initial phases of the fatal process, preventing the in-hospital AMI-CFR to be used as a reliable estimator of the population AMI-CFR. In that respect

10 population-based, acute coronary syndrome registries remain irreplaceable. Since we were not able to assess whether the proportion of unrecognized, early AMI deaths is equally distributed across hospitals, the inter-hospital comparison may, apart from unevenly distributed, dubious coding practices [34], be biased as well.

15 **Statistical modeling**

To achieve the fairest possible inter-hospital comparison we performed two types of multivariable logistic regressions leaving out respectively transferred-out cases, and all transferred cases. In both types of analysis a risk-adjustment for age, gender, CCI and cardiogenic shock was performed. All the models had a C-index, a measure of the

20 discriminative performance of the models, of 0.832 to 0.844, that are comparable to those obtained in a study evaluating five risk scores (PURSUIT, GUSTO-1, GRACE, SRI and EMMACE) for risk stratification of acute coronary syndromes[49]. The authors of this study conclude that simpler risk models had comparable performance to the more

23

complex ones[49]. The Simple Risk Index (SRI) for instance, which consists of age,

systolic blood pressure and heart rate, is very similar to our here-mentioned model.

In our models, we kept away from inserting either angioplasty - not to model away the

effect of angioplasty - or STEMI, because of both its correlation with cardiogenic shock

5   and its difficult-to-handle class of AMI-NOS (about 13 % of our study population and a

case-fatality rate of 86.2%), prone to biased analyses[50].

To maximally avoid the inclusion of iatrogenic, in-hospital complications into the risk-

adjustment, we also preferred the CCI, based exclusively on chronic conditions to widely

used discharge abstract-based software, which fail to distinguish co-morbidities from

10   complications [26,27]. The choice of including cardiogenic shock into the risk-

adjustment is an arguable point; being much more often a non-iatrogenic phenomenon

than a complication, we decided to incorporate it into our risk-adjustment. Indeed a recent

article devoted to cardiogenic shock stated that MI with LV failure remains the most

common cause of CS but also that approximately three fourths of patients with CS

15   complicating MI develop shock after hospital presentation of which in some, medication

use contributes to the development of shock[20].

Hierarchical models, usually taking the form of so-called random-effects models, would

have been an alternative to the logistic regression approach we used. However, outlier

20   detection based on such models is currently methodologically underdeveloped. Indeed,

the theory dealing with outliers still has to be further developed for linear mixed models,

with even less development for non-linear mixed models [43,51]. Finally, in the random-

effects models the hospitals in the set of data are considered a random sample from the

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larger population of all hospitals, contrary to fact in our study wherein the entire

population of Belgian hospitals is considered, rather than sampling from them.

Inter-hospital comparison

5   Two methods of calculating AMI lethality are included in the AHRQ's Inpatient Quality

Indicators. The first one (excluding transferred-out cases) ensures the inclusion of all

AMI patients. The second method (excluding of all transferred cases) reflected the desire

of users to have an alternative method of measuring AMI mortality that excluded patients

transferred from another hospital. However, this approach results in the loss of

10   transferred AMI patients from any quality measurement. Therefore, in order to allow

both types of interpretation we presented the results obtained from both methods.

While important, the above-mentioned quality-of-data limitations led inescapably to the

question whether the MCD were "good enough" to carry out an inter-hospital

15   comparison[52]. Contextual reasons including the accountability of both the hospitals and

the authorities, as guarantors of the quality of health care, brought us to do so as well as

the conviction "that what cannot be measured cannot be changed"[53]. Also one had to

keep in mind that administrative data, such as the MCD, not only are the most accessible

comparative data source for examining all patients admitted to a hospital, but also the

20   only ones allowing a nationwide inter-hospital comparison with at least a minimal risk-

adjustment [53-55]. Further, the magnitude of the observed inter-hospital differences in

AMI-CFRs – the highest AMI-CFR is six times higher than the lowest - and the influence

of type of hospital warrant further inquiry. Indeed, the principal interest of our study in

this regard rests on its ability of screening substandard or above-standard care, to be completed by a formal assessment, and its stimulating effect on initiatives of quality improvement.

From the transfer exercise for instance we learned that, going against the prevailing

5   guidelines[14], a considerable number of transfers was realized more than 24 hours after intake, suggesting the carrying out of an elective rather than a rescue angioplasty. The case of the five tertiary level hospitals, which in the sensitivity analysis showed the greatest AMI-CFR variability, may be related to this phenomenon. Indeed, it may that these centers frequently carry out this type of angioplasty, as it was precisely the

10   inclusion in the modeling process of shock, underrepresented in this type of patients, and angioplasty that caused the change in AMI-CFR. Since this result appeared during the modeling process, one may assume it not to be an artifact but rather an expression of sub-optimal care.

Another intriguing finding, which requires elucidation, was the apparent heterogeneity

15   regarding AMI-CFR in the group of tertiary level hospitals.

We further think to have gathered some evidence in favor of PCI over other treatments. Indeed, comparing our results with those of a previous study[12] and in line with a Swedish study, its practice seemed to have improved over time[12,56].

Finally, our analyses revealed important inter-hospital differences in medical practices

20   but do not seem to indicate a systematic, early discharge practice in any hospital, intended to diminish its AMI-CFR.

Nowadays, discharge records are used to compare AMI-CFRs between countries. It may well that these data suffer from similar limitations regarding the symptom-onset to needle-time, type of AMI, and that they are used both for reimbursement of the hospitals and for quality improvement purposes. Furthermore, in case of a hospital stay, taking

5   place in more than one department, some countries collect discharge records of these partial stays, leading to an inflation of the denominator of the rate. As a consequence, one should very cautiously interpret differences in AMI-CFRs between countries. The OECD for instance suggests that this indicator should be considered in conjunction with length-of-stay and transfer rates and recommends risk adjustment for clinical factors[11].

10

Quality improvement

In a perspective of quality improvement, implementation of evidence-based diagnostic and therapeutic practices and outcome monitoring have been shown to gradually improve outcomes in all types of hospitals and to decrease between-hospital variation[57,58].

15   More specifically, the measuring and tracking of performance is considered relevant to physicians, hospital managers, scientific bodies and policy-makers [59] and fit in the shift of focus, observed in recent years, from the "no blame" paradigm[60] to a more aggressive approach to poorly performing caregivers[61].

20   Our approach consisted mainly in a cautious ordering of findings in degrees of evidence by examining a hospital's departure both over the whole time period and over time in a perspective of improvement. Conscious of the data limitations, we refer to "screening" rather than "assessing" quality of care[62]. Therefore we avoided to establish a ranking of

the hospitals, in itself a dubious technique [63], and to make our results available to the public by so-called report cards. The latter not only have been shown not to significantly improve composite process-of-care indicators for AMI[64] but also to lead to a rising post-discharge mortality rate, conceivably due to discharging patients in unstable

5   conditions[65]. Further, taking the organizational nature of adverse events into account, we provided an anonymous feedback to the clinicians, the hospital management, the Belgian College of Cardiologists and the policymakers. As an input for the College of Cardiologists, we aimed at identifying the few, biggest outliers, which constitute an operationally manageable group to scrutinize with respect to the putative superior or

10   substandard quality of care provided, and to propose corrective measures if necessary. Not outlying hospitals, displaying substantial departures, are suggested to proceed to an internal audit. Conversely, in our opinion it is more efficient to advise the vast majority of hospitals, finding themselves in the inconclusive zone, to comply with updated evidence-based guidelines.

15   To conclude, we are of the opinion that administrative data may provide hospitals and policy makers with enough evidence to encourage quality improvement initiatives. However, to measure progress it will be necessary to (1) routinely assess and assure the completeness and accuracy of the data; (2) to have univocal case definitions; and (3) to be able to trace patients across hospitals.

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Disclaimer

The authors of this article are responsible for its content. No statement in this article should be construed as an official position of the Belgian Federal Service of Health, Food Chain Safety and Environment, Directorate-General for the Organization of Health Care Establishments.

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