

BMJ Open

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Journal:	BMJ Open
Manuscript ID	bmjopen-2016-011526
Article Type:	Research
Date Submitted by the Author:	19-Feb-2016
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Primary Subject Heading:	Health services research
Secondary Subject Heading:	Epidemiology
Keywords:	PRIMARY CARE, HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Determinants of OOH service users’ potential inappropriate referral and non-referral to the ED

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Word count: 3946

Funding

Funding for this study was provided by 60% research grants (codice: 60A07-0595/14) from the University of Padua. The funding parties had no role in the study design, data collection, analysis and interpretation, drafting of the manuscript, or decision to submit the paper for publication.

No additional data available

Contributorship statement:

All the named authors fulfil the authorship criteria, and nobody else fulfilling the criteria has not been included as an author.

Alessandra Buja monitored data collection, wrote the statistical analysis plan, cleaned and analyzed the data, conducted the literature search and drafted and revised the paper. She is guarantor.

Roberto Toffanin wrote the design plan.

Stefano Rigon designed the data collection and recork linkage tools and monitored data collection.

Paolo Sandonà conducted the literature search and drafted and revised the paper.

Tommaso Carrara conducted the literature search and drafted and revised the paper.

Gianfranco Damiani and Vincenzo Baldo conceptualized the data and revised the draft of the paper.

Article summary

The study assesses OOH referrals to ED, considering the appropriateness of both ED non-referrals and ED referrals by OOH physicians, and delineating the sociodemographic and clinical, and the environmental and logistic determinants of any inappropriate behavior.

There are not many works on this topic in the literature. The value of this population study lies in that it was conducted not on a limited sample or on selected patients, but using a register of routinely collected data, meaning that the findings cannot be distorted by any research hypothesis.

Abstract

Background A growing presence of inappropriate patients has been recognized as one of the main factors influencing emergency department (ED) overcrowding, which is a very widespread problem all over the world. Out-of-hours (OOH) physicians, on the other hand, must avoid delaying the diagnostic and therapeutic course of patients with urgent medical conditions. The aim of this study was to analyze the appropriateness of patient management by OOH services, in terms of both their inappropriate referral of non-urgent cases to the ED.

Methods This is an observational retrospective cohort study based on data collected in 2011 in the Local Health Authority No. 4, Region Veneto, Italy. After distinguishing patients contacting the OOH service who were referred to the ED from those who were not, and checking for patients actually presenting to the ED within 24 hours thereafter, these patients' medical management was judged as appropriate or inappropriate.

Results The analysis considered 22,662 OOH service contacts recorded in 2011. The cases of potentially inappropriate non-referral were 392 (1.7% of all contacts), and the cases of potentially inappropriate referral 1207 (5.3% of all contacts). Age, nationality, type of disease, and type of intervention by the OOH service are the main variables associated with the appropriateness of patient management.

Conclusion These findings may be useful for pinpointing the factors associated with a potentially inappropriate patient management by OOH services and thus contribute to improving the deployment of health care and the quality of care delivered by OOH services.

Keywords: Out of hour service, health care services, emergency department, patient referral, patient management.

Introduction

Primary care serves as the cornerstone for building a strong healthcare system that ensures positive health outcomes and health equity.[1,2] Out-of-hours (OOH) services are a fundamental part of primary healthcare, providing continuity of care for patients with urgent clinical conditions who cannot wait until the next working day to see a doctor. OOH physicians consequently act as gatekeepers for the provision of secondary care for patients with problems that are not life-threatening and who do not need immediate high-level care, and for referring cases to the emergency department (ED) if they have clinical conditions requiring urgent treatment or higher-level diagnostic services without delay.[3]

Like emergency medical services, OOH physicians deal with the whole spectrum of age groups and diagnoses, but the two types of service differ in their organization, policy and structure, and they are not interchangeable. Patients presenting to the ED with primary care problems are more economically managed by primary care doctors with no significant difference in clinical outcome.[4,5] For patients who are genuinely urgent cases, on the other hand, non-referral or delayed referral to the ED can pose a more serious problem: prehospital times are often a matter of life and death, and delaying hospital admission even by just a few hours raises the risk of death associated with several diseases.[6-9]

In recent times there has been a significant worldwide increase in the number of visits to the ED, relating mainly to higher numbers of non-urgent cases. In Italy, for example, the non-urgent cases seen at the ED have grown by 5-6% a year over the past 5 years, and this is partly as a consequence of inappropriate referrals by primary care physicians.[10] Similarly, visits to the ED in the United States rose from about 90 million in 1992 to 130 million in 2012, reaching 420 visits per 1,000 population/year.[11] In Australia, ED visits have increased by 3.5% a year. The situation is no better in Europe: France, Germany and the UK have seen a significant increase in the number of

cases seen at the ED. Non-urgent patients have been recognized as a potentially avoidable contributor to the problem of overcrowding at the ED: research has shown that a mean 40% of patients seen at the ED have non-urgent problems that could be managed by primary care services. There is no generally accepted and practical definition of what constitutes an 'appropriate' case for ED, and what constitutes an 'emergency'. It is therefore not surprising that we find an enormous variability (from 6% to 80%) in the reported proportions of visits judged to be inappropriate.[12] Numerous studies have reported that an excessive number of patients with non-urgent clinical conditions are seen at the ED, but few have focused on the degree to which physicians' inappropriate referrals contribute to this problem. Some studies in Europe assessed the influence of OOH primary care services on ED attendance, and found that improving the OOH services reduced the population's recourse to the ED.[13,14] A very few studies also considered patients who were erroneously not referred to the ED, and most of these cases were due to inaction by GPs and other primary care providers.[15] In the case of curative services, the relationship between time and effectiveness is crucial, making it important to ensure that patients go to the right place at the right time for the right intervention.[16] There are no studies on this issue in Italy, apart from a recent study showing that about 9% of patients who contact OOH primary care services are referred to the ED by the OOH physician – but this study does not focus on the appropriateness of such referrals.[17] As safe, good-quality, consistent and effective in-hours and OOH primary care services are crucial for providing care as close to the patient's home as possible, the aim of this study was to investigate how often OOH physicians' referral or non-referral of patients to the ED are potentially inappropriate. After identifying the dimension of the problem, a second step involves seeking the socio-demographic, process/context, and clinical variables associated with a higher risk of potential inappropriate referral or non-referral.

Material and methods

Context

The Italian NHS (National Health System) was established in 1978 and modeled along the lines of the British NHS. It is a mainly public system financed by general taxation. From an organizational viewpoint, the Italian territory is divided into 140 Local Health Authorities (LHAs), each responsible for providing health services to its local population.

All Italian citizens or foreigners residing in Italy are registered with a general practitioner (GP) and they are supposed to consult their GP for new health conditions. During the day, patients can visit the general practice where they are registered; after hours, they can consult one of the local OOH services. Despite regional differences being introduced when responsibilities for the NHS were decentralized, OOH services are still regulated by a nationally-shared agreement that defines the tasks, activities and salaries of OOH physicians, and the infrastructure and resources to be allocated to OOH services by the LHA. Italian OOH services operate every day of the week from 8 pm to 8 am, at weekends from 10 am on Saturdays to 8 am on Mondays, plus bank holidays, and also from 8 am to 8 pm on days when GPs are attending continuing education courses. The OOH services receive telephone calls from patients and deliver their services by providing advice over the phone, visiting a patient at home (or in a rest home), or examining them as walk-in patients (at premises provided by the LHA). OOH physicians decide whether patients need a home visit, a consultation at the local OOH office, or advice over the phone (all services provided by the OOH physician taking the call). If a patient's condition is judged to be life-threatening, an ambulance may be sent.

People can access the ED at their own discretion or they can be referred by a physician. At the ED they are received by a nurse who assigns them a triage color code, depending on the severity and urgency of their case. After patients have been examined by a physician, their triage code may be changed.

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3 1 *Setting*
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5 2 The study was conducted in the LHA “ULSS 4 – Alto Vicentino”, which extends in the north-
6
7 3 western part of the Veneto region and serves a population of about 190,000 with a mean density of
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9 4 111 inhabitants per square mile (290/km²). In 2011, foreign residents accounted for approximately
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11 5 10.3% of the total population (about 2% more than the national average). The LHA “ULSS 4” has
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13 6 three OOH service points with a total of 25 physicians working on a rota system for 24 hours a
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15 7 week. During service periods, patients have to phone to a single call center that records their
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17 8 personal details using an electronic call management system before they can talk to a doctor. In
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19 9 2006 the LHA “ULSS 4” implemented an IT system that enables OOH doctors to connect to GPs
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21 10 working at a primary healthcare center, or to the local hospital’s ED, and to consult a patient’s
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23 11 personal health records.
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30 14 *Participants and materials*
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32 16 This study was based on data collected from 1 January to 31 December 2011 in the LHA 4
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34 17 electronic database. A contact to request OOH care (as a statistical unit) was defined as any walk-in
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36 18 patient visit, home visit, rest home visit, or telephone consultation followed by no further contact in
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38 19 the 12 hours thereafter (so OOH contacts were recorded as telephone consultations only if the
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40 20 physician provided advice over the phone and did not see the patient afterwards, neither at the walk-
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42 21 in clinic, nor at the patient’s home or rest home). The computer database of OOH contacts recorded
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44 22 patients’ demographic details, i.e. sex, age, nationality and place of residence, so Google Maps
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46 23 could be used to calculate the distance of their home from the nearest OOH service point. Further
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48 24 information was recorded concerning the primary care services available for a given patient’s
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50 25 condition, e.g. non-cancer integrated homecare, cancer-related integrated homecare, palliative
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52 26 homecare, and nursing homecare. The electronic database also recorded logistic aspects such as:
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54 27 date of contact, classified for analytical purposes as working or non-working days (the latter
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56 28 including Saturdays and days before public holidays); time of contact, classified as daytime (8 am
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to 8 pm) or night-time (8 pm to 8 am). The clinically relevant variables recorded for each contact included the diagnosis, which was grouped into major diagnostic categories,¹ some of which were collapsed, and another six categories (health certification, death certification, renewal of medical prescriptions, information on drugs, fever, and others not specified). For the purpose of this study, OOH contacts for death certification or for medical prescriptions or certification were disregarded. All contacts made by non-residents were also ignored.

The database also records the possible OOH outputs for each contact, classified as patients returning home or remaining at home (if the contact involved the patient being seen at the walk-in clinic, at home, or at a rest home), referral to an ED, or telephone counselling alone. The database is also linked with some socio-demographic details of the OOH physicians handling the contacts (such as years since they graduated, sex, type of employment contract [temporary substitute or permanent post-holder]).

Another database at the ED records all cases seen at the ED after contacting the OOH services. In addition to demographic and logistic variables, the ED database also records other important information: the incoming triage code assigned by nurses and the outgoing triage code assigned by physicians (white = noncritical patients who should receive primary care; green = not life-threatening conditions; yellow = critical patients at risk of their clinical condition deteriorating; red = very critical patient needing immediate treatment); any activation of a short-stay observation period; and discharge from the ED (classified as patient: hospitalized; arrived dead; sent home; sent to another institute; died at the ED; refused hospitalization; left the ED before being examined; left the ED before the indication; referred for outpatient care).

¹ Major diagnostic categories (MDC) are formed by dividing all possible principal diagnoses (based on the ICD-9) into 25 mutually-exclusive diagnostic areas.

Outcome definition

A case seen at the ED was considered urgent and potentially appropriate (as recently defined by the Italian agency for regional health services, AGENAS)[19] if it met at least one of the following conditions:

- red or yellow outgoing triage code (if no outgoing case was assigned, red or yellow incoming triage code);
- patient hospitalized or refused hospitalization;
- patients assessed for trauma;
- short-stay observation was activated;
- arrived dead or died in ED.

Patients who contacted the OOH services were divided into two groups according to whether or not they were referred to the ED afterwards. Both groups included patients who actually went to the ED within 24 hours after contacting the OOH and patients who did not.

Patients not referred to the ED were considered as cases of “potentially inappropriate non-referral” if they went spontaneously to the ED within 24 hours after contacting the OOH services and were found to meet at least one of the criteria for appropriate access to the ED.

Patients referred to the ED were considered as cases of “potentially inappropriate referral” if they did not go to the ED within 24 hours, or if they did go to the ED but it was found that they did not meet at least one of the criteria for appropriate access to the ED.

Statistical methods

Statistical analyses were performed using the STATA12 software.

The data were summarized as numbers (percentages) of patients for categorical variables and as means (with standard deviations) for continuous variables. Bivariate analyses were run to measure mean differences using the independent t-test for continuous variables, and the chi-square test for categorical variables.

Two logistic regression models were applied, one for each dependent variable: potentially inappropriate non-referrals to the ED by the OOH service; and potentially inappropriate referrals to the ED by the OOH service.

The regression tested the socio-demographic, process-context, and clinical variables associated with the dependent variable.

A p-value of less than 0.05 was considered significant.

Ethical considerations

The data analysis was conducted on anonymized aggregated data with no chance of individuals being identifiable. The study complied with the Declaration of Helsinki and with Italian Law n. 196/2003 on the protection of personal data. The recent resolution n. 85/2012 of the Italian Guarantor for the Protection of Personal Data also confirmed the allowability of processing personal data for medical, biomedical and epidemiological research, and that data concerning health status may be used in aggregated form in scientific studies. Permission to use non-identifiable, individual data extracted from administrative databases was granted by ULSS 4 Veneto Region, which are responsible for the use of the data on their respective populations.

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3 1 **Results**

4 2

5 3 From 1st January 2011 to 31st December 2011, there were 23,980 people who contacted the LHA 4

6 4 OOH service. After excluding 403 non-residents, 425 requests for the certification of a death, 371

7 5 requests for medical prescriptions, and 119 requests for medical certificates, the contacts considered

8 6 in our analysis amounted to 22,662. Overall, 20,596 patients (90.9%) who contacted the OOH

9 7 service were not referred to the ED, and 19,238 of these patients (84.9% of the total sample) did not

10 8 go to the ED; 2,066 patients (9.1%) were referred to the ED by the OOH physician. In general,

11 9 3,002 patients (13.2%) went to the ED within 24 hours after contacting the OOH service (1,644

12 10 [7.2%] after being referred to the ED by the OOH physician, and 1,358 [6%] at their own

13 11 discretion). 422 patients (1.9%) patients referred to the ED by the OOH physician did not go to the

14 12 ED.

15 13

16 14 The total number of cases potentially managed inappropriately by the OOH service, in terms of

17 15 referrals and non-referrals to the ED, amounted to 1,599 (about 7% of the sample): 392 were

18 16 patients inappropriately not referred to the ED (1.7%); and 1,207 were patients inappropriately

19 17 referred to the ED (5.3%) (see figure 1).

20 18

21 19 **Table 1** shows the sample’s characteristics, and **Table 2** shows the demographic, context and

22 20 clinical characteristics of the people contacting the OOH services by referral to the ED and its

23 21 appropriateness.

24 22 **Tables 3a and 3b** show the variables associated with a higher risk of inappropriate management. In

25 23 particular, Table 3a shows the variables associated with inappropriate non-referral to the ED, and

26 24 Table 3b the variables associated with inappropriate referral to the ED.

27 25

Discussion

This study addressed the phenomena of inappropriate patient referral and non-referral to the ED by OOH physicians. The study revealed that the determinants of inappropriate non-referral to the ED mirror the determinants of inappropriate referral, e.g. older age reduces the probability of inappropriate referral and increases the risk of inappropriate non-referral.

Only one in eight patients went to the ED after contacting the OOH service, and less than one in twenty who contacted the OOH subsequently went to the ED at their own discretion and then failed to meet the criteria for urgent medical care. This confirms the gatekeeping role of the OOH physicians and underlines the importance of this service in ensuring a continuity of primary health care while preventing patients from going to the ED instead of a primary care service. The unwarranted use of secondary health care services gives rise to a lack of continuity of care and generates an overload that adversely affects ED activities.[20] A previous systematic review found, however, that action taken to increase OOH primary care services did not generate any reduction in ED attendance (though the studies considered in this review received low global quality ratings and various different models of OOH primary medical care service had been considered).[21] Another previous study [17] also showed that decisions to refer patients to ED were associated not only with the clinical and process-logistic characteristics of the patient, but also with certain characteristics of the physicians involved, which influenced their inclination to refer patients to the ED, demonstrating that the efficacy of OOH physicians in their gatekeeping role is also associated with their personal traits.

Our present study found that less than 10% of cases (7%) were handled in a potentially inappropriate manner. As regards inappropriate ED referrals, we found that less than one in twenty of all patients contacting the OOH services (5.3%) were referred to the ED and subsequently did not

1 meet the criteria for urgent treatment, while more than half of the patient referrals to the ED by the
2 OOH physicians were ultimately found inappropriate. In theory, OOH physicians are contacted
3 when patients have borderline health conditions that are not urgent enough for them to go to the ED,
4 but too severe for them to wait until the next working day. This delicate borderline situation should
5 be borne in mind when we consider the above percentages. According to an English study the
6 percentage of cases inappropriately managed by means of phone triage services delivered by the
7 NHS-24 service is around 35% according to GPs' subsequent re-assessment.[22] An Australian
8 study reported instead that about 10% of patient referrals to the ED by GPs were inappropriate.[23]
9 It is rather difficult and risky to attempt to draw comparisons between studies conducted on
10 different healthcare systems and using different methods to assess "appropriateness", these figures
11 are considerably lower than the percentage of inappropriateness identified for self-referred patients,
12 which reaches as high as 80%,[12] demonstrating once again the important gatekeeping role of the
13 OOH services in relation to low-acuity patients.

14
15 Of course, inappropriate non-referral to the ED is a more serious issue because a diagnostic delay in
16 a genuinely urgent patient may even be fatal. Our study found this situation fairly infrequent
17 (1.7%). To the best of our knowledge, no other published studies have investigated the frequency of
18 potentially inappropriate non-referrals to the ED with which we might draw a comparison.

19
20 With a view to enhancing the quality of OOH services, it would be wise to address the determinants
21 of OOH physicians' potentially inappropriate management of the patients who contact them.
22 Foreigners (especially those with a limited command of the Italian language) are at higher risk of
23 inappropriately not being referred to the ED, due to language-related misunderstandings and also
24 because cross-cultural miscommunication can generate misconceptions, misinterpretations, and an
25 inadequate assessment of the patient's clinical condition.[24-26] The importance of language
26 consistency in patient-provider communications has been emphasized as a means for recording an

1 accurate medical history, for instance.[27] According to the Joint Commission, between 1995 and
2 2002, communication problems were the root cause of almost 65% of sentinel events (unexpected
3 events that led to death or severe physical or psychological injury).[28] Although communication
4 difficulties between doctor and patient pose a problem that is not easy to solve, giving preference to
5 face-to-face visits instead of telephone exchanges, and having access to a shared interpreter service
6 on call 24/h are possible strategies for reducing the inappropriate management of such patients.

7 The odds of inappropriate ED non-referral were also found to increase with patients' age, atypical
8 disease presentations, polypharmacy, and multiple comorbidities, which may complicate patient
9 management.[29] Cognitive impairment, which is more common among the elderly, could also
10 negatively influence the likelihood of appropriate patient management. Cognitively impaired older
11 patients can have trouble remembering things, become confused, and have attention deficits or
12 difficulty expressing themselves.[30] An analysis of error reports submitted to the Applied
13 Strategies for Improving Patient Safety (ASIPS) indicated that communication problems
14 represented the most common error process in the ambulatory care setting.[31,32] Failure to ensure
15 complete communication between healthcare providers and patients was also associated with a
16 higher risk of clinical harm. A possible recommendation for elderly patients is to obtain information
17 from another family member too, if possible. Having said all that, the higher probability of OOH
18 services seeming to inappropriately not refer elderly people to the ED - especially when the patients
19 concerned then go to the ED anyway - may relate to the ED physicians having a greater propensity
20 to admit older patients to hospital as a prudential choice.[33]

21 Our study revealed that not only socio-demographic and clinical conditions, but also logistic and
22 organizational variables may be determinants of potentially inappropriate non-referral to the ED. In
23 particular, we found that face-to-face interviews with the OOH personnel were less likely to be
24 managed inappropriately than telephone contacts. Another study reported that telephone
25 consultations were shorter and less detailed than face-to-face visits for similar clinical problems,
26 increasing the potential for diagnostic or management errors.[34] The phenomenon of inappropriate

1 non-referral to the ED for patients managed by the OOH services over the phone could be contained
2 by adopting well-structured procedures based on checklists and protocols, or more advanced
3 solutions such as decision-supporting software packages, to help doctors consulted over the phone
4 provide comprehensive advice [35,36]. A general approach should be adopted to identify ways to
5 actively address the root causes of patient safety incidents in order to reduce the risk of something
6 going wrong, rather than more passive methods that encourage staff to be more vigilant in their
7 working practice [37]. This differs from the approaches taken in the past, which would tend to focus
8 on asking health professionals to take more care, for example, when prescribing medication.

9 Turning to the other age groups, older children and younger adult categories had lower odds of
10 inappropriate referral to the ED than infants. A cross-sectional examination of ED attendances in
11 England found age strongly related to inappropriate referral [38]. The odds were higher in the very
12 young (with peak attendances in one- and two-year-olds), and high between the mid-teens and mid-
13 twenties, followed by a steady drop with aging thereafter. The sizable presence of young people
14 inappropriately attending EDs around the world has been recognized in various studies, as
15 emphasized in the review conducted by Carret.[39] Our findings thus suggest that intervention to
16 prevent CI should target early childhood and young adolescence. The phenomenon probably
17 reflects the pressures of parenthood,[40,41] or a lack of confidence with children's diseases. Given
18 the difficulty of managing pediatric patients, and infants especially, pediatric OOH services need to
19 be expanded, or else training courses could be organized to improve OOH physicians'
20 understanding of pediatric emergencies.

21 Our analysis showed that, among the OOH physicians, regular post-holders were less likely to
22 inappropriately refer patients to the ED than their temporary substitutes. This may be an indication
23 of the former's greater work experience, but could also relate partly to the fact that some people
24 contacting the OOH services are frequent attenders, and probably well known to the permanent
25 staff, who consequently find it easier to manage their disorders.[42] Using the available data on the

OOH physicians (and taking each OOH physician's personal identification code into account) might be useful for giving physicians regular feedback on their performance, which can be compared with a benchmark, for instance. It has been demonstrated in the literature that this could have a positive impact on their performance.[43]

Our study suffers from several limitations. One stems from our arbitrary classification of potentially inappropriate referrals to the ED (based on a national definition of appropriateness) that clearly influences the reported prevalence of potentially inappropriate management in our sample. There is no general agreement on how to define appropriateness of ED use in the literature, however. Another limitation lies in that our analysis was conducted only on the LHA 4 records, so we were unable to follow up any patients who were admitted to a ED outside the territory covered by the LHA 4; the scientific literature indicates, however, that patients usually go to the ED in their own district.[44] As for the strengths of our research, this was a population-based study conducted not on a limited or selected sample of patients, but using a register of routinely collected data. The findings consequently could not be distorted by any research hypothesis.

Conclusion

This work paints a comprehensive picture of the predictors of inappropriate behavior on the part of OOH physicians in terms of their referral or non-referral of patients to the ED. It goes to show that administrative data can be used to monitor this phenomenon and its determinants. Our findings may be useful in improving the OOH services, and also in defining a program of continuing professional education for OOH doctors more focused on their real needs. The novelty of our work means, however, that further studies are needed to confirm the validity of these results.

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5 **Competing interest**
6

7 The authors have no competing interests to disclose. The authors affirm that the manuscript is an
8 honest, accurate, and transparent account of the study being reported; that no important aspects of
9 the study have been omitted.
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19 **Keypoints**
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21 The determinants of inappropriate non-referral to the ED mirror the determinants of inappropriate
22 referral, e.g. older age reduces the probability of inappropriate referral and increases the risk of
23 inappropriate non-referral.
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26 Not only socio-demographic and clinical conditions, but also logistic and organizational variables
27 may be determinants of potentially inappropriate non-referral to the ED.
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30 The improvement of OOH services by means of different organizational, structural and formative
31 strategies could benefit of this data to be greater focused on their real needs.
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Table 1: Characteristics of the sample contacting the OOH service by referral or non-referral to the ED

		Not referred n=20596	Referred n=2066
<i>Patients' demographic variables</i>			
Sex	Male 10450	90.58%	9.42%
	Female 12212	91.14%	8.86%
Age	0-1 years 1254	95.06%	4.94%
	2-14 y 4984	95.97%	4.03%
	15-18 y 624	94.55%	5.45%
	19-44 y 6245	93.55%	6.45%
	45-64 y 3927	90.07%	9.93%
	65-74 y 1867	86.45%	13.55%
	75-84 y 2067	81.71%	18.29%
Pediatric cases (0-14y)	>84 y 1694	79.63%	20.37%
	No 16424	89.02%	10.98%
Nationality	Yes 6238	95.78%	4.22%
	Italian 20099	90.46%	9.54%
	Foreign 2560	94.22%	5.78%
<i>Patients' process and context variables</i>			
Distance from nearest OOH	0-5 km 11214	90.18%	9.82%
	>5 km 10322	91.59%	8.41%
Time of day	8-20 19366	91.61%	8.39%
	20-8 3296	86.62%	13.38%
Day	Working day 7368	89.89%	10.11%

		Holiday 8285	91.41%	8.59%
		Day before a holiday 6799	91.22%	8.78%
Type of OOH		Phone advice 9970	92.46%	7.54%
intervention		Home visit 2134	76.48%	23.52%
		Ambulatory visit 10558	92.31%	7.69%
OOH		Temporary substitute		
physician		17169	90.54%	9.46%
		Post-holder 5493	91.95%	8.05%
Gender of		Male 14489	89.76%	10.24%
OOH		Female 8173		
physician			92.87%	7.13%
<i>Patients' clinical variables</i>				
Death within a		No 20846	91.96%	8.04%
year		Yes 1816	78.58%	21.42%
Home		No 22594	90.91%	9.09%
physiotherapy		Yes 68	80.88%	19.12%
Home nursing		No 20973	91.81%	8.19%
services		Yes 1689	79.34%	20.66%
Assisted at		No 21976	91.22%	8.78%
home by GP		Yes 686	80.17%	19.83%
Disease		Dermatological 1501	97.34%	2.66%
		Musculoskeletal 1453	91.40%	8.60%
		Ophthalmological 532	84.96%	15.04%
		Odontostomatological 634	97.79%	2.21%
		Oncological and	79.72%	20.28%

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hematological	143		
Ear-nose-throat	2744	96.57%	3.43%
Pregnancy and reproductive system	194	84.02%	15.98%
Psychiatric	381	88.98%	11.02%
Respiratory	1734	86.45%	13.55%
Trauma	752	76.60%	23.40%
Nervous system	853	77.49%	22.51%
Infectious	389	97.17%	2.83%
Genitourinary system		89.47%	10.53%
	1092		
Gastroenterological	3148	89.36%	10.64%
Fever	2835	97.85%	2.15%
Endocrinological	127	85.83%	14.17%
Advice about ongoing therapy	1969	99.29%	0.71%
Cardiovascular	1348	71.74%	28.26%
Not specified	833	91.24%	8.76%

Table 2: Bivariate analysis of characteristics of patients and their potentially inappropriate management by referral and non-referral to the ED

		Not referred			Referred		
		n. 20596			n. 2066		
		App.	Inapp.	p	App.	Inapp.	p
Patients' demographic variables		n=20204	n=392		n=859	n=1207	
		%	%		%	%	
Sex	Male	97.98	2.02	0.268	40.75	59.25	0.468
	Female	98.19	1.81		42.33	57.67	
Age	0-1 years	98.57	1.43	<0.001	12.9	87.1	<0.001
	2-14 y	98.85	1.15		25.87	74.13	
	15-18 y	98.81	1.19		26.47	73.53	
	19-44 y	99.18	0.82		25.06	74.94	
	45-64 y	98.33	1.67		34.62	65.38	
	65-74 y	96.41	3.59		51.38	48.62	
	75-84 y	95.44	4.56		52.91	47.09	
	>84 y	94.74	5.26		64.93	35.07	
	Pediatric cases (0-14y)	No	97.81		2.19	<0.001	
Yes		98.79	1.21	22.81	77.19		
Nationality	Italian	97.99	2.01	0.003	42.91	57.09	<0.001
	Foreign	98.88	1.12		24.14	75.86	
Patients' process context variables							
Distance from nearest OOH	0-5 km	98.25	1.75	0.149	41.05	58.95	0.635
	>5 km	97.98	2.02		42.09	57.91	

	Time of day	8-20	98.46	1.54		41.29	58.71	
					<0.001			0.613
		20-8	95.83	4.17		42.63	57.37	
	Day	Working day	97.99	2.01		40.94	59.06	
		Holiday	98.12	1.88	0.823	43.4	56.6	0.431
		Day before a holiday	98.11	1.89		40.03	59.97	
	Type of OOH	Phone advice	97.56	2.44		41.36	58.64	
	intervention	Home visit	94.49	5.51	<0.001	67.33	32.67	<0.001
		Ambulatory visit	99.21	0.79		25.86	74.14	
	OOH physician	Temporary substitute	98.17	1.83		39.96	60.04	
					0.198			0.004
		Post-holder	97.88	2.12		47.51	52.49	
	Gender of OOH	Male	98.15	1.85		41.94	58.06	
					0.425			0.592
	physician	Female	98	2		40.65	59.35	
	Patients' clinical variables							
	Death within	No	98.46	1.54		35.18	64.82	
					<0.001			<0.001
	a year	Yes	93.27	6.73		69.15	30.85	
	Home	No	98.09	1.91		41.6	58.4	
					0.301			0.819
	physiotherapy	Yes	100	0		38.46	61.54	
	Home nursing	No	98.38	1.62		37.22	62.78	
					<0.001			<0.001
	services	Yes	94.03	5.97		63.04	39.96	
	Assisted at	No	98.21	1.79		39.95	60.05	
					<0.001			<0.001
	home by GP	Yes	94	6		64.71	35.29	
	Disease	Dermatological	99.86	0.14		7.5	92.5	
		Musculoskeletal	98.49	1.51	<0.001	22.4	77.6	<0.001
		Ophthalmological	99.78	0.22		1.25	98.75	

Odontostomatological	100	0	7.14	92.86
Oncological and hematological	93.86	6.14	65.52	34.48
Ear-nose-throat	99.62	0.38	1.06	98.94
Pregnancy and reproductive system	96.93	3.07	32.26	67.74
Psychiatric	96.46	3.54	38.1	61.9
Respiratory	97.60	2.40	52.34	47.66
Trauma	98.61	1.39	100	0
Nervous system	96.37	3.63	43.23	56.77
Infectious	100	0	18.18	81.82
Genitourinary system	97.44	2.56	32.17	67.83
Gastroenterological	96.16	3.84	36.72	63.28
Fever	98.31	1.69	26.23	73.77
Endocrinological	96.33	3.67	44.44	55.56
Advice about ongoing therapy	98.82	1.18	28.57	71.43
Cardiovascular	96.48	3.52	47.77	52.23
Not specified	96.58	3.42	35.62	64.38

Table 3a: Multivariate logistic regression results for associations between patients’ characteristics and their inappropriate management – for cases not referred to the ED

Inappropriate non-referral to the ED		Odds ratio	95% confidence interval	P
Sex (ref. Male)	Female	0.75	0.61 - 0.92	0.007
Age (ref. 0-1 years)	2-14 y	1.00	0.57 - 1.73	0.994
	15-18 y	1.12	0.46 - 2.75	0.805
	19-44 y	0.69	0.39 - 1.23	0.212
	45-64 y	1.28	0.73 - 2.25	0.392
	65-74 y	2.25	1.26 - 4.02	0.006
	75-84 y	2.18	1.22 - 3.89	0.008
	>84 y	2.06	1.12 - 3.78	0.020
Nationality (ref. Italian)	Foreign	1.59	1.04 - 2.47	0.034
Distance from nearest OOH (ref. 0-5 km)	>5 km	1.19	0.97 - 1.47	0.101
Time of day (ref. 8-20)	20-8	2.30	1.80 - 2.94	<0.001
Day (ref. Working day)	Holiday	1.27	0.98 - 1.64	0.073
	Day before a holiday	1.42	1.08 - 1.86	0.012
Home physiotherapy (ref. No)	Yes	n=1		
Home nursing services (ref. No)	Yes	1.21	0.86 - 1.71	0.279
Assisted at home by GP (ref. No)	Yes	1.04	0.67 - 1.61	0.860

Death within a year (ref. No)	Yes	1.65	1.19 - 2.30	0.003
OOH physician (ref. Temporary substitute)	Post-holder	0.93	0.66 - 1.30	0.652
Gender of OOH physician (ref. Male)	Female	1.27	1.02 - 1.59	0.030
Disease (ref. Dermatological)	Musculoskeletal	7.29	1.69 - 31.45	0.008
	Ophthalmological	1.50	0.13 - 16.59	0.742
	Oncological and hematological	10.39	2.07 - 52.13	0.004
	Ear-nose-throat	3.10	0.68 - 14.18	0.146
	Pregnancy and reproductive system	28.34	5.37 - 149.68	<0.001
	Psychiatric	9.89	2.15 - 45.41	0.003
	Respiratory	9.40	2.24 - 39.53	0.002
	Trauma	8.42	1.78 - 39.91	<0.007
	Nervous system	13.52	3.16 - 57.90	<0.001
	Genitourinary system	12.39	2.91 - 52.72	0.001
	Gastroenterological	17.13	4.20 - 69.88	<0.001
	Fever	8.43	2.03 - 35.01	0.003
	Endocrinological	8.89	1.58 - 49.98	0.013
	Advice about ongoing therapy	4.27	0.99 - 18.32	0.051
	Cardiovascular	10.72	2.54 - 45.18	0.001
	Not specified	13.39	3.14 - 57.03	<0.001

Type of OOH intervention	Home visit	1.09	0.82 - 1.47	0.542
(ref. Phone)	Ambulatory visit	0.48	0.36 - 0.65	<0.001

Table 3b: Multivariate logistic regression results for associations between patients’ characteristics and their inappropriate management – for cases referred to the ED

Inappropriate referral to the ED		Odds	95%	P
		ratio	confidence interval	
Sex (ref. Male)	Female	1.23	0.98 - 1.54	0.076
Age	2-14 y	0.60	0.21 - 1.75	0.349
(ref. 0-1 years)	15-18 y	0.21	0.06 - 0.77	0.019
	19-44 y	0.27	0.10 - 0.74	0.010
	45-64 y	0.17	0.06 - 0.45	<0.001
	65-74 y	0.12	0.04 - 0.33	<0.001
	75-84 y	0.15	0.05 - 0.39	<0.001
	>84 y	0.15	0.05 - 0.41	<0.001
Nationality (ref. Italian)	Foreign	0.88	0.52 - 1.48	0.633
Distance from nearest OOH	>5 km	0.86	0.69 - 1.08	0.202
(ref. 0-5 km)				
Time of day (ref. 8-20)	20-8	1.00	0.76 - 1.33	0.966
Day (ref. Working day)	Holiday	1.11	0.85 - 1.46	0.431
	Day before a holiday	1.27	1.95 - 1.70	0.114
Home physiotherapy (ref.	Yes	3.05	0.88 - 10.55	0.079
No)				
Home nursing services (ref.	Yes	1.04	0.74 - 1.45	0.824
No)				
Assisted at home by GP (ref.	Yes	0.95	0.60 - 1.49	0.812

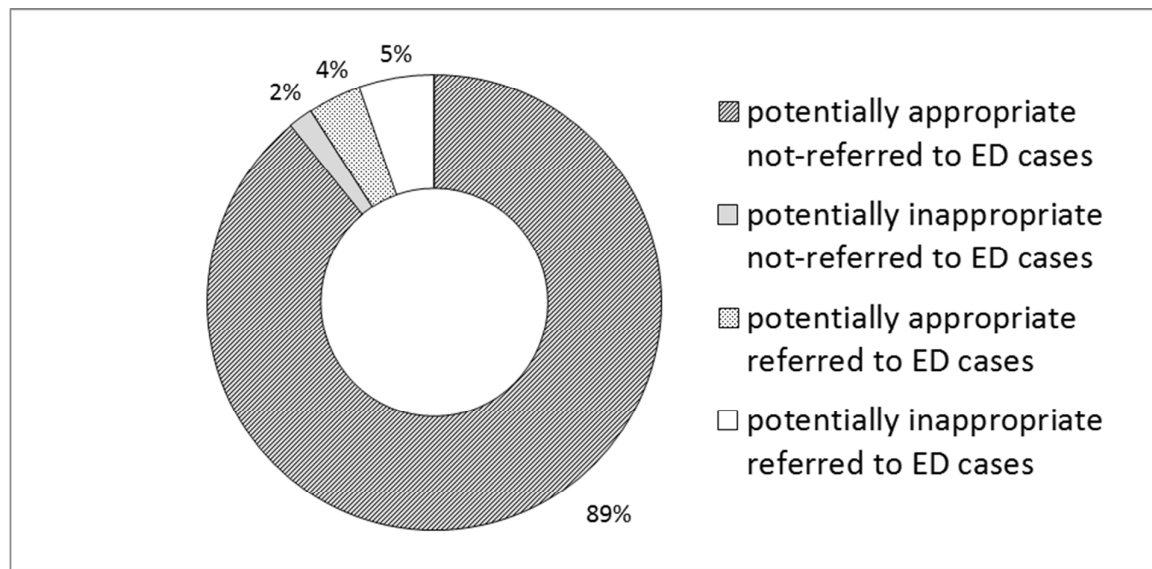
No)				
Death within a year (ref. No)	Yes	0.46	0.33 - 0.64	<0.001
OOH physician (ref. Temporary substitute)	Post-holder	0.64	0.47 - 0.89	0.007
Gender of OOH physician (ref. Male)	Female	1.12	0.87 - 1.44	0.392
Disease (ref. Dermatological)	Musculoskeletal	0.48	0.13 - 1.72	0.258
	Ophthalmological	7.16	0.71 - 72.26	0.095
	Odontostomatologic al	1.08	0.10 - 11.90	0.949
	Oncological and hematological	0.16	0.04 - 0.72	0.017
	Ear-nose-throat	8.21	0.81 - 82.92	0.074
	Pregnancy and reproductive system	0.17	0.04 - 0.74	0.018
	Psychiatric	0.41	0.10 - 1.66	0.211
	Respiratory	0.23	0.07 - 0.80	0.021
	Nervous system	0.26	0.08 - 0.92	0.036
	Infectious	0.56	0.07 - 4.38	0.583
	Genitourinary system	0.26	0.07 - 0.92	0.037
	Gastroenterological	0.22	0.06 - 0.76	0.016
	Fever	0.27	0.07 - 1.06	0.061
	Endocrinological	0.26	0.05 - 1.25	0.093
	Advice about	0.40	0.07 - 2.31	0.305

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ongoing therapy				
Type of intervention (ref. Phone)	Cardiovascular	0.22	0.06 - 0.75	0.016
	Not specified	0.38	0.10 - 1.42	0.148
	Home visit	0.43	0.32 - 0.59	<0.001
	Ambulatory visit	1.33	1.00 - 1.79	0.052

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Figure 1 shows the distribution of the patients by group.



STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract YES pag 3, line 9
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found YES pag 3
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported YES pag 4-5
Objectives	3	State specific objectives, including any prespecified hypotheses YES pag 5, lines 20-24
Methods		
Study design	4	Present key elements of study design early in the paper YES page 7-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection YES page 7-8
Participants	6	(a) Cohort study— Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up YES pag 7, lines 17-21, page 8 lines 4-6
		Cohort study—For matched studies, give matching criteria and number of exposed and unexposed Not pertinent
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable YES page 9, pag 10 lines 10-11 described above
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group YES pag 8
Bias	9	Describe any efforts to address potential sources of bias YES page 16, lines 6-15
Study size	10	Explain how the study size was arrived at YES, the sample was composed of one year contacts to OOH
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why YES, page 8
Statistical methods	12	a) Describe all statistical methods, including those used to control for confounding

YES page 10

(a) Describe any methods used to examine subgroups and interactions

(c) Explain how missing data were addressed

Cohort study—If applicable, explain how loss to follow-up was addressed

Yes page 16

(e) Describe any sensitivity analyses

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Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed page 11, lines 3-17
		(b) Give reasons for non-participation at each stage <i>not pertinent</i>
		Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders Yes table 1 and 2
		(b) Indicate number of participants with missing data for each variable of interest <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount) <i>not pertinent</i>
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time Yes figure 1
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included Yes, table 3
		(b) Report category boundaries when continuous variables were categorized Yes, table 3
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives Yes, pag 12, lines 5-8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Yes pag 16, lines 6-15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence Yes all discussion
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable,

for the original study on which the present article is based

Yes, pag 1 , lines 26-28

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

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Determinants of out-of-hours service users' potentially inappropriate referral or non-referral to an emergency department: a retrospective cohort study in a Local Health Authority, Veneto Region, Italy

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-011526.R1
Article Type:	Research
Date Submitted by the Author:	07-May-2016
Complete List of Authors:	Buja, Alessandra; University of Padua, Department of Molecular Medicine, Public Health Section, Laboratory of Public Health and Population Studies, Baldo, Vincenzo; University of Padua, Dept. of Molecular Medicine of the University of Padua, Laboratory of Public Health and Population Studies Rigon, Stefano; Azienda ULSS N 4 Alto Vicentino, Epidemiological Unit Toffanin, Roberto; Azienda ULSS N 4 Alto Vicentino, Health Director Sandonà, Paolo; Azienda ULSS N 4 Alto Vicentino, Out of Hour Service Carrara, Tommaso; Università degli Studi di Padova, Department of Molecular Medicine, Public Health Section, Laboratory of Public Health and Population Studies, Damiani, Gianfranco; Università Cattolica del Sacro Cuore Sede di Roma, Department of Public Health
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Epidemiology
Keywords:	PRIMARY CARE, HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Determinants of out-of-hours service users' potentially inappropriate referral or non-referral to an emergency department: a retrospective cohort study in a Local Health Authority, Veneto Region, Italy

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Word count: 4610

Funding

Funding for this study was provided by 60% research grants (code: 60A07-0595/14) from the University of Padua. The funding parties had no role in the study design, data collection, analysis and interpretation, drafting of the manuscript, or decision to submit the paper for publication.

For peer review only

No additional data available

Contributorship statement:

All the named authors fulfil the authorship criteria, and nobody else fulfilling the criteria has not been included as an author.

Alessandra Buja monitored data collection, wrote the statistical analysis plan, cleaned and analyzed the data, conducted the literature search and drafted and revised the paper. She acts as guarantor.

Roberto Toffanin wrote the design plan.

Stefano Rigon designed the data collection and record linkage tools, and monitored data collection.

Paolo Sandonà conducted the literature search, and drafted and revised the paper.

Tommaso Carrara conducted the literature search, and drafted and revised the paper.

Gianfranco Damiani and Vincenzo Baldo conceptualized the data and revised the draft of the paper.

Abstract

Background A growing presence of inappropriate patients has been recognized as one of the main factors influencing emergency department (ED) overcrowding, which is a very widespread problem all over the world. On the other hand, out-of-hours (OOH) physicians must avoid delaying the diagnostic and therapeutic course of patients with urgent medical conditions. The aim of this study was to analyze the appropriateness of patient management by OOH services, in terms of their potentially inappropriate referral or non-referral of non-emergency cases to the ED.

Methods This was an observational retrospective cohort study based on data collected in 2011 by the Local Health Authority No. 4 in the Veneto Region (Italy). After distinguishing between patients contacting the OOH service who were or were not referred to the ED, and checking for patients actually presenting to the ED within 24 hours thereafter, these patients' medical management was judged as potentially appropriate or inappropriate.

Results The analysis considered 22,662 OOH service contacts recorded in 2011. The cases of potentially inappropriate non-referral to the ED were 392 (1.7% of all contacts), as opposed to 1207 potentially inappropriate referrals (5.3% of all contacts). Age, nationality, type of disease, and type of intervention by the OOH service were the main variables associated with the appropriateness of patient management.

Conclusion These findings may be useful for pinpointing the factors associated with a potentially inappropriate patient management by OOH services and thus contribute to improving the deployment of health care and the quality of care delivered by OOH services.

Keywords: Out-of-hours service, health care services, emergency department, patient referral, patient management.

Article summary

- This is the first study to investigate OOH referrals to EDs, considering the appropriateness of both non-referrals and referrals by OOH physicians, and delineating the sociodemographic, clinical, environmental and logistic determinants of any inappropriate behavior.
- The strength of the study lies in the analysis of all 22,662 OOH service contacts made by the a population served by a local health authority (LHA 4 in the Veneto Region), meaning that the findings cannot be distorted by any research hypothesis.
- A limitation of the study stems from our arbitrary classification of potentially inappropriate referrals to the ED (based on a nationally-adopted definition of appropriateness), which clearly influences the reported prevalence of potentially inappropriate patient management in our sample.
- Another limitation lies in that our analysis was conducted only on the LHA 4 records, so we were unable to follow up patients admitted to a ED outside the territory covered by the LHA 4.

Introduction

Primary care serves as the cornerstone for building a strong healthcare system that ensures positive health outcomes and health equity [1]. Out-of-hours (OOH) services are a fundamental part of primary healthcare, providing continuity of care for patients with urgent clinical conditions who cannot wait until the next working day to see a doctor. OOH physicians consequently act as gatekeepers for the provision of secondary care for patients with problems that are not life-threatening and who do not need immediate high-level care. It has also been demonstrated that when general practitioners manage patients with primary care needs there is a reduction in the associated costs with no apparent detrimental effect on outcome [2,3].

OOH physicians should only refer cases to an emergency department (ED) if they have clinical conditions requiring urgent treatment or higher-level diagnostic services without delay.[4] For patients who are genuinely urgent cases, non-referral or delayed referral to the ED can pose a serious problem: prehospital times are often a matter of life and death, and delaying hospital admission even by just a few hours raises the risk of death associated with several diseases.[5-8] OOH services and EDs are two types of service that differ in their organization, policy and structure; they are not interchangeable but complementary, and both should operate appropriately to ensure the best possible functioning of the health service as a whole.

In recent times there has been a significant worldwide increase in ED attendance, relating mainly to higher numbers of non-urgent cases. In Italy, for example, the SIMEU (Italian Society of Emergency Medicine) reported in 2010 that ED visits had grown by 5-6% a year over the previous 5 years, and this was partly as a consequence of inappropriate referrals by primary care physicians.[9] Similarly, visits to the ED in the United States rose from about 92.6 million in 1993 to 133.6 million in 2013, reaching 423 visits per 1,000 population/year.[10] The Australian Institute of Health and Welfare (AIHW) recently reported that 2,176,612 ED attendances in 2012–2013 were potentially referrals by general practitioners (GPs) [11]. The situation is much the same in

Europe: France, Germany and the UK have seen a significant increase in the number of cases seen at the ED. Non-urgent patients have been recognized as a potentially avoidable contributor to the problem of ED overcrowding: research found a prevalence of inappropriate ED use that varied from 10% to 90%, depending on the criteria used to judge appropriateness, and in nearly half of the studies it ranged from 24% to 40% [12]. There is no generally accepted and practical definition of what constitutes an 'appropriate' case for referral to the ED, and what constitutes an 'emergency'. It is therefore hardly surprising that we find an enormous diversity in the reported proportions of visits judged to be inappropriate [12].

Numerous studies have reported that an excessive number of patients with non-urgent clinical conditions are seen at the ED, but few have focused on the degree to which physicians' inappropriate referrals contribute to this problem. Some studies in Europe assessed the influence of OOH primary care services on ED attendance, and found that improving the OOH services reduced the population's recourse to the ED [13,14].

Only a very few studies also considered patients who were erroneously not referred to the ED, and most of these cases were due to inaction by GPs and other primary care providers [15]. In the case of curative services, the relationship between timing and efficacy is crucial, making it important to ensure that patients go to the right place at the right time for the right intervention [16]. Safe, good-quality, consistent and effective in-hours and OOH primary care services are crucial for providing care as close to a patient's home as possible.

The aim of this study was to investigate how often OOH physicians' patient referrals or non-referrals to the ED are potentially inappropriate. After identifying the dimension of the problem, a second step involves seeking the socio-demographic, process/context, and clinical variables associated with a higher risk of potentially inappropriate patient referral or non-referral to the ED.

Material and methods

Context

The Italian NHS (National Health System) was established in 1978 and modeled along the lines of the British NHS. It is a mainly public system financed by general taxation. From an organizational viewpoint, the Italian territory is divided into 140 Local Health Authorities (LHAs), each responsible for providing health services to its local population.

All Italian citizens or foreigners residing in Italy are registered with a general practitioner (GP) and they are supposed to consult their GP for health conditions. During the day, patients can visit the general practice where they are registered; after hours, they can consult one of the local OOH services, which have infrastructure and resources allocated by the LHA. Despite regional differences being introduced when responsibilities for the NHS were decentralized, OOH services are still regulated by a nationally-shared agreement that defines the tasks, activities and salaries of OOH physicians. Dedicated personnel for OOH services are recruited from waiting lists drawn up by the LHA, and preference is given to qualified GPs. OOH services in Italy are currently provided by about 12,057 physicians working under an agreement with the LHA at 2,893 OOH service delivery points. They are either regular post-holders, or temporary substitutes, and about one in three of them are qualified GPs [17]. Italian OOH services operate every day of the week from 8 pm to 8 am, at weekends from 10 am on Saturdays to 8 am on Mondays, plus bank holidays, and also from 8 am to 8 pm on days when GPs attend continuing education courses. The OOH physicians receive telephone calls from patients and deliver services that may involve: providing advice over the phone; visiting a patient at home (or in a rest home); examining them at the walk-in clinic (at premises provided by the LHA). However it is not necessary to book visits to the walk-in clinic, and patients may attend without any previous phone contact. If a patient's condition is judged to be unmanageable in the primary care setting, the patient may be advised to go directly to

1 the ED in their own car. If a patient’s condition is judged to be life-threatening, an ambulance may
2 be called instead.

3 People can access the ED at their own discretion, or they may be referred by a physician. At the ED
4 they are received by a triage nurse who assigns them a color code, depending on the severity and
5 urgency of their case. After patients have been examined by a physician, their triage code may be
6 changed.

7
8 *Setting*

9 The study was conducted at the LHA “ULSS 4 – Alto Vicentino”, which occupies an area in the
10 north-western part of the Veneto region and serves a population of about 190,000 with a mean
11 density of 111 inhabitants per square mile (290/km²). In 2011, foreign residents accounted for
12 approximately 10.3% of the total population (about 2% more than the national average). This LHA
13 has three OOH service points with a total of 25 physicians working on a rota system for 24 hours a
14 week. During service periods, patients have to phone a single call center that records their personal
15 details using an electronic call management system before they can talk to a doctor. In 2006, the
16 LHA “ULSS 4” implemented an information technology system that enables OOH doctors to
17 consult a patient’s personal health records held by their GPs or the local hospital.

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20 *Participants and materials*

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22 This study was based on data recorded from 1 January to 31 December 2011 in the LHA 4
23 electronic database. A contact to request OOH services (as a statistical unit) was defined as any
24 walk-in patient visit, home visit, rest home visit, or telephone consultation followed by no further
25 contact in the 12 hours thereafter (so OOH contacts were recorded as telephone consultations only
26 if the physician provided advice over the phone and did not see the patient afterwards, neither at the
27 walk-in clinic, nor at the patient’s home or rest home). The computer database of OOH contacts
28 acquires patients’ demographic details (sex, age, nationality and place of residence) from the LHA’s

administrative archives, so Google Maps could be used to calculate the distance of their home from the nearest OOH service point. The database also captures further information from the LHA archives concerning the primary care services available for a given patient's condition, e.g. non-cancer integrated homecare, cancer-related integrated homecare, palliative homecare, and nursing homecare. The electronic database also records logistic aspects such as: date of contact, classified for analytical purposes as working or non-working days (the latter including Saturdays and days before public holidays); time of contact, classified as daytime (8 am to 8 pm) or night-time (8 pm to 8 am). Patients' diagnoses were recorded by means of major diagnostic categories,¹ some of which were collapsed for the purposes of the present study, and the recording system also created another six new categories (state of health certification, death certification, renewal of medical prescriptions, information on drugs, fever, and 'others not specified'). For the purposes of this study, OOH contacts concerning death certification, medical prescriptions, or state of health certificates were disregarded because these conditions could not be associated with a potential patient referral to an ED. All contacts made by non-residents were ignored too. The database also records the possible OOH outputs for a given contact, classified as patients returning home or remaining at home (if the contact involved the patient being seen at the walk-in clinic, at home, or at a rest home), referral to an ED, or telephone counselling alone. The database is also linked with some socio-demographic details of the OOH physicians handling the contacts (such as years since they graduated, gender, type of employment contract [temporary substitute or permanent post-holder]).

Another database at the ED records all cases seen at the ED after contacting the OOH services. This ED database was record-linked with the OOH database using a unique identifier code for each patient. The linkage concerned only ED attendances within 24 hours after contacting the OOH service. In addition to demographic and logistic variables, the ED database also records other

¹ Major diagnostic categories (MDC) were obtained by dividing all possible principal diagnoses (based on the ICD-9) into 25 mutually-exclusive diagnostic areas.

important information: the incoming triage code assigned by nurses and the outgoing triage code assigned by physicians (white = noncritical patients who should receive primary care; green = not life-threatening conditions; yellow = critical patients at risk of their clinical condition deteriorating; red = very critical patient needing immediate treatment); any activation of a short-stay observation period; and discharge from the ED (classified as patient hospitalized, arrived dead, sent home, sent to another institute, died at the ED, refused hospitalization, left the ED before being examined, or referred for outpatient care).

Outcome definition

A case seen at the ED was considered urgent and potentially appropriate if it met at least one of the following conditions (as recently defined by the Italian agency for regional health services, AGENAS)[18]:

- red or yellow outgoing triage code (if no outgoing code was assigned, red or yellow incoming triage code);
- patient hospitalized or refused recommended hospitalization;
- patients assessed for trauma;
- short-stay observation was activated;
- arrived dead or died at the ED.

Patients who contacted the OOH services were divided into two groups according to whether or not they were referred to the ED. Both groups included patients who actually went to the ED within 24 hours after contacting the OOH and others who did not.

- Among those not referred to the ED (first group), patients were considered as cases of “potentially inappropriate non-referral” if they went spontaneously to the ED within 24 hours after contacting the OOH services and were found to meet at least one of the criteria for appropriate access to the ED.
- Among those referred to the ED (second group), patients were considered as cases of “potentially inappropriate referral” if they did not go to the ED within 24 hours, or if they did go to the ED, but it was found that they did not meet at least one of the criteria for appropriate access to the ED.

Statistical methods

Statistical analyses were performed using the STATA12 software.

The data were summarized as numbers (percentages) of patients for categorical variables. Bivariate analyses were run to assess differences in counts for categorical variables using the chi-square test (or Fisher’s test when less than 5 cases were expected).

Two logistic regression models were applied, one for each dependent variable:

- potentially inappropriate non-referrals to the ED by the OOH service (for this regression a Firth’s penalized likelihood approach was applied to correct for rare events);
- potentially inappropriate referrals to the ED by the OOH service.

The two regressions tested the socio-demographic, process/context, and clinical variables associated with the dependent variables.

A p-value of less than 0.01 was considered significant, to take multiple comparisons into account.

Ethical considerations

The data analysis was conducted on anonymized aggregated data with no chance of individuals being identifiable. The study complied with the Declaration of Helsinki and with Italian Law n. 196/2003 on the protection of personal data. The recent resolution n. 85/2012 of the Italian

1 Guarantor for the Protection of Personal Data also confirmed the allowability of processing
2 personal data for medical, biomedical and epidemiological research, and that data concerning health
3 status may be used in aggregated form in scientific studies. Permission to use non-identifiable,
4 individual data extracted from administrative databases was granted by the ULSS 4 Veneto Region,
5 which is responsible for any use of the data concerning the population it serves.

For peer review only

Results

From 1st January to 31st December 2011, the LHA 4 OOH service was contacted by 23,980 people (see flow chart 1).

Around 9% of all patients contacting the OOH service were referred to the ED. **Table 1** shows the sample's characteristics of by referral group. The percentage of patients referred to the ED increased with patients' age, and was higher at night (13.4% from 8 pm to 8 am) than during the day (8.4% from 8 am to 8 pm). Patients requiring nursing care, physiotherapy or GP homecare were more likely to be referred to the ED after contacting the OOH service (the proportions were 20.66%, 19.12%, and 19.83%, respectively). Cardiovascular disease (28.3%) and trauma (23.4%) were the diagnostic categories of patients most likely to be referred to the ED.

The total number of cases potentially inappropriately managed by the OOH service, in terms of referrals and non-referrals to the ED, amounted to 1,599 (about 7% of the sample): 392 were cases of potentially inappropriate non-referral to the ED (1.7%); and 1,207 were cases of potentially inappropriate referral to the ED (5.3%); this latter group includes 422 patients who did not go to the ED despite being referred there (20.4% of all those referred) and 785 who did go to the ED but who did not meet any of the criteria for potentially appropriate access (38.0% of all those referred to the ED).

Table 2 shows the demographic, process/context and clinical characteristics of the patients contacting the OOH services by referral to the ED and its appropriateness. For example, the percentage of patients inappropriately referred to the ED was higher for infants up to one year old (reaching 87.1%) and decreased with age (35.1% in patients >84 years old); vice versa, the percentage of inappropriate non-referrals increased with age, reaching 5.3% for patients >84 years old.

Tables 3a and 3b show the results of two logistic regression models. In particular, **Table 3a** shows the measure of association between the demographic, process/context and clinical variables with potentially inappropriate non-referrals to the ED. The regression confirmed that potentially

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inappropriate non-referrals increased with age, revealing a two-fold higher odds ratio for 65-74 and 75-84 year-olds than for the newborn. Females appeared to have significantly lower odds of being inappropriately not referred to the ED. Foreign people were at higher risk of being inappropriate not referred to the ED than Italians (OR 1.59), though the difference did not reach statistical significance ($p=0.03$). Contacting the OOH service at night also coincided with a two-fold higher odds of potentially inappropriate referral than for daytime contacts. A number of diagnostic categories were associated with higher odds of potentially inappropriate non-referral than for the diagnostic category taken for reference (dermatological). Contacts involving patients attending the walk-in clinic were only half as likely as patients managed by means of telephone consultations alone to be cases of potentially inappropriate non-referral to the ED.

Table 3b shows the measure of the association between the variables and inappropriate referrals to the ED. Unlike the first regression, the odds of potentially inappropriate referral to the ED dropped with increasing age (as compared with the newborn). There were no significant differences with regard to contacts' nationality or gender. Patients who died within a year of contacting the OOH service had lower odds of being referred inappropriately to the ED. Also the contacts managed by post-holder in respect to those managed by temporary holder had lower odds of being referred inappropriately to the ED. None of the diagnostic categories changed the likelihood of potentially inappropriate referral vis-à-vis the reference category. Contacts handled by means of a home visit were only half as likely as those managed by means of a telephone consultation alone to be cases of potentially inappropriate referral to the ED.

Discussion

This study addressed the phenomenon of potentially inappropriate patient referral and non-referral to the ED by OOH physicians. The study revealed that some determinants of potentially inappropriate non-referral to the ED mirror those of potentially inappropriate referral, e.g. older age reduces the probability of inappropriate referral and increases the risk of inappropriate non-referral.

Frequency of potentially inappropriate handling of OOH contacts

Only one in eight patients went to the ED after contacting the OOH service, and less than one in twenty who contacted the OOH subsequently went to the ED at their own discretion and failed to meet the criteria for urgent medical care. This confirms the gatekeeping role of OOH physicians and underlines the importance of this service in ensuring a continuity of primary health care and preventing patients from going to the ED instead of a primary care service. The unwarranted use of secondary health care services gives rise to a lack of continuity of care and generates an overload that adversely affects ED activities.[19] A previous systematic review found, however, that action taken to increase OOH primary care services did not generate any reduction in ED attendance (though the studies considered in this review received low global quality ratings and various different models of OOH primary medical care service had been considered).[20] Another previous study [21] also showed that decisions to refer patients to ED were associated not only with the patient's clinical and process/context characteristics, but also with the particular physician involved: there were statically significant differences in the adjusted odds of referral to EDs between physicians working at the same OOH services, meaning that each doctor's attitude had an important influence on their referral rates.

The present study found that less than 10% of cases (7%) were handled by the OOH services in a potentially inappropriate manner. As regards potentially inappropriate ED referrals, we found that

less than one in twenty of all patients contacting the OOH services (5.3%) were referred to the ED inappropriately. In theory, OOH physicians are contacted when patients have borderline health conditions that are not urgent enough for them to go to the ED, but too severe for them to wait until the next working day. This delicate borderline situation should be borne in mind when we consider the above percentages. According to an English study the percentage of cases inappropriately managed by means of telephone triage services delivered by the NHS-24 service is around 35%, judging from GPs' subsequent re-assessment.[22] An Australian study reported instead that about 10% of patient referrals to the ED by GPs were inappropriate.[23] It is rather difficult to draw comparisons between studies conducted on different health care systems and using different methods to assess "appropriateness". These figures are in any case considerably lower than the percentage of inappropriateness identified for self-referred patients, which reaches as high as 80% [24], confirming once again the important gatekeeping role of the OOH services in relation to low-acuity patients.

Potentially inappropriate non-referral to the ED

Of course, inappropriate non-referral to the ED is a more serious issue because a diagnostic delay in a genuinely urgent patient may even be fatal. Our study found this situation fairly infrequent (1.7%). To the best of our knowledge, no other published studies have investigated the frequency of potentially inappropriate non-referrals to the ED with which we might draw a comparison. We might nonetheless argue that the low rate of inappropriate non-referral to the ED identified in this study could be partly thanks by the IT system that enables OOH physicians to consult patients' electronic medical records and check their medical history as soon as they make contact. Generally speaking, communication breakdown is a major contributor to diagnostic errors and an increasingly recognized preventable factor in medical mishaps. Using new technologies to enhance communication between health providers and health systems could therefore facilitate the consultation of patients' medical records [25], though a literature review found that improper use of

such technologies can give rise to errors in the electronic hospital records, which can in turn lead to errors that endanger patients' safety or negatively affect the quality of their care [26].

With a view to enhancing the quality of OOH services, it would be wise to address the determinants of OOH physicians' potentially inappropriate management of the patients who contact them. The odds of inappropriate ED non-referral were found to increase with patients' age, atypical disease presentations, polypharmacy, and multiple comorbidities, which may complicate patient management.[27] Cognitive impairment, which is more common among the elderly, could also negatively influence the likelihood of appropriate patient management. Cognitively impaired older patients can have trouble remembering things, become confused, and have attention deficits or difficulty expressing themselves.[28] An analysis of error reports submitted to the Applied Strategies for Improving Patient Safety (ASIPS) indicated that communication problems represented the most common error process in the ambulatory care setting.[29] Failure to ensure complete communication between health care providers and patients was also associated with a higher risk of clinical harm. The apparently higher likelihood of OOH services inappropriately not referring elderly people to the ED (especially those patients who then go to the ED anyway) may relate, however, to ED physicians having a greater propensity to admit older patients to hospital as a prudential choice.[30]

Our study revealed that not only socio-demographic and clinical conditions, but also logistic and organizational variables may be determinants of potentially inappropriate non-referral to the ED. In particular, we found that patients attending the OOH walk-in clinic were less likely to be managed inappropriately than those only making telephone contact. Another study reported that telephone consultations were shorter and less detailed than face-to-face visits for similar clinical problems, increasing the risk of diagnostic or management errors.[31] The phenomenon of inappropriate non-referral to the ED for patients managed by the OOH services over the phone could be contained by adopting well-structured procedures based on checklists and protocols, or more advanced solutions

such as decision-supporting software packages, to help doctors consulted over the phone provide comprehensive advice [32,33]. An approach applying root cause analysis should be adopted to identify proactive ways to address patient safety incidents with a view to reducing the risk of error, rather than more passive methods that encourage staff to be more vigilant in their working practice [34, or to take more care when prescribing medication, for example.

Potentially inappropriate referral to ED

Older children and adults had lower odds of inappropriate referral to the ED than infants. A cross-sectional examination of ED attendance in England found age strongly related to inappropriate referral [35]. The odds were highest for the very young (peaking for one- and two-year-olds), and were also high between the mid-teens and mid-twenties, followed by a steady drop with aging thereafter. The sizable presence of young people inappropriately attending EDs around the world has been recognized in various studies, as emphasized in the review conducted by Carret.[12] These findings suggest that action to prevent inappropriate management should target early childhood and young adolescence. The phenomenon probably reflects the pressures of parenthood,[36,37] or a lack of confidence with children’s diseases. Given the difficulty of managing pediatric patients, and infants especially, pediatric OOH services need to be expanded, or training courses could be organized to improve OOH physicians’ understanding of pediatric emergencies.

Our analysis showed that, among the OOH physicians, regular post-holders were less likely to inappropriately refer patients to the ED than their temporary substitutes. This may be an indication of the former’s greater work experience, but could also relate partly to the fact that some people contacting the OOH services are frequent attenders, and probably well known to the permanent staff, who consequently find it easier to manage their disorders.[38] Using the available data on OOH physicians (also taking each OOH physician’s personal identification code into account) might be useful for the purpose of giving physicians regular feedback on their performance, which

could be compared with a benchmark, for instance. It has been demonstrated in the literature that this could have a positive impact on their performance.[39]

Limits and strengths

Our study suffers from several limitations. One stems from our arbitrary classification of potentially inappropriate referrals to the ED (based on a national definition of appropriateness) that clearly influences the reported prevalence of potentially inappropriate patient management in our sample. There is no general consensus on how to define appropriateness of ED use in the literature. In addition contacts at OOH services and at ED happened at a different time, by personnel equipped with different diagnostic features. Another limitation lies in that our analysis was conducted only on the LHA 4 records, so we were unable to follow up patients admitted to an ED outside the territory it serves. The scientific literature suggests, however, that patients usually go to their nearest ED, in their own district.[40] The main strength of our research, on the other hand, lies in that this was a population-based study conducted not on a limited or selected sample of patients, but using a register of routinely-collected data, so our findings could not be biased by any research hypothesis.

Conclusion

This work paints a comprehensive picture of the predictors of potentially inappropriate behavior on the part of OOH physicians in terms of their referral or non-referral of patients to the ED. It goes to show that administrative data can be used to monitor this phenomenon and its determinants. Our findings may be useful in improving the OOH services, and also in defining a program of continuing professional education for OOH doctors more focused on their real needs. The novelty of our work means, however, that further studies addressing the factors associated with potentially inappropriate referral and non-referral of patients to the ED are needed to confirm these results.

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Competing interests

The authors have no competing interests to disclose. The authors declare that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted.

Data Sharing Statement

No data are available to share

Key points

The determinants of potential inappropriate non-referral to the ED mirror the determinants of potential inappropriate referral, e.g. older age reduces the likelihood of inappropriate referral and increases the risk of inappropriate non-referral.

Not only socio-demographic and clinical conditions, but also logistic and organizational variables may contribute to potentially inappropriate non-referral to the ED.

Improving OOH services by means of different organizational, structural and training strategies could be beneficial in this setting, ensuring a greater focus on patients’ real needs and avoiding ED misuse.

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Table 1: Characteristics of the sample contacting the OOH service by patients'

referral or non-referral to the ED

		Not referred	Referred
		n=20596	n=2066
<i>Patients' demographic variables</i>			
Sex	Male 10450	90.6%	9.4%
	Female 12212	91.1%	8.9%
Age	0-1 years 1254	96.0%	4.0%
	2-14 y 4984	95.0%	4.0%
	15-18 y 624	94.6%	5.4%
	19-44 y 6245	93.6%	6.4%
	45-64 y 3927	90.1%	9.9%
	65-74 y 1867	86.5%	13.5%
	75-84 y 2067	81.7%	18.3%
Pediatric cases (0-14y)	>84 y 1694	79.6%	20.4%
	No 16424	89.0%	10.0%
	Yes 6238	95.8%	4.2%
Nationality	Italian 20099	90.5%	9.5%
	Foreign 2560	94.2%	5.8%
<i>Patients' process and context variables</i>			
Distance from nearest OOH	0-5 km 11214	90.2%	9.8%
	>5 km 10322	91.6%	8.4%
Time of day	8-20 19366	91.6%	8.4%
	20-8 3296	86.6%	13.4%
Type of day	Working day 7368	89.9%	10.1%

		Holiday 8285	91.4%	8.6%
		Day before a holiday 6799	91.2%	8.8%
Type of OOH		Phone advice 9970	92.5%	7.5%
intervention		Home visit 2134	76.5%	23.5%
		Walk-in clinic visit 10558	92.3%	7.7%
OOH		Temporary substitute		
physician		17169	90.5%	9.5%
		Post-holder 5493	92.0%	8.0%
Gender of		Male 14489	89.8%	10.2%
OOH		Female 8173		
physician			92.9%	7.1%
<i>Patients' clinical variables</i>				
Death within a		No 20846	92.0%	8.0%
year		Yes 1816	78.6%	21.4%
Home		No 22594	90.9%	9.1%
physiotherapy		Yes 68	80.9%	19.1%
Home nursing		No 20973	91.8%	8.2%
services		Yes 1689	79.3%	20.7%
Assisted at		No 21976	91.2%	8.8%
home by GP		Yes 686	80.2%	19.8%
Disease		Dermatological 1501	97.3%	2.7%
		Musculoskeletal 1453	91.4%	8.6%
		Ophthalmological 532	85.0%	15.0%
		Odontostomatological 634	97.8%	2.2%
		Oncological and	79.7%	20.3%

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hematological	143		
Ear-nose-throat	2744	96.6%	3.4%
Pregnancy and reproductive system	194	84.0%	16.0%
Psychiatric	381	89.0%	11.0%
Respiratory	1734	86.5%	13.6%
Trauma	752	76.6%	23.4%
Nervous system	853	77.5%	22.5%
Infectious	389	97.2%	2.8%
Genitourinary system		89.5%	10.5%
	1092		
Gastroenterological	3148	89.4%	10.6%
Fever	2835	97.9%	2.1%
Endocrinological	127	85.8%	14.2%
Advice about ongoing therapy	1969	99.3%	0.7%
Cardiovascular	1348	71.7%	28.3%
Not specified	833	91.2%	8.8%

Table 2: Bivariate analysis of characteristics of patients and their potentially inappropriate management by referral and non-referral to the ED

		Not referred			Referred		
		n. 20596			n. 2066		
		App.	Inapp.	p	App.	Inapp.	p
<i>Patients' demographic variables</i>		n=20204	n=392		n=859	n=1207	
		%	%		%	%	
Sex	Male	98,0	2,0	0.268	40,8	59.2	0.468
	Female	98.2	1.8		42.3	57.7	
Age	0-1 years	98.6	1.4	<0.001	12.9	87.1	<0.001
	2-14 y	98.9	1.1		25.9	74.1	
	15-18 y	98.8	1.2		26.5	73.5	
	19-44 y	99.2	0.8		25.1	74.9	
	45-64 y	98.3	1.7		34.6	65.4	
	65-74 y	96.4	3.6		51.4	48.6	
	75-84 y	95.4	4.6		52.9	47.1	
	>84 y	94.7	5.3		64.9	35.1	
	Pediatric cases (0-14y)	No	97.8		2.2	<0.001	
Yes		98.8	1.2	22.8	77.2		
Nationality	Italian	98,0	2.0	0.003	42.9	57.1	<0.001
	Foreign	98.9	1.1		24.1	75.9	
<i>Patients' process and context variables</i>							
Distance from nearest OOH	0-5 km	98.3	1.7	0.149	41.1	58.9	0.635
	>5 km	98.0	2.0		42.1	57.9	
Time of day	8-20	98.5	1.5	<0.001	41.3	58.7	0.613

		20-8	95.8	4.2		42.6	57.4	
	Type of day	Working day	98.0	2.0		40.9	59.1	
		Holiday	98.1	1.9	0.823	43.4	56.6	0.431
		Day before a holiday	98.1	1.9		40.0	60.0	
	Type of OOH	Phone advice	97.6	2.4		41.4	58.6	
	intervention	Home visit	94.5	5.5	<0.001	67.3	32.7	<0.001
		Walk-in clinic visit	99.2	0.8		25.9	74.1	
	OOH physician	Temporary substitute	98.2	1.8	0.198	40.0	60.0	0.004
		Post-holder	97.9	2.1		47.5	52.5	
	Gender of	Male	98.2	1.8		41.9	58.1	
	OOH physician	Female	98	2	0.425	40.7	59.3	0.592
	<i>Patients' clinical variables</i>							
	Death within	No	98.5	1.5		35.2	64.8	
	a year	Yes	93.3	6.7	<0.001	69.2	30.8	<0.001
	Home	No	98.1	1.9		41.6	58.4	
	physiotherapy	Yes	100	0	0.301	38.5	61.5	0.819
	Home nursing	No	98.4	1.6		37.2	62.8	
	services	Yes	94.0	6.0	<0.001	63.0	40.0	<0.001
	Assisted at	No	98.2	1.8		40.0	60.0	
	home by GP	Yes	94	6	<0.001	64.7	35.3	<0.001
	Disease	Dermatological	99.9	0.1		7.5	92.5	
		Musculoskeletal	98.5	1.5		22.4	77.6	
		Ophthalmological	99.8	0.2	<0.001	1.2	98.8	<0.001
		Odontostomatological	100	0		7.1	92.9	
		Oncological and	93.9	6.1		65.5	34.5	

hematological				
Ear-nose-throat	99.6	0.4	1.1	98.9
Pregnancy and reproductive system	96.9	3.1	32.3	67.7
Psychiatric	96.5	3.5	38.1	61.9
Respiratory	97.6	2.4	52.3	47.7
Trauma	98.6	1.4	100	0
Nervous system	96.4	3.6	43.2	56.8
Infectious	100	0	18.2	81.8
Genitourinary system	97.4	2.6	32.2	67.8
Gastroenterological	96.2	3.8	36.7	63.3
Fever	98.3	1.7	26.2	73.8
Endocrinological	96.3	3.7	44.4	55.6
Advice about ongoing therapy	98.8	1.2	28.6	71.4
Cardiovascular	96.5	3.5	47.8	52.2
Not specified	96.6	3.4	35.6	64.4

Table 3a: Results of multivariate logistic regression for associations between patients' characteristics and their potentially inappropriate management – for cases not referred to the ED					
Potentially inappropriate non-referral to the ED		Odds ratio	95% confidence interval	P	
Sex (ref. Male)	Female	0.75	0.61 - 0.92	0.007	
Age (ref. 0-1 years)	2-14 y	0.99	0.57 - 1.69	0.939	
	15-18 y	1.17	0.49 - 2.79	0.731	
	19-44 y	0.68	0.39 - 1.20	0.187	
	45-64 y	1.26	0.72 - 2.20	0.421	
	65-74 y	2.21	1.25 - 3.92	0.007	
	75-84 y	2.14	1.21 - 3.80	0.009	
	>84 y	2.03	1.11 - 3.69	0.021	
Nationality (ref. Italian)	Foreign	1.62	1.04 - 2.47	0.029	
Distance from nearest OOH (ref. 0-5 km)	>5 km	1.19	0.97 - 1.47	0.103	
Time of day (ref. 8-20)	20-8	2.30	1.80 - 2.93	<0.001	
Type of day (ref. Working day)	Holiday	1.27	0.98 - 1.64	0.073	
	Day before a holiday	1.42	1.08 - 1.86	0.012	
Home nursing services (ref. No)	Yes	1.21	0.86 - 1.71	0.269	
Assisted at home by GP (ref. No)	Yes	1.05	0.68 - 1.62	0.834	
Death within a year (ref. No)	Yes	1.65	1.19 - 2.30	0.003	
OOH physician	Post-holder	0.93	0.66 - 1.30	0.651	

(ref. Temporary substitute)					
Gender of OOH physician					
	Female	1.27	1.02 - 1.58	0.030	
(ref. Male)					
Disease (ref. Dermatological)					
	Musculoskeletal	5.99	1.59 - 22.41	0.008	
	Ophthalmological	1.79	0.26 - 13.65	0.573	
	Oncological and	8.87	2.02 - 38.59	0.004	
	hematological				
	Ear-nose-throat	2.60	0.65 - 10.35	0.176	
	Pregnancy and	24.63	5.38 - 112.7	<0.001	
	reproductive system				
	Psychiatric	8.26	2.06 - 33.05	0.003	
	Respiratory	7.63	2.09 - 27.86	0.002	
	Trauma	7.14	1.73 - 29.46	0.007	
	Nervous system	11.02	2.96 - 41.05	<0.001	
	Genitourinary	10.10	2.73 - 37.35	0.001	
	system				
	Gastroenterological	13.76	3.90 - 48.60	<0.001	
	Fever	6.82	1.90 - 24.56	0.003	
	Endocrinological	7.96	1.64 - 38.50	0.010	
	Advice about	3.49	0.94 - 13.03	0.063	
	ongoing therapy				
	Cardiovascular	8.70	2.38 - 31.83	0.001	
	Not specified	10.90	2.95 - 40.38	<0.001	
Type of OOH intervention					
	Home visit	1.10	0.82 - 1.47	0.543	
(ref. Phone)					
	Walk-in clinic visit	0.49	0.36 - 0.66	<0.001	

Table 3b: Results of multivariate logistic regression for associations between patients’ characteristics and their potentially inappropriate management – for cases referred to the ED

Potentially inappropriate referral to the ED		Odds ratio	95% confidence interval	P
Sex (ref. Male)	Female	1.23	0.98 - 1.54	0.076
Age (ref. 0-1 years)	2-14 y	0.60	0.21 - 1.75	0.349
	15-18 y	0.21	0.06 - 0.77	0.019
	19-44 y	0.27	0.10 - 0.74	0.010
	45-64 y	0.17	0.06 - 0.45	<0.001
	65-74 y	0.12	0.04 - 0.33	<0.001
	75-84 y	0.15	0.05 - 0.39	<0.001
	>84 y	0.15	0.05 - 0.41	<0.001
Nationality (ref. Italian)	Foreign	0.88	0.52 - 1.48	0.633
Distance from nearest OOH (ref. 0-5 km)	>5 km	0.86	0.69 - 1.08	0.202
Time of day (ref. 8-20)	20-8	1.00	0.76 - 1.33	0.966
Type of day (ref. Working day)	Holiday	1.11	0.85 - 1.46	0.431
	Day before a holiday	1.27	1.95 - 1.70	0.114
Home physiotherapy (ref. No)	Yes	3.05	0.88 - 10.55	0.079
Home nursing services (ref. No)	Yes	1.04	0.74 - 1.45	0.824
Assisted at home by GP (ref. No)	Yes	0.95	0.60 - 1.49	0.812
Death within a year (ref. No)	Yes	0.46	0.33 - 0.64	<0.001

OOH physician (ref. Temporary substitute)	Post-holder	0.64	0.47 - 0.89	0.007
Gender of OOH physician (ref. Male)	Female	1.12	0.87 - 1.44	0.392
Disease (ref. Dermatological)	Musculoskeletal	0.48	0.13 - 1.72	0.258
	Ophthalmological	7.16	0.71 - 72.26	0.095
	Odontostomatologic al	1.08	0.10 - 11.90	0.949
	Oncological and hematological	0.16	0.04 - 0.72	0.017
	Ear-nose-throat	8.21	0.81 - 82.92	0.074
	Pregnancy and reproductive system	0.17	0.04 - 0.74	0.018
	Psychiatric	0.41	0.10 - 1.66	0.211
	Respiratory	0.23	0.07 - 0.80	0.021
	Nervous system	0.26	0.08 - 0.92	0.036
	Infectious	0.56	0.07 - 4.38	0.583
	Genitourinary system	0.26	0.07 - 0.92	0.037
	Gastroenterological	0.22	0.06 - 0.76	0.016
	Fever	0.27	0.07 - 1.06	0.061
	Endocrinological	0.26	0.05 - 1.25	0.093
	Advice about ongoing therapy	0.40	0.07 - 2.31	0.305
	Cardiovascular	0.22	0.06 - 0.75	0.016

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Type of intervention (ref. Phone)	Not specified	0.38	0.10 - 1.42	0.148
	Home visit	0.43	0.32 - 0.59	<0.001
	Walk-in clinic visit	1.33	1.00 - 1.79	0.052

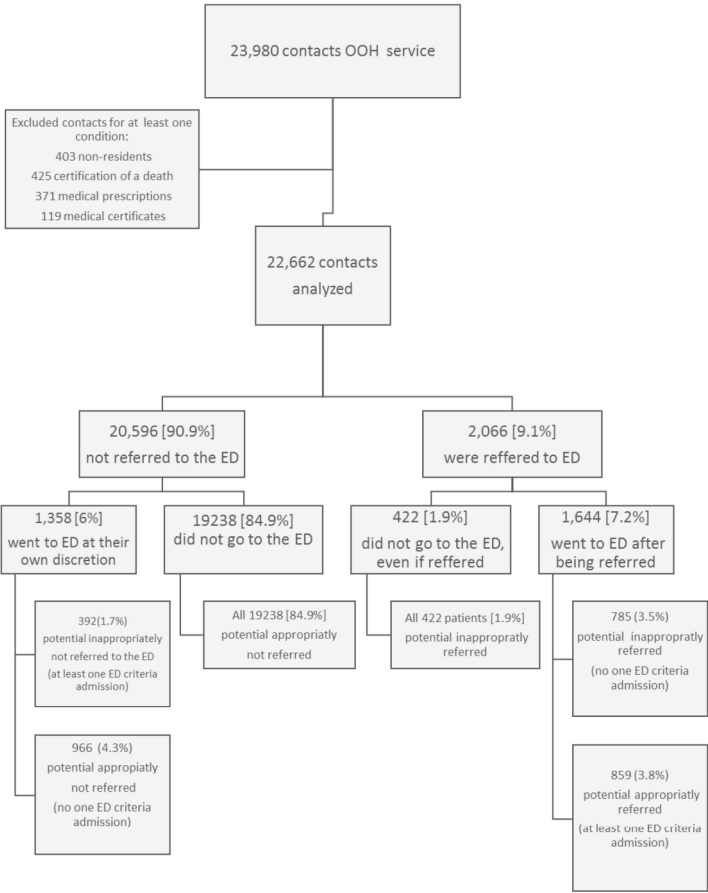
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Figure 1: Distribution of patients contacting the OOH service

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Figure 1: Distribution of patients contacting the OOH service



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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract YES pag 3, line 9
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found YES pag 3
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported YES pag 4-5
Objectives	3	State specific objectives, including any prespecified hypotheses YES pag 5, lines 20-24
Methods		
Study design	4	Present key elements of study design early in the paper YES page 7-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection YES page 7-8
Participants	6	(a) Cohort study— Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up YES pag 7, lines 17-21, page 8 lines 4-6
		Cohort study—For matched studies, give matching criteria and number of exposed and unexposed Not pertinent
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable YES page 9, pag 10 lines 10-11 described above
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group YES pag 8
Bias	9	Describe any efforts to address potential sources of bias YES page 16, lines 6-15
Study size	10	Explain how the study size was arrived at YES, the sample was composed of one year contacts to OOH
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why YES, page 8
Statistical methods	12	a) Describe all statistical methods, including those used to control for confounding

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YES page 10

(a) Describe any methods used to examine subgroups and interactions

(c) Explain how missing data were addressed

Cohort study—If applicable, explain how loss to follow-up was addressed

Yes page 16

(e) Describe any sensitivity analyses

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Results

Participants	13*	(a)	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed page 11, lines 3-17
		(b)	Give reasons for non-participation at each stage <i>not pertinent</i>
			Consider use of a flow diagram
Descriptive data	14*	(a)	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders Yes table 1 and 2
		(b)	Indicate number of participants with missing data for each variable of interest <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount) <i>not pertinent</i>
Outcome data	15*		<i>Cohort study</i> —Report numbers of outcome events or summary measures over time Yes figure 1
Main results	16	(a)	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included Yes, table 3
		(b)	Report category boundaries when continuous variables were categorized Yes, table 3
		(c)	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17		Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion

Key results	18	Summarise key results with reference to study objectives Yes, pag 12, lines 5-8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Yes pag 16, lines 6-15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence Yes all discussion
Generalisability	21	Discuss the generalisability (external validity) of the study results

Other information

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable,
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for the original study on which the present article is based
Yes, pag 1 , lines 26-28

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

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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BMJ Open

Determinants of out-of-hours service users' potentially inappropriate referral or non-referral to an emergency department: a retrospective cohort study in a Local Health Authority, Veneto Region, Italy

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-011526.R2
Article Type:	Research
Date Submitted by the Author:	14-Jun-2016
Complete List of Authors:	Buja, Alessandra; University of Padua, Department of Molecular Medicine, Public Health Section, Laboratory of Public Health and Population Studies, Baldo, Vincenzo; University of Padua, Dept. of Molecular Medicine of the University of Padua, Laboratory of Public Health and Population Studies Rigon, Stefano; Azienda ULSS N 4 Alto Vicentino, Epidemiological Unit Toffanin, Roberto; Azienda ULSS N 4 Alto Vicentino, Health Director Sandonà, Paolo; Azienda ULSS N 4 Alto Vicentino, Out of Hour Service Carrara, Tommaso; Università degli Studi di Padova, Department of Molecular Medicine, Public Health Section, Laboratory of Public Health and Population Studies, Damiani, Gianfranco; Università Cattolica del Sacro Cuore Sede di Roma, Department of Public Health
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Epidemiology
Keywords:	PRIMARY CARE, HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Manuscripts

Determinants of out-of-hours service users' potentially inappropriate referral or non-referral to an emergency department: a retrospective cohort study in a Local Health Authority, Veneto Region, Italy

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Word count: 4610

Funding

Funding for this study was provided by 60% research grants (code: 60A07-0595/14) from the University of Padua. The funding parties had no role in the study design, data collection, analysis and interpretation, drafting of the manuscript, or decision to submit the paper for publication.

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No additional data available

Contributorship statement:

All the named authors fulfil the authorship criteria, and nobody else fulfilling the criteria has not been included as an author.

Alessandra Buja monitored data collection, wrote the statistical analysis plan, cleaned and analyzed the data, conducted the literature search and drafted and revised the paper. She acts as guarantor.

Roberto Toffanin wrote the design plan.

Stefano Rigon designed the data collection and record linkage tools, and monitored data collection.

Paolo Sandonà conducted the literature search, and drafted and revised the paper.

Tommaso Carrara conducted the literature search, and drafted and revised the paper.

Gianfranco Damiani and Vincenzo Baldo conceptualized the data and revised the draft of the paper.

Abstract

Background A growing presence of inappropriate patients has been recognized as one of the main factors influencing emergency department (ED) overcrowding, which is a very widespread problem all over the world. On the other hand, out-of-hours (OOH) physicians must avoid delaying the diagnostic and therapeutic course of patients with urgent medical conditions. The aim of this study was to analyze the appropriateness of patient management by OOH services, in terms of their potentially inappropriate referral or non-referral of non-emergency cases to the ED.

Methods This was an observational retrospective cohort study based on data collected in 2011 by the Local Health Authority No. 4 in the Veneto Region (Italy). After distinguishing between patients contacting the OOH service who were or were not referred to the ED, and checking for patients actually presenting to the ED within 24 hours thereafter, these patients' medical management was judged as potentially appropriate or inappropriate.

Results The analysis considered 22,662 OOH service contacts recorded in 2011. The cases of potentially inappropriate non-referral to the ED were 392 (1.7% of all contacts), as opposed to 1207 potentially inappropriate referrals (5.3% of all contacts). Age, nationality, type of disease, and type of intervention by the OOH service were the main variables associated with the appropriateness of patient management.

Conclusion These findings may be useful for pinpointing the factors associated with a potentially inappropriate patient management by OOH services and thus contribute to improving the deployment of health care and the quality of care delivered by OOH services.

Keywords: Out-of-hours service, health care services, emergency department, patient referral, patient management.

Article summary

- This is the first study to investigate OOH referrals to EDs, considering the appropriateness of both non-referrals and referrals by OOH physicians, and delineating the sociodemographic, clinical, environmental and logistic determinants of any inappropriate behavior.
- The strength of the study lies in the analysis of all 22,662 OOH service contacts made by the a population served by a local health authority (LHA 4 in the Veneto Region), meaning that the findings cannot be distorted by any research hypothesis.
- A limitation of the study stems from our arbitrary classification of potentially inappropriate referrals to the ED (based on a nationally-adopted definition of appropriateness), which clearly influences the reported prevalence of potentially inappropriate patient management in our sample.
- Another limitation lies in that our analysis was conducted only on the LHA 4 records, so we were unable to follow up patients admitted to a ED outside the territory covered by the LHA 4.

Introduction

Primary care serves as the cornerstone for building a strong healthcare system that ensures positive health outcomes and health equity [1]. Out-of-hours (OOH) services are a fundamental part of primary healthcare, providing continuity of care for patients with urgent clinical conditions who cannot wait until the next working day to see a doctor. OOH physicians consequently act as gatekeepers for the provision of secondary care for patients with problems that are not life-threatening and who do not need immediate high-level care. It has also been demonstrated that when general practitioners manage patients with primary care needs there is a reduction in the associated costs with no apparent detrimental effect on outcome [2,3].

OOH physicians should only refer cases to an emergency department (ED) if they have clinical conditions requiring urgent treatment or higher-level diagnostic services without delay.[4] For patients who are genuinely urgent cases, non-referral or delayed referral to the ED can pose a serious problem: prehospital times are often a matter of life and death, and delaying hospital admission even by just a few hours raises the risk of death associated with several diseases.[5-8] OOH services and EDs are two types of service that differ in their organization, policy and structure; they are not interchangeable but complementary, and both should operate appropriately to ensure the best possible functioning of the health service as a whole.

In recent times there has been a significant worldwide increase in ED attendance, relating mainly to higher numbers of non-urgent cases. In Italy, for example, the SIMEU (Italian Society of Emergency Medicine) reported in 2010 that ED visits had grown by 5-6% a year over the previous 5 years, and this was partly as a consequence of inappropriate referrals by primary care physicians.[9] Similarly, visits to the ED in the United States rose from about 92.6 million in 1993 to 133.6 million in 2013, reaching 423 visits per 1,000 population/year.[10] The Australian Institute of Health and Welfare (AIHW) recently reported that 2,176,612 ED attendances in 2012–2013 were potentially referrals by general practitioners (GPs) [11]. The situation is much the same in

Europe: France, Germany and the UK have seen a significant increase in the number of cases seen at the ED. Non-urgent patients have been recognized as a potentially avoidable contributor to the problem of ED overcrowding: research found a prevalence of inappropriate ED use that varied from 10% to 90%, depending on the criteria used to judge appropriateness, and in nearly half of the studies it ranged from 24% to 40% [12]. There is no generally accepted and practical definition of what constitutes an 'appropriate' case for referral to the ED, and what constitutes an 'emergency'. It is therefore hardly surprising that we find an enormous diversity in the reported proportions of visits judged to be inappropriate [12].

Numerous studies have reported that an excessive number of patients with non-urgent clinical conditions are seen at the ED, but few have focused on the degree to which physicians' inappropriate referrals contribute to this problem. Some studies in Europe assessed the influence of OOH primary care services on ED attendance, and found that improving the OOH services reduced the population's recourse to the ED [13,14].

Only a very few studies also considered patients who were erroneously not referred to the ED, and most of these cases were due to inaction by GPs and other primary care providers [15]. In the case of curative services, the relationship between timing and efficacy is crucial, making it important to ensure that patients go to the right place at the right time for the right intervention [16]. Safe, good-quality, consistent and effective in-hours and OOH primary care services are crucial for providing care as close to a patient's home as possible.

The aim of this study was to investigate how often OOH physicians' patient referrals or non-referrals to the ED are potentially inappropriate. After identifying the dimension of the problem, a second step involves seeking the socio-demographic, process/context, and clinical variables associated with a higher risk of potentially inappropriate patient referral or non-referral to the ED.

Material and methods

Context

The Italian NHS (National Health System) was established in 1978 and modeled along the lines of the British NHS. It is a mainly public system financed by general taxation. From an organizational viewpoint, the Italian territory is divided into 140 Local Health Authorities (LHAs), each responsible for providing health services to its local population.

All Italian citizens or foreigners residing in Italy are registered with a general practitioner (GP) and they are supposed to consult their GP for health conditions. During the day, patients can visit the general practice where they are registered; after hours, they can consult one of the local OOH services, which have infrastructure and resources allocated by the LHA. Despite regional differences being introduced when responsibilities for the NHS were decentralized, OOH services are still regulated by a nationally-shared agreement that defines the tasks, activities and salaries of OOH physicians. Dedicated personnel for OOH services are recruited from waiting lists drawn up by the LHA, and preference is given to qualified GPs. OOH services in Italy are currently provided by about 12,057 physicians working under an agreement with the LHA at 2,893 OOH service delivery points. They are either regular post-holders, or temporary substitutes, and about one in three of them are qualified GPs [17]. Italian OOH services operate every day of the week from 8 pm to 8 am, at weekends from 10 am on Saturdays to 8 am on Mondays, plus bank holidays, and also from 8 am to 8 pm on days when GPs attend continuing education courses. The OOH physicians receive telephone calls from patients and deliver services that may involve: providing advice over the phone; visiting a patient at home (or in a rest home); examining them at the walk-in clinic (at premises provided by the LHA). However it is not necessary to book visits to the walk-in clinic, and patients may attend without any previous phone contact. If a patient's condition is judged to be unmanageable in the primary care setting, the patient may be advised to go directly to

1 the ED in their own car. If a patient’s condition is judged to be life-threatening, an ambulance may
2 be called instead.

3 People can access the ED at their own discretion, or they may be referred by a physician. At the ED
4 they are received by a triage nurse who assigns them a color code, depending on the severity and
5 urgency of their case. After patients have been examined by a physician, their triage code may be
6 changed.

7
8 *Setting*

9 The study was conducted at the LHA “ULSS 4 – Alto Vicentino”, which occupies an area in the
10 north-western part of the Veneto region and serves a population of about 190,000 with a mean
11 density of 111 inhabitants per square mile (290/km²). In 2011, foreign residents accounted for
12 approximately 10.3% of the total population (about 2% more than the national average). This LHA
13 has three OOH service points with a total of 25 physicians working on a rota system for 24 hours a
14 week. During service periods, patients have to phone a single call center that records their personal
15 details using an electronic call management system before they can talk to a doctor. In 2006, the
16 LHA “ULSS 4” implemented an information technology system that enables OOH doctors to
17 consult a patient’s personal health records held by their GPs or the local hospital.

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20 *Participants and materials*

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22 This study was based on data recorded from 1 January to 31 December 2011 in the LHA 4
23 electronic database. A contact to request OOH services (as a statistical unit) was defined as any
24 walk-in patient visit, home visit, rest home visit, or telephone consultation followed by no further
25 contact in the 12 hours thereafter (so OOH contacts were recorded as telephone consultations only
26 if the physician provided advice over the phone and did not see the patient afterwards, neither at the
27 walk-in clinic, nor at the patient’s home or rest home). The computer database of OOH contacts
28 acquires patients’ demographic details (sex, age, nationality and place of residence) from the LHA’s

administrative archives, so Google Maps could be used to calculate the distance of their home from the nearest OOH service point. The database also captures further information from the LHA archives concerning the primary care services available for a given patient's condition, e.g. non-cancer integrated homecare, cancer-related integrated homecare, palliative homecare, and nursing homecare. The electronic database also records logistic aspects such as: date of contact, classified for analytical purposes as working or non-working days (the latter including Saturdays and days before public holidays); time of contact, classified as daytime (8 am to 8 pm) or night-time (8 pm to 8 am). Patients' diagnoses were recorded by means of major diagnostic categories,¹ some of which were collapsed for the purposes of the present study, and the recording system also created another six new categories (state of health certification, death certification, renewal of medical prescriptions, information on drugs, fever, and 'others not specified'). For the purposes of this study, OOH contacts concerning death certification, medical prescriptions, or state of health certificates were disregarded because these conditions could not be associated with a potential patient referral to an ED. All contacts made by non-residents were ignored too. The database also records the possible OOH outputs for a given contact, classified as patients returning home or remaining at home (if the contact involved the patient being seen at the walk-in clinic, at home, or at a rest home), referral to an ED, or telephone counselling alone. The database is also linked with some socio-demographic details of the OOH physicians handling the contacts (such as years since they graduated, gender, type of employment contract [temporary substitute or permanent post-holder]).

Another database at the ED records all cases seen at the ED after contacting the OOH services. This ED database was record-linked with the OOH database using a unique identifier code for each patient. The linkage concerned only ED attendances within 24 hours after contacting the OOH service. In addition to demographic and logistic variables, the ED database also records other

¹ Major diagnostic categories (MDC) were obtained by dividing all possible principal diagnoses (based on the ICD-9) into 25 mutually-exclusive diagnostic areas.

important information: the incoming triage code assigned by nurses and the outgoing triage code assigned by physicians (white = noncritical patients who should receive primary care; green = not life-threatening conditions; yellow = critical patients at risk of their clinical condition deteriorating; red = very critical patient needing immediate treatment); any activation of a short-stay observation period; and discharge from the ED (classified as patient hospitalized, arrived dead, sent home, sent to another institute, died at the ED, refused hospitalization, left the ED before being examined, or referred for outpatient care).

Outcome definition

A case seen at the ED was considered urgent and potentially appropriate if it met at least one of the following conditions (as recently defined by the Italian agency for regional health services, AGENAS)[18]:

- red or yellow outgoing triage code (if no outgoing code was assigned, red or yellow incoming triage code);
- patient hospitalized or refused recommended hospitalization;
- patients assessed for trauma;
- short-stay observation was activated;
- arrived dead or died at the ED.

Patients who contacted the OOH services were divided into two groups according to whether or not they were referred to the ED. Both groups included patients who actually went to the ED within 24 hours after contacting the OOH and others who did not.

- Among those not referred to the ED (first group), patients were considered as cases of “potentially inappropriate non-referral” if they went spontaneously to the ED within 24 hours after contacting the OOH services and were found to meet at least one of the criteria for appropriate access to the ED.
- Among those referred to the ED (second group), patients were considered as cases of “potentially inappropriate referral” if they did not go to the ED within 24 hours, or if they did go to the ED, but it was found that they did not meet at least one of the criteria for appropriate access to the ED.

Statistical methods

Statistical analyses were performed using the STATA12 software.

The data were summarized as numbers (percentages) of patients for categorical variables. Bivariate analyses were run to assess differences in counts for categorical variables using the chi-square test (or Fisher’s test when less than 5 cases were expected).

Two logistic regression models were applied, one for each dependent variable:

- potentially inappropriate non-referrals to the ED by the OOH service (for this regression a Firth’s penalized likelihood approach was applied to correct for rare events);
- potentially inappropriate referrals to the ED by the OOH service.

The two regressions tested the socio-demographic, process/context, and clinical variables associated with the dependent variables.

A p-value of less than 0.01 was considered significant, to take multiple comparisons into account.

Ethical considerations

The data analysis was conducted on anonymized aggregated data with no chance of individuals being identifiable. The study complied with the Declaration of Helsinki and with Italian Law n. 196/2003 on the protection of personal data. The recent resolution n. 85/2012 of the Italian

1 Guarantor for the Protection of Personal Data also confirmed the allowability of processing
2 personal data for medical, biomedical and epidemiological research, and that data concerning health
3 status may be used in aggregated form in scientific studies. Permission to use non-identifiable,
4 individual data extracted from administrative databases was granted by the ULSS 4 Veneto Region,
5 which is responsible for any use of the data concerning the population it serves.

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Results

From 1st January to 31st December 2011, the LHA 4 OOH service was contacted by 23,980 people (see **Figure 1**).

Around 9% of all patients contacting the OOH service were referred to the ED. **Table 1** shows the sample's characteristics of by referral group. The percentage of patients referred to the ED increased with patients' age, and was higher at night (13.4% from 8 pm to 8 am) than during the day (8.4% from 8 am to 8 pm). Patients requiring nursing care, physiotherapy or GP homecare were more likely to be referred to the ED after contacting the OOH service (the proportions were 20.66%, 19.12%, and 19.83%, respectively). Cardiovascular disease (28.3%) and trauma (23.4%) were the diagnostic categories of patients most likely to be referred to the ED.

The total number of cases potentially inappropriately managed by the OOH service, in terms of referrals and non-referrals to the ED, amounted to 1,599 (about 7% of the sample): 392 were cases of potentially inappropriate non-referral to the ED (1.7%); and 1,207 were cases of potentially inappropriate referral to the ED (5.3%); this latter group includes 422 patients who did not go to the ED despite being referred there (20.4% of all those referred) and 785 who did go to the ED but who did not meet any of the criteria for potentially appropriate access (38.0% of all those referred to the ED).

Table 2 shows the demographic, process/context and clinical characteristics of the patients contacting the OOH services by referral to the ED and its appropriateness. For example, the percentage of patients inappropriately referred to the ED was higher for infants up to one year old (reaching 87.1%) and decreased with age (35.1% in patients >84 years old); vice versa, the percentage of inappropriate non-referrals increased with age, reaching 5.3% for patients >84 years old.

Tables 3a and 3b show the results of two logistic regression models. In particular, **Table 3a** shows the measure of association between the demographic, process/context and clinical variables with potentially inappropriate non-referrals to the ED. The regression confirmed that potentially

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inappropriate non-referrals increased with age, revealing a two-fold higher odds ratio for 65-74 and 75-84 year-olds than for the newborn. Females appeared to have significantly lower odds of being inappropriately not referred to the ED. Foreign people were at higher risk of being inappropriate not referred to the ED than Italians (OR 1.59), though the difference did not reach statistical significance ($p=0.03$). Contacting the OOH service at night also coincided with a two-fold higher odds of potentially inappropriate referral than for daytime contacts. A number of diagnostic categories were associated with higher odds of potentially inappropriate non-referral than for the diagnostic category taken for reference (dermatological). Contacts involving patients attending the walk-in clinic were only half as likely as patients managed by means of telephone consultations alone to be cases of potentially inappropriate non-referral to the ED.

Table 3b shows the measure of the association between the variables and inappropriate referrals to the ED. Unlike the first regression, the odds of potentially inappropriate referral to the ED dropped with increasing age (as compared with the newborn). There were no significant differences with regard to contacts' nationality or gender. Patients who died within a year of contacting the OOH service had lower odds of being referred inappropriately to the ED. Also the contacts managed by post-holder in respect to those managed by temporary holder had lower odds of being referred inappropriately to the ED. None of the diagnostic categories changed the likelihood of potentially inappropriate referral vis-à-vis the reference category. Contacts handled by means of a home visit were only half as likely as those managed by means of a telephone consultation alone to be cases of potentially inappropriate referral to the ED.

Discussion

This study addressed the phenomenon of potentially inappropriate patient referral and non-referral to the ED by OOH physicians. The study revealed that some determinants of potentially inappropriate non-referral to the ED mirror those of potentially inappropriate referral, e.g. older age reduces the probability of inappropriate referral and increases the risk of inappropriate non-referral.

Frequency of potentially inappropriate handling of OOH contacts

Only one in eight patients went to the ED after contacting the OOH service, and less than one in twenty who contacted the OOH subsequently went to the ED at their own discretion and failed to meet the criteria for urgent medical care. This confirms the gatekeeping role of OOH physicians and underlines the importance of this service in ensuring a continuity of primary health care and preventing patients from going to the ED instead of a primary care service. The unwarranted use of secondary health care services gives rise to a lack of continuity of care and generates an overload that adversely affects ED activities.[19] A previous systematic review found, however, that action taken to increase OOH primary care services did not generate any reduction in ED attendance (though the studies considered in this review received low global quality ratings and various different models of OOH primary medical care service had been considered).[20] Another previous study [21] also showed that decisions to refer patients to ED were associated not only with the patient's clinical and process/context characteristics, but also with the particular physician involved: there were statically significant differences in the adjusted odds of referral to EDs between physicians working at the same OOH services, meaning that each doctor's attitude had an important influence on their referral rates.

The present study found that less than 10% of cases (7%) were handled by the OOH services in a potentially inappropriate manner. As regards potentially inappropriate ED referrals, we found that

less than one in twenty of all patients contacting the OOH services (5.3%) were referred to the ED inappropriately. In theory, OOH physicians are contacted when patients have borderline health conditions that are not urgent enough for them to go to the ED, but too severe for them to wait until the next working day. This delicate borderline situation should be borne in mind when we consider the above percentages. According to an English study the percentage of cases inappropriately managed by means of telephone triage services delivered by the NHS-24 service is around 35%, judging from GPs' subsequent re-assessment.[22] An Australian study reported instead that about 10% of patient referrals to the ED by GPs were inappropriate.[23] It is rather difficult to draw comparisons between studies conducted on different health care systems and using different methods to assess "appropriateness". These figures are in any case considerably lower than the percentage of inappropriateness identified for self-referred patients, which reaches as high as 80% [24], confirming once again the important gatekeeping role of the OOH services in relation to low-acuity patients.

Potentially inappropriate non-referral to the ED

Of course, inappropriate non-referral to the ED is a more serious issue because a diagnostic delay in a genuinely urgent patient may even be fatal. Our study found this situation fairly infrequent (1.7%). To the best of our knowledge, no other published studies have investigated the frequency of potentially inappropriate non-referrals to the ED with which we might draw a comparison. We might nonetheless argue that the low rate of inappropriate non-referral to the ED identified in this study could be partly thanks by the IT system that enables OOH physicians to consult patients' electronic medical records and check their medical history as soon as they make contact. Generally speaking, communication breakdown is a major contributor to diagnostic errors and an increasingly recognized preventable factor in medical mishaps. Using new technologies to enhance communication between health providers and health systems could therefore facilitate the consultation of patients' medical records [25], though a literature review found that improper use of

such technologies can give rise to errors in the electronic hospital records, which can in turn lead to errors that endanger patients' safety or negatively affect the quality of their care [26].

With a view to enhancing the quality of OOH services, it would be wise to address the determinants of OOH physicians' potentially inappropriate management of the patients who contact them. The odds of inappropriate ED non-referral were found to increase with patients' age, atypical disease presentations, polypharmacy, and multiple comorbidities, which may complicate patient management.[27] Cognitive impairment, which is more common among the elderly, could also negatively influence the likelihood of appropriate patient management. Cognitively impaired older patients can have trouble remembering things, become confused, and have attention deficits or difficulty expressing themselves.[28] An analysis of error reports submitted to the Applied Strategies for Improving Patient Safety (ASIPS) indicated that communication problems represented the most common error process in the ambulatory care setting.[29] Failure to ensure complete communication between health care providers and patients was also associated with a higher risk of clinical harm. The apparently higher likelihood of OOH services inappropriately not referring elderly people to the ED (especially those patients who then go to the ED anyway) may relate, however, to ED physicians having a greater propensity to admit older patients to hospital as a prudential choice.[30]

Our study revealed that not only socio-demographic and clinical conditions, but also logistic and organizational variables may be determinants of potentially inappropriate non-referral to the ED. In particular, we found that patients attending the OOH walk-in clinic were less likely to be managed inappropriately than those only making telephone contact. Another study reported that telephone consultations were shorter and less detailed than face-to-face visits for similar clinical problems, increasing the risk of diagnostic or management errors.[31] The phenomenon of inappropriate non-referral to the ED for patients managed by the OOH services over the phone could be contained by adopting well-structured procedures based on checklists and protocols, or more advanced solutions

1 such as decision-supporting software packages, to help doctors consulted over the phone provide
2 comprehensive advice [32,33]. An approach applying root cause analysis should be adopted to
3 identify proactive ways to address patient safety incidents with a view to reducing the risk of error,
4 rather than more passive methods that encourage staff to be more vigilant in their working practice
5 [34, or to take more care when prescribing medication, for example.

6
7 *Potentially inappropriate referral to ED*

8 Older children and adults had lower odds of inappropriate referral to the ED than infants. A cross-
9 sectional examination of ED attendance in England found age strongly related to inappropriate
10 referral [35]. The odds were highest for the very young (peaking for one- and two-year-olds), and
11 were also high between the mid-teens and mid-twenties, followed by a steady drop with aging
12 thereafter. The sizable presence of young people inappropriately attending EDs around the world
13 has been recognized in various studies, as emphasized in the review conducted by Carret.[12] These
14 findings suggest that action to prevent inappropriate management should target early childhood and
15 young adolescence. The phenomenon probably reflects the pressures of parenthood,[36,37] or a
16 lack of confidence with children's diseases. Given the difficulty of managing pediatric patients, and
17 infants especially, pediatric OOH services need to be expanded, or training courses could be
18 organized to improve OOH physicians' understanding of pediatric emergencies.

19
20 Our analysis showed that, among the OOH physicians, regular post-holders were less likely to
21 inappropriately refer patients to the ED than their temporary substitutes. This may be an indication
22 of the former's greater work experience, but could also relate partly to the fact that some people
23 contacting the OOH services are frequent attenders, and probably well known to the permanent
24 staff, who consequently find it easier to manage their disorders.[38] Using the available data on
25 OOH physicians (also taking each OOH physician's personal identification code into account)
26 might be useful for the purpose of giving physicians regular feedback on their performance, which

could be compared with a benchmark, for instance. It has been demonstrated in the literature that this could have a positive impact on their performance.[39].

Limits and strengths

Our study suffers from several limitations. One stems from our arbitrary classification of potentially inappropriate referrals to the ED (based on a national definition of appropriateness) that clearly influences the reported prevalence of potentially inappropriate patient management in our sample. There is no general consensus on how to define appropriateness of ED use in the literature. In addition contacts at OOH services and at ED happened at a different time, by personnel equipped with different diagnostic features. Another limitation lies in that our analysis was conducted only on the LHA 4 records, so we were unable to follow up patients admitted to an ED outside the territory it serves. The scientific literature suggests, however, that patients usually go to their nearest ED, in their own district.[40] The main strength of our research, on the other hand, lies in that this was a population-based study conducted not on a limited or selected sample of patients, but using a register of routinely-collected data, so our findings could not be biased by any research hypothesis. It goes to show that administrative data can be used to monitor this phenomenon and its determinants. Another recent study described a new database infrastructure (iCAREdata) linking data from General Practice Cooperatives, Emergency Departments and Pharmacies during out-of-hours care. This data, with the same vision of the present study, could be used for feedback reports for individual GPCs or EDs, benchmarking and giving the opportunity to optimize the quality, safety, and the organization of OOH care Moreover it could be used to define a program of continuing professional education for OOH doctors more focused on their real needs [41].

1
2
3 **Conclusion**

4 This work paints a comprehensive picture of the predictors of potentially inappropriate behavior on
5
6 the part of OOH physicians in terms of their referral or non-referral of patients to the ED. The
7
8 novelty of our work in fact will require that further studies addressing the factors associated with
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10 potentially inappropriate referral and non-referral of patients to the ED are needed to confirm these
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13 results.
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For peer review only

Competing interests

The authors have no competing interests to disclose. The authors declare that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted.

Data Sharing Statement

No data are available to share

Key points

The determinants of potential inappropriate non-referral to the ED mirror the determinants of potential inappropriate referral, e.g. older age reduces the likelihood of inappropriate referral and increases the risk of inappropriate non-referral.

Not only socio-demographic and clinical conditions, but also logistic and organizational variables may contribute to potentially inappropriate non-referral to the ED.

Improving OOH services by means of different organizational, structural and training strategies could be beneficial in this setting, ensuring a greater focus on patients' real needs and avoiding ED misuse.

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Table 1: Characteristics of the sample contacting the OOH service by patients'

referral or non-referral to the ED

		Not referred n=20596	Referred n=2066
<i>Patients' demographic variables</i>			
Sex	Male 10450	90.6%	9.4%
	Female 12212	91.1%	8.9%
Age	0-1 years 1254	96.0%	4.0%
	2-14 y 4984	95.0%	4.0%
	15-18 y 624	94.6%	5.4%
	19-44 y 6245	93.6%	6.4%
	45-64 y 3927	90.1%	9.9%
	65-74 y 1867	86.5%	13.5%
	75-84 y 2067	81.7%	18.3%
Pediatric cases (0-14y)	>84 y 1694	79.6%	20.4%
	No 16424	89.0%	10.0%
Nationality	Yes 6238	95.8%	4.2%
	Italian 20099	90.5%	9.5%
	Foreign 2560	94.2%	5.8%
<i>Patients' process and context variables</i>			
Distance from nearest OOH	0-5 km 11214	90.2%	9.8%
	>5 km 10322	91.6%	8.4%
Time of day	8-20 19366	91.6%	8.4%
	20-8 3296	86.6%	13.4%
Type of day	Working day 7368	89.9%	10.1%

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	Holiday	8285	91.4%	8.6%
	Day before a holiday	6799	91.2%	8.8%
Type of OOH	Phone advice	9970	92.5%	7.5%
intervention	Home visit	2134	76.5%	23.5%
	Walk-in clinic visit	10558	92.3%	7.7%
OOH	Temporary substitute			
physician		17169	90.5%	9.5%
	Post-holder	5493	92.0%	8.0%
Gender of	Male	14489	89.8%	10.2%
OOH	Female	8173		
physician			92.9%	7.1%
<i>Patients' clinical variables</i>				
Death within a	No	20846	92.0%	8.0%
year	Yes	1816	78.6%	21.4%
Home	No	22594	90.9%	9.1%
physiotherapy	Yes	68	80.9%	19.1%
Home nursing	No	20973	91.8%	8.2%
services	Yes	1689	79.3%	20.7%
Assisted at	No	21976	91.2%	8.8%
home by GP	Yes	686	80.2%	19.8%
Disease	Dermatological	1501	97.3%	2.7%
	Musculoskeletal	1453	91.4%	8.6%
	Ophthalmological	532	85.0%	15.0%
	Odontostomatological	634	97.8%	2.2%
	Oncological and		79.7%	20.3%

hematological	143		
Ear-nose-throat	2744	96.6%	3.4%
Pregnancy and reproductive system	194	84.0%	16.0%
Psychiatric	381	89.0%	11.0%
Respiratory	1734	86.5%	13.6%
Trauma	752	76.6%	23.4%
Nervous system	853	77.5%	22.5%
Infectious	389	97.2%	2.8%
Genitourinary system		89.5%	10.5%
	1092		
Gastroenterological	3148	89.4%	10.6%
Fever	2835	97.9%	2.1%
Endocrinological	127	85.8%	14.2%
Advice about ongoing therapy	1969	99.3%	0.7%
Cardiovascular	1348	71.7%	28.3%
Not specified	833	91.2%	8.8%

Table 2: Bivariate analysis of characteristics of patients and their potentially inappropriate management by referral and non-referral to the ED

		Not referred			Referred		
		n. 20596			n. 2066		
		App.	Inapp.	p	App.	Inapp.	p
<i>Patients' demographic variables</i>		n=20204	n=392		n=859	n=1207	
		%	%		%	%	
Sex	Male	98.0	2.0	0.268	40.8	59.2	0.468
	Female	98.2	1.8		42.3	57.7	
Age	0-1 years	98.6	1.4	<0.001	12.9	87.1	<0.001
	2-14 y	98.9	1.1		25.9	74.1	
	15-18 y	98.8	1.2		26.5	73.5	
	19-44 y	99.2	0.8		25.1	74.9	
	45-64 y	98.3	1.7		34.6	65.4	
	65-74 y	96.4	3.6		51.4	48.6	
	75-84 y	95.4	4.6		52.9	47.1	
	>84 y	94.7	5.3		64.9	35.1	
Pediatric cases (0-14y)	No	97.8	2.2	<0.001	44.3	55.7	<0.001
	Yes	98.8	1.2		22.8	77.2	
Nationality	Italian	98.0	2.0	0.003	42.9	57.1	<0.001
	Foreign	98.9	1.1		24.1	75.9	
<i>Patients' process and context variables</i>							
Distance from nearest OOH	0-5 km	98.3	1.7	0.149	41.1	58.9	0.635
	>5 km	98.0	2.0		42.1	57.9	
Time of day	8-20	98.5	1.5	<0.001	41.3	58.7	0.613

	20-8	95.8	4.2		42.6	57.4	
Type of day	Working day	98.0	2.0		40.9	59.1	
	Holiday	98.1	1.9	0.823	43.4	56.6	0.431
	Day before a holiday	98.1	1.9		40.0	60.0	
Type of OOH	Phone advice	97.6	2.4		41.4	58.6	
intervention	Home visit	94.5	5.5	<0.001	67.3	32.7	<0.001
	Walk-in clinic visit	99.2	0.8		25.9	74.1	
OOH physician	Temporary substitute	98.2	1.8	0.198	40.0	60.0	0.004
	Post-holder	97.9	2.1		47.5	52.5	
Gender of	Male	98.2	1.8		41.9	58.1	
OOH physician	Female	98.0	2	0.425	40.7	59.3	0.592
<i>Patients' clinical variables</i>							
Death within	No	98.5	1.5		35.2	64.8	
a year	Yes	93.3	6.7	<0.001	69.2	30.8	<0.001
Home	No	98.1	1.9		41.6	58.4	
physiotherapy	Yes	100	0	0.301	38.5	61.5	0.819
Home nursing	No	98.4	1.6		37.2	62.8	
services	Yes	94.0	6.0	<0.001	63.0	40.0	<0.001
Assisted at	No	98.2	1.8		40.0	60.0	
home by GP	Yes	94.0	6	<0.001	64.7	35.3	<0.001
Disease	Dermatological	99.9	0.1		7.5	92.5	
	Musculoskeletal	98.5	1.5		22.4	77.6	
	Ophthalmological	99.8	0.2	<0.001	1.2	98.8	<0.001
	Odontostomatological	100	0		7.1	92.9	
	Oncological and	93.9	6.1		65.5	34.5	

hematological				
Ear-nose-throat	99.6	0.4	1.1	98.9
Pregnancy and reproductive system	96.9	3.1	32.3	67.7
Psychiatric	96.5	3.5	38.1	61.9
Respiratory	97.6	2.4	52.3	47.7
Trauma	98.6	1.4	100	0
Nervous system	96.4	3.6	43.2	56.8
Infectious	100	0	18.2	81.8
Genitourinary system	97.4	2.6	32.2	67.8
Gastroenterological	96.2	3.8	36.7	63.3
Fever	98.3	1.7	26.2	73.8
Endocrinological	96.3	3.7	44.4	55.6
Advice about ongoing therapy	98.8	1.2	28.6	71.4
Cardiovascular	96.5	3.5	47.8	52.2
Not specified	96.6	3.4	35.6	64.4

Table 3a: Results of multivariate logistic regression for associations between patients'

characteristics and their potentially inappropriate management – for cases not referred to the ED

Potentially inappropriate non-referral to the ED		Odds ratio	95% confidence interval	P
Sex (ref. Male)	Female	0.75	0.61 - 0.92	0.007
Age	2-14 y	0.99	0.57 - 1.69	0.939
(ref. 0-1 years)	15-18 y	1.17	0.49 - 2.79	0.731
	19-44 y	0.68	0.39 - 1.20	0.187
	45-64 y	1.26	0.72 - 2.20	0.421
	65-74 y	2.21	1.25 - 3.92	0.007
	75-84 y	2.14	1.21 - 3.80	0.009
	>84 y	2.03	1.11 - 3.69	0.021
Nationality (ref. Italian)	Foreign	1.62	1.04 - 2.47	0.029
Distance from nearest OOH	>5 km	1.19	0.97 - 1.47	0.103
(ref. 0-5 km)				
Time of day (ref. 8-20)	20-8	2.30	1.80 - 2.93	<0.001
Type of day	Holiday	1.27	0.98 - 1.64	0.073
(ref. Working day)	Day before a holiday	1.42	1.08 - 1.86	0.012
Home nursing services	Yes	1.21	0.86 - 1.71	0.269
(ref. No)				
Assisted at home by GP	Yes	1.05	0.68 - 1.62	0.834
(ref. No)				
Death within a year (ref. No)	Yes	1.65	1.19 - 2.30	0.003
OOH physician	Post-holder	0.93	0.66 - 1.30	0.651

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(ref. Temporary substitute)

Gender of OOH physician

Female	1.27	1.02 - 1.58	0.030
(ref. Male)			

Disease (ref. Dermatological)

Musculoskeletal	5.99	1.59 - 22.41	0.008
Ophthalmological	1.79	0.26 - 13.65	0.573
Oncological and hematological	8.87	2.02 - 38.59	0.004
Ear-nose-throat	2.60	0.65 - 10.35	0.176
Pregnancy and reproductive system	24.63	5.38 - 112.7	<0.001
Psychiatric	8.26	2.06 - 33.05	0.003
Respiratory	7.63	2.09 - 27.86	0.002
Trauma	7.14	1.73 - 29.46	0.007
Nervous system	11.02	2.96 - 41.05	<0.001
Genitourinary system	10.10	2.73 - 37.35	0.001
Gastroenterological	13.76	3.90 - 48.60	<0.001
Fever	6.82	1.90 - 24.56	0.003
Endocrinological	7.96	1.64 - 38.50	0.010
Advice about ongoing therapy	3.49	0.94 - 13.03	0.063
Cardiovascular	8.70	2.38 - 31.83	0.001
Not specified	10.90	2.95 - 40.38	<0.001

Type of OOH intervention

Home visit	1.10	0.82 - 1.47	0.543
(ref. Phone)			
Walk-in clinic visit	0.49	0.36 - 0.66	<0.001

Table 3b: Results of multivariate logistic regression for associations between patients'

characteristics and their potentially inappropriate management – for cases referred to the ED

Potentially inappropriate referral to the ED		Odds ratio	95% confidence interval	P
Sex (ref. Male)	Female	1.23	0.98 - 1.54	0.076
Age (ref. 0-1 years)	2-14 y	0.60	0.21 - 1.75	0.349
	15-18 y	0.21	0.06 - 0.77	0.019
	19-44 y	0.27	0.10 - 0.74	0.010
	45-64 y	0.17	0.06 - 0.45	<0.001
	65-74 y	0.12	0.04 - 0.33	<0.001
	75-84 y	0.15	0.05 - 0.39	<0.001
	>84 y	0.15	0.05 - 0.41	<0.001
Nationality (ref. Italian)	Foreign	0.88	0.52 - 1.48	0.633
Distance from nearest OOH (ref. 0-5 km)	>5 km	0.86	0.69 - 1.08	0.202
Time of day (ref. 8-20)	20-8	1.00	0.76 - 1.33	0.966
Type of day (ref. Working day)	Holiday	1.11	0.85 - 1.46	0.431
	Day before a holiday	1.27	1.95 - 1.70	0.114
Home physiotherapy (ref. No)	Yes	3.05	0.88 - 10.55	0.079
Home nursing services (ref. No)	Yes	1.04	0.74 - 1.45	0.824
Assisted at home by GP (ref. No)	Yes	0.95	0.60 - 1.49	0.812
Death within a year (ref. No)	Yes	0.46	0.33 - 0.64	<0.001

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OOH physician (ref. Temporary substitute)	Post-holder	0.64	0.47 - 0.89	0.007
Gender of OOH physician (ref. Male)	Female	1.12	0.87 - 1.44	0.392
Disease (ref. Dermatological)	Musculoskeletal	0.48	0.13 - 1.72	0.258
	Ophthalmological	7.16	0.71 - 72.26	0.095
	Odontostomatologic al	1.08	0.10 - 11.90	0.949
	Oncological and hematological	0.16	0.04 - 0.72	0.017
	Ear-nose-throat	8.21	0.81 - 82.92	0.074
	Pregnancy and reproductive system	0.17	0.04 - 0.74	0.018
	Psychiatric	0.41	0.10 - 1.66	0.211
	Respiratory	0.23	0.07 - 0.80	0.021
	Nervous system	0.26	0.08 - 0.92	0.036
	Infectious	0.56	0.07 - 4.38	0.583
	Genitourinary system	0.26	0.07 - 0.92	0.037
	Gastroenterological	0.22	0.06 - 0.76	0.016
	Fever	0.27	0.07 - 1.06	0.061
	Endocrinological	0.26	0.05 - 1.25	0.093
	Advice about ongoing therapy	0.40	0.07 - 2.31	0.305
	Cardiovascular	0.22	0.06 - 0.75	0.016

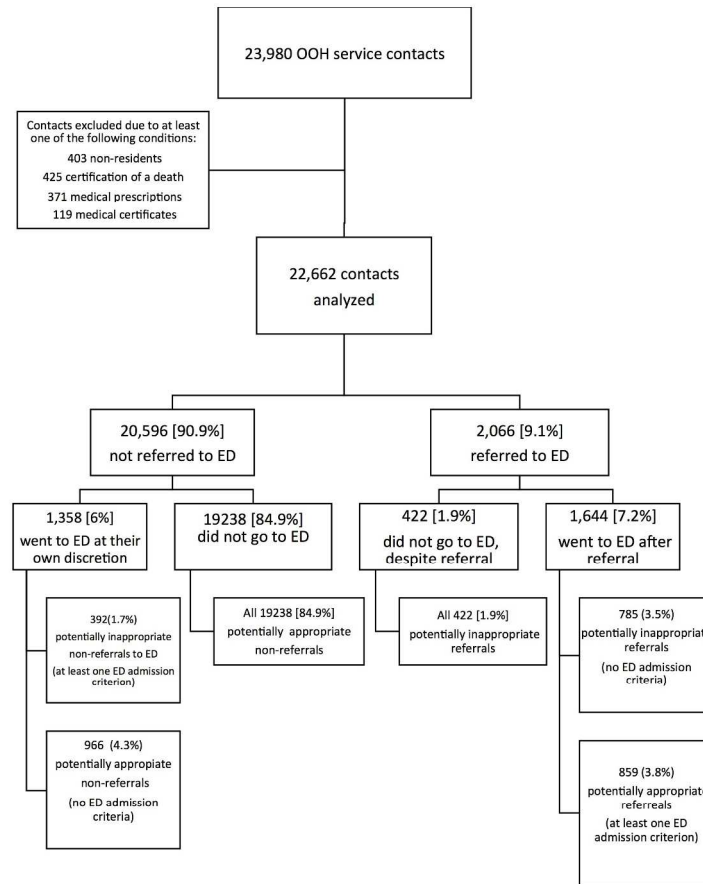
Type of intervention (ref. Phone)	Not specified	0.38	0.10 - 1.42	0.148
	Home visit	0.43	0.32 - 0.59	<0.001
	Walk-in clinic visit	1.33	1.00 - 1.79	0.052

For peer review only

Figure 1: Distribution of patients contacting the OOH service

For peer review only

Figure 1: Distribution of patients contacting the OOH service



209x297mm (300 x 300 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract YES pag 3, line 9
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found YES pag 3
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported YES pag 4-5
Objectives	3	State specific objectives, including any prespecified hypotheses YES pag 5, lines 20-24
Methods		
Study design	4	Present key elements of study design early in the paper YES page 7-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection YES page 7-8
Participants	6	(a) Cohort study— Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up YES pag 7, lines 17-21, page 8 lines 4-6
		Cohort study—For matched studies, give matching criteria and number of exposed and unexposed Not pertinent
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable YES page 9, pag 10 lines 10-11 described above
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group YES pag 8
Bias	9	Describe any efforts to address potential sources of bias YES page 16, lines 6-15
Study size	10	Explain how the study size was arrived at YES, the sample was composed of one year contacts to OOH
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why YES, page 8
Statistical methods	12	a) Describe all statistical methods, including those used to control for confounding

YES page 10

(a) Describe any methods used to examine subgroups and interactions

(c) Explain how missing data were addressed

Cohort study—If applicable, explain how loss to follow-up was addressed

Yes page 16

(e) Describe any sensitivity analyses

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Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed page 11, lines 3-17
		(b) Give reasons for non-participation at each stage <i>not pertinent</i>
		Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders Yes table 1 and 2
		(b) Indicate number of participants with missing data for each variable of interest <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount) <i>not pertinent</i>
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time Yes figure 1
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included Yes, table 3
		(b) Report category boundaries when continuous variables were categorized Yes, table 3
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives Yes, pag 12, lines 5-8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Yes pag 16, lines 6-15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence Yes all discussion
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable,

for the original study on which the present article is based

Yes, pag 1 , lines 26-28

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

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.