



BMJ Open Protocol for evaluating quality and safety for the public through home care nursing in Italy: a multicentre cross-sectional descriptive observational study (AIDOMUS-IT)

Annamaria Bagnasco ^{1,2}, Rosaria Alvaro,^{2,3} Loreto Lancia,^{2,4} Duilio Fiorenzo Manara,^{2,5} Maurizio Zega,^{6,7} Gennaro Rocco,^{2,8} Laura Rasero,^{2,9} Beatrice Mazzoleni,^{10,11} Loredana Sasso ^{1,2}, AIDOMUS-IT Collaborator Group

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For numbered affiliations see end of article.

Correspondence to

Professor Loredana Sasso;
l.sasso@unige.it

ABSTRACT

Introduction Considering the increasing complexity of care and workload for home care nurses due to the ageing of the population, it is crucial to describe the work environment and the community care setting. The aim of this study protocol is to map the characteristics and identify gaps of home care in the community to design future interventions aimed at ensuring quality and safety.

Methods and analysis This is a national cross-sectional descriptive observational study using the survey method. Nurses from all participating community care centres will be recruited through convenience sampling by the coordinators of each centre, who will act as facilitators for this study. All community care recipients and their informal carers during the study period will be invited to complete a survey.

To map the characteristics and identify gaps of home care in the community, three sources of data will be collected: (1) organisational characteristics, professional satisfaction, intention to leave and burn-out; (2) experience of care recipients and their informal carers and (3) improper access to the emergency department, readmission to hospital, comorbidities, services offered and users' level of autonomy, and main and secondary diagnoses. Considering the total Italian nursing population of approximately 450 000 registered nurses, a sample size of 1% of this population, equal to approximately 4600 nurses, was hypothesised.

This study started in July 2022 and is planned to end in December 2023.

Data will be analysed using descriptive and inferential statistics.

Ethics and dissemination This study protocol was approved by the Liguria Regional Ethics Committee in November 2022. Informed consent will be obtained from participants and confidentiality will be ensured. Data collected for this study will be kept anonymised in a protected database.

The results of the study will be disseminated mainly through conferences, publications and meetings with government representatives.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ An online data collection form will be used so that the survey can be completed on any mobile devices and enable immediate quality control of the entered data.
- ⇒ The study will be conducted at a national level.
- ⇒ Local facilitators will be trained to support survey uptake and completion.
- ⇒ Limitations may be related to the number of missing answers, self-selection bias and the organisational structure of home care in Italy, which differs across regions.

INTRODUCTION

There is a clear association between nurse-patient relationship, patient mortality and health deterioration.¹ The European RN4CAST study has shown that in hospitals with higher nurse staffing levels, there are better outcomes for both patients and nurses.² Although the main outcome measure was mortality rate, the RN4CAST study also enabled to investigate other indicators such as patient safety, adverse events, quality of care, nursing ratios and skill mix.¹ However, most of the studies concerning nurse-patient ratios and quality of care have been conducted in hospital settings,^{3 4} but in the community, these aspects are still mostly unexplored.

As the older adult population and chronic degenerative diseases increase, care and social complexity is greater, generating a growing demand for home care nursing services.^{3 5 6} Moreover, with the reduction of resources for hospitals many services are being delegated to community care facilities.⁷ This situation requires home care nurses caring for older



people with increasingly complex conditions to have advanced competencies.⁸ According to Aase *et al*,⁹ quality care entails having the ‘right competency’ and ability to cooperate with other professional groups, placing the patient at the centre of all the activities. The qualitative dimensions of the structural characteristics (ie, system, documentation) and the ‘soft’ dimensions (ie, dignity, relationships) are important for the conceptualisation of quality by health professionals and should be considered when conducting quality improvement activities also in community care settings.¹⁰

Some of the causes of hospital readmission and inappropriate access to the emergency department (ED) are the interruptions in communication between home care staff, patients and families, and healthcare providers; flaws in healthcare processes; lack of resources including equipment, qualified staff, or on-site providers; and failure to identify home care goals.¹¹ Poor communication and organisation between home care and hospital services lead to negative patient outcomes, poorer health conditions, and unnecessary or incorrect treatment resulting in waste of resources and increased healthcare costs.¹⁰

With greater workloads and complexity, the need to provide appropriate staffing levels and skill mix is a constant challenge.⁵ Rationing care has safety implications for complex patients living in their homes, and increases the amount of time required to care for these patients.¹² However, little evidence is available regarding what constitutes an appropriate level of nurse staffing in various community settings, making it difficult to implement staffing requirements or legislation in the community setting.¹

In addition to understaffing, another issue is insufficient skill mix to provide high-quality home care.⁶ Care at home is provided by various health professionals, whose scopes of practice often overlap by working in teams that have a variable and less defined organisational structure than those of hospital settings.³ Having the right number of competent nurses, who are able to effectively work in multidisciplinary teams with other health professionals (eg, healthcare workers and general practitioners) is important to achieve better patient care outcomes, reduced mortality rates and increased productivity.¹² Furthermore, home care nurses also need to know how to interact with informal carers.¹⁰

With the new ‘Regulation establishing the models and standards for the development of community care within the Italian National Health Service’,¹³ the reorganisation of community care and the inclusion of greater numbers of family and community nurses, it is timely and important to map the characteristics and gaps of home care nursing in Italy.

METHODS

Aims

Main objective

To map the characteristics of nursing community care management and the quality of home care in Italy.

Secondary objectives

- ▶ Describe the staffing levels in the field of domiciliary nursing.
- ▶ Describe the levels of work environment in the field of domiciliary nursing.
- ▶ Describe the levels of caseload in the field of domiciliary nursing.
- ▶ Describe the phenomenon of missed care in the field of domiciliary nursing.
- ▶ Identify the levels of skill mix for the quality of care in the field of domiciliary nursing.
- ▶ Describe the level of quality perceived by home care recipients and their caregivers.

Study design

A multicentre cross-sectional descriptive observational study that uses the survey method. The study uses quantitative data from three sources to obtain information from the points of view of home care nurses, the perceptions of patients and their informal carers of the care they received, and then compare this information with the objective data regarding the provision of care collected through the clinical records:

1. Primary data through an online questionnaire sent to domiciliary nurses at a single point in time. This source will enable to collect data on organisational characteristics (eg, nursing work environment). Data regarding nurses’ job satisfaction, intention to leave home care and burn-out will also be collected.
2. Secondary data on the experience of patients and their informal carers. This source will enable to collect data on the way their care is managed, their communication with health professionals and between health professionals, information received while home care is being provided, information received on how to manage their care at home after the intervention at home.
3. Detailed data from home care clinical-healthcare databases with a special focus on improper accesses to the ED, readmissions to hospital, comorbidities, services offered, and care recipients’ level of autonomy, and main and secondary diagnoses.¹⁴

See diagram showing how these three sets of data sources are linked to the research questions ([figure 1](#)).

Study setting

The study will be conducted on home care services provided in community districts at a national level. Home care is a service provided in the district aimed at providing home-based interventions characterised by different levels of intensity and complexity including specific care pathways and personalised care plans.

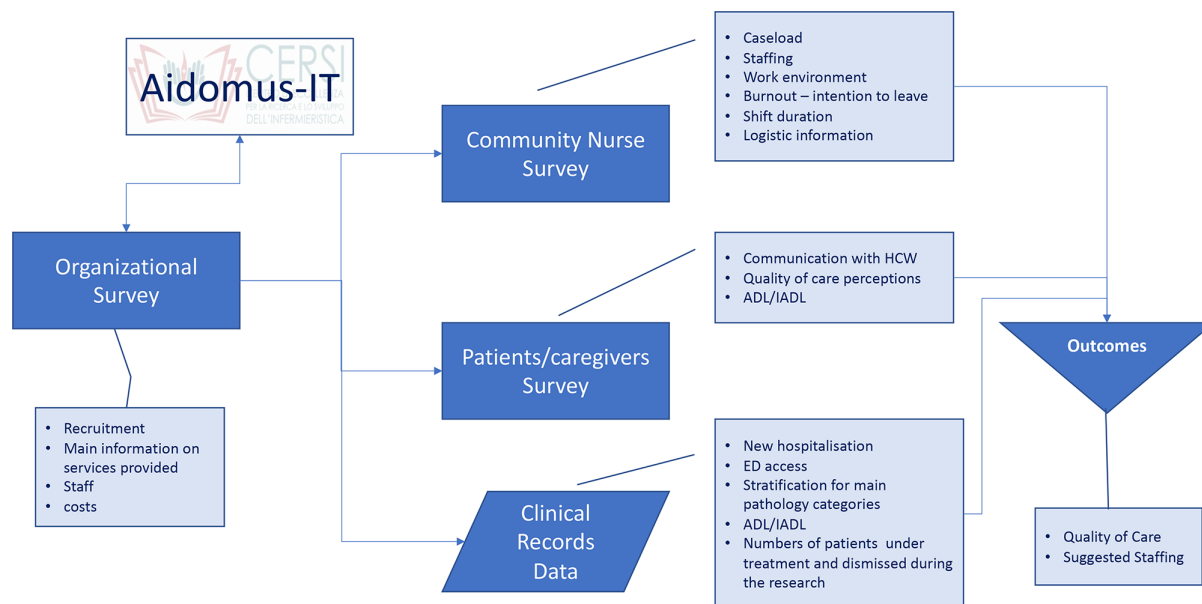


Figure 1 Diagram showing the link between three data sources and how they respond to research questions.

Study participants

The target population for this study are home care nurses, home care recipients and their informal carers (for the purposes of this study, the informal carer is the contact person identified by the healthcare professionals of the districts). Participation implies acceptance of the letter of presentation of the study by the general director of the community healthcare centre.

Recruitment

Since in Italy, no data are available regarding the number of nurses working in the community setting, a preliminary survey will enable us to conduct a census of all the nurses that work in the community across 19 of the 20 Italian regions, involving the greatest possible number of community care centres.

Nurses from all participating community care centres will be recruited through convenience sampling by the coordinators of each centre, who will act as facilitators for this study. All community care recipients and their informal carers during the study period will be invited to complete the survey.

Eligibility criteria

Inclusion criteria for the nurses:

- ▶ Be a registered nurse.
- ▶ Provide domiciliary care in a district of the Italian territory.
- ▶ Provide informed consent.

Inclusion criteria for care recipients/informal carers:

- ▶ Care recipients and their informal carers taken charge by the community services participating in this study.
- ▶ Informed consent for care recipients and their informal carers.

Exclusion criteria for the nurses:

- ▶ There are no exclusion criteria regarding age, sex, ethnic group or socioeconomic status. There are no

enrolment restrictions in relation to fertile status, pregnancy and/or other nurses' characteristics.

Exclusion criteria for care recipients/informal carers:

- ▶ Care recipients and informal carers who access community services, but also use other services that do not involve domiciliary care (eg, outpatients' services).

Study variables

- ▶ Staffing and skill mix of the nursing team in community care, defined in terms of hours of care provided to each patient, nurse–patient ratios or an equivalent measure (eg, nurses per district population).¹⁵
- ▶ Work environment defined as the organisational characteristics of a work environment that facilitate or limit professional nursing practice.¹⁶
- ▶ Caseload defined as the set of activities provided to people who require care from the local nursing service in a specific period and in a specified location.¹⁵
- ▶ Missed care defined as any aspect of the care needed by a person that is omitted (in part or totally) or delayed.^{17 18}
- ▶ Skill mix defined as the proportion of nurses compared with total care staff, including nurses, general nurses and healthcare workers in each unit.¹⁹
- ▶ Customer satisfaction defined as the level of the satisfaction of care recipients and their informal carers with the care provided by health professionals.²⁰

Procedures

This study started in July 2022 and is planned to end in December 2023.

The nursing managers/contact persons will be invited to participate in organisational meetings with the scientific director and/or the members of the scientific committee. In addition, they will be asked to provide data on the population demographics and characteristics, the

characteristics of the territory (ie, size, services offered), staffing and the types of services provided.

All the nurses of the participating centres will be invited to participate via email, which will contain a link enabling a reserved access to the information material and the study questionnaire. By accepting to respond to the survey, participants confirm their consent to participate in the study.

For the respondents (ie, nurses, care recipients and informal carers), the duration of their participation in the study will be short and the questionnaire will be administered only once. No other study procedures shall require a follow-up with the participants.

Sample size

The minimum sample size required for each academic participating centre is 460 nurses, based on a 5% margin of error, a 20% drop-out rate and a 95% level of confidence. Considering the total Italian nursing population of approximately 450 000 registered nurses, a sample size of approximately 1% of the population or 4600 nurses was hypothesised.

Instruments

The nurse survey

The first page of the survey provides information about informed consent, the purpose of the study, assuring participants that their responses will be kept confidential and not disclosed, especially to their employer, the voluntary nature of the study, a webpage with frequently asked questions and the contact information of the PI for Italy and the PI of the participating centre. By completing and sending the questionnaire, participants express their consent to participate in the research. The following steps will be followed:

1. The coordinators of the participating community districts will send a weekly reminder via email or WhatsApp to solicit participation in the study.
2. No identifying information will be required from respondents ensuring confidentiality.
3. To ensure confidentiality, the survey can be completed also outside the work environment using personal smartphones, tablets or personal computers (PCs) at home.
4. Partly completed surveys can be resumed from where the respondent left off.
5. User-friendly dashboards will enable to provide real-time response rates to the research team, which will be communicated to the Principal Investigator (PI) of the participating centre.

The survey data will be uploaded directly onto the CERSI.FNOPI.IT server. The community healthcare centres will receive their data in the form of a report on the results of their centre. The data will be aggregated to protect respondents' confidentiality.

An email and telephone number will be provided on each communication sheet and page of the electronic

survey, which respondents may use to solve technical problems or ask further information.

After finishing the survey, the anonymous data of the survey responses will be saved on password-protected servers hosted by a certified service provider. The original anonymous raw data will be kept by CERSI-FNOPI for 10 years.

The patient survey

Information on the patients' outcomes will be drawn from the data available in the medical and nursing records regarding rehospitalisations, comorbidities, services offered, autonomy level of the care recipient and principal and secondary diagnoses that will be collected by the PI of the participating centre.

Patient satisfaction data will be derived from the patient survey. Patients will be recruited by home care nurses based on the inclusion criteria. The first page of the survey provides information on informed consent, including the purpose of the study, confidentiality, the voluntary nature of their participation and the contact information of the PI for Italy and the PI of the participating centre. The informed consent form must be signed by the patient before participating in the study.

Information on patient outcomes derived from data in hospital databases regarding improper accesses to the ED and rehospitalisations will be collected by the PIs of the participating hospitals or their delegates.

The selection procedure will be evaluated based on available data regarding the organisation of services, obtained from an exploratory survey.

The informal carer survey

Informal carer satisfaction data will be collected through the Informal Carer Survey. The first page of the survey provides information on informed consent, including the purpose of the study, assuring participants the confidentiality of their responses, the voluntary nature of the study and the contact information of the PI for Italy and the PI of the participating centre. The informed consent form must be signed by the informal carer before participating in the survey.

Benchmarking procedures

The community healthcare centres can choose to receive a final benchmarking report that compares each centre with the anonymised data of the other centres. To protect the confidentiality of participating nurses, community healthcare centres will receive a report on their centre's results only in an aggregate form. The report will be shared with the PI of the participating centre.

Data analyses

A preliminary analysis of specific raw data will be conducted to detect any inconsistent and missing data. The clean data will be divided into datasets containing information at various levels: district/zone/community, at home, patients/informal carers and nurses.

Similarly, to what occurs in acute hospital settings, as the number of patients per nurse increases, also negative outcomes increase (eg, complications, patient mortality, nurses' intention to leave, burn-out and missed care),² we hypothesise that excessive caseloads in the community setting could entail similar negative outcomes both for nurses and the people they care for. Therefore, the independent variable we hypothesise will condition the results of this study is 'caseload'.

To this end, two main analyses will be conducted: the first will be a descriptive and comparative analysis of the variables that summarise similarities and differences, and strengths and weaknesses of the nursing workforce. In these analyses, data at the nurse level will be used in an aggregate form.

The second will use models for the detailed analysis of the associations between independent and dependent variables. The analysed independent variables will concern staffing and variables regarding the work environment. The dependent variables will include both the indicators of nurses' perception of their work and patient outcome variables.

Analyses will be conducted using regression models to estimate the mean differences for the continuous outcome variables or differences in the ORs of various negative events for nurses and patients.

Multivariate analyses will be conducted for all nurses and patients in the individual districts/zones/communities. Three analyses will be conducted, the first will explore factors related to nurses' work environment with procedures for risk adjustment. Logistic regression models will be used with data on patient caseload (demographic characteristics, comorbidities, diagnostic categories, level of autonomy) to identify the factors that influence most the quality of home care.

The second analysis will evaluate the association between the characteristics of the district/zone/community (workloads and work environment) and nurse outcome measures.

The third analysis will evaluate the association between the characteristics of the district/zone/community (workloads and work environment) and the patient outcomes (data collected from the clinical records of the home care services in the community).

The fourth analysis will evaluate the economic impact in terms of costs and outcomes, by analysing the direct and indirect costs, and other outcomes of concern as envisioned by the National Health Service. An impact analysis of the 5-year budget will be conducted to propose any alternative strategies.

Ethics and dissemination

This study protocol was approved by the Liguria Regional Ethics Committee on the 29 November 2022 (Ref. number 675/2022—DB id 12844). If the participating centres require the approval of their own local ethics committees, all the necessary documentation will be sent.

This study protocol was developed in full respect of the rights of the participants according to local law on good research and clinical practice, although no medications will be administered and according to the EU General Data Protection Regulation.²¹

The study will be conducted in agreement with the Declaration of Helsinki (version Fortaleza, 2013) and current rules on good practice. The online survey may be accessed only after participants read the information sheet and give their consent. Participation in this study is voluntary and the decision to refuse consent or withdraw from the study at any time will be guaranteed. Participants shall not receive any fees or reimbursements.

Patient and public involvement

For the development of this study protocol, patients or the public were not involved.

Including patient and public involvement (PPI) statements aligns closely with *BMJ Open's* values of transparency and inclusiveness. We hope that including PPI statements in all articles is the first step of many for *BMJ Open* in encouraging patient involvement.

Confidentiality

The promoter of this study shall protect all sensitive personal data of the subjects involved in the study in agreement with European legislation on data protection.²¹

Data processing

All collected data will be made available only to the research team. To protect privacy, the data of individuals will be entered through an online system with reserved and controlled access, using a numerical identification code standing for the research centre and one for each individual. Any personal information, which may enable to track participants' identity will not be recorded.

Access to the data collection form will be password protected. Data will be saved in the database anonymously and only the investigators shall be able to track the identity of the respondents.

All anonymised data will be kept for at least ten years by CERSI-FNOPI.

Limitations

The limitations of the study may be related to the number of missing answers, self-selection bias and the organisational structure of home care in Italy, which differs across regions.

Dissemination

The results of this study protocol will be disseminated by CERSI-FNOPI through abstracts, posters and oral presentations at conferences, and published in peer-reviewed scientific journals. The findings will also be shared by CERSI-FNOPI with the centres that participated in this study, and with national and local government representatives, policy-makers and stakeholders.

**Author affiliations**

- ¹Department of Health Sciences, University of Genoa, Genoa, Italy
²Scientific Committee CERSI-FNOPI, Federazione Nazionale Ordini Professioni Infermieristiche, Rome, Italy
³Department of Biomedicine and Prevention, University of Rome Tor Vergata, Rome, Italy
⁴Department of Clinical Medicine, Public Health, Life and Environmental Sciences, University of L'Aquila, L'Aquila, Italy
⁵Associate Professor of Nursing, Vita-Salute San Raffaele University, Milano, Italy
⁶Director of Nursing, University Policlinic A. Gemelli IRCCS, Roma, Italy
⁷FNOPI Board Member, Federazione Nazionale Ordini Professioni Infermieristiche, Rome, Italy
⁸Scientific Director, Center of Excellence for Nursing Scholarship, Rome, Italy
⁹Associate Professor, Department of Health Sciences, University of Florence, Florence, Italy
¹⁰Director of the Undergraduate Nursing Degree Program, Humanitas University Milan, Milan, Italy
¹¹National General Secretary FNOPI, Federazione Nazionale Ordini Professioni Infermieristiche, Rome, Italy

Collaborators AIDOMUS-IT Collaborator Group: Alessandra Burgio, Paolo Landa, Yari Longobucco, Milko Zanini.

Contributors AB and LS: jointly wrote the manuscript. AB, RA, LL, DFM, MaZ, GR, LR, BM and LS were responsible for selection and recruitment of participants. AB and LS: designed the system for AIDOMUS-IT data and management. AB, RA, LL, DFM, MiZ, GR, LR, BM and LS shall contribute to data collection. AB, RA, LL, DFM, MaZ, GR, LR, BM and LS reviewed and edited the manuscript. AB submitted the AIDOMUS-IT Study Protocol to the Local Ethics Committee. AB, RA, LL, DFM, MiZ, GR, LR, BM and LS contributed to the aims and the design of this study protocol. AB: conducted statistical analyses. PL: conducted health economics analyses. YL and MiZ: developed the surveys.

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ORCID iDs

Annamaria Bagnasco <http://orcid.org/0000-0002-9079-8460>
 Loredana Sasso <http://orcid.org/0000-0001-5886-5937>

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