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Protocol_Impact of a telephone triage service for non-critical emergencies in Switzerland: a cross-sectional study

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ABSTRACT

BACKGROUND: Telephone triage services (TTS) play an increasing role in the delivery of healthcare. The objective of this study was to characterize the users of a TTS for non-critical emergencies, describe the types of advice given and their subsequent observation, and assess the influence of TTS on the use of the healthcare system in a sanitary region of Switzerland.

METHOD: Data from a TTS based in the French part of Switzerland will be analyzed. This service consists of a medical contact center for non-critical emergencies, with trained nurses available 24/7. We created a questionnaire based on literature search and inspired by other questionnaire to assess these different points. All calls for medical complaints from adults (people aged > 18 years old) during a 3 months period (from July 2018 to September 2018) will be listed. 20 calls per day will be randomly selected with the software STATA. Research students will contact users 2 to 4 weeks after the initial call to reach a total sample of 430 users. In this descriptive study, the main outcome is to evaluate if the call to TTS change the attitude of care (dichotmomous variable yes/no). We expected a change in 20% of users of CTMG (p = 0.2) with a 99% confidence interval of (15% - 25%). Using the general formula ?=??/22?(1−?)/?2 we find n = 425, being e=0.05 the half width of the desired confidence interval, ?=0.01 the 1's complement of the confidence level (99%), and ??/2 the (1−?/2) quantile of the standard normal distribution (?=0.01 → ??/2 =2.58). We will use STATA15.0 to perform the statistical analyses.

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1. http://www.obsan.admin.ch/sites/default/files/publications/2015/obsan_bulletin_2013-03_f.pdf. 2. Carret MLV, Fassa AG, Domingues MR. Inappropriate use of emergency services: a systematic review of prevalence and associated factors. Cad Saude Publica. 2009;25(1):7-28. 3. Dale J, Green J, Reid F, Glucksman E, Higgs R. Primary care in the accident and emergency department: II. Comparison of general practitioners and hospital doctors. BMJ. 1995;311(7002):427-430. 4. Gill JM. Use of hospital emergency departments for nonurgent care: A persistent problem with no easy solutions. Am J Manag Care. 1999;5(12):1565-1568. 5. Holt TA, Fletcher E, Warren F, et al. Telephone triage systems in UK general practice: analysis of consultation duration during the index day in a pragmatic randomised controlled trial. Br J Gen Pract. 2016;66(644):e214-218. 6. Hansen EH, Hunskaar S. Telephone triage by nurses in primary care out-of-hours services in Norway: an evaluation study based on written case scenarios. BMJ Qual Saf. 2011;20(5):390-396. 7. Dahlgren K, Holzmann MJ, Carlsson AC, Wandell P, Hasselstrom J, Ruge T. The use of a Swedish telephone medical advice service by the elderly - a population-based study. Scand J Prim Health Care. 2017;35(1):98-104. 8. Deshpande A, Khoja S, Lorca J, et al. Asynchronous telehealth: a scoping review of analytic studies. Open Med. 2009;3(2):e69-91. 9. 2017. SR. 10. McAteer A, Hannaford PC, Heaney D, Ritchie LD, Elliott AM. Investigating the public's use of Scotland's primary care telephone advice service (NHS 24): a population-based cross-sectional study. Br J Gen Pract. 2016;66(646):e337-346. 11. Li L, Lake R, Raban MZ, et al. Medication-related calls received by a national telenursing triage and advice service in Australia: a retrospective cohort study. BMC Health Serv Res. 2017;17(1):197. 12. Stacey D NH, Fisher A, Robinson D, Joyce J, Pong RW. Telephone, Centre TSSRaaSoCC, Office PTrnOCC, for Health Technology Assessment. 13. Warren FC, Calitri R, Fletcher E, et al. Exploring demographic and lifestyle associations with patient experience following telephone triage by a primary care doctor or nurse: secondary analyses from a cluster randomised controlled trial. BMJ Qual Saf. 2015;24(9):572-582. 14. Bunn F, Byrne G, Kendall S. The effects of telephone consultation and triage on healthcare use and patient satisfaction: a systematic review. Br J Gen Pract. 2005;55(521):956-961. 15. Mair F, Whitten P. Systematic review of studies of patient satisfaction with telemedicine. BMJ. 2000;320(7248):1517-1520. 16. Reinius P, Johansson M, Fjellner A, Werr J, Ohlen G, Edgren G. A telephone-based case-management intervention reduces healthcare utilization for frequent emergency department visitors. Eur J Emerg Med. 2013;20(5):327-334. 17. Mulcahy D, O'Callaghan C, Hannigan A. Nurse Triage in an Irish Out-of-hours General Practice Co-Operative. Ir Med J. 2017;110(3):530. 18. Shah SM, Cook DG. Socio-economic determinants of casualty and NHS Direct use. J Public Health (Oxf). 2008;30(1):75-81. 19. Cook EJ, Randhawa G, Large S, Guppy A, Chater A. A U.K. case study of who uses NHS direct: investigating the impact of age, gender, and deprivation on the utilization of NHS direct. Telemed J E Health. 2012;18(9):693-698. 20. Rimner T, Blozik E, Begley C, Grandchamp C, von Overbeck J. Patient adherence to recommendations after teleconsultation: survey of patients from a telemedicine centre in Switzerland. J Telemed Telecare. 2011;17(5):235-239. 21. Gallagher M, Huddart T, Henderson B. Telephone triage of acute illness by a practice nurse in general practice: outcomes of care. Br J Gen Pract. 1998;48(429):1141-1145. 22. Moscato SR, David M, Valanis B, et al. Tool development for measuring caller satisfaction and outcome with telephone advice nursing. Clin Nurs Res. 2003;12(3):266-281. 23. Bieler G, Paroz S, Faouzi M, et al. Social and medical vulnerability factors of emergency department frequent users in a universal health insurance system. Acad Emerg Med. 2012;19(1):63-68. 24.

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BACKGROUND AND PROJECT RATIONALE

During the last years in Switzerland, like in many other countries, we observed a large increase in the use of emergency services for mild cases, causing significant waiting time and potentially a delay in management of severe cases 1-4. Telephone triage and advice services play a significant role in the delivery of healthcare 5-7 and have increasingly been used as a mean for health-care delivery 8. Introduced in the sixties, the Centrale Téléphonique des Médecins de Garde (CTMG) in Lausanne receive around 200'000 calls per year, predominantly out of hours 9. The CTMG consists of a medical contact center with trained nurses, available 24 hours a day, 7 days a week for the population of the canton de Vaud and canton de Neuchâtel. In 2017, 58% of calls concerned adult cases 35.8% for paediatrics cases and 5.9% for pharmacies activities9. Different studies recently assess the profile of users of primary care telephone advice service worldwide 10,11.
Actually we have no information about the users of this service, the fate of patients after calls 12 nor about their satisfaction in Lausanne. We created a questionnaire to assess sociodemographic aspect of users, medical reason of call, satisfaction 13-15 of users and the impact of CTMG use on healthcare sanitary system use. We will compare the results with other countries 13,16-19 and with other similar Swiss centers 20.
Different studies tend to show a reduction in consultations with primary care physicians or emergency centers for frequent users of emergencies, after a telephone communication with a nurse or a general practionner 16,21.

PROJECT OBJECTIVES AND DESIGN

Hypothesis and primary objective
The first aim of this project is to assess the reason of calls (type of complaint), the socio-demographic aspects (age, sex, address) and health status of CTMG users and type of advice provided (transfer to emergency services, appointment in a care center during the day or defer consultation with the general practitioner) at the CTMG.
The secondary objectives are to evaluate if the use of the CTMG changed the intentions of users after the call (intention to consult in an emergency department, intention to take medication, etc.) and to assess the satisfaction of the users of the CTMG.
We created a questionnaire based on literature search and inspired by other questionnaire to assess these different points 10,22. The questionnaire has not been validated but has been approved by experts from the CTMG and the 144 team and tested with participants similar to the target population. The questionnaire will be hetero-administered by phone.

Primary and secondary endpoints
Using a socio-demographic questionnaire, we will measure sex, age, nationality, marital status, living place (city vs. country), level of education, professional activity and monthly house income of the CTMG users. We will also assess if the participants have children and if they are living alone or with others persons.
We will evaluate health status and access to health care of CTMG users such as presence of medical illnesses and medication. The questionnaire will also assess if CTMG users have a general practitioner as well as contact with other healthcare professionals. We will also evaluate the proportion of "frequent users" of emergency services which are defined by four or more emergency department visits the previous 12 months23.
The use of internet for medical problem and the reason of call to the CTMG will also be collected. We will also take information on the timing of the call (the week days or week-end, hour, month) and finally the satisfaction of users of the CTMG.

Project design
All calls for medical complaints from adults (people aged > 18 years old) during a 3 months period (from July 2018 to September 2018) will be listed by the main investigator with the help of the chief and the chief assistant of operations (adjointe opérationnelle) of the CTMG. Calls of adults living in canton de Vaud will be selected via the informatics system from the CTMG (SAGA) and 20 calls per day will be randomly selected by the main investigator with the software STATA. Trained students will call the selected participants two to four weeks after the initial (index) call. They will present the study, check inclusion/exclusion criteria and ask for informed consent. They will also answer to questions. The goal is to include 5-8 calls a day, according to the availability of students, 7 days per week during 3 months to reach a total sample of 430 users.
Research students will explain the project, answer any questions and ask for participation. After oral consent for the use of CTMG call records and as well as consent to answer the questionnaire, CTMG users will have the possibility to answer the questionnaire directly by phone or ask for an appointment in a 1 to 3 days delay (less than 4 weeks after the call). Answers will be directly recorded in REDCap, a secured file, by the students.
During half a day, students will be trained by the research assistant to be able to answer questions and pass the

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questionnaire and they will be coached by the team at any time.
Time to pass the questionnaire is estimated to be 10 minutes.
The REDCap questionnaire consists in two parts:
1) A hetero-administered questionnaire including: socio-demographic data; advice given at the time of the initial call and what has been done; expectations before the call; outcome after the call; and satisfaction with management. This part will be completed directly on REDCap during the encounter with the students after the oral consent has been obtained.
2) A retrospective part on the basis of data recorded by the CTMG during the initial call including: socio-demographic data; type of complaint, type of advice provided. This part will be completed on REDCap in a second time after the inclusion.
All data will be collected anonymously. Every users of the CTMG who will participate will be identified by a unique code number and all identifying information will be removed. Data will be stored on encrypted and password-protected drives.

MATERIALS TEXT

PROJECT POPULATION AND STUDY PROCEDURES

Project population, inclusion and exclusion criteria
The CTMG answers approximately 200'000 calls per year, 58.3% for adults cases, 35.8% for paediatrics cases, 5.9% for pharmacies activities 9.
In this descriptive study, the main outcome is to evaluate if the call to CTMG change the attitude of care (dichotmomous variable yes/no). We expected a change in 20% of users of CTMG (p = 0.2) with a 99% confidence interval of (15% - 25%). Using the general formula ?=??/22?(1−?)/?2 we find n = 425, being e=0.05 the half width of the desired confidence interval, ? =0.01 the 1's complement of the confidence level (99%), and ??/2 the (1−?/2) quantile of the standard normal distribution (? =0.01 → ??/2 =2.58). So the aim is to include around 430 users during the 3 months period of the study, (i.e. about 5 participants per day).
Eligible calls will be randomly selected by the principal investigator and the students will contact the users according to the list given by the PI until they reach at least 5 to 8 eligible participants per day. If after two attempts the student fail to contact the selected user or if the user don't want to participate, the student will contact the next person on the list. If the student include less than 5 participants during a day, he/she will report the inclusion the day after.
Inclusion criteria:
- adults ≥ 18 years
- good knowledge of French
- able to give an informed consent
- living in the canton de Vaud
- called the CTMG from July 2018 to September 2018
Exclusion criteria:
- relocation outside of the canton de Vaud
- death

Recruitment, screening and informed consent procedure
The name and phone number of the users adults living in canton de Vaud who have called the CTMG will be listed on a secure Excel document for the randomisation every two weeks directly from the CTMG registrant program. The chief assistant of operations from the CTMG will organize the listing and will transmit the list to the principal investigator.
The principal investigator will randomly select calls every day using the software STATA. Students will contact the selected users and will register on the Excel file the inclusion process (contact: y/n, inclusion criteria y/n, exclusion criteria y/n, informed consent: y/n, inclusion y/n). Given the sample size, we have not stratified the random selection of participants, however, after one month, we will evaluate if this procedure allows to include a balanced sample in terms of age, sex and living place (city vs country) and if the sample is representative of global CTMG users. If not, we will process to a stratified randomisation.
The principal investigator will train students during group sessions of two hours so that they will be able to explain to each participant the nature of the study, its purpose, the procedures involved, the expected duration of the questionnaire, the potential risks and benefits and any discomfort it may entail. Each potential participant contacted will be informed that the participation in the study is voluntary and that he/she may withdraw from the study at any time and that withdrawal of consent will not affect his/her subsequent medical assistance and treatment.
If a participant decides to withdraw from the study, we will continue to use the information already collected so that the research will not be compromised but we will delete the code linking data and patient name. At that point, even the members of the research team will not be able to identify which data are linked to which participants. This information will be explained to the participants using the "participant information form and informed consent form", which will be read by the students to the participants during the phone call. The oral patient information and the oral consent form will be submitted to the CER-VD

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to be reviewed and approved. The oral consent of a participant, must be obtained before the participant is submitted to any study procedure.
There will be no compensation for participation to the study.

Study procedures
The assistant researcher, principal investigator will make the “randomization” and analyze data recorded by the CTMG and the students with the help of the co-investigator. She will be able to coached students at any time.

Withdrawal and discontinuation
The sponsor-investigator may terminate the study prematurely according to certain circumstances for example:
- ethical concerns,
- insufficient participant recruitment (< 50 participants/year),
Data will be collected anonymously; questionnaires will be identified solely by the participant’s code number.

STATISTICS AND METHODOLOGY

Statistical analysis plan
Descriptive statistics will be computed for demographic characteristics. Data will be analyzed using usual descriptive statistics. Proportions and means (with standard deviation) or medians (with IQR) will be calculated. Description of the main outcomes will be performed. T-tests and Chi square tests will be used to explore possible associations between health problems and patient characteristics. We will also compare selected health variables to those of the general Swiss population based on the OFSP statistics. We will use STATA15.0 to perform the statistical analyses.

Handling of missing data
For the survey, if missing values are reasonably small (i.e. less than 10%), we will not impute missing data.

SAFETY WARNINGS

REGULATORY ASPECTS AND SAFETY

Local regulations / Declaration of Helsinki
This research project will be conducted in accordance with the protocol, the Declaration of Helsinki24, the principles of Good Clinical Practice, the Human Research Act (HRA) and the Human Research Ordinance (HRO)25 as well as other locally relevant regulations.

Notification of safety and protective measures (HRO Art. 20)
Not applicable.

Serious events (HRO Art. 21)
We do not expect any serious event with this study.

Radiation
Not applicable.

Amendments
Substantial changes to the project set-up, the protocol and relevant project documents will be submitted to the Ethics Committee for approval according to HRO Art. 18 before implementation. Exceptions are measures that have to be taken immediately in order to protect the participants.

End of project
Upon project termination, the Ethics Committee is notified within 90 days.
All survey data (original questionnaires, excel and STATA files) will be kept in a secured file at the PMU for a minimum of ten years.

Insurance
Not applicable.

FURTHER ASPECTS

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Overall ethical considerations
All members of the research team are under the obligation of professional confidentiality.
Oral informed consent will be obtained from all participants before the beginning of the interviews; no data will be collected before. Participants can at any time withdraw from the project but data collected on REDCap will be used nonetheless.
If the study must be interrupted, the CER-VD will be informed within 90 days (ORH, art 22)25F. No essential changes will be done prior to ethical authorization (ORH, art. 18)25.

Risk-Benefit Assessment
This research project comes under Risk Category A (ORH art.7)25; planned research activities for collecting personal data entail only minimal risk and burdens.
No direct benefit will be present for participant. The aim of this study is to have a better understood of the activities of the CTMG.

If applicable: Rationale for the inclusion of vulnerable participants
Not applicable.

QUALITY CONTROL AND DATA PROTECTION

Quality measures
For quality assurance the Ethics Committee may visit the research sites. Direct access to the source data and all project related files and documents must be granted on such occasions.

Data recording and source data
Project data is recorded with an electronic Case Report Form (eCRF) on REDCap®. Original and copy of the eCRF will be kept in a secure file on the server of the PMU for a minimum duration of ten years. All survey data (original questionnaires, excel and STATA files) will be kept in a secured file at the PMU for a minimum of ten years.

Confidentiality and coding
Project data will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfil their duties within the scope of the research project. On the CRFs and other project specific documents, participants are only identified by a unique participant number.
The participant's right to privacy will be respected and the complete study team will comply with applicable privacy laws. Especially, anonymity of the participants will be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals.
Individual subject medical information obtained as a result of this study is considered confidential and disclosure to third parties is prohibited. Subject confidentiality will be further ensured by utilizing subject identification code numbers to correspond to treatment data in the computer files.
For data verification purposes, authorized representatives of the Sponsor (-Investigator), a competent authority, or an ethics committee may require direct access to parts of the medical records relevant to the study, including participants' medical history.

Retention and destruction of study data and biological material
Not applicalble.

Time table 62w

1	Study materials	12w
2	Ethical review	12w
3	Data collection	12w

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4	Coding/Analyzing data	16w
5	Writing of the manuscipts	24w

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