IMPACT OF STRUCTURAL AND ORGANIZATIONAL REFORMS ON RESIDENTS' DAILY WORK.

Clinical study protocol

Study type:	Time motion study with a before and after comparison.
Study registration:	Intended registry : ISRCTN
Study identifier:	MED2DAY
Principal investigator:	Dr Antoine Garnier
Protocol version and date:	V1.0 du 26.02.2018, rev number 8

STUDY ADMINISTRATIVE STRUCTURE AND SIGNATURES

The investigators and trial statistician have approved the protocol version V1.0 (dated 26.02.2018), and confirm hereby to conduct the study according to the protocol, current version of the World Medical Association Declaration of Helsinki, ICH-GCP guidelines or ISO 14155 norm if applicable and the local legally applicable requirements.

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26. 2. 2018

(Date)

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1   STUDY SYNOPSIS

Study Title:	Impact of Structural and Organizational Reforms on Residents' Daily Work.
Study ID:	MED2DAY
Version and Date:	V1.0, 26.02.2018
Trial registration:	Intended registry: ISRCTN
Background and Rationale:	Because of an increasing number of complex polymorbid patients, a heavier administrative burden, and the evolution of young residents' expectations, organization of work in internal medicine wards is of outmost importance. In a 2015 study, we showed that residents spent 1.5 hours on administrative tasks and 1.7 hours with patients per day. In addition, residents switched activity on average 15 times per hour. This study motivated major reforms: task delegation to non-medical professionals, reorganization of the workday's schedule, and implementation of an early morning inter-professional decision meeting. An associated reduction in administrative and working hours and increased time with patients could greatly improve job satisfaction and attractiveness for internal medicine.
Objectives:	We aim to quantify the impact of the organizational and structural reforms implemented in our department between 2016 and 2017 on: 1) residents' administrative workload; 2) continuity and adequacy of work; 3) duration of shifts, and 4) time spent with patients.
Outcomes:	• Time spent for administrative tasks (primary outcome) • Amount of task switching per hour. • Mismatch between observed activities compared to the departmental work schedule. • Effective duration of observed shifts. • Time spent in presence of a patient.
Study design:	Time and motion study with a before and after comparison.
Inclusion / Exclusion criteria:	Inclusion criteria: all residents registered in the internal medicine department during the study, having graduated from a medical school, and with informed consent. Exclusion criteria: none.
Measurements and procedures:	Trained observers will follow residents during a randomized dayshift and record activities and context, using a dedicated tablet application. Additionally, residents will be included in focus group.
Number of Participants:	35 participants, observed twice (70 observations). Based on our previous study, this number will be sufficient and cost-effective to show a significant reduction of 20 % of administrative tasks.
Study Duration:	4 months
Study Schedule:	May to August 2018
Investigators:	Antoine Garnier, Vanessa Kraege, Matteo Monti, David Gachoud, Marie Méan, Nathalie Wenger, Olivier Lamy, Peter Vollenweider, Gérard Waeber, Pedro Marques Vidal, Julien Castioni
Study Centre:	Lausanne University Hospital, Switzerland (CHUV)
Statistical Considerations:	Using an average time spent on administrative tasks (92 minutes per dayshift), a standard error of 36 minutes, a one-sided test, a significance of 0.05, a power or 80%, and supposing equally sized samples (36 residents as in our 2015 baseline study), then the minimum detectable effect size will be 20 minutes, which corresponds to a reduction of just over 20% of the time dedicated to administrative tasks. Calculations were performed using the power twomeans command of stata and recalculating the standard deviation from the standard error.

2 ABSTRACT

Background: Due to an increasing number of complex polymorbid patients, a heavier administrative burden, and the evolution of young residents' expectations, organization of work in internal medicine wards is of outmost importance. In a 2015 study, we showed that residents spent 1.5 hours on administrative tasks and 1.7 hours with patients per day. In addition, residents switched activity on average 15 times per hour. This study motivated major reforms: task delegation to non-medical professionals, reorganization of the workday's schedule, and implementation of an early morning inter-professional decision meeting. An associated reduction in administrative and working hours and increased time with patients could greatly improve job satisfaction and attractiveness for internal medicine.

Aim: We aim to quantify the impact of the organizational and structural reforms implemented in our department between 2016 and 2017 on residents' administrative workload, continuity and adequacy of work, duration of shifts, and time spent with patients.

Method: We will use a before and after design, comparing residents' activities during shifts with time and motion studies. We will include all residents working on the internal medicine ward in Lausanne University Hospital. The before group was observed in 2015 and results are already published. The after group will be observed in 2018, using the exact same methods and tools. The intervention is made of major reforms implemented between 2016 and 2017, which will be reported in detail. The primary outcome will be time spent for administrative tasks. We will also measure the amount of task switching per hour, the mismatch between observed activities compared to the departmental work schedule, the effective duration of observed shifts, and the time spent in presence of patients. We added a qualitative part by means of focus groups composed of observed residents.

Results and expected benefits: We already have 697 hours of observation on the before group. For the after group, we expect to include 35 residents. Each resident being observed twice, we will gather between 700 and 900 hours of observation. Based on our previous study, this number will be sufficient to show a significant reduction of 20 % of administrative tasks (20 minutes per shift). A significant reduction of administrative burden will give an objective assessment of the impact of our reforms but will also confirm the options we took to develop the framework for future young residents and keep hospital internal medicine attractive. Such a time-and-motion study, which has been already replicated in another hospital, is a consistent base for auditing workplace quality, compared to other quality indicators like the average length of stay of patients.

3   BACKGROUND AND RATIONALE

Over the last decades, the work of general internal medicine residents has changed dramatically because of the escalating polymorbidity and complexity of inpatients, the growing volume of managed clinical data, and the intensifying of economic pressure on healthcare systems.(Nardi *et al.*, 2007; Zulman *et al.*, 2016) Besides, young internists' expectations towards the profession are evolving with the millennials. As largely stated across the media, they want a work-life balance and believe in "working to live" rather than "living to work". They need other incentives than just hard work. They want meaningful engagement and to be able to build relationships with people.(Unger, 2016)

In this setting, work organization is of great importance to provide high quality care but also to ensure adherence of the next generations of internists. Work organization is how an institution defines workers' schedules, interactions, meetings, and responsibilities. It is the framework for residents to achieve high quality and efficiency of provided care, added-value medical education, and worker satisfaction.(Judge *et al.*, 2001; Kahn *et al.*, 2017) Old ways have to change if we want to keep filling the reservoir of future clinicians in internal medicine.

Few quantitative studies focus on how residents organize and spend their time in hospital wards of internal medicine. Moreover, comparisons are limited by different health systems and medical education programmes. Administrative burden, continuity of work, and time with patients, are the major concern of the literature and are related to physician satisfaction.

The administrative burden of residents is made of clinical documentation, writing discharge summaries, organizing exams, and seeking for information. Use of information technologies has increased in healthcare and the electronic medical record (EMR) is now crucial. However, negative effects have also been described such as: increasing time spent by physicians on administrative tasks and writing notes,(Poissant *et al.*, 2005) and reducing communication between patients and physicians.(Alkureishi *et al.*, 2016) Fletcher *et al.* (2012) observed that the largest proportion of residents' time was spent in clinical computer work (40 %). Westbrook *et al.* (2008) observed that time interns spent documenting (22%) was almost double the time they were engaged in direct patient care. Sinsky *et al.* (2016) described American physicians' time allocation in ambulatory settings and confirmed that they also spend up to 50% of their time using the EMR. However, with so much time using a computer, EMR systems still fail to meet physicians' expectations toward harnessing, synthetizing and presenting available data. (Zulman *et al.*, 2016)

Countless partners and teamwork are characteristic of hospitals but may lead to many interruptions, degrading the quality and continuity of work of physicians. Westbrook *et al.* (2008) showed that doctors were multitasking 20% of time and were interrupted every 21 minutes.

More time spent with patients was shown to improve patient satisfaction, patient education, and health promotion activities, (Wilson *et al.*, 1992) as well as to reduce inappropriate prescribing and malpractice claims (Dugdale *et al.*, 1999). Ammenwerth *et al.* (2009) observed that nearly as much time was being spent for documentation as on direct patient care. Block *et al.* (2013) observed that residents spent a minority (12%) of their time in direct patient care.

In 2015, we aimed to understand our self-organization better before initiating any intervention in our university hospital. We initiated a time and motion study and collected 697 hours of observation. On average, residents spent 1.5 hours per day for administrative tasks without

any added clinical value, 5.2 hours using computers, and 1.7 hours with patients. Activities directly related to patients accounted for 28.0%. Residents switched from one task to another 15 times an hour. (Mean *et al.*, 2017; Wenger *et al.*, 2017)

Based on our study and literature review, we identified the following reforms with a high potential of improvement (**Table 1**).

(1) Medical-administrative tasks performed by residents should be regularly reassessed for suppression or at least reduction. If possible, they should either be automated with an effective EMR, or delegated.(Castioni *et al.*, 2017; Erickson *et al.*, 2017) We observed that our residents spent on average 92 minutes per day on administrative tasks. We structurally increased administrative support: we hired additional medical secretaries thus liberating more time for added-value medical tasks. We also increased our collaboration with the IT department and improved the efficiency of writing discharge summaries.

(2) Inter-professional team meetings are known to improve communication and coordination between healthcare providers.(Geary *et al.*, 2009; Prystajecky *et al.*, 2017; Wild *et al.*, 2004) They may also have an impact on hospital performance measures.(Curley *et al.*, 1998; O'Mahony *et al.*, 2007) However, we observed that inter-professional meetings in our ward were not frequent enough to cope with patient flows and thus forced staff to obtain information in parallel, often duplicating work and contradicting/interrupting each other. We also observed that the late timing in the day (afternoon) was inefficient. We therefore increased the frequency of meetings from 2 per week to 1 per day by redefining the early handoff meeting as an inter-professional decision meeting.

(3) Ward rounds should focus on accurate patient assessment and appropriate communication with them on their condition and care plan.(Gachoud *et al.*, 2013; Norgaard *et al.*, 2004) We observed that residents switched from one task to another up to 15 times per hour, which questions work efficiency.(Mean *et al.*, 2017) Phone calls, providers, prescriptions, and file reading, very often interrupt ward rounds, partly because of a lack of both doctors' and nurses' preparation time. We therefore shifted the medical round to a later time so as to increase preparation time. In addition, we developed a specific structure for medical rounds, including a series of steps to be followed.

(4) We observed a mismatch between expected resident activities according to the official schedule and those observed.(Garnier *et al.*, 2018) This is one evidence that old habits do not fit with the current reality anymore. We therefore reorganized the schedule, for example by shifting postgraduate education sessions to 1:00 pm each day.

Since our first study in 2015, we constantly evolved and introduced other improvements, like any leading institution.

3.1 Study objectives
We aim to quantify the impact of these major organizational and structural reforms on:
- Administrative workload of residents.
- Continuity and adequacy of work.
- Duration of shifts.
- Time spent with patients.

3.2 Justification
A reform, even with a good change management, is costly. It costs work, time, money, and may induce unexpected effects. Therefore, it is important to collect pertinent information for cost-benefit assessment. Our aim is more than just to implement another project; it is to make

our profession evolve, by observing people and their environment, and by deeply intervening on our organization.

Administrative workload is a clear indicator of the quality of our process, of the opportunities for delegation, and of efficient resident training regarding self-organisation. Reduction of administrative workload does not forcibly lead to less work; it also allows the resident to dedicate more time for added-value or patient-oriented activities. It also means that our process and work organization are efficient and attractive for future internists. As administrative burden is constantly increasing, even a small reduction can be considered as a success.

Continuity and adequacy of work will be examined in particular. We believe that an internist's most valuable activities are to think, to understand, and to make the right decisions for patients. For this, residents need to work without being interrupted, a particularly challenging condition given the need for communication between all people who care for patients. Ensuring a continuous workflow with few interruptions will keep residents concentrated on the core business of the internist.

Effective durations of shift need to be assessed and associated with the number of patients in one's charge. Millennials no longer consider achieving more work hours as an act of bravery. They prefer to commit to a well operating community. Less work hours means better quality of life and less risk of burnout.

Finally, the right time duration to be spent with patients every day is not known, but more time with patients means better quality of care. Young internists – and the media – value that time, which they associate with humanity, communication and patient engagement. Patients must be included in an effective operational management.

The results of our study will provide important information about work organization in the internal medicine department of the Lausanne University Hospital (CHUV). Still, we are convinced that it will be of major interest for all general internal medicine wards. This study, which has already been replicated in another Swiss hospital,(Frey *et al.*, 2017) is a unique opportunity to set a new and better basis for auditing the quality of workplaces, compared to other quality indicators like the average length of stay of patients. In it, we see some new metrics for auditing organizations and proposing innovative solutions to our common issues. We want to create new ways of doing our job and share it with others because future internists will need efficient and up-to-date tools.

The results of our study, whether positive or negative, will be an important step in our research field. We aim to pursue exploration of clinical governance in general internal medicine, quality improvement, and daily life of internists. In the coming years, we will address the role of clinical supervision, inter-professional collaboration, and integration of advanced technologies in our core competencies.

4 METHODS

4.1 Study outcomes

4.1.1 Primary outcome
The primary outcome will be the **time spent for administrative tasks**, defined as the sum of the four following activities (see **appendix table 1** for all definitions):

Patient administrative tasks	(defined as administrative tasks for the patient: booking appointments, writing the voucher for radiography or specialized consultation, and adding laboratory tests)
Non-patient administrative tasks	(defined as an activity unrelated to the patient, directly or indirectly, e.g., answering professional e-mails)
Discharge summary redaction	(defined as any activity related to writing hospitalization reports: brief report and discharge letter. Includes revision of reports)
Looking for information	(defined as looking in the paper record, EMR, computer archives, or other medical record. Excludes admission activity. Excludes literature reviewing)

4.1.2 Secondary outcomes
- Amount of task switching per hour, as defined in Mean *et al.* (2017).
- Task mismatch defined as time spent in observed activities but unexpected in the related timeframe of schedule.
- Effective duration of observed shifts.
- Time spent in presence of a patient.

4.2 Study design
Time and motion study with a before and after comparison.

4.2.1 General study design
We will assess the impact of organizational and structural reforms achieved these last years by a **before and after comparison**. We did the observation "before" between May and July 2015, which is our baseline study. We already published the method and results as a time-motion study (Wenger *et al.*, 2017). At that time, none of the described reforms had begun. The "after" observation will be done using exactly the same method regarding recruitment and training of observers, definition of activities, and data collection. Statistical methods for comparison are described in the section 4.7. We will also precisely describe and quantify the interventions made between the before and after observations: what we did, when and how we implemented them, issues and success they caused, change management, and costs.

We will gather additional data, as described in section 4.5.3: localisation in the hospital, indirect measurement of computer usage (clicks), and dactylography skills. These additional data will improve our study and help understand our observations better. They will be correlated to observation and available for future study.

Finally, using focus groups composed of the observed residents, we will gather opinions and comments about the raw results, for example how does one define too many administrative tasks.

4.3 Study population

All residents fulfilling all of the following <u>inclusion</u> criteria are eligible for the study:

- Graduation from a medical school in Switzerland or equivalent.
- Holding a resident position on the internal medicine ward during the study.
- Informed consent.

There are no <u>exclusion</u> criteria but a resident cannot be observed in case of:

- End of contract (left the department) before observation.
- Sickness the day of observation.
- Not working on the ward (research position, continuous care, night or week-end).

If a resident is missing on the planned day of observation, no matter the reason, a new observation is randomly rescheduled. If a new observation cannot be rescheduled, we will record the reason.

4.4 Description of interventions

In view of the complexity of multiple interventions, we first need to report all significant reforms that have occurred in the Department. We will describe the rationale for change, the change management process, the issues and the lessons learnt, the costs, and the expected benefits. Each identified initiator of a reform will fill in a report structured with general and specific questions. **Table 1** summarizes the reforms implemented between 2016 and 2017.

Designation	Type of reform	Expected benefits on outcomes					Other benefits		
		administrative burden	interruption / task-switching	task-mismatch	effective duration of shifts	time with patient	quality of care	average lengths of stay	employee's satisfaction
Medical secretary allocation and delegation	Structural	⇩			⇩	⇧	⇧	⇩	⇧
Senior physician allocation to IT department	Structural	⇩		⇩		⇧			⇧
Early inter-professional decision meeting	Organizational	⇩			⇩		⇧	⇩	
Ward rounds improvement	Organizational		⇩	⇩		⇧	⇧		⇧
Week schedule reorganization	Organizational		⇩	⇩	⇩	⇧	⇧		⇧
Departmental guidelines for frequent disease	Organizational	⇩					⇧	⇩	⇧

Table 1. Reforms implemented in the CHUV internal medicine department, 2016 – 2017.
IT: information technologies

It will not be possible to attribute a specific effect to a specific reform but this is not an issue. As every institution, we are committed to continuous improvement in many ways and no reform will be implemented alone. The aims and extent of reforms highly depend on local settings.

4.5 Data collection

We will collect three kinds of data: activities of residents during a shift (section 4.5.1); characteristics of the residents and the setting of the observation (section 4.5.2), and additional data (section 4.5.3).

4.5.1 Observation of activities during a shift

<u>Definition of a shift</u>

The official dayshift begins at 08:00 and ends at 18:00. The evening shift begins at 16:30 and ends at 23:00. Starting in 2017, following legal regulation changes, the official day shift ends at 18:24 and the evening shift ends at 24:00. However, observation will start when residents arrive at their workplace on the ward - but not earlier than 30 minutes before the official time - and stop when they definitely leave the workplace at the end of the day, no matter how early or late. Night shifts and weekends will not be observed.

<u>Observation and randomisation</u>

We will observe all eligible residents twice, on two different days, for the duration of a whole shift. The period of observation will last 2 months. We will randomize the days of observation with a stratification for day and evening shifts and for days of the week. After randomisation, observation days are attributed to observers, based on their availability but blindly to the observed residents. The observer will get contextual information about the intern (place of work, patients in charge, rooms in charge, supervisor) on the night before. On the assigned day of observation, he will wait for the intern at his regular workplace, 30 minutes before the official beginning of the shift. If resident-observer contact is not made 15 minutes before the official beginning of the shift, the observer will call the intern to make first contact. During dayshifts, a second observer will relay the first after 6 hours of observation.

Observers will use the dedicated tablet application developed in our department as described in Wenger *et al.* (2017).

<u>Selection and training of observers</u>

We will recruit and pre-select candidates with personal interest in internal medicine, ongoing or completed undergraduate medical education, fluent French speaking and understanding, and easiness with IT devices.

Candidates will have to learn description of activities based on an e-learning at home, using a web-based flashcard application. Investigators will train observers during a common half-day, within a few weeks before study. During the training, a standardized 1-hour video will be broadcasted and coded by the candidates. Selection will be based on reliability of video coding. After selection, each observer will follow a resident during a half-day, as blank observation. During a dedicated meeting, the observers will have the opportunity to ask questions, identify difficulties and get feedback. We will gather questions and answers in a document distributed to the observers.

4.5.2 Characteristics of the residents and the setting of the observations

We will collect the variables described in **Table 2** for both before and after observations.

Observed residents	Setting of the 2-month observations
• age	• number of admissions in ward
• sex	• number of beds and occupancy rate
• country of diploma	• average length of stay
• postgraduate training (months)	• rate of 30-day readmission
• postgraduate training in internal medicine	• average case mix index
• distance from hospital to home	• mean age of patients
• number of patients in his charge	• mean lead time of discharge summary
	• FTE of residents, senior and attending physicians, and nurses

Table 2. Characteristics of residents and setting of observation. FTE: full-time equivalents

4.5.3 Additional data

We will gather additional consistent data, which will be available for future observation and comparison.

- Using a technical device (beacons), we will record the precise indoor location of the resident during observation. Location will be correlated to activities.
- Using software and IT logs, we will collect the number of clicks, mouse distances, and EMR usage during observation.
- Using certified tests, we will assess dactylography skills of residents and correlate them with medical record activities.
- Using focus groups, we will correlate the results of observations with a qualitative analysis described in section 4.6.

4.6 Focus group

The focus group is a qualitative research method using group interviews. Focus group participants are invited to discuss topics proposed by the researcher, usually in a semi-structured way with a set of predefined open-ended questions. Focus groups rely on group dynamics to gather and explore participants' perspectives. While the researcher acts as a moderator, group discussions deepen and enrich the original perspective of each participant. (Britten *et al.*, 1995; Kuper *et al.*, 2008; Moreau *et al.*, 2004)

All observed residents will be invited to focus groups at the end of the observation period. We will organize 4 to 6 sessions, depending on the number of participants (about 8 per group). An experienced moderator will guide the sessions, which will be audio recorded for further transcription. Nonverbal instances will be observed during the discussions and gathered by a research assistant. Focus group discussions will be transcribed verbatim and thereafter analyzed. Inductive analysis will be performed by two independent researchers and agreement between researchers will be looked after. This process will yield a series of critical themes representing the key results of this part of the project.

The aim of the qualitative analysis is to gain insight of what lies behind the numerical results and to understand which behaviors, beliefs or situations could explain these results. In view of the objectives of the study, the moderator will explore following questions:

- Having seen the raw results and your experience, how do you appreciate the primary and the four secondary outcomes results? Is it not enough, right amount, or too much?
- What are the causes of mismatch, interruption or perturbation?
- What are the needs for professional satisfaction? How can we meet your expectations?

4.7 Statistical methods

A first analysis will be conducted to produce the descriptive results for this study. Descriptive results for the participant's characteristics will be expressed as average ± standard deviation or as number of participants and (percentage) according to the variable of interest. We will use a mixed model using the participant as a cluster to compute means and corresponding 95% confidence intervals for the times dedicated to each activity. The percentage of a participant's shift time devoted to each activity will be computed by dividing the time for that activity by the total shift duration.

The second analysis will compare the first and second surveys. The analysis will be conducted using mixed models using the participant as a cluster (random part) and adjusting for the participant's characteristics (fixed part). Results of the multivariate analysis will be presented as multivariable adjusted average and corresponding 95% confidence interval. One-sided tests will be used and statistical significance will be considered for $p < 0.05$.

4.7.1 Hypothesis

The null hypothesis is that no intervention changed any outcome. The alternative hypothesis is that interventions reduced the time spent for administrative tasks. Secondly, it reduced task-switching and, on the contrary, increased time with patients.

4.7.2 Sample size

Based on four previous and similar studies (Ammenwerth *et al.*, 2009; Block *et al.*, 2013; Fletcher *et al.*, 2012; Westbrook *et al.*, 2008) that studied between 12 to 29 doctors, we have chosen a convenient sample of 35 residents. Each resident will be observed during two shifts.

Using an average time spent on administrative tasks (92 minutes per dayshift), a standard error of 36 minutes, a one-sided test, a significance of 0.05, a power or 80%, and supposing equally sized samples (either 36 doctors or 66 observations as in our 2015 baseline study), then the minimum detectable effect size will be 20 minutes, which corresponds to a reduction of just over 20% of the time dedicated to administrative tasks. Calculations were performed using the **power twomeans** command of stata and recalculating the standard deviation from the standard error. The full code can be provided upon request.

Depending on the final number of residents consenting to participate, we will end up with a sample size of up until 70 observations.

4.7.3 Dataset

The observer, using a tablet application will record following data:

(1) **Activities**. 22 activities were defined for our 2015 baseline study and are presented in the **appendix 1**. Activities are exclusives: a resident cannot do two activities at the same time.

(2) **Circumstances.** The observers will record following circumstances for each activity. They are not exclusive: presence of the patient, usage of computer, usage of phone or smartphone, presence of one or more colleague.

(3) **Perturbation.** Perturbation is a factor slowing or compromising the current activity. Perturbation begins with detection of the problem and ends with return to the index situation. They are exclusive: usage problem; missing information; missing people; communication conflict

(4) **Timestamp.** Each time a resident starts a new activity or when circumstances change, a timestamp with precision up to the second is recorded. Delta between two timestamp defines the duration of an activity. At the end of the day, a timestamp "end of observation" is recorded.

4.7.4 Data management

The data from each observation shift will be saved in an Excel file, using a tablet with a dedicated application allowing recording of activities and settings in real-time. Each line in the text file will contain the task and the task start time, so that the task times flow continuously. The time spent on all occurrences of each task will be summed to generate the total time spent on each task for each subject. The final database will be saved in Stata format and hosted in one of the CHUV servers. All databases will be accessible by the investigators of the study only. The CHUV has implemented strict security policies regarding IT infrastructure and data protection, which are detailed in **appendix 2** and **3**. Paper and electronic data will be kept for a period of 10 years and then destroyed/erased according to the CHUV protocol.

4.8   Methods of minimizing bias
Based on literature and our previous study, we identified the following potential biases.

(1) The observation bias (Hawthorne's effect) cannot be avoided. We will recruit observers among medical students, acting like other students in our ward. We will not communicate the day of observation to the resident. No contact between the observer and the resident will be allowed with the following exception: observer may occasionally ask the resident for precision about the current activity, if in any doubt about what he is doing.

(2) Observers might misinterpret the current activity of a resident, occasionally or systematically. We will train observers with a standard video and blank observations. During a subsequent meeting, the observers will share their experiences and each dubious interpretation of activities will be answered and protocoled. Finally, we will assess and publish reproducibility during the practice session.

(3) The workload of a resident highly depends on the number of patients in his charge, day of observation, and backlog of administrative task. To minimize this, we will randomize the shifts to be observed, with stratification to the day of the week.

(4) We are already aware of the results of the "before" observation. We might therefore misguide observers towards the expected outcomes. During the study period, the observers and the investigator will be blinded to the results. A single designated investigator will check and process collected data to avoid IT issue.

(5) Residents may misinterpret the present study as a way for the management to check their duty hours and then retaliate, despite the assurance of anonymization. This misunderstanding could lead to major modifications in the behaviour of some residents but it will not be possible to assess in what way: would they stay later on purpose or, on the contrary, end at the official time? We will mitigate this risk by designing an external and neutral person as "ombudsman".

(6) The design of our study is based on a consistent observation on both before and after groups. Nevertheless, we considered the implemented reforms as interventions and chose outcomes described in the present protocol afterwards. We may thus have eliminated unfavourable outcomes.

4.9   Safety
No safety issue is associated with the present protocol.

5   ETHICAL AND REGULATORY ASPECTS

In 2015, for our baseline study, the local ethical committee certified that no protocol approval was required, arguing the absence of intervention or collection of data on patients. The present study will use the same design but we will still renew the request to the local ethical committee. We will inform all participants during a dedicated meeting. Presentation support will be kept available. We will ask for written consent before the randomization of observation. We will not disclose the identity of residents refusing consent to the management. No patient identity nor other characteristic will be recorded during the study. Observers are legally bound to confidentiality as mentioned in al 2, art 321 and art 321bis CP.

5.1   Conflict of interest
None.

6   COMMUNICATION OBJECTIVES

Based on the 2015 baseline study experience, we will communicate the results as follows:

(1) **SSMIG-Foundation**: We will first send an intermediate report to the SSMIG-Foundation with the preliminary results, including the description of interventions indicated in section 4.4.

(2) **Specialty congresses**: We will submit the content of the report as an abstract to the SSMIG annual meeting. Preliminary results will be communicated in internal medicine congresses like SSMIG, ECIM, ACP Congress, and others. We expect to present several posters and/or oral presentations.

(3) **Scientific publications**: We will submit the main results to a high impact factor journal; the first target journal will be *Annals of internal medicine*. We also expect to submit at least two other manuscripts, either as a full article or as a short communication. The focus group results will be published apart and in more details. Clinical governance and human resources aspects will also be addressed.

Subject	Type	Journals (example)
Main article : primary and secondary outcomes	original research	Ann Int Med
Results of focus group : comments and expectations of residents	full article	Eur J of IM
Correlation of localisation and activities	short report	BMJ quality and safety
Ward rounds : in/out of the room	full article	BMC Med Educ
Comparison with other hospitals, after replication studies (see below).	full article	Swiss med wlky

Table 3. Publication plan

(4) **Quality and clinical governance networks**: We will share our work through several groups as: *Quality Improvement in Swiss Primary and Hospital Care* or *Académie suisse pour la qualité en médecine*.

(5) **Lay media**: Our publication in *Annals of internal medicine* reached the top 5% of all research outputs scored by Altmetric (2017) and received a clear interest in local (www.letemps.ch, www.nzz.ch) and international (www.foxnews.com) non-scientific media. A collaboration with the media relations group of the CHUV will be established: multilingual press releases will be issued jointly and sent to interested media upon publication of the main results; whenever possible, the media channels of the scientific journals will be solicited to increase public visibility of our findings. Short communications will be also published in the social network accounts of the CHUV, and interviews or press conferences – if requested – will be given in close relationship with the media relations group of the CHUV.

(6) Replication studies: Baden hospital replicated our 2015 baseline study in 2017.(Frey *et al.*, 2017) We will continue to encourage replication studies in Switzerland and abroad, by freely transferring tools and methods.

7 STUDY SCHEDULE

Table 4 and **Figure 1** present the study schedule. To avoid bias related to the beginning and end of rotations, and seasonal variation of activity, it is absolutely mandatory to match the period of observations (★) with the 2015 baseline study. Therefore, we will prepare the study until the "point of no return" (✈). In the absence of funding, the study will be postponed to the following year.

Tasks	Start	End
Preparation	01.01.2018	11.05.2018
Protocol preparation	01.01.2018	27.02.2018
Protocol submission	28.02.2018	28.02.2018
Ethical committee approval	05.03.2018	27.04.2018
IT tools preparation	05.03.2018	11.05.2018
Tablet application	05.03.2018	27.04.2018
Building observers team	09.04.2018	18.05.2018
Recruitment of observers	09.04.2018	26.04.2018
Pre-selection of candidates	27.04.2018	27.04.2018
E-learning	27.04.2018	30.04.2018
Half-day training (all candidates together)	01.05.2018	01.05.2018
Selection of observers	02.05.2018	02.05.2018
Point of no return (no fund, no study) ✈	**07.05.2018**	**07.05.2018**
Half-day blank observation (one per observer)	07.05.2018	18.05.2018
Study time	14.05.2018	31.08.2018
Randomization of days of observation	14.05.2018	18.05.2018
Observations ★	**21.05.2018**	**20.07.2018**
Focus group	30.07.2018	31.08.2018
Analysis	23.07.2018	31.12.2018
Processing of data	23.07.2018	24.08.2018
Focus group analysis	03.09.2018	28.09.2018
Statistical analysis	27.08.2018	21.09.2018
Description of intervention	24.07.2018	28.09.2018
Writing	01.10.2018	31.12.2018
Communication	03.12.2018	30.05.2019
Intermediate report to SSMIG-foundation	03.12.2018	31.12.2018
Presentation and publication	01.01.2019	30.05.2019

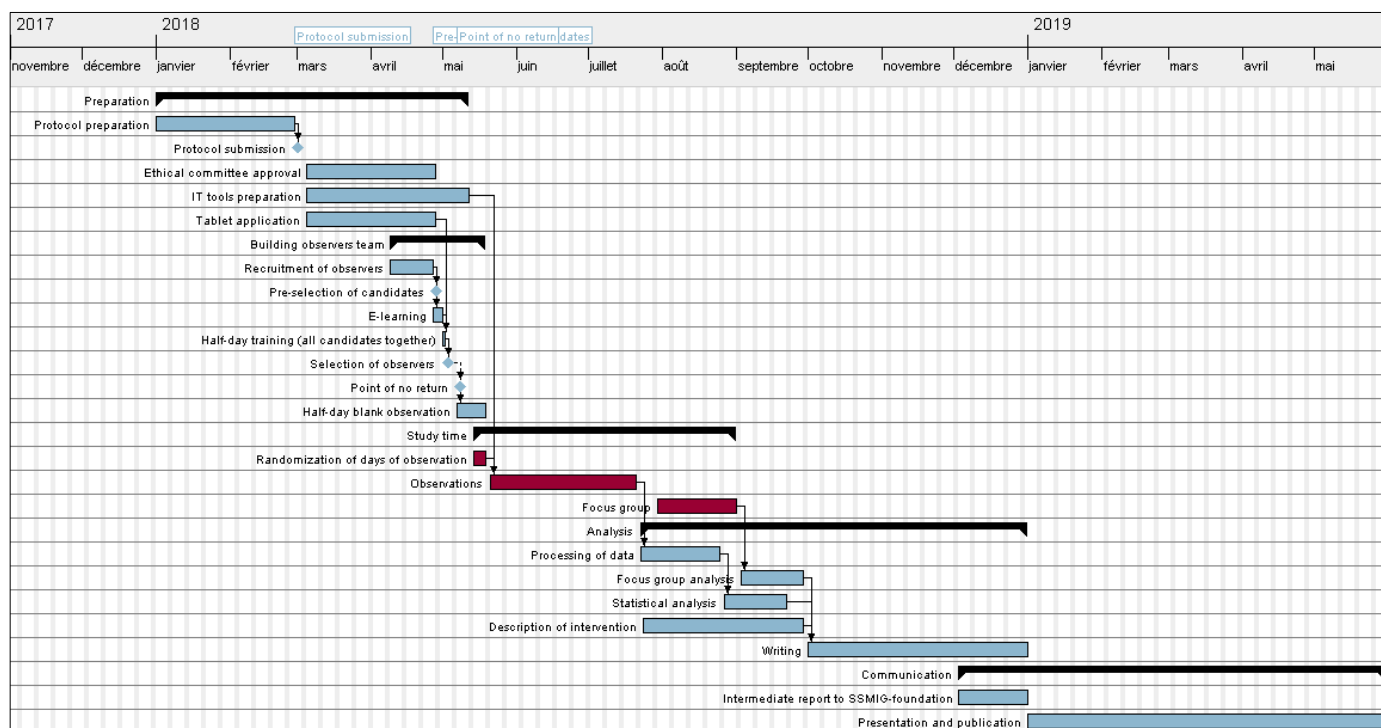*Table 4. Detailed study schedule with milestones. IT: Information technologies.*

Figure 1. Gantt chart for study plan.

8   BUDGET ESTIMATION

Table 5 presents the forecasted expenses and incomes of the study. The data of the 2015 baseline study are available without additional charge.

Item	Amount and rate	Expenses	Incomes Internal funding	SSMIG-foundation
Cost of observer labour: Day hours 6 am to 8 pm) Special hours (8 pm to 6 am)	24 CHF / hour 31 CHF / hour			
Half-day training Half-day blank observations	4 hours 8 hours			
Number of observers	5 to 8			
One day shift One evening shift	11 to 15 hours 4 h and 3 to 5 special h			
Number of observed shifts	70 (2 x 35)			
Total day hours	50 * (11 to 15) + 20 * (4) + 12 * (5 to 8) = 690 to **926 hours**	CHF 22'220		CHF 22'220
Total special hours	20 * (3 to 5) = 60 to **100 hours**	CHF 5'020		CHF 5'020
Project manager	3 months, part time	CHF 10'000	CHF 7'000	CHF 3'000
Dactylography skill test	35 * 30 CHF	CHF 1'050		CHF 1'050
Recording device (tablet)	4 * 400 CHF	CHF 1'600		CHF 1'600
Preparation of tablet application		CHF 5'000	CHF 5'000	
Devices for localization (beacons)	50 * 50 CHF + 500 CHF	CHF 3'000		CHF 3'000
Focus group manager		CHF 12'000	CHF 7'000	CHF 5'000
Statistician fee	50 * 120 CHF	CHF 6'000	CHF 6'000	
Publication fee provision		CHF 2'000		CHF 2'000
Communication, transport, posters		CHF 1'000		CHF 1'000
Overhead	(15%)	CHF 9'110	CHF 3'000	CHF 6'110
Total		**CHF 78'000**	**CHF 28'000**	**CHF 50'000**

Table 5. Estimation of expenses and incomes for the study.

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10   APPENDICES

Appendix 1   Description of the 22 possible activities of the resident, that an observer may record using the dedicated tablet application.

Appendix 2   Politique de sécurité des systèmes d'information des hospices / CHUV. Hospices-CHUV. Direction générale. 26.08.2005 (available upon request)

Appendix 3   Exigences de sécurité des systèmes informatiques. 02.03.2016 (available upon request).

Appendix table 1. Description of the 22 possible activities of the resident, that an observer may record using the dedicated tablet application. * Activities considered as administrative tasks for the primary outcome.

Category	Activity	Description
Directly related to patients	Admission	Anamnesis, clinical examination, and communication with the patient. Starts when the resident is looking after a new patient.
	Patient rounds	Daily medical round of inpatients the resident is in charge of: EMR review, anamnesis, clinical examination, prescription of treatments, and orders. Also includes daily sign-out round at the nursing desk.
	Patient discharges activities	Preparation for patient discharge: Prescription writing, last interview with the patient, and delivery and explanation of prescription.
	Clinical procedures	All medical procedures performed by the resident on a patient, including but not limited to arterial blood gas testing and punctures (e.g., ascites, lumbar, or pleural).
	Out of unit support	Attendance of the resident alongside the patient outside the ward: Oversight during examinations, transfer to another department, and emergencies.
Communication	News delivery	Bad news or therapeutic orientations that need a specific additional interview and patient educational therapy.
	Family meeting	Communication with family, close relatives, or nonprofessional caregivers. Time for providing information, explanation, and collecting information and opinions.
Indirectly related to patients	Looking for information *	Looking for information in the paper record, EMR, computer archives, or other medical record. Excludes admission activity.
	Literature review	Looking for scientific data to improve/determine patient management, including medical textbooks, scientific papers, and Web sites.
	Writing in medical record	Writing notes, problems list, handoffs, or examination results. Excludes admission activity and discharge report.
	Discharge summary redaction *	Any activity related to writing hospitalization reports: brief report and discharge letter. Includes revision of reports.
	Handoffs	Giving or receiving handoff, including preparation of documents, attending a handoff meeting, receiving/giving telephone information, or sharing information.
	Supervision	Discussion with a senior physician (chief resident or chief physician) focused on a patient and resulting in a decision on patient management.
	Talking with providers/collaborators	Collecting information, booking an appointment, requesting examination or specialized consultation, and asking for consultants' advice.
	Patient administrative tasks *	Administrative tasks for the patient: booking appointments, writing the voucher for radiography or specialized consultation, and adding laboratory tests.
	Multidisciplinary board	Multidisciplinary boards and meetings between professionals to discuss management of ≥1 patient.
Academic	Receiving training	Participation in a training conference or the attending round (medical round supervised by the chief physician), self-preparation, and paper review.
	Teaching	Resident teaches students, collaborators, and nurses. Includes supervision of an admission done by a student.
	Academic research	Research work, thesis, and publications. Excludes literature review.
Non-medical tasks	Non-patient administrative task *	Activity unrelated to the patient, directly or indirectly (e.g., answering professional e-mails).
	Personal activities	Time dedicated to the resident's personal needs unrelated to the clinical activity: food, restroom, and private use of telephone or computer.
Transition	Transition time	Time required for transition to another activity: moving, handwashing, dressing, and fetching or bringing something.