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Feasibility of a connected interface implementation to foster the continuity of inpatient care: A pilot protocol for physicians handovers, in a tertiary maternity

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We use this protocol in our group to work on the methodological procedures of a clinical trial or the purpose of transparency. The name of the study is Electronic Record for Continuity of Patient Care: A use case for Doctor's handovers in hospitals. Trial Registration: ClinicalTrials.gov: http://ensaiosclinicos.gov.br/rg/RBR-5n4686/ f

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Abstract

Background: Handovers sessions are relevant medical activities in hospitals. Effective communication during the transfer of care is critical to foster the continuity of medical assistance and patient safety. In this opportunity, Electronic Health Records (EHR) has the potential to provide prompt and reliable information for authorized users of electronic systems, supporting decisions and offering alerts for critical conditions.

Objective: To report a study protocol to evaluate the impact of an electronic handover implementation that supports the information transference of care, during doctors shifts sessions.

Methods: Research protocol for connected interface implementation, single-group clinical trial to compare data-quality outcomes pre-post implementation of the intervention. A a random sample of handover sessions will be selected to assess the impact of the intervention. During the predeployment step, paper-based handover formularies will be recollected and analyzed. The priorities of health information transfer during handover, as well as its legal and security aspects will be used to add requirements to the novel system of communication. The handover system, integrated with the existent electronic medical record, will be developed according to the best clinical practice in care transference and obstetric protocols based on evidence. After EHR implementation, an after-before analysis will assess the impact of the invention. Primary outcomes are the quality of information registered in the medical handover record and data security, namely authenticity and traceability. As a secondary outcome, the duration of the transfer of care an external observer using a chronometer will evaluate sessions.

Results: The study began in March 2018 with the training of the researchers to collect data during handover sessions. The first in loco evaluation of a handover session occurred: 2018-04-20. Planned date for the post-deployment evaluation is: 2019-08-31. Data analysis will be finalized and the final results are expected for December / 2019. This feasibility trial will confirm whether a connected interface implementation could impact in the quality of information transferred during doctors shifts sessions.

Ethics and dissemination: Ethics review board approved the trial protocol. The authors intend to share the minimal anonymized data set necessary to replicate study findings.

Attachments

PDF

ICTRP Search Portal....

191KB

Background

1 The hospital environment has a dynamic nature with potential for breakdowns in communication [1]. Handovers sessions periodically happen to transfer professional responsibility for some or all care for a patient between physicians and/or professional group [2]. The implementation of the electronic handover has the challenge to ensure this dynamism, enabling the safe updating of information on care and patient-related behaviors [3]. Electronic approaches have been described to overcome the deficits of variable and unstructured forms of clinical handover [4]. Electronic Health Record (EHR) is a longitudinal health record with entries by healthcare practitioners in multiple sites where care is provided [5]. Such essential properties of the registry are supposed to provide prompt and reliable information for authorized users of electronic systems, supporting decisions and offering alerts for critical conditions [6]. This report is a study protocol to evaluate the impact of a connected interface implementation with an existent EHR to support the information transference of care during doctors shifts sessions.

Methods

2 **Study design**

Research protocol for connected interface implementation, single-group clinical trial to compare data-quality outcomes pre-post implementation of the intervention.

3 **Setting**

The scenario of this study is tertiary care university-affiliated maternity, with 2900 births-per-year and 31 beds. A staff of novice and senior physicians gathers five doctors working 12 hours on duty; one of them is the leader in charge. Verbal and written handovers occur twice a day, at 7 am and 7 pm.

4 **Research ethics approval**

The protocol of research was approved by the institutional review boards in Brazil, the Ethics Committees of the Universidade Federal de Minas Gerais, with a national register number in Plataforma Brasil: CAAE 82095517.3.0000.5149. A written informed consent was obtained from each participant of the monitored handovers.

5 **Dissemination policy**

The authors intend to share the minimal deidentified data set necessary to replicate the study findings.

6 **Declaration of interests**

There are no financial and other competing interests for the investigators, for the overall trial.

7 **Eligibility criteria**

Handover sessions randomly selected to assess the quality of health information in the written documentation. Exclusion criterion is the handover briefings in which physicians do not agree with the voluntary participation in the study.

8 **Intervention**

The intervention is an electronic handover interface, internally developed in the existent electronic medical record. The steps to choose the solution and implementation of the intervention are followed:

a) Analysis of the initial scenario and challenges for the electronic handover implementation

- Scientific background: to explore evidence and experience reports with a literature review concerning electronic handovers. Learning from previous experience.
- Challenges of the local situation: To access local practices of medical handovers with exploratory visits. A survey analysis of handover practices directed to clinical managers of the hospital.
- Legal electronic medical record (EMR) issues to attend: To explore standards for health data specification. To establish the needs for the system to ensure the persistence in the database, and to protect individual data.
- Stakeholders and end-users expectations: To confer with the chief information officer (CIO), as well as the Local Quality and Safety Committee, and with the Clinical Directory.

b) Requirements analysis and specification

- Functional: to point needs to overcome the deficits of variable and unstructured forms of clinical handover
- Non-functional: to specify constraints on the services or functions offered by the system

c) A pilot test for validation: to evaluate the user impression and re-designed the template with the end-user in mind, if necessary. To provide an implement version control, to manage code development. When existent, to analyze valid reasons to do not implement a specified requirement.

d) Full implementation: Promotion and installation with the training of end-users.

e) Monitoring and analysis of the pre- post implementation scenario: A 3-month follow-up of the electronic handover implementation to evaluate system efficiency with primary

and secondary endpoints.

Expected result

A connected interface will able physicians to prompt access to individual clinical data and easily prepare an electronic written summary to support handover routine.

9 **Primary outcomes**: Specific metrics will assess endpoints of interest to compare pre-post implementation

- Outcome 1: The quality of information registered in medical handover written reports.
- Outcome 2: Security of demographics and health information recorded in medical handover records.

10 **Secondary outcome**

Lenght of the transfer of care sessions between doctors shifts; evaluated by an external observer using a chronometer. 00:00:00

11 **Data collection**

a) Analysis of the initial scenario and challenges for the electronic handover implementation

Tool 1: Questionnaire about care transitions practices directed to clinical managers of the Hospital to explore local practices of medical handovers.
TOOL1_SURVEY.pdf

b) Standard procedure to measure primary an secondary endpoints

Tool 2 : Quality of information registered in the medical handover written reports. The variables to assess quality are:

- Authenticity of data, and traceability of the report: patient identification as complete name and number of the hospital register, bed location, date and time of registration,

the name of responsible professional, the existence of a secure copy of the handover report.

- Analysis of data quality in handovers content: clinical history, facts about the hospitalization, diagnosis, alerts for severe conditions, critical problems or values, adverse events, allergies, plan care. The existence of such data will evaluate the quality of central elements in the communication of the transfer of responsibility for care, based on SBAR handoff technique of communication: situation, background, assessment, recommendation [7].

TOOL2_QUALITY_OF_INFORMATIO...

c) The length of handover session will be measured using a chronometer.

12 **Trainig and certification of observers**

Before monitoring handover sessions, four observers are trained and certificated by the main investigator at 04/14/2018. Data collection will be performed by health professionals and medical academics who have undergone training following the standard operational procedures. Tools for data recollection were pre-tested with real clinical histories obtained during the scenario exploring.

SOP_SESSIONS-EN.pdf

13 **Pre and post intervention evaluation timeline**

	STUDY PERIOD		
	Pre-implatation	Intervention	Post-implatation
TIMEPOINT**	*3 months* $-t_3$	0	*3 months* $+t_3$
ENROLMENT:			
Random sessions of medical handover	X		x
Informed consent for the physisicians	X		
INTERVENTION: Implementation of an electronic handover interface		X	
ASSESSMENTS: Primary outcome 1 - Quality of information in written handover reports Primary outcome 2 - Authenticity of data, and traceability of the handover report	X		X
Secondary outcome - The length of handover session	x		X

14 Statistical methods for data analysis

a) Sample size: To test the hypothesis of equivalence between the pre-post intervention on the quality of data, a sample of 349 clinical histories is necessary to detect an effect size of 15%. We assumed an alpha error of 0.05 and a power of test 0.80 to support a chi-square test with one degree of liberty.

Sampling intends to arrange two groups randomly selected pre- and post-intervention with 175 clinical histories each one. For this, 18 handover sessions will be selected in each group, with the expectation of 10 individual clinical reports per handover. For the control-group, an electronic system chose for chance 18 date-time of handovers, in a list of 180 consecutive date-times between April and June/2018. After 3 months of the full implementation of the intervention, similar approach will select the case-group.

b) Data analysis: Demographics and baseline characteristics of the study group, as well the intervention measurements, will be summarized by the frequencies and the mean and standard deviation (SD), the whereas median and interquartile range will be preferred for non-normally distributed continuous variables.

Regarding primary endpoints, category variables will be compared by means of association tests. Regarding the secondary endpoint, length of handover sessions, the modification of this numeric varible will be compared by independent t-test. The significance level for hypothesis tests will be 5%, together with 95% confidence intervals.

15 **Appendices**

Ethical approval

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