Measuring Clinical Workflow to Improve Quality and Safety

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28.1 What Is Clinical Workflow?

Clinical workflow at its most simple is the sequence of steps associated with delivering healthcare—the 'who, what, when, where, for how long, and in what order' of each task. However, healthcare is complex and dynamic with many interdependencies. In such an environment, tasks are rarely completed in a linear, step-wise fashion. Work tasks may be paused, interrupted, performed simultaneously, or be inter-dependent on other tasks or other clinicians. In many settings clinicians manage the care of multiple patients concurrently [1]. While information technology may assist in streamlining some processes and providing guidance during task completion, it often changes workflows in both expected and unexpected ways [2].

Quantitatively measuring clinical work patterns requires some form of classification for categorising elements of work. For example, clinical work can be conceptualised in terms of broad categories of: direct care with patients; communication with patients/families/colleagues; test ordering and reviewing results; documentation; managing medications; indirect care tasks associated with organising equipment, information, coordination of care tasks; teaching and mentoring; social interactions and breaks; and administration. The complexity of clinical work increases with each additional person, process or technology added to the system.

Each step in a process is a point at which clinical work (healthcare) can go right or wrong. Thus, each step in clinical workflows is a potential target for improving the safety and quality of care delivered. Many factors will impact the safety of clinical work, from an individual's level of fatigue, to the organisational culture, e.g. whether staff feel able to seek advice. An understanding of clinical work, including the characteristics of individuals and the environments in which work is performed, is essential for the targeting of safety interventions. Safe clinical work is responsive to contextual factors, many of which may not be predictable. Thus, understanding how clinicians use strategies to manage and adapt their work in response to contextual factors [3] is central to understanding how to support resilient and safe health systems.

Since the publication of the Institute of Medicine's report To Err Is Human in 1999 [4],

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L. Donaldson et al. (eds.), *Textbook of Patient Safety and Clinical Risk Management*, https://doi.org/10.1007/978-3-030-59403-9_28

there has been growing concern about the potential for medical errors due to the disruptive nature of clinical work environments. Hospital environments have been characterised by dynamism, complexity, interrelations, time and resource constraints, and have been identified to be at greater risk of errors than many other settings [5–8]. Due to the interconnected nature of clinical work, the introduction of a new technology or other system interventions may have unintended knock-on effects. A thorough understanding of clinical workflow contributes to the anticipation and containment of such unintended consequences.

28.2 Studying Clinical Workflow

28.2.1 Approaches for Studying Clinical Workflows

Some traditional methods used to study clinical work and its resultant outcomes (safety), include compiling and assessing medicolegal claims, medical record review, performance assessment, international quality and safety indicator benchmarking, and initiatives such as the Italian National Outcome Plan (Italian PNE). Each of these approaches contributes data to provide information on particular safety issues on which there may be potential to intervene. Often evaluations of safety rely upon such administrative data but many of these sources fail to reveal the context in which clinical care was performed: the social dynamics, the interactions with devices and tools, behaviours that adapt to circumstances, and the patient's changing condition.

Direct observation of clinical work in situ provides an opportunity to gain new insights into the relationships between the way work is performed in everyday situations and the safety of care delivered. Data focusing on clinical workflow and clinical outcomes are essential for identifying critical issues and organisational solutions to improve quality of care, ensuring reasonable workloads and the well-being and safety of both healthcare providers and patients.

Quantitative studies of clinical work can deliver data on the time spent managing different types of activities, their frequency and duration, along with the frequency, duration and sources of interruptions and disruptions to work. The extent to which clinicians work on multiple tasks (multitasking) can also be assessed. These data can be compared with staff perceptions of their work patterns. For example, measuring observed sources of interruptions compared to reports of interruption sources by staff may identify types of interruptions which cause the most disruption/annoyance to clinical staff [9]. Thus, sharing quantitative direct work observational data with staff provides a valuable source of evidence to raise awareness of actual work practices and can inform the design of interventions to support safe work.

Gathering comprehensive information about clinical workflows within a wider organisational context is not a simple matter; at best, data will represent a snapshot related to a specific time frame and be closely related to specific social and organisational dynamics. Further linking work patterns to specific outcomes can be methodologically challenging.

28.2.2 Time and Motion Studies

'Time and motion' research is an overarching term for a range of direct observation methods that aim to continuously observe and record an individual's activities over a certain period of time. Early examples of time and motion studies in healthcare often focused on efficiency. Time and motion clinical workflow studies have more recently been moving towards linking workflows and clinical outcomes, but this is more challenging.

The development of technological tools for collecting time and motion observations has allowed the design of more comprehensive, multidimensional studies. A variety of computer-based tools are available for recording time and motion data to study clinical workflow [10]. Such tools free observers from recording, for example,

detailed time-task information, as electronic timestamps are automated. Such tools have moved beyond just collection of information about task frequency and time to consider dimensions such as the location of work, people involved, and tools/equipment used. Given research evidence of the potential safety implications of excessive interruptions to clinical work [11], most tools will also seek to collect information about interruptions/disruptions and multitasking behaviours.

One such tool is the Work Observation Method By Activity Timing (WOMBAT) technique [12], originally developed in 2007, which provides a reliable method for investigating clinical work and communication patterns, and how these are impacted by the implementation of interventions such as health information technologies. WOMBAT advanced existing time and motion methods by enabling the collection of multiple dimensions of work (e.g. who, what, when, why and how) that are all accurately timestamped, thus better reflecting the complexity of clinical work. Rather than only being able to record one task at a time, WOMBAT can record multiple tasks occurring simultaneously (multitasking), capture all the characteristics of the tasks that are occurring, as well as automatically timestamping the duration of each task and the duration of overlapping (multitasking) time. WOMBAT can also be used to record tasks that have been interrupted by another task, capture the characteristics of the interrupting task, capture the duration that the task remains interrupted, as well as if, and when, the interrupted task is returned to. Comprehensive contextual information about the other people involved in tasks (e.g. patients, colleagues), time of day/week, location and any other characteristics can be included in a WOMBAT data collection template to capture and build a picture of how clinical work is performed in the real world. These rich, multidimensional data assist in elucidating the links between workflow and safety. The workflow time study approach combined with surveys or interviews increases the potential to capture work complexity, social dynamics and personal motivations. Obtaining baseline data about current patterns of work is also important for assessing the effects of interventions designed to improve care delivery models.

28.2.3 What Types of Questions Can Clinical Workflow Studies Answer?

Clinical workflow studies can be used to investigate a range of questions related to the relationship between work and safety. For example, to:

- Describe and compare the work patterns of different professional groups to consider implications for cognitive load and safety. Also, to allow comparisons between groups, settings, time and countries [13–15].
- Assess compliance with safety procedures. For example, Gon et al. investigated specific hand hygiene practices among birth attendants in Zanzibar [16].
- Identify workflow effects on cognitive load (e.g. interruptions, multitasking) and errors. For example, by examining the extent of interruptions to work, response to interruptions and also whether these interruptions were associated with task errors [1, 5, 11, 17, 18].
- Measure the impact of interventions or new practices on clinical workflows, and the potential impacts of any changes to safety [15, 19–21]. For example, Westbrook et al. conducted a study of pharmacists' work in the UK and Australia before and after the implementation of an electronic medication management system to assess changes in their task-time distribution and interruption rates [15] (Table 28.1).

28.2.4 Interruptions

One area of clinical workflow that has received more intensive study has been the association between errors and work interruptions [44]. Interruption science represents one of the models for how we can approach the broader study of socio-technical systems in patient safety [45]. The combination of multitasking (carrying out multiple tasks simultaneously) and interruptions

Table 28.1 Studies using the Work Observation Method By Activity Timing (WOMBAT) technique to measure clinical workflow and relationships with patient safety

Clinical workflow studies measuring work patterns of different groups			
Ampt et al. [22]	2007	Registered nurses	Australia
Ampt and Westbrook [23]	2007	Nurses (geriatric, respiratory, renal/vascular)	Australia
Ballerman et al. [24]	2011	ICU staff (physicians, nurses, respiratory therapists, unit clerks)	Canada
Bellandi et al. [25]	2018	Doctors and nurses in surgical units	Italy
Cavaye et al. [26]	2018	Community pharmacists	Australia
Graham et al. [27]	2018	ED physicians	Canada
Hand et al. [28]	2019	Renal dialysis dieticians	USA
Holmqvist et al. [29]	2018	Nurses in home healthcare	Sweden
Lehnbom et al. [30]	2016	Paediatric hospital pharmacists	Australia
Shaw et al. [31]	2011	ICU nurses	Canada
Westbrook et al. [32]	2011	Nurses	Australia
Westbrook and Ampt [12]	2009	Nurses	Australia
Westbrook et al. [33]	2008	Hospital doctors	Australia
Sinsky et al. [34]	2016	Physicians (primary, cardiology, orthopaedics)	USA
Clinical workflow studies examining contextual factors that impact workflow			
Arabadzhiyska et al. [35]	2013	Junior doctors	Australia
Hefter et al. [36]	2015	ICU physicians and physician assistants	USA
Hefter et al. [37]	2015	ICU physicians	USA
Hefter et al. [38]	2016	ICU physicians	USA
Li et al. [39]	2016	ICU physicians	Australia
Richardson et al. [13]	2016	Junior doctors	Australia
Walter et al. [17]	2014	ED clinicians, ward doctors, ward nurses	Australia
Walter et al. [3]	2017	ED physicians	Australia
Walter et al. [1]	2019	ED physicians	Australia
Clinical workflow studies examining cognitive load, interruptions, multitasking, errors			
Ballerman et al. [40]	2010	ICU staff (physicians, nurses, respiratory therapists, unit clerks)	Canada
Ballerman et al. [21]	2012	ICU staff (physicians, nurses, respiratory therapists, unit clerks)	Canada
Ballerman et al. [41]	2010	ICU staff (physicians and nurses)	Canada
Bellandi et al. [25]	2018	Doctors and nurses in surgical units	Italy
Hefter et al. [37]	2015	ICU physicians	USA
Hefter et al. [38]	2016	ICU physicians	USA
Walter et al. [17]	2014	ED clinicians, ward doctors, ward nurses	Australia
Walter et al. [3]	2017	ED physicians	Australia
Walter et al. [1]	2019	ED physicians	Australia
Westbrook et al. [11]	2018	ED physicians	Australia
Westbrook et al. [33]	2008	Hospital doctors	Australia
Clinical workflow studies examining effect of interventions or changes in practice			
Ballerman et al. [42]	2011	ICU staff (physicians, nurses, respiratory therapists)	Canada
Callen et al. [19]	2013	Nurses (Rheumatology dept)	Australia
Georgiou et al. [20]	2017	ED physicians	Australia
Westbrook et al. [2]	2013	Hospital physicians and nurses	Australia
Westbrook et al. [9]	2017	Nurses	Australia
Westbrook et al. [15]	2019	Hospital pharmacists	UK and Australia
Westbrook et al. [14]	2016	Hospital pharmacists	UK and Australia
Lo et al. [43]	2010	Hospital pharmacists	Australia
Clinical workflow studies examining compliance with specific safety procedures			
Gon et al. [16]	2018	Birth attendants in labour wards	Zanzibar
Westbrook et al. [9]	2017	Nurses	Australia

is a potent latent source of clinical error [33, 46, 47]. Direct observation in situ can assist in understanding the nature of interruptions and their impacts. For example, a study of emergency department physicians measured the relationships between interruptions and prescribing errors and demonstrated that physicians were nearly three times as likely to make a clinical prescribing error when interrupted [11].

The strategies that clinicians use to respond to interruptions can also be observed [3, 17]. Such data may provide insights into why many interruptions do not result in harm [44] and point to interventions which may effectively reduce unnecessary interruptions, as well as mitigate their negative effects. Considerable attention during the study design phase must be placed on clearly defining what constitutes an interruption and the types of response behaviours which may be observed [46].

28.2.5 Multitasking

Multitasking is an important dimension of clinical work. Workflow measurements have often not accounted for multitasking in a sophisticated way, that is, they have often had observers identify the primary task and ignore the collection of data on secondary tasks. More recent studies have started to develop methods for capturing concurrent work tasks and investigating their effects on cognitive load. For example, Westbrook et al. showed that among emergency physicians, multitasking while prescribing medication was associated with making more administrative/procedural errors (for example not using standard terminology), but not associated with an increase in clinical prescribing errors (e.g. wrong dose) [11].

28.3 Cultural and Organisational Considerations in Conducting Clinical Workflow Studies

Although tools such as WOMBAT provide a standardised methodology for conducting clinical workflow research, there are many important local factors to be considered when conducting these types of studies.

Examples of practical issues that must be considered include:

- *Study design*. Consider if a validated study data collection template (e.g. modelled on a published workflow study) would be suitable or if customisation is required to suit the local context (e.g. physical locations, types of clinical work tasks to be observed) or the particular research focus.
- *Ethical considerations*. Considerations around local ethics approval requirements, voluntary recruitment of study participants, obtaining consent from participants to be observed, procedures for study withdrawal, how to inform patients, and procedures for what observers should do if they observe a potential safety issue.
- *Patient privacy*. Clinicians may need to conduct procedures, physically assess the patient or discuss sensitive aspects of patient care, and thus observers need to always be cognisant of and respect patient privacy and dignity.
- *Engagement*. To facilitate buy-in from hospital management and staff, it is helpful to hold information sessions to discuss the research and introduce the observers, develop a positive rapport with staff, alleviate potential concerns about scrutiny of individual work practices (i.e. data from multiple participants is aggregated), and arrange feedback sessions to report key research findings.

28.4 Data Quality, Analysis and Interpretation in Clinical Workflow Studies

There are several challenges in analysing and interpreting data collected in time and motion studies [48]. Some difficulties concern the data processing steps needed in order to perform further statistical modelling, and stem from the data format and nature. Others are related to data quality and inter-observer variability, and further ones concern sampling units and the type of statistical tests that can be applied.

28.4.1 Important Practical Considerations with Ensuring Data Quality in Workflow Studies

- *Study data collection*
  Whenever practicable, it is preferable to use a validated data collection tool/technique. This ensures that the data variables to be collected have been previously tested and their definitions/scope well developed. Use of validated data collection categories also allows for direct comparison across study findings.
- *Sample selection*
  Consider the research questions and, thus, the type of staff that need to be included in the study sample (e.g. all staff or a specific professional group). Develop a sampling strategy to ensure that the collected data are representative across the sample of staff (i.e. proportion of time each participant or participant group is observed should be distributed appropriately, so that no one participant's/group's work practices are overrepresented proportionally to their contribution to the staff mix).
- *Observational period*
  With the study research objectives in mind, consideration needs to be given to determining the observation period (e.g. day/evening/night shifts, weekdays, weekends, public holidays). Observation periods should be equally distributed, and observation of participants should be randomised across the selected times/days/observers. The length of each observation session also needs to be considered. Depending on the work activities being captured, observer fatigue may set in after 2 h of intensive observation and impact data quality.
- *Observers*
  Observers are integral to the success of any observational workflow study. Consideration needs to be given to observer selection (e.g. is it vital for the observer to be a clinician or have clinical knowledge/understanding?). For example, in a study about nursing activities, ward nurses have the advantage of being familiar with the organisational process but must acquire skills and experience in using and interacting with the observation tool. External observers, on the other hand, can be more facilitated in interacting with WOMBAT, but require more training and discussion with healthcare workers to correctly identify and record observed activities. Observer training is also critical to ensure they understand the methods of data collection and are intimately familiar with the definitions/scope of the work activity variables to be collected. Where more than one observer is collecting data, inter-rater reliability among the observers needs to be measured to ensure data consistency and integrity. For studies with a long period of data collection, random inter-observer reliability measures should be undertaken throughout the data collection period to ensure the consistency of observers over time.

28.4.2 Analysis

A dataset from a time and motion study typically comprises data collected in different observation sessions, conducted at different times during the day/week, and possibly by different observers. In its minimal form, the dataset will have as many records as the number of "tasks" observed in the various sessions, one record (i.e. row) for each task. Observer, session and task-related information will be stored in several columns, along with other timing information (e.g. start and end times). In the presence of multitasking, to be able to accurately compute task-specific statistics, such as interruption rates or proportions of task times, for each task categories one must first identify all the instances of multitasking involving tasks of the same category. In these cases, in fact, simply summing up the durations of all the observed tasks in a category to get the denominators for computing rates or proportions (but also for regression modelling) would lead to underestimation of these statistics, since all multitasking instances (i.e. time intervals) involving two or more tasks of the same category would be counted twice or more. Identifying these instances and correcting the computation of the

statistics from raw data is not a trivial task and algorithms can have issues of computational time complexity.

To estimate confidence intervals and test hypotheses about differences between groups, valid methods can be, respectively, bootstrap resampling and Monte Carlo permutation tests. For both goals, in fact, parametric methods have limitations when the test measure is the proportion of a continuous variable (such as time on specific types of tasks), since the sample size is not clearly defined (there are conceptual ambiguities related to task definition), and the few proposed methods can have drawbacks such as allowing nonsensical intervals extremes (i.e. upper limit above 100%). Multilevel regression modelling is also an appropriate method for association studies, since it allows inclusion of covariates to control for factors that can be hard to control for in observational studies in a real context, and also to account for individual variability between participants, observers and setting/location. This is particularly suitable for multicentric studies in which multiple observers are used, and random variability related to these factors could reduce statistical power and undermine the possibility to draw conclusions on the effectiveness of interventions and/or limit the generalisability of the results.

28.4.3 Inter-observer Reliability

Finally, inter-observer reliability assessment, required when several observers are involved and to verify learning progress during training of observers, also presents many challenges, due to the multivariate, timestamped and ordered nature of the data from observation studies, which limits the applicability of traditional inter-rater reliability assessment methods [49]. First of all, measures such as Cohen's kappa, are only applicable to one variable at the time, so that high k scores for one aspect can be achieved even if two observers disagree substantially on other variables object of their observation (e.g. the presence/absence of multitasking, the category of the second tasks). Secondly, computing these measures first requires matching pairs of tasks from different observers' data referring to the same task, a problem that cannot be done with perfect certainty. A way to overcome this issue could be that of either using non parametric tests to compare aggregate proportions between different observers, which avoids completely the need of pairing tasks, or to restructure the data in smaller time windows (e.g. 1 s) which can be perfectly aligned and matched, although restructuring can be tricky and sometimes computationally costly. Janson and Olsson, moreover, proposed a measure of agreement between two or more observers on multivariate categorical data which could be used on the time window data to overcome the limitations concerning single measures [50, 51]. More generally speaking, it is necessary to be aware that a single method for assessing IOR will be always necessarily insufficient to address all the different aspects on which observers in time and motion studies can disagree, that there can be trade-offs between different possible alternatives that should be considered in the light of the specific study's aims, and strive to adopt a composite method whenever possible to limit the impact of observers' bias, and to be as transparent and detailed as possible in reporting the exact methods used.

28.4.4 Disseminating Findings to Influence Practice and Policy

An aspect that is often overlooked is the importance of disseminating the results of time and motion studies. It is clear that disseminating the outcome of a study in scientific peer-reviewed journals and at conferences is essential for increasing our understanding of workflow in healthcare contexts and of complex—and possibly disruptive—phenomena such as interruptions and multitasking. As was previously highlighted, given the great variability in workflow studies and in the light of the unique challenges they posit, it is very important to be explicit in reporting the details of the methodology, including the definitions of task categories, interruptions and

multitasking, as well as the IOR assessment strategy and methods used, beside the actual measures, to ease results interpretation and comparisons with different studies/contexts.

Less considered is the relevance of results dissemination within the organisational context in which a study was conducted. After a study was conducted workshops or dedicated ad hoc events should always be organised to present the results to the healthcare workers that were observed and the organisation's management team. Besides increasing staff awareness of the relevance of these phenomena and of their possible consequences in terms of errors, presenting and discussing results is a way to better understand and interpret the results. Involving all actors in the identification and refinement of possible organisational solutions to reduce or minimise the negative impact of these phenomena and ultimately increase safety and quality of care is also likely to increase the uptake of future interventions.

28.5 Conclusion

There is much to be learnt from the specific analysis of clinical workflow and how it relates to patient safety [5]. Time and motion studies provide a robust method by which to measure clinical workflows, particularly taking advantage of new electronic tools for data collection. Close collaborations between clinical staff and researchers conducting such studies is central for success, from the design stage to the final interpretation of results. Most importantly is ensuring that new information is used to inform changes in practice and policy which support clinical staff in their work to deliver safe care to patients.

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