Anna Maria Grugnetti[1], Rosario Caruso[2], Domenico Scognamiglio[3], Maria Cristina Monti[4], Cinzia Garofalo[3], Maria Cristina Monti[3], Mauro Oreste Meles[3], Cristina Arrigoni[5]

# Effects of Implementing Standardized Organizational Interventions on Drug Therapy Management (DTM): A Quasi-Experimental Study

[1] IRCCS Policlinic San Matteo Foundation and Department of Public Health, Experimental and Forensic Medicine, Section of Hygiene, University of Pavia, Italy
[2] Health Professions Research and Development Unit, IRCCS Policlinico San Donato, San Donato Milanese, Italy
[3] Azienda Socio Sanitaria Territoriale (ASST), Unità Operativa di Chirurgia, Lodi, Italy
[4] Department of Public Health, Experimental and Forensic Medicine, Unit of Clinical Biostatistic and Epidemiology, University of Pavia, Italy
[5] Department of Public Health, Experimental and Forensic Medicine, Unit of Hygiene, University of Pavia, Italy

**ABSTRACT. Background.** *Interruptions occurring during the drug preparation and administration have a documented effect on patients' safety. However, literature has paid little attention to show how the introduction of a set of standardized organizational interventions, based on the combination of the current evidence, could reduce the number of interruptions occurring during drug therapy management. For this reason, this study used the most recent evidence to combine a set of standardized organizational interventions, and it was aimed to assess the effect of those interventions on the number of interruptions occurring during drug therapy management (Hypothesis a) and the overall duration of the therapy administration (Hypothesis b).*
**Methods.** *A quasi-experimental study was performed, using pre- and a post- organizational implementation data collections in a single Italian center. The data collections were related to the interruptions and 40 shifts were randomly selected for both pre- and post-phase, respectively on December 2016 and February 2017. The standardized organizational interventions were implemented using the current evidence on this topic.*
**Results.** *The standardized organizational interventions decreased the interruptions in the post-implementation phase, but those had not an effect on the duration of the therapy administration.*
**Conclusions.** *This study represented an updated evidence, which describes the effect of a standardized and evidence-based set of organisational interventions' implementation on drug therapy management. Our results suggest a number of hints for managers and future researches. Managers should keep into account the usefulness of those interventions, while future researches with experimental designs are needed to provide harder evidence on this topic.*

*Key words:* disruption, distractions, interruptions, medication errors, therapy, nurses.

**RIASSUNTO. L'effetto dell'implementazione di un set standardizzato di interventi organizzativi sulla gestione della terapia farmacologica: uno studio quasi-sperimentale.** *Introduzione.* Le interruzioni di terapia hanno un documentato effetto sulla sicurezza dei pazienti in ospedale. Tuttavia, le evidenze a sostegno dell'introduzione di standardizzati accorgimenti organizzativi per ridurre le interruzioni sono ancora scarse. Per questo motivo, questo studio ha usato le più recenti evidenze combinate un modo standardizzato, con lo scopo di testare se tali interventi avessero un effetto sul numero di interruzioni (ipotesi a) o sulla complessiva durata della somministrazione della terapia (ipotesi b).
*Metodi.* Lo studio ha un disegno quasi-sperimentale, con approccio pre-post, in un unico centro ospedaliero

## Background

The data on drug therapy management (DTM) safety shows how the 6.5% of all the hospitalization is caused by adverse drug events in the United Kingdom (UK), providing an annual expense for the population estimated around 200-400 millions of pounds (1). Within all the reports of drug-related adverse events occurred in the UK from 2005 to 2010, 9.68% of them reported errors closely linked to DTM process (2). Moreover, the evidence shows that interruptions during DTM lead to an increased risk of errors and to increase the same errors' severity (3,4). In everyday nurses' working life, the interruptions during DTM are very common in different clinical settings (5). Properly, those interruptions are considered to be an important cause of injury for hospitalized patients (6,7). Therefore, implementing standardized and evidence-based organisational interventions to decrease the interruptions is challenging, and it is closely linked to the complexity of the DTM, which is typically defined as a highly multi-disciplinary process that involves physicians, pharmacists, nurses and patients (8).

In this regard, nurses play a paramount role to ensure safety, due to there are able to prevent errors at each stage of the DTM process, and to promote organisational interventions to achieve higher patients' safety outcome (4,9,10). Despite the many different and diverse organizational interventions used to address the best standards in DTM, literature highlights how errors are still significant for patients' safety and how those organisational interventions need to be supported by stronger evidence (8). Accordingly, the interruptions are identified by many authors as the main cause of errors during the DTM process (6,11,12).

### DTM interruptions

An interruption is defined as the unexpected event that influences the flow and the continuity of a task, inducing a temporary stop (13). A large number of interruptions occurs during care activities delivery, but the most frequent interruptions are related to DTM process (14-17). For this reason, different and diverse organizational interventions were developed by nurses to reduce those interruptions and, consequently, to ensure higher patients safety (18-24).

**Italiano.** I dati sono stati raccolti sulle interruzioni in 40 turni che sono stati selezionati in modo random in ogni fase (pre-implementazione e post-implementazione). Il periodo di raccolta dati era compreso tra dicembre 2016 e febbraio 2017. Un set di interventi standardizzati è stato sviluppato per questo studio.
*Risultati.* Il set di interventi standardizzati ha diminuito le interruzioni nel periodo di post-implementazione, ma non ha avuto effetti sul tempo di somministrazione della terapia. **Conclusioni.** Questo studio rappresenta una evidenza aggiornata nella descrizione dell'effetto di un set di interventi standardizzati sulle interruzioni di terapia. I nostri risultati forniscono spunti per successivi approfondimenti. I manager dovrebbero considerare i risultati di questo lavoro sulla tematica delle interruzioni, così come i ricercatori dovrebbero utilizzare questo studio per futuri approfondimenti con disegni sperimentali.

**Parole chiave:** interruzioni, distrazioni, errori di terapia, terapia, infermieristica.

Organisational interventions included some interventions, such as the use of tabards or bands (18-24), the possibility to indicate 'non-interruption zones' where nurse can prepare therapy without interruptions (19-24) or a proper (i.e., ad hoc), and the training for the involved staff (22-24). Some authors have also described the use of specific script for the management of the incoming telephone calls during DTM (21,24), informative brochures for patients and their families (24), alerts signals in patients' rooms (19), checklists (20,23) and guidelines (19).

Those interventions seemed to be lead to a reduction of the number of interruptions, showing a reduction of those errors related to DTM (18,19,21,23,24). However, the literature currently shows several results, some evidence supports those interventions, some others show their poor effect (19,22). So far, the effect of the implementation of a standardized and an updated evidence-based set of organisational interventions on DTM is largely supported by poor evidence. For this reason, the main aim of this study was to assess the effect of the introduction of a set of standardized and evidence-based organisational on DTM. According to the empirical evidence presented above, and to best answer the study research aim, the authors set the following hypotheses (19-24):

(a) the introduction of a standardized set of organizational interventions decreases the number of interruptions occurring during DTM;

(b) the introduction of a standardized set of organizational interventions decreases the duration of the whole therapy process.

## Methods

### Study design

A quasi-experimental monocentric study was used.

### Setting

The study was conducted at the General Surgery Department of the Lodi Hospital (Italy). That facility had both single and double rooms. Nursing care delivery had a nurse/patient ratio 1:5 during the morning shift, and 1:8 during the afternoon shift. Therapy took place at some scheduled times (i.e., 6:00 a.m.; 8:00 a.m.; 12:00 a.m.; 4:00 p.m.; 6:00 a.m.; 8:00 a.m.; 12:00 p.m.), using a drug cart with all the medications need during DTM. The cart had also a laptop to facilitate the nurses' access to the patients' therapies, and to facilitate and register the delivery of medications both oral and intravenous. Each administration had to recorded by the nurse using the Information Technology management system of the involved facility. During preparation and administration of the therapy, relatives could always be present, considering that the involved facility followed a project, called *open hospital*, aimed to allow the relatives visits as much time as possible.

### Data collection and procedure

Prior to the implementation of the standardized organizational interventions, the authors identified a data collection team (*n* = 3 nurses with a 3-year Bachelor Degree in Nursing) to observe and collect the data of 40 working shifts, which were randomly chosen between three different daily scheduled times to deliver therapy. Those times were at 8:00 a.m., 4:00 p.m. and 8:00 p.m., from November to December 2016 (*pre-implementation data*). Based on the current evidence, the authors designed an *ad hoc* data collection sheet, standardizing the collected variables, as shown in Table I. The identified data collection team was identified and trained in October 2016. Therefore, the team was directly educated on the study protocol contents by the study researches. In order to avoid data collection bias, the observations coming from the shifts of the data collection team were excluded from the sample used for this study. Then, the sample was given by the observations coming from the shifts of nurses belonging to the wards of the General Surgery department of the Lodi Hospital. All the nurses involved in this study received detailed information on the research purposes and methods during a meeting held in October 2016. Moreover, according to the involved facility policy, each involved nurse had a skill evaluation performed by the ward-head nurse, and it was aimed to assign a level of competence (skill level) ranged from 1 to 5, where 1 = novice and 5 = expert (Table I). That competence evaluation was performed in the involved facility following the Dreyfus model, applying Benner competence framework (25). Specifically, level 1 was refereed to newly-hired nurses or nurses with less than 6 months of experience in the clinical setting, level 2 to nurses with experience in the clinical context of at least 6 months, level 3 to nurses with an experience of 2-3 years in those clinical setting, level 4 to nurses with 4-5 years' experience in those clinical setting, while level 5 was referred to nurses with more than 5 years of clinical experience.

Each involved nurse recorded the data collection sheet, indicating the variables related to interruptions showed in Table I. The pre-implementation phase was on December 2016. At the end of the data collection for the pre-implementation phase a set of standardized organizational interventions was implemented:

- Tabards were dressed by nurses during DTM to indicate that the nurse was engaged in the therapy and should not be stopped. On each coat is reported: '*Please do not interrupt me, I am administering the therapy*'.
- Non-stop therapy zones, specifically marked with a sign, to provide nurses a quiet area for preparing the therapy. The sign reported: '*Non-interruption zone. I'm currently preparing the therapy, do not disturb*'.
- Signs applied at the sides of the therapy cart to show that the nurse was engaged in the therapy process and should not be interrupted. The reported: '*For the safety of our patients, I do not interrupt, I am administering the therapy*'.
- Incoming call management: telephone calls were handled by nurses not involved in the preparation/administration of the therapy or by the support staff.
- Educational strategies: department, medical, nursing and support staff were informed a meeting held in December 2016, in the presence of the Nursing Manager of the Departmental Area and the Nursing Coordinator.
- Information brochures: informative brochures were delivered to patients at the time of hospitalization, and informative leaflets were distributed to families and visitors.

The standardized organizational interventions were adopted from January 2017 onward. At the end of February 2017 (post-implementation phase), the data collection team observed and collected data using the same approach of the pre-implementation observations. Thus, they collected observations from 40 working shifts, which were randomly chosen between three different daily scheduled times to deliver therapy (end of February). Those times were at 8:00 a.m., 4:00 p.m. and 8:00 p.m., and the collected variables related to the interruptions used for data collection are those shown in Table I.

**Statistical analysis**

Descriptive statistics were calculated as appropriate (mean, median, standard deviation and inter-quartile range, IQR). Mann-Whitney Test was used to compare the quantitative data of pre- and post-implementation periods. Differences were considered statistically significant with a $P < 0.05$. *Poisson* regression models were used to evaluate whether pre- and post-implementation period interruption can be explained by a linear combination of predictors, after the exploration of the univariate analysis. The use of log-linear models allows quantifying how the number of interruptions may vary for a one-unit increase in the considered predictors and the relative confidence intervals (95% CI). Linear regression models have been used to evaluate whether the duration therapy administration between pre- and post- implementation can be explained by a linear combination of predictors. The data were analysed using Microsoft Office Excel 2007 and Stata 14 (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).

**Ethical considerations**

This study was approved by the Ethic Committee of Cremona, Mantova and Lodi (Italy). All participants received an illustrative sheet with clear and detailed information regarding the purpose of the study and the ways in which it is being conducted. According to the study protocol and Italian laws, for this study participants provided verbal consent, due to no patients' data were collected and therefore no written consent was required. Thus, the data collection was conducted anonymously and then processed in a confidential way. Patients did not undergo any procedure that was exempt from normal daily clinical practice and were informed of the purpose of the study through the information brochure delivered at the time of entry in the ward.

Table I. *Standardization of the Collected variables*

| | | |
|---|---|---|
| Descriptive variables | Descriptive 1 | Level of competence (Novice = 1; Advanced beginner = 2; Competent = 3; Proficient = 4; Expert = 5) |
| | Descriptive 1 | Therapy scheduled timing (hours 8 a.m. – 4 p.m. – 8 p.m.) |
| | Descriptive 3 | Duration of therapy administration |
| | Descriptive 4 | Number of administrated drugs for each therapy scheduled timing |
| Variables related to the interruptions | Interruption 1 | Number of overall interruption for each observed therapy |
| | Interruption 2 | Number of Interruptions by physicians |
| | Interruption 3 | Number of interruptions by healthcare staff (e.g., healthcare assistants, personnel employed in the hospital) |
| | Interruption 4 | Number of Interruptions by in-calls |
| | Interruption 5 | Number of interruptions by patients |
| | Interruption 6 | Number of Interruptions by relatives or visiting guests (e.g., patients friends) |
| | Interruption 7 | Number of interruptions due to the lack of drugs availability or device needed to administrate the therapy |
| | Interruption 8 | Number of interruptions due to issue related to the physicians prescription on the sheet therapy (e.g. lack of signs, unclear prescription) |
| | Interruption 9 | Number of interruption by clinical emergencies |
| | Interruption 10 | Number of interruption by the activation of a doorbell alarm |
| | Interruption 11 | Other interruptions (e.g. unexpected personal events) |

## Results

### Sampling

A total of 40 drug therapy administration observations were randomly selected for each study phase. Fifteen observations were related to the morning shifts (8:00 a.m. therapy administration), 10 observations were related to the afternoon shifts (4:00 p.m. therapy administration), and 10 observations were related to the evening (8:00 p.m. therapy administration). In the pre-implementation phase, a total of 823 drugs were administered (median of drugs per observation = 20.5; IQR 18.25), while in the post-intervention phase a total of 1109 drugs were administered (median of drugs per observation = 29.5; IQR 31.5). The differences related to the administered drugs per observation tend to be statistically significant between the pre- and the post-implementation phases ($P = 0.049$).

The nurses involved during the 40 randomly selected drug therapy observations (per each phase) were 19 (i.e., sample of involved nurses). In the pre-intervention phase, the 94% of the involved nurses were females and the 6% were males. While in the post-intervention phase, the 91% of the involved nurses were females and the 9% were males. At regard to the nurses' skill level distribution there were no difference between the two phases, where the 82% of the involved nurses had a skill level of 5, the 5.7% had a skill level of 2, and the 11% had a skill level of 1.

### Interruptions

In the pre-implementation phase, a total 418 interruptions (median of minutes of interruptions/observation = 9.5; IQR = 8) were observed while administering 823 drugs in 27 hours, and more details related to the collected variables are shown in Table II. In the post-intervention phase, a total of 144 interruptions (median of minutes of interruptions/observation = 3; IQR = 2) were observed, considering a total of 1109 drugs administered in 28 hours of observation with an average of one interruption every eight administered drugs and five interruption /hour (Table II).

Regarding to the pre-implementation phase, interruptions were mainly caused by healthcare staff (29%), visitors/guests (17%), lack of drugs availability (16%), patients (15%), medical staff (9%), incoming calls (5%), bells (5%), other breaks (3%) and unconfirmed medication (2%). While in the post- implementation phase, the interruptions were mainly caused by healthcare staff (24%), lack of drugs availability (24%), patients (17%), medical staff (11%), bells (7%), visitors (6%), other interruptions (5%), incoming calls (4%), emergency situations (1%) and unconfirmed medication (1%) (Table II). The difference of the therapy administration duration observed in minutes was not statistically significant ($P = 0.53$) between the pre-implementation (median = 41; IQR = 23.5) and post-implementation phase (median = 40; IQR = 26).

### Hypothesis (a)

The difference of the overall interruption for each observed therapy between the pre- ($n = 418$) and post- ($n = 144$) implementation phases are statistically significant ($P < 0.0001$). Those interruptions decreases considering the overall interruptions as well as those caused medical staff ($P = 0.016$) or by healthcare staff ($P < 0.0001$), incoming calls ($P = 0.046$), patients ($P = 0.045$), visitors ($P < 0.0001$), lack of drugs availability or device needed to administrate the therapy ($P = 0.0010$), and unclear prescriptions ($P = 0.047$). The differences of interruptions related to the clinical emergencies and those interruptions classified as 'other interruptions' (e.g., unexpected personal events) were not significantly differ between the pre-and post-implementation periods ($P > 0 .05$) (Table II).

Table II. *Interruptions between the pre-implementation period and post-implementation*

| | N (%) | | Median (IQR) Minutes of interruptions | | P(#) |
|---|---|---|---|---|---|
| | Pre | Post | Pre | Post | |
| Number of overall interruption/each therapy | 418 (100%) | 144 (100%) | 9.5 (8) | 3 (2) | <0.0001 |
| Number of Interruptions by physicians | 36 (9%) | 16 (11%) | 1 (1) | 0 (1) | 0.0160 |
| Number of interruptions by healthcare staff (e.g., healthcare assistants, personnel employed in the hospital) | 112 (29%) | 34 (24%) | 3 (3) | 1 (1) | <0.0001 |
| Number of Interruptions by in-calls | 20 (5%) | 6 (4%) | 0 (1) | 0 (0) | 0.0460 |
| Number of interruptions by patients | 64 (15%) | 25 (17%) | 1 (2) | 0.5 (1) | 0.0450 |
| Number of Interruptions by relatives or visiting guests (e.g., patients friends) | 69 (17%) | 8 (6%) | 1 (2) | 0 (0) | <0.0001 |
| Number of interruptions due to the lack of drugs availability or device needed to administrate the therapy | 66 (16%) | 35 (24%) | 1 (1) | 0.5 (1.25) | 0.0010 |
| Number of interruptions due to issue related to the physicians prescription on the sheet therapy (e.g. lack of signs, unclear prescription) | 9 (2%) | 1 (1%) | 0 (0) | 0 (0) | 0.0470 |
| Number of interruption by clinical emergencies | 1 (0%) | 2 (1%) | 0 (0) | 0 (0) | 0.5600 |
| Number of interruption by the activation of a doorbell alarm | 19 (5%) | 10 (7%) | 0 (1) | 0 (0) | 0.3700 |
| Other interruptions (e.g. unexpected personal events) | 12 (3%) | 7 (5%) | 0 (0.25) | 0 (0) | 0.1120 |

# P-Value estimation from the U test of Mann-Whitney

Considering the pre- implementation phase, the log-linear models (*Poisson* regressions) showed that the number of interruptions is predicted by the number of the administered drugs, the nurses' skill level, and the timing of administration (Table III). Specifically, the interruptions increase of 2.2% for a unit increase of drugs administered, of 11% for a unit increase of skill level, and of 85% when comparing the data collected at 4:00 p.m. to those collected at 8:00 a.m. In the post-implementation period, the number of interruptions was no longer predicted by independent variables of the model ($P > 0.05$) (Table III).

*Hypothesis (b)*

The duration of the therapy administration is predicted by the number of administered drugs in both the pre- and the post-implementation phases, but it is not predicted neither by the level of ability and the time of administration (Table IV). Specifically, in the pre-intervention phase, the duration of the therapy process increases by 1.13 minutes for each drug administered and in the post-implementation period increases by 1.07 minutes for each given drug ($P < 0.05$) (Table IV).

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## Discussion

Interruptions occurring during the drug preparation and administration have a documented effect on patients safety (3). However, literature has paid little attention to show how the introduction of a set of standardized organisational interventions, based on the combination of the current evidence, could reduce the number of interruptions occurring during DTM. For this reason, this study used the most recent evidence to combine a set of standardized organizational interventions, and it was aimed to assess the effect of those interventions on the number of interruptions occurring during DTM (Hypothesis a) and the overall duration of the therapy administration (Hypothesis b).

The results of this study showed that a large number of interruptions in the pre-implementation phase were observed, particularly reporting a median of 9.5 interruptions per observed shift (i.e., approximately one interruption for every two medications administered and 16 interruptions/hour). The observed interruptions in our study were higher than those documented by other researchers (16,17,19,22-24). In fact, Dante et al. (2016) recorded an average of 5.6 interruptions/hour during care activities, while Tomietto et al. (2012) recorded an average of 3.2 interruptions for each delivered therapy. Duruk et al. (2016) also reported an average of 4.3 interruptions during therapy preparation, while Freeman et al. (2013) an average of 3.29 interruptions per therapy. Less interruptions were described by Pape et. (2013), with an average of 2.25 distractions or interruptions every administered drug, while Williams et al. (2014) reported an average of 7.94 interruptions per therapy.

Our study first hypothesis was accepted, due to the interruption per therapy decreased after the implementation of the standardized and evidence-based set of organizational

**Table III.** *Interruptions predictors assessed by a Poisson regression modelling study*

| Predictors | Pre Implementation | | | Post Implementation | | |
|---|---|---|---|---|---|---|
| | *$e^{\beta eta}$ | p-value | IC 95% | *$e^{\beta eta}$ | p-value | IC 95% |
| Administrated drugs | 1.02 | 0.03 | 1.00 – 1.04 | 1.01 | 0.22 | 0.99 – 1.04 |
| Skills | 1.11 | 0.02 | 1.02 – 1.21 | 1.03 | 0.54 | 0.94 – 1.11 |
| Timing | | | | | | |
| Afternoon VS Morning | 1.85 | 0.03 | 1.06 – 3.23 | 0.93 | 0.86 | 0.43 – 2.02 |
| Night VS Morning | 1.63 | 0.002 | 1.20 – 2.22 | 1.17 | 0.38 | 0.82 – 1.67 |

* Exponential of the coefficient in the Poisson regression predictors modelling study, corresponding to the variation of the number of interruptions for the each increased considered predictors. Tests omnibus were significant as well as the overall fit of models were enough acceptable for both phases.

**Table IV.** *Predictors of the duration of the therapy administration, assessed by a multiple regression models*

| Predictors | Pre Implementation | | | Post Implementation | | |
|---|---|---|---|---|---|---|
| | β (β Stand.) | p-value | IC 95% | β (β Stand.) | p-value | IC 95% |
| Administrated drugs | 1.13 (0.620) | 0.01 | 0.29 – 1.98 | 1.07 (0.732) | 0.00 | 0.51 – 1.63 |
| Skills | -1.51 (-0.152) | 0.38 | -4.99 – 1.96 | -2.38 (-0.226) | 0.06 | -4.85 – 0.09 |
| Timing | | | | | | |
| Afternoon VS Morning | -0.03 (-0.029) | 0.99 | -21.38 – 21.32 | 12.04 (0.272) | 0.18 | -5.70 – 29.77 |
| Night VS Morning | -3.00 (-0.7) | 0.65 | -16.48 – 10.46 | 7.01 (0.171) | 0.23 | -4.53 – 18.55 |
| F | 7.53 | 0.000 | - | 12.98 | 0.000 | - |
| $R^2$ | | 0.38 | | | 0.52 | |

interventions. In fact, post-implementation phase, the duration of interruptions had a median of 3.0 minutes each administrated therapy, while the median in the pre-implementation phase was 9.5 minutes (i.e., it means the interruptions were approximately one every eight administered drugs, and 5 interruptions/hour). The observed overall reduction in therapy interruptions can be considered a positive outcome of the introduction of organational interventions, due to it could reduce the risk of errors in therapy, and their severity (3). For this reason, our results are in line with other studies in which a reduction in the number of interruptions has been previously documented, further describing the possibility to combine and standardize different interventions (18-24).

Moreover, taking into account the different type of interruptions, our study provides an insight on which kind of interruption could have a benefit from the introduction of a standardized set of organational interventions. In fact, those interruptions are mainly related to healthcare staff interference ($P < 0.0001$), lack of drugs availability ($P < 0.001$), and guests/visitors interruptions ($P < 0.0001$). Firstly, those aspects highlighted the usefulness of the information brochure delivered to patients at the beginning of hospitalization, and the placards placed in patient rooms and on the walls, and the improvement of the overall organisational attention towards DTM (e.g., reduction of interruptions related to lack of drugs availability or healthcare staff interference). In addition, an observed descriptive decrease, though not statistically significant, was recorded on the interruptions related to doorbell alarm. The lack of statistical significance may be due to the limited power for the inferential analysis. Secondly, our results showed how the training and the staff education were useful to enhance the attention towards DTM best management, influencing the interruptions related to the healthcare staff interference ($P < 0.0001$), the lack of drugs availability in the drug cart ($P < 0.001$), and also the interruptions related to physicians demands ($P = 0.0160$) or unclear prescriptions ($P = 0.0010$).

Regarding to the duration of therapy (hypothesis b), no differences were found between the predictor of the pre- and post-implementation phases. Only the number of administered drugs played as predictors of therapy duration in both the phases, while no changes were related to the other independent variables between the two regression models. However, the duration of therapy should not directly linked to the patient safety, even if it could be argued that it could have an indirect effect on safety, due to the same duration of therapy could represent the nurses' ability (9,10,26) as well as the fluidity of the DTM (i.e., less interruptions) (19,27). For this reason, the second hypothesis of our study intended explore the relations between interruptions and duration of therapy. Accordingly, if in post-implementation the interruptions had decreased, it could be reasonable that also the duration of therapy would have shown a reduction. It is probably that our sampling had not the sufficient power to detect those effects.

## Limitations and strengths

The design of the study is not the most suitable for determining the effectiveness of the standardized interventions on the number of interruptions, due to the study design to assess the effectiveness should be a Randomized Controlled Trial (RCT). However, it was useful to assess the effect of a standardized set of interventions on DTM, using a quasi-experimental design. Considering that the observations are limited to just one Italian facility, the results have to be generalized with caution. The study samples were not determined by the statistical sample size calculation, being convenience samplings, even if the randomization of the observations gave quality to the data collection. The authors were prudent in analyse the data, in fact the inferential analysis were mainly conducted using non-parametric statistics. Moreover, nurses were aware of being observed by the data collection team, and this could have caused a Hawthorne effect, in fact the influence of the data collection team on the results is unknown.

## Conclusions

This study represented an updated evidence, which describes the effect of a standardized and evidence-based set of organisational interventions' implementation on DTM. This study combined the best evidence on this topic to develop the organisational interventions, trying to face with the gap given by the diverse literature results. This study also represented a way to combine the best evidence-based approaches in reducing interruptions during DTM. Our results showed the usefulness of these set of interventions to reduce the therapy interruptions, which are often linked to DTM poor management, also causing less safety for patients. For this reason, our results encourage the managers to adopt this kind of interventions, especially raising the staff awareness on this topic. Further experimental investigations and multi-center studies could be useful to overcome the limits of the current state of knowledge related to effectiveness of this kind of organisational interventions. Future mixed-methods studies could also be useful to combine the patients' perceptions of those interventions and the same interventions' effect on DTM.

## Declarations

**Ethics approval and consent to participate**
This study was approved by the Ethic Committee of Cremona, Mantova and Lodi (Italy). All participants received an illustrative sheet with clear and detailed information regarding the purpose of the study and the ways in which it is being conducted. All participants have given their verbal consent to participate, in accordance to the Italian law 196/2003.

**Consent for publication**
Not Applicable.

**Availability of data and material**
Data are available on demand, contacting the correspondence author of this work.

**Competing interests**
The authors declare that they have no competing interests.

**LIST OF ABBREVIATIONS**

DTM: drug therapy management

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**Correspondence:** *Prof. Cristina Arrigoni, Dipartimento di Sanità Pubblica, Medicina Sperimentale e Forense - Sezione di Igiene, University of Pavia, Via Forlanini 2, 27100 Pavia, Italy, cristina.arrigoni@unipv.it*