Methodological Study to Develop Standard Operational Protocol on Intravenous (IV) Drug Administration For Children and to Assess its Implication

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Abstract

Introduction: Medicine administration forms a major part of the registered nurse's role. Medicines are prescribed by a physician and dispensed by the pharmacist but responsibility for correct administration rests with the registered nurse. Fatal consequences have been noted following wrong drug, dose, diluent and unsterile technique. The objective of this study was to develop standard operational protocol (SOP) on Intravenous (IV) drug administration and checklist to assess the implementations of the developed SOP. **Material and Methods:** A methodological research design was adapted to carry out the study. Medicine wards (4-B, 4-C, 5-B and 5-C), Emergency room, PICU at Advanced Paediatric Centre (APC) of Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh. Thirty observations of IV drug administration and 58 bedside nurses working during July-September 2015. A prospective methodological study was performed to generate SOP. Total 17 FGDs were conducted and data was analysed with SPSS (Version-20.0). **Results:** The Content Validity Index (CVI) of SOP and checklist was 99.77% that means all items in both SOP and checklist are valid. Cronbach's-alpha was calculated to assess Internal Consistency of checklists. Over-all standardized Cronbach's alpha was calculated 0.94 that means all items in the checklist are internally consistent and contributing to the total reliability of the checklist. All the nurses felt that SOP is useful. **Conclusion:** Valid and feasible SOP for drug administration to children through IV route along with valid and reliable checklist was developed. It is recommended to use this document for drug administration for children.

Key words: Intravenous, Nurses, Delphi-technique, CVI, FGD

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How to cite
Bijarania SK, Saini SK, Verma S. Methodological Study to Develop Standard Operational Protocol on Intravenous (IV) Drug Administration For Children and to Assess its Implication. J Nepal Paediatr Soc 2017;37(2):153-158.

doi: http://dx.doi.org/10.3126/jnps.v37i2.17170

Introduction

Standard Operating Protocols (SOPs) are written documents showing the steps of activities, necessary to complete tasks according to institutional policies[1]. In a Health care institute SOPs advocate the step-by-step performance of any procedure required to provide care to the patients by a trained staff[2]. It is a helpful written document for newly recruited care providers to perform their expected services in that set-up[3].

Intravenous drug administration is the facilitation of safe and effective administration of medicine and fluid to neonate/ infant/ toddler/ preschool/school-going. Fatal consequences have been noted following wrong drug, dose, diluent and unsterile techniques[4-6]. Nurses are chief participant in drug administration and accountable for correct drug administration in their assigned patients[7,8]. Large numbers of drugs are used in Paediatric Medicine ward according to the severity of child's disease condition. The availability of SOPs for drug administration in such wards can make a difference in patient's prognosis[9-13]. In Medical Ward, APC, PGIMER, no such document is noted in respect to drug administration. As per author's knowledge none of other institute in India has a documented well-developed SOPs for drug administration in paediatric wards. The need for a well-developed drug administration protocol for reducing the errors in drug administration is must in tertiary care centres such as PGIMER, Chandigarh. Therefor the present study aimed to provide evidence-based literature for health care providers to help themselves at the time of drug administration.

Material and Methods

Methodological research design was adapted to develop SOP on IV drug administration for children, admitted in Advanced Paediatric Centre (APC), Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh. Institutional ethical committee PGIMER, Chandigarh approved the study protocol. Permission to conduct the study was also obtained from the respective authority of the department. Researcher himself approached all the participants and briefly explained the purpose of the study. Informed written consent was obtained from all participants before commencement of the study. Participant's confidentiality was maintained.

The data was analyzed by SPSS software (Version-20.0). Cronbach's-alpha was calculated to assess Internal Consistency of checklists. The overall Cronbach's-alpha value of checklists was 0.947. Table-1 (Part-1 & 2) shows, when corrected item to total correlation was applied on 43 items of tool, 41 items had item score to total score correlation between 0.2-0.953 whereas 2 items in the tool had item score to total score correlation < 0.2 showing their incompatibility with the overall tool. When the individual item was deleted the value of Cronbach's-alpha was increased for 8 items including one item whose score to total score correlation was < 0.2. That means these 8 items were not contributing to the total reliability of tool and could be discarded. The results were discussed with Delphi panelists; all members were in the favor of keeping all items because they were also equally important in SOP even if the low correlation indicated in the individual item score.

Results

Valid and feasible SOP for IV drug administration for children along with valid and reliable checklist was developed. For ready references SOP in the form of booklet and poster's binder carrying pictures of drug administration technique were made available to all medicine units of APC, PGIMER, Chandigarh.

Inclusion Criteria	Phases of research project
Nurses who gave consent to participate in this study were involved.	**1. Preparation Phase**: Preliminary draft of SOP and checklist was generated in the following four steps (a) *Assessment of The Current Practices,* (b) *Literature was reviewed* related to standard care practices of IV drug administration, (c) *Ten Focus Group Discussions (FGDs)* were conducted and (d) Consultation with specialists of Pediatric Nursing and Pediatric Medicine, incorporating the results of assessment of current practices and valuable suggestions of bed side nurses' gathered in FGDs.
	2. Validation Phase: Delphi technique was applied for the assessment of content validity of preliminary draft. The Delphi panel included 13 members from the field of Pediatric Medicine and Nursing. Total four rounds were conducted to develop the SOP.
	3. Pilot Study (I^{st} Tryout): conducted after third round of validation that revealed that the existing pictures in the protocol were not clear. The final fourth SOP draft was prepared by replacing existing pictures in protocol with clear and afresh pictures. *Content Validity Index* (CVI) of SOP and Checklist for all items was calculated 99.77% after fourth round.
	4. Checking The Reliability (II_{nd} Tryout): was performed at Medicine units (4-B, 4-C, 5-B and 5-C), Emergency and PICU, APC, PGIMER, Chandigarh. Researcher observed 30 procedures of IV drug administration during second and third week of September 2015.
	5. Evaluation: seven FGDs were conducted to get reviews of bedside nurses about the usefulness of SOP.

Table 1: Reliability of checklist on IV drug administration (Part-1) (N=30)

S.No.	Items	Scale Mean if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
1	Selects appropriate **Supplies and Articles** to prepare tray			
i	Compartment tray	4.80	0.589	0.702
ii	Hand sanitizer	4.80	0.589	0.702
iii	Burette (Paediatric Drip set (PD set)	4.97	0.464	0.703
iv	Dilution solutions	4.80	0.589	0.702
v	Kidney tray	5.63	0.224	0.745
vi	Chlorehexidine/ spirit swabs	4.80	0.589	0.702
vii	Clean or sterile gloves (if required)	5.17	0.398	0.730
viii	Paper bag	5.70	0.407	0.714
ix	Sterile additional pack	5.47	0.471	0.706
2	**At the time of drug preparation**			
i	Check for any pre-medication before medication administration	6.20	0.187*	0.887
ii	Asks the parents about any medication allergies and the child's former responses to drug	6.57	0.516	0.876
iii	Opens additional pack and open a sterile syringe into the opened sterile pad	6.87	0.859	0.852
iv	Cleans the cap of vial with spirit swab and let dry the cap	6.27	0.455	0.877
v	Withdraws the needle and syringe and keep them on sterile pack.	6.87	0.859	0.852
vi	Keeps the filled syringe in sterile pack and takes it to the child without showing the needle	6.87	0.859	0.852
3	**At the time of drug administration**			
i	Explains the procedure to the child /parents clearly using appropriate language and take consent from parents to administer drug to the child	6.33	0.473	0.877
ii	Asks the parents about any known medication allergies	6.37	0.326	0.886
iii	Keep a dry swab under the cannula hub	6.77	0.721	0.861
iv	Cleans the white stopper of cannula	6.20	0.318	0.883
v	Keeps the white stopper on a sterile additional pad	6.87	0.859	0.852
vi	Cleans the cannula hub with squeezed Chlorehexidine/spirit swab	6.30	0.367	0.882
vii	Observes vitals of the child carefully during & after administration	12.90	0.289	0.950**
viii	Uses divertional technique while administration of drug to the child	12.73	0.543	0.946
ix	Stops injection of the medicine if the child suddenly becomes lethargic or hyperactive	13.47	-0.112*	0.953**

Notes: Overall scale mean is 26.50, Overall reliability is .947 (standardised Cronbach's alpha), * Items in the tool which shows item to total correlation <0.2, ** Items in the tool whose Cronbach's Alpha value increased if Item deleted.

Table 2: Reliability of checklist on IV drug administration (Part-2) (N=30)

1	Items	Scale Mean if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
i	**Steps for preparation of drug with Burette (PD set)**			
ii	Opens the burette from sterile packing and hang over the IV fluid bottle holder	12.80	0.953	0.940
iii	Primes the burette tubing with 15 ml of infusion solution	12.80	0.953	0.940
iv	Fills the prescribed amount of infusion solution	12.80	0.953	0.940
v	Cleans the drug inducer port on the burette with spirit/ Chlorehexidine swab and let dry it	12.80	0.953	0.940
vi	Injects the prefilled medicine in to the burette and mixed thoroughly with the IV solution by agitating the burette several times	12.80	0.953	0.940
vii	Discards 10 ml solution of primed tubing	12.80	0.953	0.940
2	**Steps for administration of Infusion via Burette (PD set)**			
i	Clean the injection port with an alcohol swab and allow drying it.	12.83	0.857	0.941
ii	Insert syringe hub to flush the line with 2 mL normal saline	12.80	0.953	0.940
iii	Check the site again for patency	12.80	0.953	0.940
iv	Attach the primed tubing of burette to the 10 cms extension or direct to the vein cannula	12.80	0.953	0.940
v	Adjust drip rate to administer the solution at the prescribed rate by the physician	12.80	0.953	0.940
vi	Adds 10-15 NS to flush the drug in drip set	12.80	0.953	0.940
3	**After drug administration to the child**			
i	Flushes tubing/cannula with 5 ml of normal saline or running IV fluid	12.93	0.474	0.947
ii	Praises the child/ use non-verbal approach for cooperation	12.77	0.242	0.950**
iii	Observes the child for 15-20 minutes for any side effects and ask the parents to inform you any untoward sign/symptoms if appear after drug administration	13.30	0.408	0.948**
iv	Allow the child to express his or her feeling	13.27	0.371	0.950**
v	Reassures the child that next time will be easier	13.47	0.304	0.948**
vi	Stay with child and gives feed back /instruction to the child/parent if required	13.57	0.202	0.948**
vii	Reminds/tells the parents about the timings of next dose	13.57	0.202	0.948**

Notes: Overall scale mean is 26.50, Overall reliability is .947 (standardised Cronbach's alpha), * Items in the tool which shows item to total correlation <0.2, ** Items in the tool whose Cronbach's Alpha value increased if Item deleted.

Discussion

SOPs describe the activities necessary to complete tasks according to institutional regulations, provincial laws. These are used to remove variation in procedure performance because every individual develops his/her own concept of procedure's process on scientific basis[1]. Present study was undertaken because no such SOP on IV drug administration notified in APC wards, PGIMER.

Initially the review of literature was done to check the availability of SOPs and checklists for drug administration worldwide. Only national and international literature of SOPs and checklists related to drug administration was not enough to gather sufficient information for development of SOP and checklist. Assessment of current-practices of drug administration was also equally important to know about the regular

practices of drug administration. In five observations of IV drug administration at APC, PGIMER, Chandigarh, researchers observed that all bedside-nurses followed few steps but few were totally ignored though those steps were also equally important to be performed.

To know the reason of ignorance, a series of FGDs were conducted. The number of FGDs to be conducted depends upon the purpose of study, along with the heterogeneity of group[14]. Another study favors that FGDs should be continued until repetition of themes is not started[15]. During this study, the saturation of information was achieved after 10 FGDs. The size of the group should be of between 6-12 people because large group precludes adequate participation by most members and small group fails to provide significant greater coverage on the topic[16]. In present study all FGDs were conducted with small group of 6-7 members who had 4-5 years of exclusive-experience of pediatric bedside nursing because few guidelines suggest that smaller groups (4-6 members) are allowed when the members have much experience to share[16,17]. On the base of gathered information finally a preliminary draft of SOP and checklist was prepared.

For further refinement in the preliminary draft of protocol and checklist Delphi-technique was used. The Delphi-technique is well suited as a method for consensus building and to establish content validity[18]. Current study had a heterogeneous Delphi panel of 13 experts included seven members of nursing faculty and six faculty members from pediatrics medicine. In a Similar study done by Kaushal et al. Delphi members were eleven[19]. D'Souza et al. used an interdisciplinary panel of seven national and international experts for development of a tool for assessing preterm infants[20]. George et al. had a panel comprised of 10 members[21].

Delphi-technique employs repeated rounds in which printed drafts of drug administration procedures are given to the Delphi-panelists until a common consensus is reached. In the present study, though the consensus of panelists was achieved after third round but few changes were required after first tryout. To make these changes feasible fourth round was

conducted before development of final version of SOP and checklist. In similar studies conducted by Kaushal et al. common consensus was reached in four Delphi-rounds[19], according to George et. al. three rounds were sufficient[21].

The overall CVI of current study from the panel of experts was calculated 99.77% indicating the validity of the individual item. In a similar study, conducted by D'Souza et al. the overall CVI was 95%[20].

The reliability of these Checklists was ensured by Cronbach's alpha to determine the internal consistency or average correlation of items in a survey-instrument to gauge its reliability[22]. The overall Cronbach's alpha value of checklists was 0.947 and item score correlation to overall score was in-betweens 0.2-0.953. In a similar study by George et al. overall value of alpha was 0.76[21]. Another study Kaushal et al. revealed Cronbach's alpha value 0.97[19]. The corrected item to total correlation was applied upon 43 items of tool, 41 items had item score to total score correlation between 0.2-0.953 whereas two items in the tool had item score to total score correlation < 0.2 showing their incompatibility with the overall tool. When the individual item was deleted the value of Cronbach's alpha was increased for 8 items including one item whose score to total score correlation was < 0.2. That means these 8 items were not contributing to the total reliability of tool and could be discarded. The results were discussed with Delphi-panelists; all members were in the favor of keeping all items because they were also equally important in SOP even if the low correlation indicated in the individual item score.

Conclusion

No institutes in India have documented any well-developed SOPs for IV drug administration in paediatric wards. SOP on IV drug administration is established which is valid and feasible along with reliable and valid checklists. It is recommended to use this SOP for IV drug administration for children at all levels (primary, secondary and tertiary). Checklist should be used by nurse administrators to assess the implementation of SOP.

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