Paediatrics Section

Methodological Study to Develop Standard Operational Protocol on Intramuscular (IM), Intradermal (ID) and Subcutaneous Drug Administration for Children

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ABSTRACT

Introduction: Medicine administration is a major role played by registered nurses. Medicines are prescribed by the physician and dispensed by the pharmacist but responsibility for meticulous administration rests with the registered nurse. It becomes even more important when drugs are to be administered to children. Drug administration via Intramuscular (IM), Intradermal (ID) and Subcutaneous route is a complex process. Errors are associated with medicine administration.

Aim: The objective of this study was to develop Standard Operational Protocol (SOP) for IM, ID and Subcutaneous drug administration and checklist to assess the implementation of the developed SOP.

Materials and Methods: A methodological research design adapted to carry out the present study to develop standard operational protocol for IM, ID and subcutaneous drug administration for children, admitted

in Advanced Paediatric Centre, Post Graduate Institute of Medical Education and Research, Chandigarh, India. The study included 58 bedside nurses and 90 observations of medicine administration procedure.

Results: The Content Validity Index (CVI) was prepared to assess the validity of content (items) of SOPs and checklists. Over all Cronbach's-alpha values was calculated to assess the internal consistency of Items in SOPs and checklists. CVI of SOP and checklists were 98.51%, 97.83% and 99.03%. Over all Cronbach's-alpha values were calculated 0.96, 0.82 and 0.95. All the nurses felt that SOPs are useful.

Conclusion: Valid and feasible SOPs for drug administration in children along with valid and reliable checklists were developed. It is recommended to use this document for drug administration in children to prevent any possible error during drug administration to children.

INTRODUCTION

Standard Operating Protocols (SOPs) are written document 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 respective set-up [3].

IM, ID and subcutaneous drug administration is the safe and effective infiltration of medicine to neonate/infant/toddler/preschool/school going children. Fatal consequences have been noted following wrong drug/dose/diluent administration or unsterile techniques [4,5]. According to Harvard Medical Practice Study, 30% of

patients following drug-related injuries either died or disabled for more than 6 months [6]. Nursing profession is the chief participant in drug administration and contributes to patient care [7]. Nurses are accountable for meticulous drug administration in their assigned patients [8]. Hence, the availability of SOPs for drug administration makes a difference in patient's prognosis [9-12]. In Medical Ward, APC, PGIMER, Chandigarh, India no such document is noted in respect to drug administration. As per my knowledge none of the other institutes in India has a documented well-designed SOP for drug administration in Pediatric wards. The need for a well-designed drug administration protocol for reducing the errors in drug administration is must in Tertiary Care Centers [13]. Therefore the present study aimed to provide evidence-based literature for nurses to practice at the time of drug administration.

MATERIAL AND METHODS

Methodological research design was adapted to carry out the present research to develop a SOP on IM, ID and subcutaneous drug administration for children admitted in Advanced Paediatric Centre (APC), Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, India. The present study was conducted between April-September 2015 and the overall duration was one year. Ethics clearance was taken from the Institutional Ethical Committee. Participants were 58 bedside nurses working during April-September 2015. Informed written consent was obtained from all participants before commencement of the study and the confidentiality was maintained throughout study. Sample size was 30 observations of each IM, ID and subcutaneous drug administration. Nurses who were working in (Pediatric wards) PGIMER other than APC were excluded. Nurses who gave consent to participate in this study were considered.

The tentative plan to carry out research project was in the following five phases:

(i) Preparation Phase,

(ii) Validation Phase,

(iii) Pilot Study (Ist Tryout),

(iv) Checking the Reliability (IInd Tryout), and

(v) Evaluation.

(i) Preparation Phase

This was the preliminary phase and a preliminary draft of SOP and checklists was developed at the end of this phase. In this phase, component of procedures of drug administration to the children were determined; item pool was generated and organized in the following four steps:

1. Assessment of the current practices- Current Practices of drug administration via IM, ID and subcutaneous routes were assessed with the help of observational checklists [carrying all the steps (preparation, administration and termination) of procedure] in Paediatric Medicine units (4-B, 4-C, 5-B, 5-C, Emergency room, PICU, OPD and Immunization room) of APC, PGIMER, Chandigarh.

2. Literature was reviewed- Literature related to standard care practices of IM, ID and subcutaneous drug administration in pediatric wards through Internet teaching, books, national and international journals, manuals and web search.

3. Saturation of information- It was achieved after ten focus group discussions, conducted during 3rd -15th July 2015 (with bed side nurses working in APC) in the Mother's room of Paediatric Emergency Department. All FGDs included a guided questionnaire to assess problems faced by nurses during drug administration and also to develop SOP on IM, ID and subcutaneous drug administration. Total 58 bedside working nurses were included from respective departments of pediatric medicine wards, PICU, Emergency, OPD and Immunization room to seek their suggestions. Out of these 58 bedside nurses, 6 were newly recruited, who had less than six months of experience, five bedside nurses had 6-12 months of experience, there were 16 bedside nurses who had 1-4 years of experience and remaining 31 bedside nurses had more than 4 years of experience.

4. The preliminary draft- Primary draft of SOP and observational checklist of procedure to assess the implementation of protocol were prepared by relevant literature search on standard drug administration practices, incorporating the results of assessment of current practices and valuable suggestions from bed side nurses were gathered in FGDs. The protocol included sequences of drug administration procedure.

(ii) Validation Phase

In this phase Delphi technique was applied for the assessment of content validity of preliminary draft. A Delphi panel consisting of 13 members from the field of Pediatric Medicine and Nursing was formulated. To seek expert opinion four subsequent rounds were conducted to reach the final consensus. During each round each member of the panel was given the copy of tool [Preliminary draft of SOPs and checklists carrying all the steps of procedure (drug preparation, administration and termination) of IM, ID and subcutaneous drug administration] and they were requested to pool in their suggestions to check each item for face validity and content validity by keeping in mind the following points:

1. Items listed in the protocol were relevant to subjects and were easily understandable and meaningful for users.

2. Sequence and relevance were maintained. In the first draft, a copy of preliminary draft of protocol and checklist was given to each member of the panel and corrected copies received back. Incorporating panelists' valuable suggestions, modifications were done in the tool. The second draft, had all steps of procedures under four main headings:

a) Articles required for procedure,

b) Steps at the time of drug preparation,

c) Steps at the time of drug administration to the child and,

d) Steps after drug administration to the child.

With these changes, the draft was re-circulated among panelists for second round. Corrected copies with suggestions like to add drug calculation formula for

paediatric dose calculations were received.

In third draft, after incorporating all suggestions main headings were again divided into sub-headings. The 2nd main heading (steps at the of time drug preparation) included sub heading (three checks), under 3rd main heading (steps at the time of drug administration to the child) a sub heading (nine rights of patients) and 4th main heading (steps after drug administration to the child) given a sub heading (biomedical waste management). All the procedures were combined together to give a form of booklet. Binders of posters carrying important pictures of drug administration technique were also prepared. Thus, prepared draft was re-circulated among all members of Delphi panel for third round. No more corrections/suggestions were received. All panelists suggested to carry out first tryout of SOPs.

(iii) Pilot study
First tryout was performed in ward 6-C and Immunization room, APC, PGIMER, Chandigarh, India. It revealed that the existing pictures in protocol were not clear. The final fourth draft of SOP was prepared by replacing existing pictures in protocol with fresh and clear pictures. To check the face validity and item validity, a copy of fourth draft was re-circulated among Delphi panelists and a common consensus was achieved from all panelists at the end of fourth round and Content Validity Index (CVI) of SOP and checklists for all items were calculated 98.51%, 97.83% and 99.03% respectively for IM, ID and subcutaneous routes.

To calculate CVI universal agreement approach was used. In this approach two categories "agreed" and "Not agreed" were given to each item in the checklist and SOP. The formula to calculate CVI used was:

$$CVI = \frac{\text{No of items "agreed" by all panelists}}{\text{Total no. of Items in the checklist/SOP}} \times 100$$

(iv) Second (IInd) Try Out
It was done to check the reliability of checklists in Medicine units (4-B, 4-C, 5-B and 5-C), OPD, Immunization room and PICU. Study Population included all bedside nurses and procedures of IM, ID and subcutaneous drug administration performed during the month of September 2015. Sampling Technique was purposive. Sample Population was 90 observations of IM, ID and subcutaneous drug administration (30 observations for each procedure).

All bedside nurses of Paediatric Medicine units were educated with the help of Power point presentation on drug administration techniques for IM, ID and Subcutaneous routes. They were trained by giving demonstrations of IM, ID and subcutaneous drug administration in their wards and re-demonstrations were taken to ensure that they were practicing as per

protocol. Training was given during all three shifts of duty (morning, evening and night) for the complete last week of August 2015. There after they were asked to practice drug administrations in their unit as per protocol. Individual candidate was given a prepared booklet on IM, ID and subcutaneous drug administration. A binder of posters carrying pictures of IM, ID and subcutaneous drug administration technique was kept at nursing stations of all units.

(v) Evaluation
To assess the reliability of the checklists, after one week of operationalization of SOPs, researcher using observational checklists, observed 90 procedures (30 for each procedure) of IM, ID and subcutaneous drug administration in the second and third week of September 2015.

STATISTICAL ANALYSIS
The data was analyzed by SPSS (Version-20). Cronbach's alpha was calculated to assess internal consistency of checklists of IM, ID and subcutaneous drug administration.

RESULTS
[Table/Fig-1a,b] on IM drug administration shows the over all Cronbach's alpha value of checklists was 0.962. This total score correlation was obtained by addition of all 59 item's score in the tool. When this total score correlation was correlated with 59 items of tool, 55 items had item score to total score correlation between 0.2-0.83 whereas 4 items had individual correlation score<0.2 showing their incompatibility with the overall tool. When the individual item deleted the value of Cronbach's alpha was not increased even for any single item of the tool. That means all items were equally contributing in total reliability of tool and any single item could not be discarded.

[Table/Fig -2] on ID drug administration shows the over all Cronbach's alpha value of checklists was 0.821. The corrected item to total correlation was applied on 24 items of the tool, 13 items had individual item score to total score correlation in between 0.2-0.75 whereas, 11 items had individual correlation <0.2 showing their incompatibility with the overall tool. When the individual item was deleted, the alpha value was increased only for 3 items who's total score correlation was < 0.2. It means those 3 items were not contributing in the total reliability of tool and could be discarded.

[Table/Fig-3a,b] on subcutaneous drug administration shows that the overall Cronbach's alpha value of checklists was 0.954. The total correlation was applied on 53 items of tool and found that 40 items had item score to total score correlation in between 0.2-0.91 though the 13 items in the tool had correlation < 0.2, showing their incompatibility with the tool. When the individual

Items	Scale Mean if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Selects appropriate Supplies and Articles to prepare tray	42.53	.389	.933
Compartment tray	42.00	.518	.932
Hand sanitizer	41.97	.232	.934
Sterile syringe (2cc/5 cc/10cc) to dilute powdered medicine in vial	41.97	.232	.934
Sterile needles – 2 (one to withdraw medicine from vial and second to inject medicine to the child)	42.33	-.107*	.938
Needle 24-25 G, 5/8 inch (under 12 months)	42.43	.248	.935
Needle 24-25 G, 1 inch (12 months or above)	42.83	.307	.934
For deltoid region 24-25 G, 5/8 inch	42.37	.408	.934
Dilution solutions	41.97	.273	.934
Emergency cart (containing equipment for treating a patient in case of anaphylactic shock or cardiac arrest)	42.03	.407	.933
Chlorhexidine/spirit swabs	42.30	.362	.936
Clean or sterile gloves	42.77	.395	.933
Kidney tray	42.80	.362	.933
Paper bag	42.37	.555	.932
Sterile additional pack	41.97	.834	.931
At the time of drug preparation	41.97	.834	.931
Communicates with child and parents in pleasant manner	41.97	.834	.931
Check ten rights	41.97	.834	.931
Check for any premedication before medicine administration	41.97	.834	.931
Asks the parents about any medication, allergies and the child's former responses to drug	41.93	.534	.933
Ask child/parents for any bleeding disorder	41.93	.611	.933
Checks label of medicine three times (Three checks)	41.97	.834	.931
• When taking from patient or trolley	41.97	.834	.931
• Before withdrawing/pouring	41.97	.834	.931
• Before administration of drug	42.80	-.072*	.938
Checks Signature of Physician	42.13	.400	.933
Checks Expiry date of drugs	42.27	.440	.933
Checks for skin test (If applicable)	41.93	.611	.933
Calculates correct dose with formula	41.97	.834	.931
Opens additional pack and open a sterile syringe into the opened sterile pad	42.60	.459	.933
Washes her hands /use Alcohol rub before preparation of drug	42.30	.272	.934
Cleans the cap of vial with spirit swab and let dry the cap	42.50	.331	.935
Withdraws the required amount of NS/distilled water and push it into the powdered medicine vial	41.97	.834	.931
Withdraws the needle and syringe and keep them on sterile pad.	41.97	.834	.931
Dissolves the powdered medicine by rotating the vial in both palms	42.37	.555	.932
Expels air bubbles from the syringe by inventing the syringe and push the plunger of syringe	41.97	.834	.931
Changes the needle with new one	41.97	.834	.931
Keeps the filled syringe in sterile pack	42.37	.555	.932

[Table/Fig-1a]: Reliability of checklist on IM drug administration (n=30).
Overall scale mean is 42.90
Overall reliability is .962 (standardised Cronbach's alpha)
* Items in the tool which shows item to total correlation <0.2

Items	Scale Mean if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
At the time of drug administration	41.97	.834	.931
Explains the procedure to the child /parents clearly using understandable language and take consent from parents to administer drug to the child	41.97	.834	.931
Uses non-threatening/divertional approach for drug administration to child	41.97	.834	.931
Asks the parents about any known medication allergies	42.00	.671	.932
Provides privacy	41.97	.834	.931
Cleans the site with Chlorhexidine/spirit swab	41.97	.834	.931
Grasps the muscle between the thumb and fingers	41.97	.834	.931
Draws back on the plunger to ensure that the needle is not in a blood vessel	41.93	.611	.933
After drug administration to the child			
Does not massage the site but apply pressure for some time	42.40	.227	.935
Encourages child to move/walk	42.13	.543	.932
Praises the child/ use non-verbal approach for cooperation	42.50	.462	.933
Observes the child for 15-20 minutes for any side effects	42.53	.419	.933
Allows the child to express his or her feeling	42.53	.456	.933
Reassure the child that next time will be more easier	41.97	.440	.933
Terminate the Bio Medical Waste (BMW)	41.93	.611	.933
Burns the needle in the needle burner or sharp- container (blue bucket)	41.93	.611	.933
Cuts the syringe hub and separate the plunger and discards in red bucket	41.93	.611	.933
Discards the used swabs in to yellow bucket	41.93	.611	.933
Discards the used vial/ampules/glass bottles in blue bucket	41.93	.611	.933
Discards the wrapper/packing in black bucket	42.07	.003*	.936
Removes gloves and washes hands	41.93	-.096*	.935
Records the medication with signature, date, time, dose and effects observed	41.93	-.096*	.935
Stays with the child and gives feed back to the child/parents	42.50	.361	.934
Reminds/tells the parents about the timing of next dose	42.27	.242	.935

[Table/Fig-1b]: Reliability of checklist on IM drug administration (n=30).
Overall scale mean is 42.90
Overall reliability is 0.962 (standardised Cronbach's alpha)
* Items in the tool which shows item to total correlation <0.2

item was deleted, the alpha value was increased for any single item of the tool. That means all items were equally contributing in total reliability of tool and any single item could not be discarded.

All results were discussed with Delphi panelists. All members favored to keep all items because they were also equally important in the SOP even if the low correlation indicated in the Cronbach's Alpha value.

In the evaluation phase seven FGDs were conducted during 23-27 September 2015 to get reviews of bedside nurses about the usefulness of booklet and posters prepared on drug administration. All bedside nurses expressed their satisfaction on availability of this booklet by saying that "We feel that readymade material is available with us to study and for referral". The main problems faced by the staff during drug administration are:

1. Time-consuming procedures, as one nurse said, "Initially it consumes around ten minutes extra per patient but with practice it becomes routine". Another one replied with "In an emergency service children require quick treatment"

2. Lack of availability of supplies, as per another nurse "sterile supply of additional packs for every individual patient are not available in sufficient quantity, even kidney trays are also not available in wards".

DISCUSSION

SOP provides pre-hand information about all articles

Items	Scale Mean if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Selects appropriate supplies and articles to prepare tray	9.53	.279	.819
Medication or vaccine to be delivered			
Distilled water	10.13	.489	.808
Paper bag	10.20	.551	.805
Sterile pack	10.23	.712	.795
At the time of drug preparation			
Checks for any discoloration or presence of any precipitates in the drug	9.53	.279	.819
Opens sterile additional pack and open a sterile syringe into the opened sterile pad	10.00	.650	.798
Changes the needle with new one	9.53	.178*	.821
Keeps the filled syringe in sterile pack and take it to the child without showing the needle	10.00	.650	.798
For deltoid site			
Identifies the Lt. deltoid muscle for ID administration 3-5 cms below the acromion process	10.47	178*	.821
Inserts the needle with bevel uppermost, just into the skin	10.47	.178*	.821
Stabilizes the injection site	10.37	.140*	.833**
Pushes plunger slowly forward until 5 mm bleb appears	10.47	.178*	.821
Quickly withdraws the needle at the same angle	10.47	.178*	.821
Does not apply the pressure	10.47	.178*	.821
Applies the sterile gauge /cotton swab to the injection site	10.47	.178*	.821
Marks the site with pen for observation	9.53	-.220*	.830**
After drug administration to the child*			
Praises the child/ use non-verbal approach for co operation	9.53	.178*	.821
Observes the child for 15-20 minutes for any side effects	9.90	.508	.807
Allows the child to express his or her feeling	9.83	.673	.797
Reassure the child that next time will be more easier	9.97	.751	.791
Removes gloves and washes hands	9.53	.077*	.823**
Stays with the child and give feedback/instruction to the child	10.17	.325	.818
Reminds/tells the parents about the timings of next doses	10.20	.462	.810

[Table/Fig-2]: Reliability of checklist on Intradermal drug administration (n=30).
Overall scale mean is 10.50
Overall reliability is 0.821 (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 > .821

required for the procedure and it also gives description of total steps to be undertaken for the completion of procedure. So all the required articles can be arranged before beginning of procedure to save time and any shortage can be rectified pre-hand. To complete all the steps of procedure Ideal consumption of time for individual procedure can be calculated. In such a way ideal time required for all procedures to be performed upon every individual child in each ward, during each shift of duty can be estimated. So as per the number of children admitted and the numbers of procedures to be performed to provide care to individual admitted child in each ward during each shift of duty, total consumption of time can be estimated. On the basis of ideal estimated

time for ideal practice of procedure the ideal required number of bedside nurses can also be estimated. Hence, the SOP can address shortage/excess of staff for ideal practice. Present study was undertaken to develop SOP for APC, PGIMER.

Initially, the review of literature was done to check the existing 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. Because every institute has its oven policies, sources of fund, supplies of equipment, men power and patients burden to avail medical and nursing services. Assessment of current-

Items	Scale Mean if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Selects appropriate supplies and articles to prepare tray			
Non-sterile gloves (one pair)	38.97	.100*	.937
Chlorehexidine/ spirit swab, gauze pad	38.57	.360	.936
Cotton balls and paper bag	38.23	.709	.933
Sterile additional pack	38.87	.159*	.937
Needles 24-25 G, 5/8 inch (2) (for < 12 months)	38.40	.274	.937
Needles 24-25 G, 5/8 inch (2) (for >12 months)	38.67	-.222*	.942
Syringe (1cc & 5cc) & distilled water or NS	38.33	.511	.934
Emergency cart (containing equipment for treating a patient in case of anaphylactic shock or cardiac arrest)	38.17	.516	.934
Medicine or vaccine to be delivered	38.13	-.020*	.937
Diluent (if required)	38.90	.175*	.937
Needle burner and Hub cutter	38.23	.696	.933
At the time of drug preparation			
Communicates with child and parents in pleasant manner	38.17	.919	.919
Checks ten rights	38.23	.605	.605
Asks the parents about any medication allergies and the child's former responses to drug	38.17	.919	.919
Checks label of medicine three times (Three checks)	38.17	.919	.919
• When taking from patient or trolley	38.13	.760	.760
• Before withdrawing/pouring	38.13	.497	.497
• Before administration of drug	38.17	.919	.919
Check the name of medicine, prescription date and Signature of Physician	38.17	.919	.919
Checks Expiry date of drugs	38.17	.919	.919
Selects the syringe size according to the volume and dose of medication	38.17	.919	.919
Selects the size of needle according to the age of child and viscosity of fluid	38.70	.121*	.121*
Opens additional pack and open a sterile syringe into the opened sterile pad	38.17	.919	.919
Cleans the cap of vial with spirit swab and let dry the cap before inserting the needle into vial	38.17	.919	.919
Expels any air bubbles from the syringe by inventing the syringe and push the plunger of syringe	38.27	.616	.616
Changes the needle with new one and primes it	38.63	.326	.326
Keeps the filled syringe in sterile pack and take it to the child without showing the needle	38.17	.919	.919
Uses 1cc (insulin) syringe only	38.17	.919	.932

[Table/Fig-3a]: Reliability of checklist on subcutaneous drug administration (n=30).
Scale mean is 39.10
Overall reliability is 0.954 (standardised Cronbach's alpha)
* Items in the tool which shows item to total correlation <0.2

practices of drug administration was also equally important to match the SOP with available resources of the particular institute. In 15 observations of IM, ID and subcutaneous drug administration, researcher observed that all bedside-nurses followed few steps but some were ignored though those steps were also equally important to be performed.

To know the reason why those few steps of procedure were not performed, a series of Focus Group Discussions (with bed side nurses) 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,

Items	Scale Mean if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
At the time of drug administration			
Approaches the child in pleasant manner	38.17	.919	.932
Explains the procedure to the child /parents clearly using understandable language and take consent from parents to administer drug to the child	38.17	.919	.932
Uses non-threatening/divertional approach for drug administration to child	38.17	.919	.932
Asks the parents about any known medication allergies	38.17	.919	.932
Selects the site for injection	38.13	.026*	.936
Assesses the previous site of injection for any hardness (if applicable)	38.47	.311	.936
Cleans the site with Chlorehexidine/spirit swab using an outward circular motion from the center to a 2" to 3" circle & allow it to dry	38.23	.630	.933
Does not touch needle or entry site	38.17	.919	.932
Injects contents steadily using a slow and continuous movement	38.20	.433	.935
Does not massage injection area	38.17	.482	.934
After drug administration to the child			
Look for any bleeding at the injection site	38.17	.585	.934
Applies gentle pressure to the site with sterile dry cotton swab	38.13	.050*	.936
Praises the child/ use non-verbal approach for cooperation	38.23	.323	.935
Observes the child for 15-20 minutes for any side effects	39.00	.239	.936
Allows the child to express his or her feeling	39.07	.162*	.936
Reassures the child that next time will be more easier	39.03	.167*	.936
Terminates the Bio Medical Waste (BMW)	38.20	.491	.934
- Burns the needle in the needle burner or sharp- container (blue bucket)	38.17	.585	.934
- Cuts the syringe hub and separate the plunger and discards in red bucket	38.17	.585	.934
- Discards the used swabs in to yellow bucket	38.17	.585	.934
- Discards the used vial/ampules/glass bottles in blue bucket	38.17	.585	.934
- Discards the used wrapper/packing covers in black bucket	38.17	.585	.934
Removes gloves and washes hands	38.13	-.090*	.937
Stays with the child and give feed back/instruction to the child/ parent	39.07	.138*	.936
Remind/ tell the parents about the timings of next dose	38.97	.188*	.936

[Table/Fig-3b]: Reliability of checklist on subcutaneous drug administration (n=30).
Overall scale mean is 39.10
Overall reliability is 0.954 (standardised Cronbach's alpha)
* Items in the tool which shows item to total correlation <0.2

the saturation of information was achieved after 10 focus group discussions sessions. The group of 6-12 members facilitates adequate participation of all members but a small size group fails to generate significant important information relevant to 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 paediatric bedside nursing because few guidelines suggest that smaller groups (4-6) are allowed when the members have much experience to share [16,17]. On the base of

gathered information finally a preliminary draft of SOPs and checklists 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 panel of 13 experts included seven members of nursing faculty and six faculty members from pediatrics medicine. In a Similar study done by Kaushal R K et al., there were eleven

Delphi members [19]. D'Souza SRB et al., used an interdisciplinary panel of seven national and international experts for development of a tool for assessing preterm infants [20]. In another study to develop protocol for care of neonates with tracheoesophageal fistula/esophageal atresia, George L et al., used a panel comprising of 10 members [21].

Delphi technique employs series of questionnaire to collect data from panelists [17]. In present study, the printed drafts of drug administration procedures were given to the Delphi panelists four times. 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 RK et al., common consensus was reached in four Delphi rounds [19], according to George L et al., three rounds were sufficient [21].

The validity of SOPs and checklists was confirmed by CVI. The overall CVI of current study from the panel of experts was calculated 100% indicating the validity of the individual item. In a similar study, conducted by D'Souza SRB et al., the overall CVI was 95% [20].

The reliability of these checklists was ensured by Cronbach's alpha because it assesses the internal consistency/average correlation of items in a tool to check its reliability [22]. The overall Cronbach's alpha value of checklists developed in current study were calculated 0.962, 0.821, 0.954 respectively for IM, ID, subcutaneous routes and item score correlation to overall score was in between 0.2-0.91. In a similar study by George L et al., overall value of alpha was 0.76 [21]. Another study Kaushal RK et al., revealed Cronbach's alpha value 0.97 [19].

LIMITATION
The tool could not be devised on large sample because of time constraints. Secondly, complete anonymity could not be maintained during the Delphi rounds as the panelists were in the same campus.

CONCLUSION
SOP on IM, ID and subcutaneous drug administration is developed which is valid and feasible along with reliable and valid checklists to implement the protocol. For ready references booklet form of SOP and poster's binder carrying pictures of drug administration technique were made available. It is recommended to use this SOP for IM, ID and subcutaneous drug administration for children. The checklist can be used by nurse administrators to assess the implementation of SOP.

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