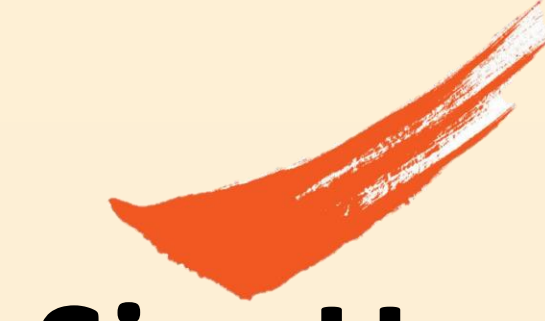




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"CAN DO SPIRIT" IN CLINICAL RESEARCH NURSING



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BACKGROUND

- SingHealth IMU is a dedicated Early Phase Clinical Research Unit
- Clinical trials are conducted according to stipulated criteria in Protocol approved by CIRB and HSA
- Pharmacokinetic (PK) *blood collection* from volunteer is one of the most common nursing procedure in the conduct of clinical trials
- Blood collection is done *manually* by Clinical Research Nurses (CRNs)
- Protocol stipulates PK blood to be collected at:
 - ✓ Pre-dose of Investigational Product (IP)
 - ✓ Post-dose of IP at 15 min, 30 min, 1 Hr, 2 Hr, 4 Hr...etc
- By practice, CRNs collect all PK blood at indicated time to an *accuracy of within 1 min*, otherwise it may be a protocol deviation

NEW CHALLENGES

- A new clinical trial posed new challenges for CRNs
- New trial protocol required blood to be collected :
 - ✓ At Pre-dose of investigational product
 - ✓ During dosing (0 sec), at Post-dose 5 sec, 10 sec, 15 sec, 20 sec, 25 sec, 30 sec, 35 sec, 40 sec, 45 sec, 50 sec, 55 sec, 1 min, 2min ...etc
- **Objectives:**
 - ✓ Blood collection at *every 5 sec* with an *accuracy of 1 sec*
 - ✓ Precise blood collection *techniques* by CRN
 - ✓ Blood collected must be clearly *identified & labelled*
 - ✓ Form A *Dedicated Team* with good co-ordination and

"CAN DO SPIRIT"

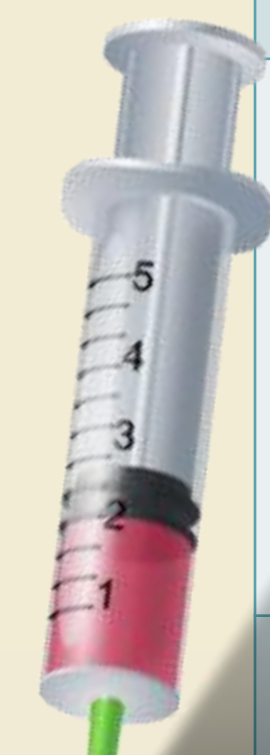
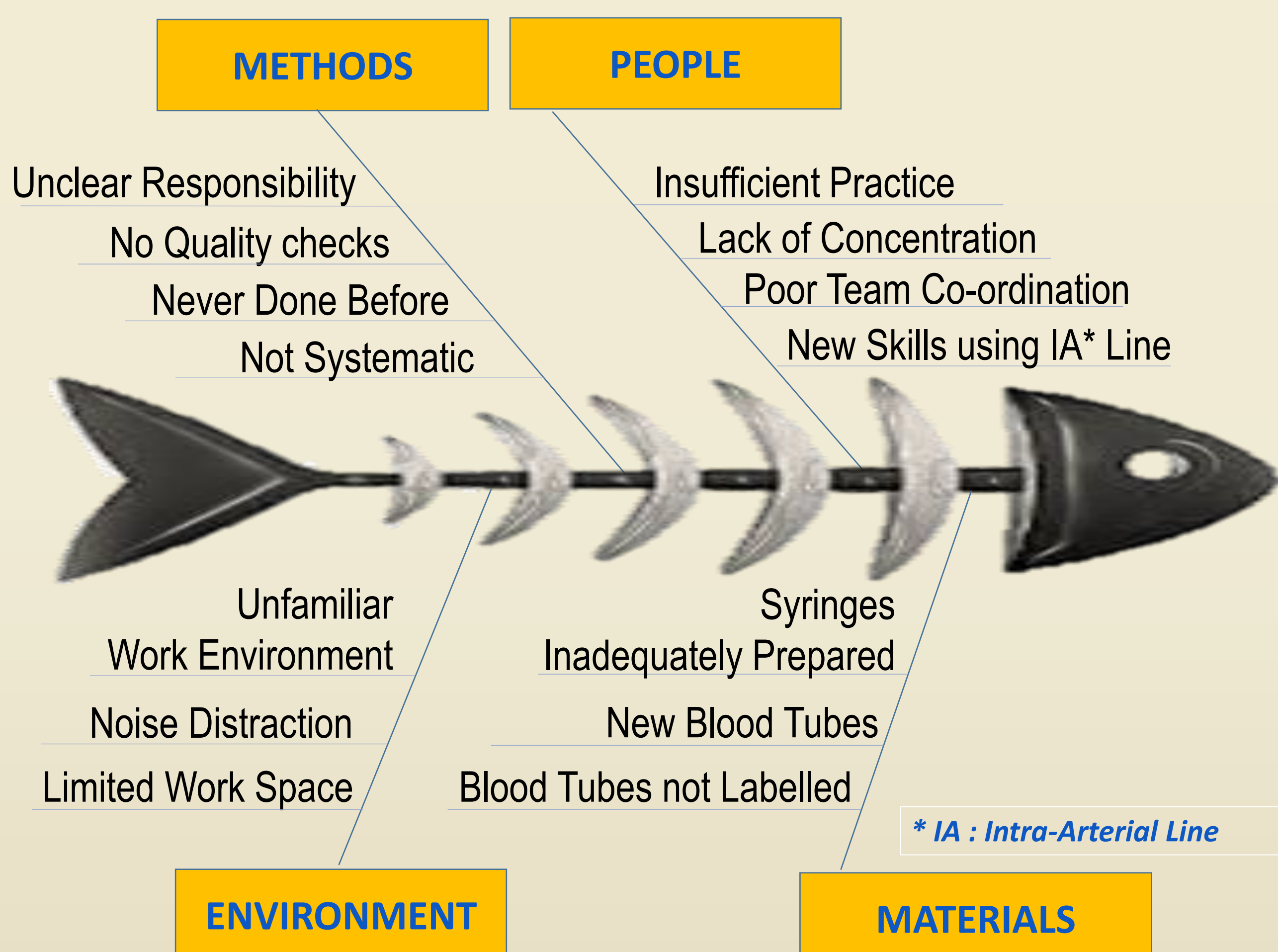
FLOWCHART OF OPERATION PROCESS

TIMELINE	CRN1 (Directs – Tracts Time)	CRN2 (Draws Blood)*	CRN3 (Provides Assistant)	CRN4 (Maintains Quality)
Pre-Dosing				
Dosing				
0 sec				
1 sec				
2 sec				
3 Sec				
4 Sec				
5 sec	Instruct to "Draw" Blood on the second and Tract Time	Collect Blood in Syringe & Pass Syringe to Assistant	Receive Syringe & Collect Blood in Tube	Receive Blood in Tube, Perform Check, & Confirm Time
6 sec				
7 sec				
8 Sec				
9 Sec				
10 sec				
11 sec				
12 sec	Instruct to "Draw" Blood on the second and Tract Time	Collect Blood in Syringe & Pass Syringe to Assistant	Receive Syringe & Collect Blood in Tube	Receive Blood in Tube, Perform Check, & Confirm Time
13 Sec				
14 Sec				
15 Sec				

Special Mention:
 Dosing: Dosing of Investigational Product
 * Before collecting blood samples, waste blood was collected and discarded; Blood must be collected manually via syringe through needless connector instead of vacutainer because it was collected from intra-arterial line

METHODOLOGY

Possible Cause & Effect of Difficulties Identified



Blood Collection Deviation > 1 sec

RESULTS

- Blood collection at 5 secs interval without deviation was achieved successfully
- A dedicated team is formed to execute blood collection workflow systematically
- Quality checks were built-in to ensure no errors and no protocol deviation

CONCLUSIONS

- Competency in new blood collection techniques, alertness cum ability to concentrate, speed plus skills & excellent systematic coordination resulted in breakthrough success, delighted Investigators and Team
 - **Practice, Practice, Practice was the key to**
- "CAN DO SPIRIT"**
- Automatic Blood Sampling System (ABSS)– a device to collect blood could be an alternative to manual blood collection. *Cost-saving of more than S\$20,000/- [Manual]*



Notes: Pharmacokinetics describes how the body affects a specific drug after administration through the mechanisms of absorption and distribution, as well as the chemical changes of the substance in the body and the effects and the routes of excretion of the metabolites of the drug. PK properties of drugs may be affected by elements such as the site of administration and the dose of administered drug. These may affect the absorption rate.

References:
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