Critical analysis of quality control standards of fresh frozen plasma in India as given by DCA and DGHS Manual

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BACKGROUND & OBJECTIVES

Quality standards of Fresh frozen plasma (FFP) are included in Drugs and Cosmetic act (DCA, Second Amendment) 2020 and Directorate General of Health Services (DGHS) Manual 3rd edition 2022.

Objective of this study is to analyse the quality control data for FFP done at our centre during last one year based on these standard and critically analyse the Indian standards (specially for the volume and Factor VIII content of the bag for FFP) and compare these standards with international Standards.

METHODS

Quality Control data of 234 FFP units (109 units from 350 ml collection and 125 units from 450 ml collection) was analysed for volume Factor VIII and Fibrinogen content of the bags.QC criteria for volume : 180-220ml from 350 ml bag, 220-300 ml from 450 ml bag and QC criteria for Factor VIII : at least 70 IU/bag and Fibrinogen 200 to 400 mg / bag were taken, as given in DCA and DGHS Manual.

Quality Control Criteria for FFP

FFP	DCA 2020	DGHS	AABB (21st Edition)	EU (EDQM (21st Edition))
Volume	180-220ml from 350 ml bag 220-300 ml from 450 ml bag	180-220ml from 350 ml bag 220-300 ml from 450 ml bag	none	± 10% of stated volume all units
factor VIII	70 IU/ Bag	70 IU/ Bag in 3rd edition DGHS 0.7 IU/ ml In 2nd edition of DGHS	Factor VIII must not be less than 70 IU per mL, in of 90% units	Average (after freezing and thawing): not less than 70 IU per 100 mL
Fibrinogen	Not specified	200-400mg 4 units or 1% per month	none	Average (after processing): ≥ 60 % of the potency of the freshly collected plasma unit

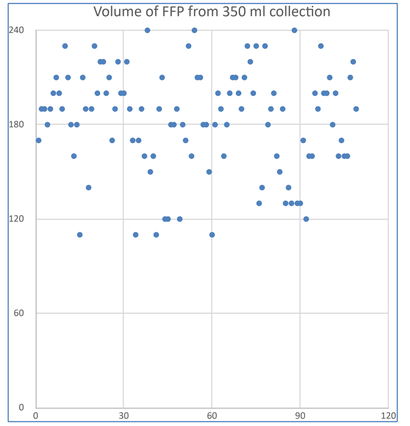
RESULTS

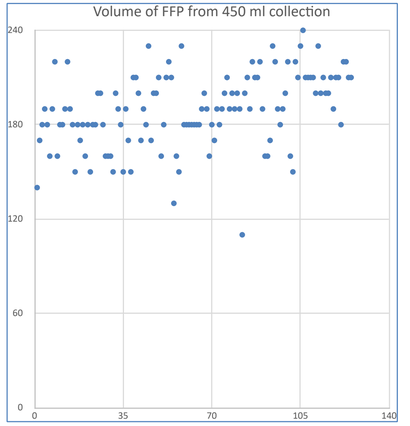
- 62 out of 109 (57%) FFP prepared from 350 ml bags and 16 out of 125 (13%) prepared from 450 ml bags passed the QC criteria for volume.
- If we take 350 ml bags where PC was not prepared and only FFP was prepared, 60 out of 82 (73%) of the bags passed the QC criteria for volume. This shows that the newer QC criteria for volume, does not count for 50 to 70 ml PC prepared from the 350 ml bags along with FFP.
- This is why FFP prepared from most of 450 ml bags failed the volume QC criteria, as PC is always prepared along with FFP from these bags.
- For Factor VIII, the earlier QC criteria was 0.7 IU/ml, which is same as given by European union. As per this criteria, 181 out of 234 FFP (77.3%) pass the QC criteria.
- In DCA 2020 Amendment, Factor VIII QC criteria is lowered to 70 IU/per bag,. As per the newer criteria 225 out of 234 (96%) of FFP pass the QC criteria.
- QC criteria of 70 IU/per bag for FFP looks inappropriate as criteria for Cryoprecipitates which are prepared from FFP is 80 IU/ per bag.

QC of FFP (Jan 23 to Dec 23)

Parameter	Quality Requirement	Number of Units tested	Range of Values	Number of Units Passing QC	Percentage
Volume	180-220 ml from 350 ml bag	234 109 , 350 ml bags	110 to 240 ml	62/ 109	57%
	220-300 ml from 450 ml bag	125, 450 ml bags	110 to 240 ml	16/125	13%
Factor VIII	70 IU/bag	234	32 to 540 IU	225/234	96%
	0.7 IU/ml	234	0.16 to 2.65 IU	181/234	77.3%
Fibrinogen	200 – 400 mg	234	182 to 1092 mg per bag	233/234	99.5%

Distribution of FFP volumes





CONCLUSION

- The present QC criteria for volume does not take into account if we have prepared a PC along with FFP or not. So there should be separate criteria for FFP volume for bags with and without PC prepared from the bag.
- QC criteria of 70 IU/per bag for FFP looks inappropriate as criteria for Cryoprecipitates which are prepared from FFP is 80 IU/ per bag.
- So a relook needs to be done in DCA QC criteria for FFP specially for volume and factor VIII content so that these criteria can measure the quality of FFP prepared in a blood centres appropriately.

REFERENCES

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