

Research article

Blood Bank Inspections in Two French Regions: A Good Experience

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Abstract

The Center-Val de Loire region (CVL) has 30 blood banks (2 Deliveries Banks (DB), 2 Relay Banks (RB), 1 Emergency Bank (EB), 25 Emergency / Relay Banks (ERB)) distributed over all these 6 departments. The Bourgogne-Franche-Comté (BFC) region has 22 blood banks (16 DB, 4 EB, 2 ERB) distributed over all these 8 departments. The French reglementation requires the production of at least one control during the period of validity of the authorization (5 years). The aim of our work is to compare the results between these two regions. The study concerns 50 establishments of health with a blood bank (18 DB, 2 RB, 3 EB, 27 ERB). The remarks and discrepancies appearing on the inspection reports led to administrative decisions (recommendations, prescriptions, injunctions) according to the gravity and the presence of a legislative text. They were arbitrarily classified into 6 groups (blood bank staff, data computer system, transport, equipment, documents and non-updated agreement). 97 remarks were collected in CVL, 71 in BFC, 169 discrepancies in CVL, 160 in BFC. The problems with blood bank staff dominate in both regions, followed by problems related to equipment and document. Injunctions are more frequent in CVL but for the same type than in BFC (blood bank staff and equipment). The results of the blood bank control of the 2 regions are quite comparable. The majority of anomalies have related with the blood bank staff. Injunctions are more frequent in CVL than in BFC.

keywords: blood bank, inspection, risk management quality assessment

Introduction

The Center-Val de Loire region (CVL) has 30 blood banks (2 Deliveries Banks (DB), 2 Relay Banks (RB), 1 Emergency Bank (EB), 25 Emergency / Relay Banks (ERB)) distributed over all these 6 departments. The Bourgogne-Franche-Comté (BFC) region has 22 blood banks (16 DB, 4 EB, 2 ERB) distributed over all these 8 departments. The French reglementation requires the production of at least one control during the period of validity of the authorization (5 years). The aim of our work is to compare the results between these two regions. That is also a good point of view over the blood banks in France.

Materials and Methods

The analysis concerns 50 Health Center (HC) with a blood bank (18DB, 2 RB, 3 EB, 27 ERB). The inspection of Blood Banks is part of a double legal framework: The French reglementation requires the production of at least one control during the period of validity of the authorization (5 years). The definitions are as follows [1]: A remark is an expression of a more or less serious defect perceived by the inspection mission and which cannot be characterized in relation to a legislative text. A discrepancy is an expression of non-

compliance with respect to an opposable legislative text. One recommendation relates to a low risk default that was found in the absence of a legal reference text. A prescription follows the finding of a discrepancy in relation to an opposable legislative text. It's a latent risk that needs attention.

An injunction follows the finding of a discrepancy in relation to an opposable legislative text. It relates to a critical and patent risk. It's a prerequisite for a « heavy » measure fixed by the law (closure, action on authorization). They were arbitrarily classified into 6 groups (blood bank staff, data computer system, transport, equipment, documents and non-updated agreement).

Results

97 remarks were collected in CVL, 71 in BFC, 169 discrepancies in CVL, 160 in BFC. The results of the administrative decisions of each region are shown in Table 1. 63 % of administrative decisions in CVL, 69% in BFC are related to prescriptions or injunctions. The administrative decisions relating to blood bank staff are in the majority in the 2 regions. It's most often the absence of a training process for personnel authorized to use the blood bank (formalization of initial

training, accreditation). The absence of regulatory training [2] is responsible for most of the injunctions. In second position, the anomalies related to documents (absence or update not carried out). Third, problems related to the equipment, in particular the absence of a maintenance contract and the qualification of conservation equipment [3].

The anomalies related to the transport of the Blood products are arrived in fourth position in CVL; it can be the absence of convention with the external service provider or inadequacy with the good practices [4]. Injunctions are more frequent in CVL but the same type than in BFC (Blood bank staff and equipment)

Table 1. The results of the administrative decisions of each region CVL and BFC.

	Recommandation		Prescription		Injunction		Total	
	CVL	BFC	CVL	BFC	CVL	BFC	CVL	BFC
<i>Blood Bank staff</i>	13	10	53	79	8	2	74	91
<i>Data computer system</i>	0	6	8	4	3	0	11	10
<i>Transport</i>	23	3	10	4	5	0	38	7
<i>Equipment</i>	23	10	32	21	11	2	66	33
<i>Documents</i>	36	41	21	40	2	0	59	81
<i>Non –updated agreement</i>	2	1	15	8	1	0	18	9
<i>Total</i>	97	71	139	156	30	4	266	231

Discussion

The anomalies related to the transport of the Blood products are arrived in fourth position in CVL; it can be the absence of convention with the external service provider or inadequacy with the good practices [4]. Injunctions are more frequent in CVL but the same type than in BFC (Blood bank staff and equipment) .The territory of BFC is larger (47.784 Km2 for 2.817.266 citizens) than the CVL region (39.151 km2 for 2.500.000 citizens). A diiferent territorial organization explains the distribution of the types of blood bank between these 2 regions (majority of ERB in CVL, Majority of DB in BFC). The anomalies of the blood bank staff are the majority in the 2 regions. This is the witness to the need for regular information from HC and the establishment of easily accessible training [5]. The problems with the blood bank equipment are significant and represent the largest number of injunctions in CVL. The absence of a maintenance contract or its inadequacy with satisfactory control (unverified alarms), the qualification of conservation equipment not carried out, the existence of material unsuitable for the conservation of blood products were the most frequently encountered anomalies. Updating documents must be imperative and followed by the quality department of the HC. The data computer system of RB, ERB and EB is a regulatory obligation [4].

In CVL, the HC have often external providers as carriers. Contracts are often incomplete and do not follow good practice [4]. Driver training in Blood products transport, the existence of an emergency kit in the event of an accident, the existence of a confidentiality.

Conclusion

The results of the blood bank control of the 2 regions are quite comparable. The majority of anomalies have related with the blood bank staff. Injunctions are more frequent in CVL than in BFC. These results are a good vision of the problems that exist in the French Blood Banks.

Abbreviations

CVL: Center Val de Loire; BFC: Bourgogne FrancheComté; DB: Deliverie Bank; RB: Relay Bank; EB: Emergency Bank; ERB: Emergency/Relay Bank; HC: Health Center

References

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