HTA and Laboratory setting: the case of an innovative blood collection tube

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Background

- The discussion concerning the use of plasma or serum tubes is still an open topic in the Laboratory setting, requiring an in-depth analysis, in particular with regard to innovative plasma blood collection tube introduction, with a mechanical separator (BD Vacutainer Barricor™)
- Compared to standard gel tubes, BD Barricor™ tubes provide a plasma sample with less cellular contamination, improved sample stability, reduced centrifugation time, no gel globules, and no fibrin due to insufficiently clotted serum tube (Fuzery et al., 2017; Dupuy et al., 2018; Cadamuro et al., 2018; Ramakers et al., 2020)

Objective

The present study aims at exploring the potential advantages related to the adoption of the innovative plasma tube, for both routine and emergency chemistry tests, in comparison with serum gel separator tubes, in terms of improvement of laboratory efficiency, by investigating its implications on TAT (Turn Around Time), and sample quality

Methods

For the achievement of the study objective, a Health Technology Assessment (HTA) study was conducted, assuming the hospital perspective, to guarantee a positive value-based impact of different technological approaches, for both hospitals and patients

An "AS IS" scenario (use of the serum gel separator tube only) was compared with a "TO BE" scenario (use of the innovative plasma blood collection tube only), to assess the economic/organizational advantages, and the capability of the innovative device, to improve pre-analytical indicators

Hemolysis level, number of samples with clotting issues, turnaround time and centrifugation time, derived from literature data for the innovative tube, were used to estimate all the potential benefits, starting from the "AS IS" real world laboratory practice, performed in three different Italian Hospitals on annual basis (on average 946,340 tubes per year, of which 19.11% as urgent requests)

Results

The potential pre-analytical benefits related to Barricor™ introduction

- The "AS IS" scenario revealed an occurrence rate of hemolysis level and samples with clotting issues, on average equal to 4.82% and 3.69%. Literature evidence available on the topic (Ramakers et al., 2020), revealed a lower occurrence rate of the above, equal to 1.2% and to 0.40%, respectively
- The introduction of BD Vacutainer Barricor™ in the "TO BE" scenario could lead to a significant decrease in the pre-analytical indicators: on average, a reduction of -55% of the hemolysis level and of -51% of clotting issues could be achieved

AS IS Scenario	Hospital # 1		Hospital # 2		Hospital # 3	
	% samples with hemolysis	N. samples with hemolysis	% samples with hemolysis	N. samples with hemolysis	% samples with hemolysis	N. samples with hemolysis
Emergency	12.01%	19,545	5.27%	8,382	0.38%	839
Routine	9.62%	41,813	1.51%	18,611	0.11%	692
Total		**61,358**		**26,993**		**1,531**
TO BE Scenario	**Hospital # 1**		**Hospital # 2**		**Hospital # 3**	
	% samples with hemolysis	**N. samples with hemolysis**	**% samples with hemolysis**	**N. samples with hemolysis**	**% samples with hemolysis**	**N. samples with hemolysis**
Emergency	1.20%	1,954	1.20%	1,909	0.11%	243
Routine	1.20%	5,213	1.20%	14,790	0.11%	692
Total		**7,167**		**16,699**		**935**
Reduction of samples with hemolysis	***-88.32%***		***-38.14%***		***-38.93%***	

AS IS Scenario	Hospital # 1		Hospital # 2		Hospital # 3	
	% samples with clotting issues	N. samples with clotting issues	% samples with clotting issues	N. samples with clotting issues	% samples with clotting issues	N. samples with clotting issues
Emergency	0.84%	1,367	0.32%	509	1.00%	2,208
Routine	0.80%	3,475	0.19%	2,342	1.00%	6,294
Total		**4,843**		**2,851**		**8,502**
TO BE Scenario	**Hospital # 1**		**Hospital # 2**		**Hospital # 3**	
	% samples with clotting issues	**N. samples with clotting issues**	**% samples with clotting issues**	**N. samples with clotting issues**	**% samples with clotting issues**	**N. samples with clotting issues**
Emergency	0.40%	651	0.19%	302	0.40%	883
Routine	0.40%	1,738	0.19%	2,342	0.40%	2,518
Total		**2,389**		**2,644**		**3,401**
Reduction of samples with clotting issues	***-50.67%***		***-7.25%***		***-60.00%***	

The potential organisational and economic impact related to Barricor™ introduction

Hospital # 1	TAT AS-IS (minutes)	TAT TO-BE (minutes)	△ TAT	△ TAT %
Emergency	74	40.1	-33.9013	-45.81%
Routine	200	166.18	-33.8226	-16.91%
Hospital # 2	**TAT AS-IS (minutes)**	**TAT TO-BE (minutes)**	**△ TAT**	**△ TAT %**
Emergency	67,12	33.48	-33.64485	-50.13%
Routine	98,3	64.79	-33.5093	-34.09%
Hospital # 3	**TAT AS-IS (minutes)**	**TAT TO-BE (minutes)**	**△ TAT**	**△ TAT %**
Emergency	40	36.4	-3.6131	-9.03%
Routine	90	56.41	-33.605	-37.34%

Switching from serum to plasma matrix allows, besides saving 30 minutes for clotting formation, a time saving equal to 1,085 hours and to 8,194 hours, for the management of hemolysis and clotting issues, respectively

	Savings from sample with emolysis	Savings from clotting samples
Hospital # 1	-61,127.83 €	-16,152.96 €
Hospital # 2	-11,611.47 €	-1,353.60 €
Hospital # 3	-627.47 €	-33,569.28 €

The Hospital financial advantage on annual basis would suggest an economic saving equal to € 92,517, in the average analysis of 946,340 tubes per year

	Costs for Scenario AS IS	Costs for Scenario TO BE	Budget Impact (Euro)	Budget Impact (%)
Hospital # 1	€ 2,233,381.87	€ 2,057,051.33	-176,330.54 €	-7.90%
Hospital # 2	€ 4,807,639.86	€ 4,742,880.05	-64,759.81 €	-1.35%
Hospital # 3	€ 2,926,218.10	€ 2,889,754.71	-36,463.39 €	-1.25%

Conclusions

- The introduction of BD Vacutainer Barricor™ may be considered as valid technological alternative, within the investigated setting
- Results demonstrated the improvement in the pre-analytical indicators, when using the innovative technology, with important benefits from an organizational and an economic point of view
- The above advantages would lead to a relevant benefit considering the patient's point of view, in particular with respect to the decrease in the number of hospital access for repeating the blood sample (1.00 vs 0.11, p-value < 0.05)
- Value-based healthcare approaches supported the strategic relevance in the advanced technology introduction, its economic sustainability and feasibility, and the process improvement

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