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BD

Value and cost-effective solution for peripheral intravenous infusion: FLAT Project Savona real world evidence

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Thematic background

- Peripheral Venous Catheter (PVC) is a largely used device in hospital setting, representing an essential element of modern medicine and the most frequent invasive procedure performed in hospitals
- However, PVCs often fail before the therapy is completed: this can occur because the device is not adequately attached to the skin, allowing the PVC to fall out, leading to complications such as phlebitis, infiltration or occlusion, with the consequent increase in patient morbidity and length of stay
- In this regard, two territorial Hospitals referring to Liguria Region (ASL N.2 Hospitals, in the Liguria Regional Healthcare Service, Italy), proposed and implemented an innovative standard procedure, that imposed the use of three specific disposable devices for washing, infusion and cleaning of PVCs

Aim of the Study

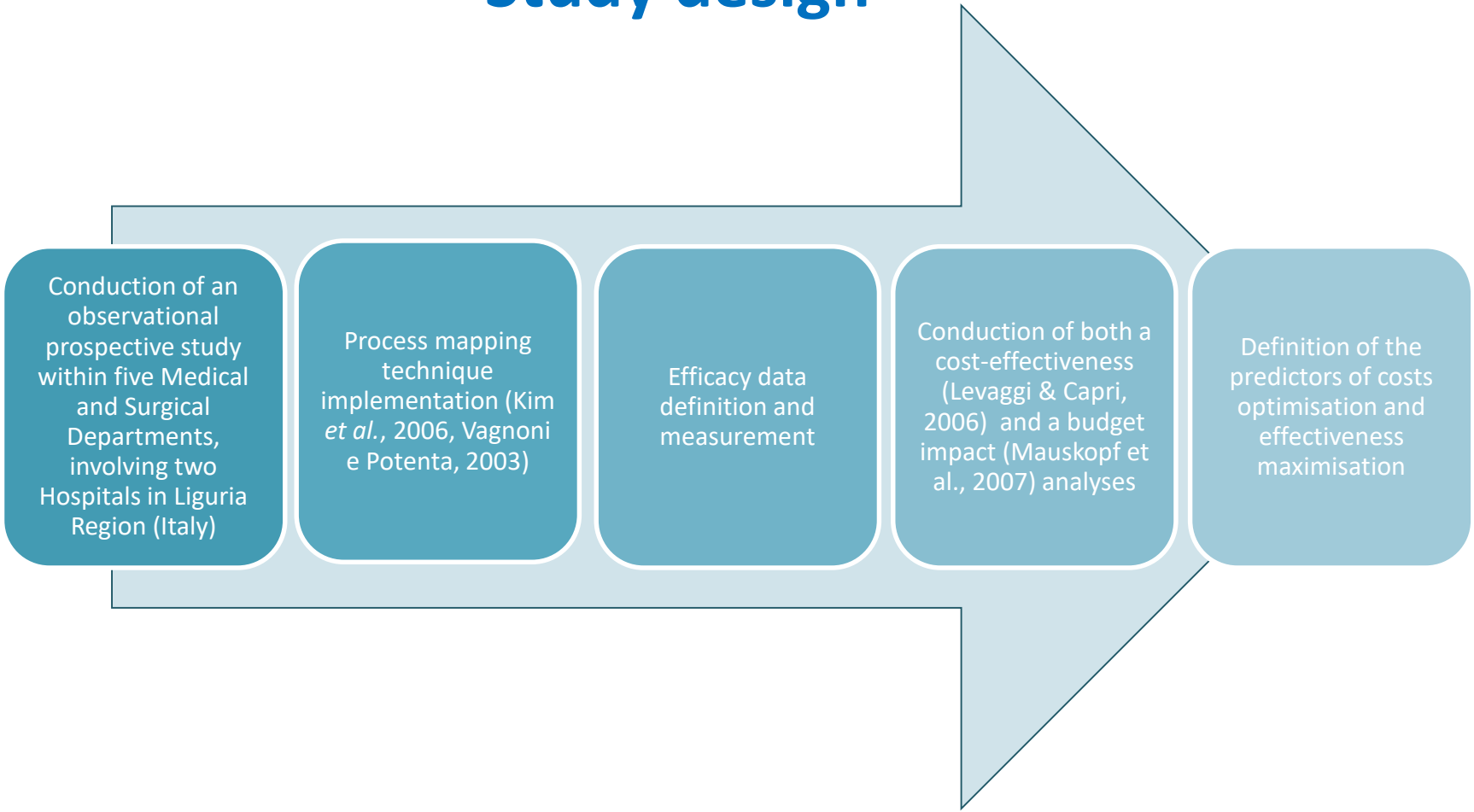
The primary aim of the study is to analyze the process of management of PVCs in the clinical practice, in relation to outcome measures achieved, and to define the related economic resources absorption, with regard to presence or absence of PVCs implant standard procedure, thus comparing different scenarios

The scenarios under assessment

The three scenarios differed on the basis of the use of BD ChloraPrep™ , BD Nexiva™ and BD Posiflush™

	Medical Devices used • BD ChloraPrep™: Disposable device used for disinfection • BD Nexiva™: innovative Peripheral Venous Catheter, to be inserted • BD Posiflush™: disposable device for washing up the patients after the catheter removal	**Activities carried out** • N. of insertion attempts <4 • Replace CVP in 96 hours • N. of washes ≥ N. of accesses to the catheter	**Being in procedure / Not being in procedure**
SCENARIO 1	✓ ✓ ✓	✓	*Being in procedure*
SCENARIO 2	✓ ✓ ✗	✗	*Not being in procedure*
SCENARIO 3	✓ ✗ ✗	✗	*Not being in procedure*

Study design



The sample under assessment - 1

Savona Hospital

- ✓ Internal Medicine 1 and Hematology Operating Unit
- ✓ Internal Medicine 2 and Intermediate Care Operating Unit
- ✓ Orthopaedic Operating Unit

REGIONE LIGURIA

Pietra Ligure Hospital

- ✓ Orthopaedic Operating Unit
- ✓ Neurosciences Operating Unit

The sample under assessment - 2

Consecutive cases of patients were enrolled on **an observational prospective study** within 5 Hospital Operative Units of Medical or Surgical Departments, involving two Hospitals in Liguria Region (Italy), from September 2018 to January 2019

Operating Units	Nr. Patients	%
Internal Medicine 1 and Hematology (Hospital of Savona)	73	19.21%
Internal Medicine 2 and Intermediate Care (Hospital of Savona)	125	32.89%
Orthopaedic (Hospital of Savona)	57	15.00%
Neurosciences (Hospital of Pietra Ligure)	52	13.68%
Orthopaedic (Hospital of Pietra Ligure)	73	19.21%
Total	380	

Population are comparable for all the three scenarios

The populations under assessment are well-matched and superimposable with regard to the above demographic characteristics, since no statistically significant differences emerged (p-value > 0.05)

	N. of patients	Average Age	Female Gender [%]	BMI (Body Mass Index)	Presence of comorbitities
Scenario 1	68 (17.89%)	72.48	52.94%	24.66	72.1%
Scenario 2	172 (45.26%)	70.98	54.07%	25.45	72.1%
Scenario 3	140 (36.84%)	70.74	54.29%	24.59	74.3%
TOTAL	380 (100.00)	71.16	53.95%	24.99	72.9%
P-value		0.776	0.869	0.094	0.897

Process Cost - 1

No statistically significant differences emerged, among scenarios, considering the total costs (*p-value* =0.323).

The validity of the innovative procedure is demonstrated, especially with regard to the management of adverse events (p-value = 0.001), whose absorption of economic resources is significantly lower

	Human Resources [€]	Cost of Accessories [€]	Cost of technology at first positioning [€]	Cost of technology after first positioning [€]	Sub-total Procedure [€]	Repositioning for adverse events [€]	Assessment of adverse events [€]	Sub-total adverse events [€]	Total Cost [€]
SCENARIO 1	€ 4.60	€ 0	€ 5.04	€ 8.24	**€ 17.88**	€1.39	€ 1.05	€ 2.44	**€ 19.60**
SCENARIO 2	€ 6.17	€ 0.61	€ 6.01	€ 7.31	**€ 20.10**	€ 3.16	€ 1.07	€ 4.23	**€ 20.99**
SCENARIO 3	€ 4.38	€ 0.96	€ 4.06	€ 8.14	**€ 17.54**	€ 3.75	€ 1.88	€ 5.63	**€ 22.42**
P-value	0.001	0.000	0.000	0.536	**0.351**	0.022	0.000	0.001	**0.323**

Process Cost aggregated in two scenarios: being in procedure *vs* not being in procedure - 2

The economic evaluation **shows the feasibility and sustainability** of Scenario 1 (being in procedure): despite higher cost in the technology used, Scenario 1 is related to a lower overall process cost, given the occurrence of fewer adverse events

	Human Resources [€]	Cost of Accessories [€]	Cost of technology at first positioning [€]	Cost of technology after first positioning [€]	Sub-total Procedure [€]	Repositioning for adverse events [€]	Assessment of adverse events [€]	Sub-total adverse events [€]	Total Cost [€]
Procedure implementation	€ 4.60	€ 0	€ 5.04	€ 8.24	**€ 17.88**	€ 1.39	€ 1.05	€ 2.44	**€ 19.60**
Not being in procedure	€ 5.28	€ 0.79	€ 5.04	€ 7.73	**€ 18.82**	€ 3.46	€ 1.48	€ 4.93	**€ 21.71**
P-value	0.004	0.000	0.412		**0.021**	0.000	0.000	0.000	**0.019**

PVCs management execution time

- The process mapping analysis revealed that, on average, the process is carried out by one healthcare professional
- Scenario 1 presented the lower time of execution (on average 4.39 minutes), and the lower cost, with a statistically significant result

	Average execution time [min]	Healthcare professionals involved [nr]
SCENARIO 1	4.39	1.02
SCENARIO 2	6.47	1.02
SCENARIO 3	4.96	1.03
P-value	0.000	0.145

A focus on PVCs effectiveness

- The achieved outcome measures revealed that, in the Scenario 1, **the 86.8% of the PVC removal was due to the end of the therapy**, and not associated to adverse events, as in the other Scenarios
- Scenario 1 consequently reported a lower average number of attempts in PVC cannulation (1.92), with a better efficacy profile

	PVC removal due to the end of therapy [%]	PVC removal due to the adverse events [%]	Average number of attempts at PVC cannulation [N.]	PVC stay in situ [days]
SCENARIO 1	86.8%	13.2%	1.92	7.91
SCENARIO 2	62.8%	37.2%	2.15	6.77
SCENARIO 3	11.40%	88.60%	2.30	6.93
P-value	0.000		0.413	0.163

A focus on PVCs effectiveness, comparing “being in procedure” *vs* “not being in procedure”

	PVC removal due to the end of therapy [%]	PVC removal due to the adverse events [%]	Average number of attempts at PVC cannulation [N.]	PVC stay in situ [days]
Procedure implementation	86.8%	13.2%	1.92	7.91
Not being in procedure	39.40%	60.60%	2.22	6.85
P-value	0.000		0.314	0.098

A focus on adverse events

- Scenario 1 presents the best performance, guaranteeing the lower level of adverse events occurrence
- The accidental displacement is an adverse event related only to the implant procedure (with an incidence rate increased in case of no procedure implementation)
- PVC removal from patient, only depends to the specific patient clinical conditions

	% of Patients	Bloodpot	Accidental Displacement	PVC removal from patient	Fever	Occlusion	Phlebitis
SCENARIO 1	13.2%	0.00%	0.00%	8.82%	0.00%	2.94%	1.47%
SCENARIO 2	37.2 %	2.33%	8.72%	5.23%	5.23%	6.98%	8.72%
SCENARIO 3	88.60%	3.57%	15.00%	11.43%	17.86%	18.57%	22.14%
P-value		0.000	0.000	0.000	0.000	0.000	0.000

A focus on adverse events, comparing “being in procedure” *vs* “not being in procedure”

	% of Patients	Bloodpot	Accidental Displacement	PVC removal from patient	Fever	Occlusion	Phlebitis
Procedure implement ation	13.2%	0.00%	0.00%	8.82%	0.00%	2.94%	1.47%
Not being in procedure	60.60%	2.95%	10.86%	8.33%	11.55%	12.48%	14.43%
p-value		0.000	0.000	0.314	0.000	0.000	0.000

A focus on adverse events, considering the only use of BD NEXIVA™ versus other PVCs

	Bloodpot	Accidental Displacement	PVC removal from patient	Fever	Occlusion	Phlebitis
BD Nexiva™	0.78%	3.36%	7.03%	1.16%	3.68%	1.32%
Traditional PVCs	5.90%	20.73%	15.66%	21.09%	25.56%	30.86%
p-value	0.000	0.000	0.000	0.000	0.000	0.000

Cost-effectiveness analysis

	Total cost	Effectiveness	CEV
SCENARIO 1	€ 19.60	86.80%	22.58
SCENARIO 2	€ 20.99	62.80%	33.42
SCENARIO 3	€ 22.42	11.40%	196.75

Dominant Scenario

Budget impact analysis

Budget impact analysis, considering 156,624 PVCs implanted on annual basis	
Baseline Scenario A – Use rate of the procedure equal to 18%	€ 1,770,719
Innovative Scenario B - Use rate of the procedure equal to 100%	€ 1,598,871
Innovative Scenario C - Use rate of the procedure equal to 50%	€ 1,684,933
Innovative Scenario D - Use rate of the procedure equal to 35%	€ 1,710,751
Δ € B-A	- € 171,848
Δ % B-A	**- 9.71%**
Δ € C-A	- € 85,786
Δ % C-A	**- 5.09%**
Δ € D-A	- € 59,968
Δ % D-A	**- 3.51%**

Conclusions: Key-Messages

Efficacy (PVC removal due to the end of the therapy and not for adverse events)

86%

Time saving per year

46,028 min

The standard PVC implant procedure

Cost saving per year: hospital perspective

€ 171,848

Cost saving per patient

€ 2.82

Cost saving per year: Liguria Region perspective

€ 980,881