

Organizational Impact of the Introduction of a New Portable Syringe Pump for Iloprost Therapy in Italian Hospital Settings

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Abstract: *Purpose:* The study aims at assessing the organizational and economic impact related to the use of a new portable syringe pump (Pompa Infonde[®], Italfarmaco S.p.A., Cinisello Balsamo, Italy) at a hospital level.

Methodology: Based on the HTA approach, the analysis assessed the organizational and economic impact of the new device at hospital level, using the traditional methods of Iloprost infusion as comparator. After a pilot evaluation, the organizational impact was assessed within 24 Italian hospitals. Structured interviews were conducted with clinicians and nurses. According to the Hospital-Based HTA approach, a questionnaire assessed the impact on human resources, training activities, internal meetings, spaces needed, facilities, clinical practice implications. Using Activity Based Costing approach, the economic evaluation was performed within the pilot center “Ospedale Civile” of Legnano, Italy.

Findings: The new device leads to a positive managerial impact, with a substantial reduction of time to monitor patients by nurses. This resulted in a better management of human resources and in a reduction in nursing cost. Although a mild negative impact on training time for personnel, the structured interviews allowed the identification of three main areas of positive impact: (i) efficiency of internal processes, (ii) clinical pathways, (iii) synergies between wards.

Originality: The organizational impact of Pompa Infonde[®], showed that it is an efficient alternative to traditional methods, with benefits in the management of patients administered with Iloprost.

Keywords: Hospital, Italy, medical device, organizational impact, prevention, rehabilitation.

1. INTRODUCTION

Health care providers increasingly seek new technological and organizational means of improving the efficiency and clinical effectiveness of care and health service delivery [1]. The assessment and evaluation of these solutions has become a major focus of investigation in health services research, especially in contexts characterized by scarcity of resources. The introduction of new

technologies (diagnostic and treatment methods, medical equipment, pharmaceuticals, rehabilitation and prevention methods) and the assessment in terms of clinical outcome but also of their integration in healthcare settings are key problems for decision-makers and researchers [2, 3].

Moreover, healthcare organizations have considerable autonomy in defining the strategy in the implementation or disinvestment of new technologies, but limited resources often lead the focus to short term goals, giving up more innovative choices.

Different levels of health services - National Ministry of Health, regional and provincial

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authorities and healthcare organizations - have adopted methods and evaluation models that can support the decision process of health policy [4].

In this context, Health Technology Assessment (HTA) has been used worldwide in order to inform decision-making in health services, at different levels (macro – health policy, meso – hospital level, micro – clinical practice) [4], and providing evidence-based information on the clinical, economic, organizational, social and ethical impacts of health technologies [5, 6].

The study presented in this paper assessed the organizational and economic impact of the introduction of a new device for the infusion of the prostacyclin (PGI₂) analogue Iloprost at a hospital level.

Iloprost is used for the treatment of peripheral arterial disease, Raynaud's phenomenon (RP) secondary to connective tissue disease (CTD), vasculitis, and pulmonary hypertension. It is traditionally infused through peristaltic pump or flow regulator, which are effective methods but they limit the autonomy of the patients [7]. Patients receiving Iloprost therapy are treated within the hospital both in inpatient and outpatient departments. In some Italian Regions, this drug can be administered at an extra-hospital level, according to Regional laws.

A previous analysis on the device was conducted within the Unit of Internal Medicine (outpatient department) of the Hospital "Ospedale Civile" of Legnano (Milan), on 120 patients (affected by RP secondary to CTD and cryoglobulinaemia). The results showed that Iloprost infusion with the use of Pompa Infonde[®] is safe, better tolerated (significantly lower incidence of side effects), more appreciated by patients and nurses, and equally effective (no difference was observed on therapeutic efficacy) compared to infusion performed with a flow regulator [7].

The purpose of the analysis presented in this paper is to assess the organizational and economic impact related to the use of a new portable syringe pump (Pompa Infonde[®], Italfarmaco S.p.A., Cinisello Balsamo, Milan) at a hospital level.

2. MATERIALS AND METHOD

The analysis was conducted using an HTA approach, based on the Guidelines for the

Economic Evaluation of Health Technologies [8], with a focus on the organizational and economic impact at hospital level: the perspective assumed for this analysis was that of the hospital ward.

The analysis, performed between October 2013 and February 2014, of the organizational impact involved 24 wards in different Regional Health Care Services, homogeneously located in the National territory (5 wards located in North-West area, i.e. Lombardy, Piedmont, Liguria; 5 in North-East area, i.e. Emilia-Romagna, Veneto, Friuli-Venezia Giulia, Autonomous Province of Trento; 7 in Central area, i.e. Tuscany, Marche, Lazio, Umbria, Abruzzo; 7 in the South and Islands area, i.e. Campania, Apulia, Calabria, Sicily, Sardinia) in order to ensure a geographical coverage of the Italian context. Two groups of wards were selected: wards that have already introduced the new device for the administration of Iloprost (46% of the total) and wards that haven't introduced it yet in clinical practice (54%). The centers involved belonged to the following clinical areas: Rheumatology (33.3%), Internal Medicine (29.2%), Angiology (16.7%), Vascular Surgery (12.5%), Allergology/Immunology (4.2%) and Clinical Medicine/Rheumatology (4.2%).

The use of the new portable syringe pump was compared with the methods of Iloprost infusion used within the wards (i.e. peristaltic pump).

A pilot evaluation was conducted in the Hospital "Ospedale Civile" of Legnano (Milan) to assess the organizational impact of the Infonde[®] pump vs. peristaltic pump.

The organizational impact of the introduction of the new device was investigated through the administration of a structured interview.

According to the Hospital-Based HTA approach, following the European Network for Health Technology Assessment (EUnetHTA) Core Model guidelines [8], a questionnaire was developed in order to assess the organizational impact of the new device in the following areas: human resources, training activities (for operators, patients and care givers), internal meetings, additional spaces, equipment and facilities, management of change in clinical practice. The impact on the organization of each item was assessed using a seven point scale (1 to 7), in which 1 corresponds to "significant negative organizational impact", 2 to "moderate negative

organizational impact”, 3 to “small negative organizational impact”, 4 to “no impact”, 5 to “small positive organizational impact”, 6 to “moderate positive organizational impact” and 7 to “significant positive organizational impact”.

Both the real impact (within the Operational Units currently using the new pump) and the potential impact of the device (within the Operational Units that have not yet implemented the pump) were assessed.

The interviews were conducted by trained researchers of the Centre for Research on Health Economics, Social and Health Care Management of LIUC University. The interviews were conducted on-site (10 centers) or by telephone (14 centers). The respondents were Head of Department/Clinical Directors, Hospital Managers and nursing staff directly involved in the use of the new device.

The results in terms of organizational impact are presented according to the topics proposed by EUnetHTA HTA Core Model [8]: processes (human resources, staff training, patient’s or caregivers’ training, communication), structure (material investments needed, such as new machines, software, furniture, spaces), management (impact on the hospital or ward’s internal processes, impact on clinical pathways) and culture.

The economic evaluation was performed within the Hospital "Ospedale Civile" of Legnano (Milan). The costs associated with the two procedures (Infonde[®] pump vs. traditional method of Iloprost infusion) were collected with a bottom-up approach, using Activity Based Costing method [9, 10]. Each procedure was divided into single phases (Iloprost preparation, infusion and monitoring, end of infusion) and the related direct costs, considering human resources, medical devices / machineries, disposables, drugs.

The analysis was conducted with the support of clinicians directly involved in the drug administration, in order to identify all cost items. All phases for a standard patient without complications were evaluated, using retrospective data collected during the study previously performed in the same Unit [7], to assess the time related with human resources in every phase.

Cost data, provided by the management control service of the hospital, are value added tax inclusive and refer to 2013.

3. RESULTS

The main results of the organizational impact are reported for the four topics: process, structure, management and culture [8].

Process

Considering this topic, the introduction of the new technology requires a brief training session for nurses involved in the use of the new technology. In particular, nurses had to learn how to program the pump, how to dilute the drug and adjust the rate of infusion. In the majority of cases, wards organized “ad hoc” training (of at least two hours) involving the personnel directly involved in Iloprost therapy’s management. Furthermore, according to the majority of respondents, a meeting was necessary to communicate the introduction of the new device to the ward staff. Few wards reported a small negative impact due to training addressed to patients, in order to explain how to manage their higher autonomy allowed by the new device.

A nil impact was observed in terms of increased or decreased number of staffing needed within the ward.

The reduction in nursing time assistance – assessed by 33% of responders - was seen as the main positive impact for process management.

Structure

A nil impact was observed (and perceived) considering the need of wider spaces, new furniture, new machines and equipment, and updates of technologies or software.

Management

Results in terms of organizational impact showed a moderate negative impact on learning time in all the 11 wards that had already introduced the new device in their clinical practice.

Clinicians and nurses (33%) perceived that the use of the new device in outpatient services had increased or could increase the number of patients administered with Iloprost therapy, thanks to the reduction of time for nursing assistance during the administration. Moreover, the possibility to treat patients on armchairs, allowed to free beds for further patients to be treated, therefore increasing

the productivity of the department. However, within wards mainly treating fragile and complex patients, this advantage was not observed nor perceived, since patients with multiple comorbidities have to be monitored in any case without allowing them to move autonomously during the therapy.

21% of responders envisaged a positive impact due to the possibility to use the new device for Iloprost administration at a primary care level. This aspect was positively perceived considering the territorial healthcare models developed within the Italian Regional Health Care Service.

A nil impact was assessed on purchasing processes.

Culture

A lack of resistance to change was perceived within the wards, only in three cases concerns were raised on this topic among nursing staff.

Fig. 1 and Table 1 show a comparison between the impact perceived by wards that had already

introduced the device and those which did not use it. On average, the impact perceived by professionals who had experience in the use of the new technology is more positive than the one of those who did not use it.

In particular, responders who had already used the device were more positive about internal processes and connections between Operational Units and clinical pathways, while even considering the negative impact, a lower perception of critical issues was observed regarding staff, patients and caregiver training, as well as on learning time.

Responders who used the device declared the need for the whole ward of 2.8 hours of training needed (on average) for nursing staff and 0.5 hours for clinicians. As a result, the average total cost for training was assessed as € 57.2.

The results of the economic analysis as for single infusion of the drug (Pompa Infonde® vs. traditional method of Iloprost infusion) are reported in Table 2.

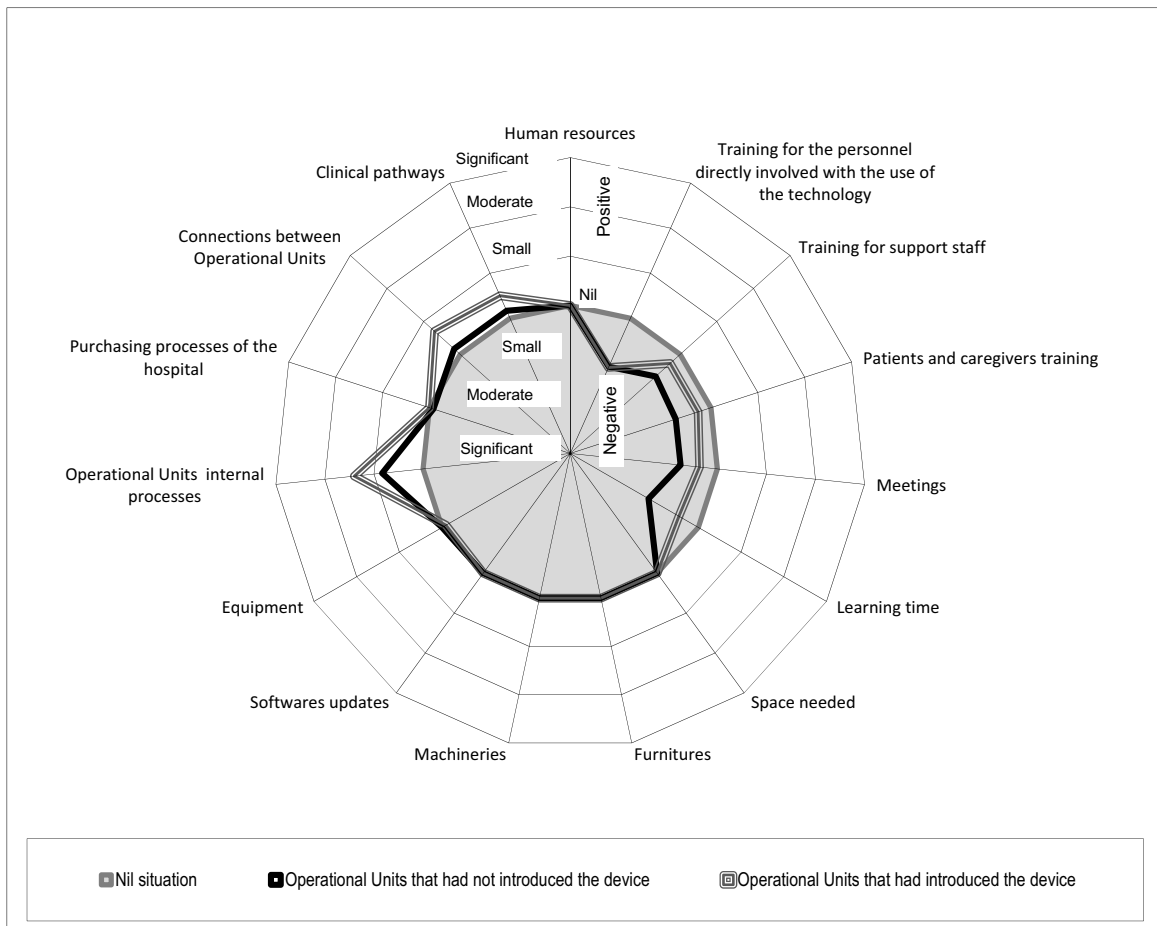


Fig. (1). Impact perceived by Operational Units that had introduced the device vs. impact perceived by those which did not used it.

Table 1. Organizational impact, mean values and standard deviation for the whole sample and the two sub-groups.

Item	Total Sample Mean (SD)	OU with new device Mean (SD)	OU with no device in use Mean (SD)
Human Resources	4.0 (±0.0)	4.0 (±0.0)	4.0 (±0.0)
Direct Staff Training	2.9 (±0.3)	2.9 (±0.3)	2.9 (±0.3)
Support Staff Training	3.5 (±0.6)	3.7 (±0.5)	3.3 (±0.7)
Patients and caregiver training	3.5 (±0.6)	3.7 (±0.5)	3.3 (±0.6)
Meetings	3.4 (±0.6)	3.6 (±0.5)	3.3 (±0.6)
Learning time	3.2 (±0.7)	3.5 (±0.5)	2.8 (±0.6)
Space needed	4.0 (±0.0)	4.0 (±0.0)	4.0 (±0.0)
Furniture	4.0 (±0.0)	4.0 (±0.0)	4.0 (±0.0)
Machineries	4.0 (±0.0)	4.0 (±0.0)	4.0 (±0.0)
Software updates	4.0 (±0.0)	4.0 (±0.0)	4.0 (±0.0)
Equipment	4.0 (±0.2)	3.9 (±0.3)	4.0 (±0.0)
Operational Unit internal process	5.1 (±1.2)	5.4 (±1.3)	4.8 (±1.0)
Purchasing process	4.0 (±0.2)	4.0 (±0.0)	3.9 (±0.0)
Connections between Operational Units	4.4 (±0.9)	4.7 (±1.2)	4.2 (±0.4)
Clinical Pathways	4.3 (±0.8)	4.5 (±1.1)	4.2 (±0.4)

Table 2. Costs related to Iloprost infusion by means of traditional method vs Pompa Infonde®.

	Traditional method of Iloprost infusion	Pompa Infonde®	Δ	% Δ
Human resources	€ 9.1	€ 5.7	-€ 3.4	-37%
Medical devices / machineries	€ 0.0	€ 0.0	€ 0.0	-
Disposables	€ 4.1	€ 5.6	€ 1.5	+35%
Drugs	€ 92.1	€ 92.1	€ 0.0	-
Total	€ 105.3	€ 103.4	-€ 1.9	-2%

The economic evaluation showed no differences between the two procedures in terms of medical devices and machineries cost (machineries costs were fully depreciated and Pompa Infonde® device was provided free of charge to the hospital), as well as drug (Iloprost) cost. The cost reduction for human resources is due to the decrease of nursing assistance time. The overall cost estimate showed how the use of the new device leads to a slight cost reduction per procedure.

4. DISCUSSION

The organizational impact of Pompa Infonde® was not previously assessed in literature, therefore the results of this investigation cannot be compared with already performed studies.

The administration of the structured interview allowed the identification of three main themes related to the positive impact of the new device.

The first one is related to the efficiency: the pump provides advantages with regard to the efficiency of internal processes of the wards. Responders perceived a positive impact on the reduction of the time of nursing assistance. Thanks to the new device, patients could leave bed and sit in an armchair, in complete autonomy. This would allow to free up outpatients' department beds for further patients to be treated, increasing the efficiency of the department. Moreover, some clinicians highlighted a better technical performance of the device compared with traditional methods, which often led "technical" problems with the risk to stop - even if temporarily - the drug infusion.

A further positive impact of the medical device is on clinical pathways. Related to this aspect, an interesting opportunity is seen by responders in the possibility for the patients to use the device at primary care level or at home. This would be possible in Italian Regions where new clinical integrated pathways are implemented.

Finally, the device could improve the connections and synergies between wards, increasing the efficiency of the organization. The pump could be shared between wards and it would allow professionals to perform specialist visits to the patients during the infusion.

A mild negative impact was perceived on learning and training time for personnel directly involved in the procedure, followed by a mild negative impact due to training for support personnel and patients/caregivers and to the initial meeting within the ward to communicate the introduction of the device. However, the quantification of costs appeared to be negligible if considering the results on patient's satisfaction [7].

Our results show that the introduction of the new device leads to positive consequence in terms of managerial impact. After the introduction of Infonde[®] pump, a substantial reduction of time to provide patient's monitoring by nurses was observed. This resulted in a better management of human resources and, from an economic point of view, in a reduction in nursing cost in the monitoring phase, compared with standard procedure, with a positive impact in a time of increasing hospital budget's constrains. The nursing assistance time in the monitoring phase is decreased by almost 10 minutes (from 15 minutes to 5 minutes), leading to a reduction of the cost of this phase.

From an organizational point of view, results also showed that the new device had no impact on additional spaces, furniture, equipment and human resources. This evidence is not obvious when considering an investment in a new technology which often results in the need for additional staff or spaces.

According to the clinician point of view, the main weakness of the new device would be the fact that patients seemed to underestimate Iloprost's side effects using a device that allows them to be more autonomous. Moreover, the advantages related to the possibility to move patients from beds to chairs in outpatients departments and make them more autonomous, are more challenging for complex patients with multiple comorbidities.

The main positive and negative features are reported in Table 3.

As a possible limitation of our findings, the economic evaluation is based on retrospective data collected within the pilot Center of Legnano on a

Table 3. Positive and negative aspect of the introduction of Infonde[®] pump.

Positive	Negative
Possibility to increase the number of patients receiving therapy	Possible resistance to change among nurses
Increased autonomy of patients during the infusion of the therapy	Complex patients with multiple comorbidities would not perceive most of the positive impacts of the Infonde [®] Pump
Better human resources management due to the reduction of the time of nursing assistance	
Connections and synergies between wards	
Potential positive impact on clinical pathways	

limited patients' sample affected by a pathology with a low prevalence. A future perspective observational multicenter study should be implemented in order to increase the robustness of the results to support decision making process.

On the other side, our study provides potential useful indications for clinical practice. Indeed, although the therapeutic effects of the administration of Iloprost are mainly related to the drug itself and its infusion duration, the use of Pompa Infonde[®] is likely to reduce the nursing assistance time, and be more comfortable for patients.

5. CONCLUSION

Our analysis supports the concept that the use of Pompa Infonde[®] is related to a number of benefits in the management of patients receiving this drug.

The possible reduction in nursing time could lead to a better management of human resources with advantages for the organization of the wards and to the possibilities for nurses to focus on complex patients, improving the quality of assistance.

A further managerial plus coming from the use of the pump (linked to the better handling and autonomy of patients) results to be the possibility to administer therapies to patients positioned on armchairs, with a potential increase in the number of daily infusions not requiring additional staff and with consequences in terms of a potential reduction of waiting lists.

Considering a medium-long term perspective, the new device could have remarkable application opportunity at territorial and home level of care. As clinicians confirmed, this easy to use device could be used also in ambulatory care or at home, still providing therapeutic efficacy and safety for the patient. The main point of these considerations is based on the series of legislative measures that are re-shaping the Italian welfare state, focusing on new models of care.

For the patient, as explained, the increasing autonomy makes the device appreciated, especially in non-complex cases [7]. For nursing staff, the ability to use a device that requires less monitoring to the patient could lead to a better management of the care process. For Directors of wards or departments, the use of the device could

improve the management of nursing staff, with the possibility to increase the number of therapies provided and allowing the access to the therapy to a growing number of patients.

In conclusion, giving these results, it appears evident that Pompa Infonde[®] represents a new and efficient alternative to traditional methods for Iloprost infusion therapy.

CONFLICT OF INTEREST

An unconditional grant was received by Italfarmaco S.p.A., to cover the costs for the collection and reprocessing of data. The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

ACKNOWLEDGEMENTS

All authors contributed substantially to the design, performance, analysis and reporting of the work.

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Received: March 06, 2015

Revised: October 27, 2015

Accepted: October 29, 2015