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Original articles

Early discharge of infectious disease patients: an opportunity or extra cost for the Italian Healthcare System?

Ricovero abbreviato nei reparti di malattie infettive: un'opportunità o un aumento di spesa per il Sistema Sanitario italiano?

Fabrizio Palmieri[1], Francesco Alberici[2], Alberto Deales[3], Gianluca Furneri[4], Francesco Menichetti[5], Nicoletta Orchi[1], Carolina Quesada-Rodriguez[6], Stefano Pilli[6], Franco Rapisarda[7], Domenica Tassielli[8], Michele Tringali[9], Silvano Esposito[10], Giuseppe Ippolito[1]

[1]Istituto Nazionale per le Malattie Infettive Lazzaro Spallanzani, IRCCS, Rome, Italy;
[2]U.O. Malattie Infettive Ospedale "Guglielmo da Saliceto", Piacenza, Italy;
[3]Area Governo Clinico, Agenzia Regionale Sanitaria Regione Marche, Italy;
[4]Direzione Scientifica I.N.R.C.A., Ancona, Italy;
[5]U.O. Malattie Infettive, Azienda Ospedaliero-Universitaria Pisana, Pisa, Italy;
[6]Divisione Life Science Simon Kucher & Partners, Milano, Italy;
[7]U.O. Farmacia, Presidio Ospedaliero 'Gravina' di Caltagirone, Catania, Italy;
[8]Policlinico Universitario Campus Bio-Medico, Rome, Italy;
[9]Direzione Generale Sanità, Regione Lombardia, Milan, Italy;
[10]U.O. Medicina Infettivologica, Facoltà di Medicina, Università degli studi di Salerno, Italy

INTRODUCTION

In western countries, infectious diseases remain an important cause of morbidity and costs. Skin and soft tissue infections (SSTI) are the most commonly diagnosed, with a broad range of clinical presentations. SSTI incidence has been estimated in about 25 per 1000 persons per year with a 7 to 10% prevalence in hospitalized patients [1-3]. SSTI is the third most common diagnosis for admission to the emergency room after chest pain and asthma, determining 2% of all emergency room visits, and 0.1% of the hospitalizations in the adult population [4]. Complicated SSTI (cSSTI) involve deep soft tissue and require significant surgical intervention, or have a significant underlying disease that complicates response to treatment (e.g. diabetes mellitus, obesity, immune deficiency) [5]. Healthcare associated infections have a high impact on resources: hospital beds, healthcare delivery and drugs, and morbidity and mortality. One of the best ways to reduce healthcare costs and improve patient care is to implement initiatives to reduce the length of hospital stays and re-admissions.

The significant economic impact that infectious diseases have worldwide, and the effect that antimicrobial resistance has (in hospitals and the community) on direct healthcare costs (in particular hospital costs) pressed administrators and physicians to develop strategies that simplify patient management and reduce costs [6]. In this context, early discharge of patients from hospitals to outpatient management becomes an interesting solution for efficient management of these patients.

Corresponding author
Fabrizio Palmieri
E-mail fabrizio.palmieri@inmi.it

Articles describing the implementation of an Early Discharge (ED) strategy are uncommon in the literature. Although there are some examples, they are often related to different disease areas, including cardio and cerebrovascular pathologies [4, 7-9]. Concerning infections, a prospective randomized controlled clinical trial was conducted in Egypt to compare ED versus continued hospitalization in febrile pediatric cancer patients with prolonged neutropenia. One hundred and twenty-nine episodes were included in the study: a statistically significant difference was found between the duration of hospitalization of ED patients (median 5 days) and hospital managed patients (median 9 days), as well as antibiotic cost per episode ($P<0.001$), and total episode cost ($P<0.001$). There was no statistically significant difference in the response to treatment at 72 hours or after necessary antimicrobial modifications [10].
Another prospective randomized controlled trial was conducted in New Zealand among 200 patients attending or referred to the emergency department with cellulitis. The aim of the study was to compare the efficacy, safety and acceptability of treatment with intravenous antibiotics for cellulitis at home and in hospital. There was no significant difference in either group for the primary outcome (days of no advancement of cellulitis, days on intravenous and oral antibiotics, days in hospital or in the homecare program and complications), while patient satisfaction was greater in patients treated at home. In this study, only about one third of patients presenting at hospital for intravenous treatment for cellulitis were considered suitable for home treatment, underlining the crucial component of appropriate patient selection [11].
This article is intended to underline the potential economic benefits deriving from ED of patients with infectious diseases (with complicated skin and soft tissue infection as the base -case scenario) within the Italian healthcare system.
The ultimate goal of this analysis is to raise awareness of the benefits of ED among the Italian scientific community and decision makers to further consider implementing early discharge strategies in appropriate settings.

MATERIALS AND METHODS

To assess the economic benefit of an ED process, we designed an economic analysis comparing two possible alternatives for the treatment of infectious diseases: standard, hospital management versus an ED strategy followed by a period of outpatient management.
The analysis was conducted from the hospital perspective; however, since both costs (outpatient and inpatient) are currently covered by the Italian regions, the overall perspective of the Italian SSN (*Servizio Sanitario Nazionale*, National Health Service) was also taken into account in the discussion section.
Where possible, we based assumptions of resource utilization and costs (inpatients: length of stay, length and type of antibiotic treatment, laboratory exams, personnel and accomodation costs; outpatients: length and type of antibiotic treatment, nurse, physician and laboratory costs) on referenced literature. In parallel, an expert panel composed of specialists in infectious diseases, hospital pharmacists, experts of outpatient care services and health economists was created to validate assumptions used in the model. The work of the panel lasted one year in which three different meetings were held to discuss and set the clinical criteria for guiding the ED of cSSTI patients. In addition, the panel classified the type and intensity of home assistance according to the treatment needs and medical conditions of discharged patients on antibiotic therapy. Finally, the expert panel validated the economic model and the sensitivity analyses performed on the main cost drivers.

Model design

The primary economic analysis focused on evaluating the average costs of an episode of complicated skin and soft tissue infection (cSSTI; base-case scenario). The average hospital costs were taken from a recent article estimating the costs of cSSTI in several Italian hospitals [12]. The same study reported an average duration of antibiotic treatment of 12.2 days, and an average length of hospital stay of 12.6 days.
For patients in the ED setting, we hypothesized 4.0 days of in-hospital management, followed by 8.6 days of outpatient care. This assumption was based on the conclusions of a publication evaluating conditions for ED in a cohort of patients with skin and soft tissue infections [13]. According to this article, many physicians delay hospital discharge of these patients until fever and other signs of inflammation have completely resolved, generally within 96 hours, which was a length of stay that resulted in line with that of other scientific articles [14].

Clinical criteria for early discharge

In-hospital observation after discontinuing antibiotic therapy was common practice in the past, but with today's knowledge, patients can be discharged earlier, when their infection gives signs of improvement. This improvement is measured by specific clinical criteria and each case needs to be assessed on a daily basis. The discharge criteria validated by our expert panel were:

1) signs and symptoms of infection should improve while induration and erythema should decrease;
2) body temperature and white blood cell counts should show a trend of improvement;
3) comorbidities should stabilize [13].

In addition, other criteria such as the patient's psycho-social factors, a satisfactory home environment and an adequate home support structure need to be confirmed. Both patient-specific and disease-specific factors are important in order to ensure a safe and successful ED program.

Home-care assistance

Models of home-care assistance already exist in Italy, and are currently applied at a regional level. A commission established by the Minister of Health in charge of evaluating the essential levels of assistance, (professional home assistance included) classified the home-care assistance into different levels [15]. These levels (low, medium and high) correspond to the complexity of the needs that have to be addressed in each case and have been translated by Lazio Region into a program for Integrated Home Assistance [16]. The expert panel took this classification into consideration, adding a functional autonomy measure to it, which is the ability to walk. This last characteristic is important, since it compromises the ability of the patient to refer to the healthcare center which could increase/decrease the number of visits of the nurse/physician during home-care assistance. In this way, a classification of four different groups of patients was included in the study: low intensity not walking (LINW), low intensity walking (LIW), high intensity not walking (HINW) and high intensity walking (HIW) (Table 1).

Clinical data

Since the objective of this analysis was the comparison of two alternative approaches from an economic viewpoint, no efficacy data was used in the model: the hypothesis being that management strategy did not affect patient outcome, as confirmed by studies comparing the two alternatives from a clinical point of view [13].

Cost and resource utilization data

The economic resources considered for the analysis were hospital and outpatient management costs. For standard hospital management, hospital-only costs were taken into account, since it was assumed the patient would spend the entire recovery period in the hospital. For the ED treatment, both hospital and outpatient costs were taken into account. Hospitalization costs were obtained from the study of Tarricone et al., who reported a daily cost of € 367.60, including antibiotic treatment costs (€ 32.84), personnel (€ 191.6), administrative and hotel costs (€ 67.31), instrumental and laboratory tests (€ 52.3), specialist visits (€ 7.76) and other costs (disposables, surgical procedures for a sum of € 15.79), excluding depreciation costs [12].

Outpatient costs included antibiotic treatment, nurse visits (necessary for treatment administration, following control of wounds), physi-

Table 1 - Patient categories as classified by the ED program.

Patient Clusters	*Description*
Low intensity walking (LIW)	Patients requiring a limited number of healthcare services who are able to walk
Low intensity not walking (LINW)	Patients requiring a limited number of healthcare services who are not able to walk
High intensity walking (HIW)	Patients who require a high level of assistance and high intensity services, but are still able to walk
High intensity not walking (HINW)	Patients who require a high level of assistance and high intensity services and are not able to walk

Source: Expert Panel.

cian visits (necessary for clinical assessment of the patient and evaluation of treatment outcomes), and laboratory costs.
The daily antibiotic costs in the outpatient setting were assumed to be equal to the inpatient setting (€ 32.84/day), assuming that all therapy costs were financed by the hospital, regardless of the setting (inpatient or outpatient).
Healthcare personnel (nurse and physician) unit costs per visit in the outpatient setting included salary and other expenses such as transportation costs, meal allowance and use of other equipment such as computer and telephone. Hourly wages were calculated on the basis of the national contract of the social cooperative, as healthcare home services are frequently bought by regions from external providers [17]. Transportation costs, meal allowance and use of other equipment were calculated on the basis of public tariffs (cost per kilometer according to the Italian Automotive Club - ACI - rates) as well as costs derived from other Italian home-care programs [18]. The total cost per nurse visit amounts to €35 considering a duration of one hour; the estimated average time of a physician's visit was a half-hour for a total cost of € 25.5.
The number of home visits was estimated through the expert panel, which assumed that nurse and physician's weekly visits would vary according to the level of assistance and the patient's ability to walk (Table 2). The number of nurse visits depends not only on the intensity of assistance and the patient's ability to walk but also on the treatment administration: in fact, a patient receiving parenteral therapy requires one daily nurse visit for drug injection/infusion. The frequency of patients receiving parenteral and oral therapy was derived from the Tarricone et al. study, where 21% of patients were treated with antibiotic therapy for which an oral form was available (Table 3) [12].
Assumptions about frequency and type of weekly laboratory tests performed during the outpatient management were extrapolated by the expert panel, using a scientific article as basis of evaluation [19]. The battery of laboratory examinations included leucogram, eritrosedimentation speed, cultures and other tests that could demonstrate the presence or not of an infection for a total cost of € 58.97.

Economic analysis
In this analysis we compared the two alternatives (standard hospital management versus ED) to prove the hypothesis that ED management would be less costly than the standard hospital management. Moreover, we decided to make a comparison with the DRG tariffs related to the ICD 9 (International Classification of Diseases) diagnoses reported in the Tarricone study [12]. Table 4 shows the diagnoses and related DRG tariffs [20]. The weighted average Diagnosis Related Group (DRG) reimbursement (wa-DRG), used as benchmark for our analysis, amounted to € 2,402.

Table 2 - Home visits in the ED scenario.

	Number per week			
Type of visit	*LIW*	*LINW*	*HIW*	*HINW*
Physician	1	1.5	2	3
Nurse (average)	5.7	6.2	6.6	7
parenteral treatment	7	7	7	7
oral treatment	1	3	5	7
Source: Expert Panel				

Table 3 - Antibiotic therapy used for cSSTI infections.

Antibiotic therapy	*% of usage*	*Oral form available*
Piperacillin/tazobactam	40	No
Amoxicillin/clavulanic acid	21	Yes
Ampicillin/sulbactam	13	No
Teicoplanin	13	No
Ceftriaxone	13	No
Source: Tarricone R. [12].		

Sensitivity analysis
Robustness of analysis was carried out through a series of univariate sensitivity analyses on the

Table 4 - cSSTI diagnosis and related DRG tariffs.

Diagnosis	*DRG number*	*DRG National tariff (€)*
Infected ulcer, not diabetic	271	4,373
Wound infection	281	1,609
Infected diabetic ulcer	294	2,584
Major abscess	278	2,006
Source: Tarricone R. [12]; DRG tariffs national book 2006.		

number of patients receiving parenteral treatment (100% and 50%), the total length of stay (decreased by 20% and submitted to a threshold analysis) and hospital costs (increased by +20%). Lastly a threshold analysis was performed on the outpatient costs.

Results, base case

In the basecase scenario, it was assumed that the total duration of antibiotic treatment and the length of stay were 12.2 and 12.6 days, respectively [12]. According to ED assumptions, the patient would spend 4.0 days in the hospital and the remaining 8.6 days in the outpatient setting, managed by a specific ED program [13]. Regarding in-hospital costs, the total inpatient cost for 4.0 days of hospitalization amounted to € 1,470. Personnel costs accounted for 52.1% of total daily hospitalization costs, being the main cost, followed by administrative and hotel costs (18.3%) and laboratory tests (14.2%).

In the remaining 8.6 days, the total home-care costs varied from € 608 in low-intensity patients to € 723 patients needing more intensive care. Table 5 illustrates the resources consumed and the overall costs during outpatient management after hospital discharge. Antibiotic treatment and nurse visits represent the drivers of expenditure, accounting for approximately 37-44% of overall outpatient costs, followed by laboratory examinations (average of 11%) and physician visit costs (average of 9%). Physician visit costs are the lowest and most variable. This variability could be explained by the stronger correlation between the number of physician visits and the severity of the patient's clinical condition.

The overall management costs (inpatient and outpatient) for a cSSTI hospitalization with anticipated discharge varies from € 2,079, in the case of LIW and € 2,193 for HINW.

Figure 1 shows a comparison between ED versus the hospital-only management (ED not implemented). These costs were also compared to the wa-DRG reimbursement for cSSTIs, which amounted to € 2,402. The comparison highlights some important findings:

1) the wa-DRG reimbursement for cSSTI infections does not fully cover the costs of 12.6 days of hospitalization (€ 4,619), with hospital costs exceeding about 92% of the reimbursement);
2) implementing an ED program would translate into significant cost reduction in all groups, compared to full hospital patient management;

Table 5 - Outpatient costs for the ED scenario.

Resource	*Costs in €*				
	LIW	*LINW*	*HIW*	*HINW*	*Mean %*
Antibiotics	269.29	269.29	269.29	269.29	41%
Nurse visits	235.34	252.56	269.78	287.00	39%
Physician visits	31	47	63	94	9%
Lab tests	72.45	72.45	72.45	72.45	11%
Total costs	608	641	674	723	100%

Duration of visits: nurse - 1 hour; physician - 30 minutes.

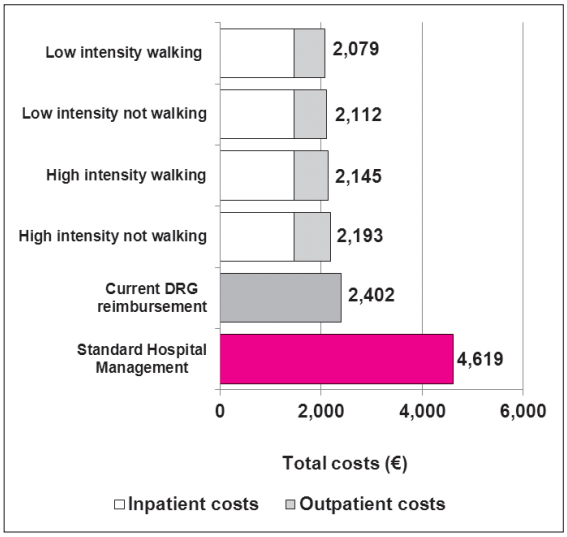

Figure 1 - Cost comparison: ED strategy versus standard hospital management.

3) reimbursement would be sufficient to cover the costs of the ED option even in the case of HINW patients, where resource consumption is the highest.

RESULTS - SENSITIVITY ANALYSIS

None of the sensitivity analyses performed significantly impacted the results. In the first sensitivity analysis, we modified the number of patients in oral-IV/IM treatment. When all patients were on parenteral antibiotics, even though resource utilization and total costs of the ED program were higher than the base case, ED remained a better option than standard hospitalization, and costs for ED were lower than the wa-DRG reimbursement threshold in each

Table 6 - Sensitivity analysis.

Parameter	*Modified input*	*ED costs*				*STD hospital management*
		LIW	*LINW*	*HIW*	*HINW*	
Drug administration	100% IV/IM	€2,130	€2,146	€2,162	€2,193	
	50% IV/IM	€2,007	€2,064	€2,121	€2,193	
Length of stay	-20%	€2,048	€2,077	€2,105	€2,144	€3,775
Hospital costs	+20%	€2,347	€2,379	€2,412	€2,461	€5,462
Base Case	-	€2,079	€2,112	€2,145	€2,193	€4,619

of the four groups of patients. In the second case, where half of the patients received parenteral therapy, ED program costs were lower than the base case due to a reduction in the nurse visits related to parenteral administration. The cost of the most expensive outpatient regimen (HINW) was 50% lower than the costs for hospitalization (€ 2,193 vs. € 4,619) (Table 6).
In the second sensitivity analysis, we tested the economic impact of a 20% reduction on the length of stay (from 12.6 to 10.1 days) for the two different strategies. In this case, hospital costs decreased to € 3,775, but still remained higher than the wa-DRG reimbursement threshold and ED approach. The length of stay would have to be decreased by 55% (5.7 days of patient stay) so that the in-hospital costs would be below the wa-DRG reimbursement. Nevertheless, even if this was the case, the ED would still be more cost-saving, determining a cost reduction of € 343 to € 407 for each patient treated (Table 7).
In the third sensitivity analysis, we assumed that the hospital costs calculated by Tarricone (with reference to 2006) could have increased by 20%. In this case, the standard hospital management increased to € 5,462 (2.3 times the wa-DRG reimbursement rate). On the other hand, the ED strategy was also no longer below the wa-DRG reimbursement threshold (€ 56 and € 58 over the threshold for LIW and HINW, respectively), but it increased in a lower percentage than the standard hospital management (18% increase for in-hospital costs versus 12% increase in average for the ED strategy).
Finally, we performed a threshold analysis of the outpatient costs: these costs had to increase by 60% in order for the ED strategy costs to become higher than the wa-DRG reimbursement threshold. In this case, total costs for the HINW would increase up to € 2,465 (€ 63 over the threshold). Again, even in this case the ED strategy remains less costly than the standard in-hospital management for all four scenarios.

DISCUSSION

Prolonged hospital stay due to moderate or severe infections has a considerable impact on direct healthcare costs. In particular, since the current Italian hospital remunerative system is based on DRG tariffs, hospitals are reimbursed through a fee for service, making this argument more relevant.
In the present article it was demonstrated that for a cSSTI hospitalization of 12.6 days, direct healthcare costs, measured by a micro-costing approach, exceeded the wa-DRG reimbursement, making this service economically disadvantageous from the healthcare provider's perspective (i.e. hospital). In some cases, the pa-

Table 7 - Threshold analysis.

	Modified input	*Inpatient costs + ED costs*				*Standard hospital management*
		LIW	*LINW*	*HIW*	*HINW*	
LOS	-55%	€1,995	€2,015	€2,036	€2,059	€2,299
Outpatient costs	+60%	€2,282	€2,335	€2,388	€2,465	
Base Case	-	€2,079	€2,112	€2,145	€2,193	€4,619

tient's condition, home environment and severity of diseases imposed prolonged hospital stay; however, the impossibility of discharging a patient does not necessarily depend on disease severity.

Certain patients who could be considered clinically eligible to be discharged are still managed by hospitals, despite the fact that IV drug administration, physician visits or other assistance services could be provided in the outpatient setting with lower costs.

The critical issue in this area is the lack of appropriate outpatient services, representing a consistent barrier to hospital discharge. In the present article, we examined the economic consequences of implementing an ED strategy for patients admitted for cSSTI under certain hypotheses taken from scientific literature and expert panel assessment. This simple analysis highlighted some important trends:

1) there is an economic advantage to managing patients outside the hospital when a patient's condition allows for early discharge and reduced inpatient stay;
2) patients requiring low-intensity care need fewer outpatient interventions than high-intensity care patients, thus allowing for obtaining a more consistent economic advantage if discharged early.

This economic evaluation presents limitations related to the type of data input used in the analysis. The first one relates to the in-hospital costs that were used, since we based them on a study conducted in 2006 [12]. This aspect has been taken into consideration in the sensitivity analysis, and the model was shown to be not sensitive to higher hospital costs, confirming the positive results obtained for the basecase scenario.

The second limitation for this model is the fact that outpatient costs were based on the observation of a theoretical model derived from the Ministry of Health and Lazio Region. In this sense, an observational study could better gather these costs; nevertheless, as shown with our threshold analysis, our model confirmed the base-case results even when out-patient costs were 60% higher than the ones used.

The third limitation of our model is the weighted average DRG reimbursement that we took into account and the differences that can be found within the regions.

In our analysis, we used the National DRG tariffs as a reference. Nevertheless, we have to consider that regions set their own tariffs and there is substantial variation compared with the national ones. In particular, the DRGs considered for this analysis present a variation ranging from +53% and -69%, with respect to the national value. In this sense, our analysis is even more meaningful for providers working in regions like Emilia Romagna, Lombardy and Veneto that set DRG tariffs consistently lower than the national ones.

The last aspect that could limit the implementation of our model is the implementation of the ED program, which we did not address since it was not the objective of this article. We assumed that the hospital would be in charge of the ED program, but in practice most outpatient post-acute care services are financed by the regions in the Italian healthcare setting, and not by a hospital outreach program. Implementation is probably the most critical issue in our model, since it is not clear who should provide the service in the end. We believe that there is not one "universal" answer, but several options that will depend on the approach of the different players. The organization of Italian local health units (LHU) and public hospitals is different among the regions; certain regions already have efficient, well organized, outpatient services (e.g. ADI, integrated home assistance), and others could have hospitals set up post-acute care settings to monitor and treat certain types of patients at home [21].

In some cases, outpatient services are outsourced to private, SSN accredited providers. Therefore, we believe that the final choice of the provider will be made on an individual basis, and should take into account the presence of already available models offering similar outpatient services.

Funding of outpatient services would need to be considered separately. Generally, outpatient services are financed by the Italian SSN through regional funding. However, if patients were discharged earlier and outpatient costs were then paid by the regional agencies, overall costs for the SSN would increase, since the region should reimburse the hospital through the DRG tariff (which cannot be currently reduced in case of a shorter patient stay) and also pay the outpatient services.

On the other hand, the hospital would increase its productivity by discharging the patient earlier. In the end, this approach would be advantageous from the hospital's perspective and disadvantageous from the SSN perspective, therefore making implementation of this model dif-

ficult. Due to the high integration between hospital and territory services, the ED program that we have proposed would be more easily implemented where the LHU manages both in and out- patient facilities. For these reasons, the necessary condition offsetting up an ED strategy is that the SSN would not face additional costs compared to the current situation.
Suggesting a solution to solve this dilemma is out of the scope of the present article, however we believe that outpatient costs must be either fully funded by the hospital, or shared between hospitals and LHU, in order to make the implementation of this strategy economically sustainable for both parties, and transform a potential economic issue into an opportunity for the Italian National Healthcare Service.
The analyses made in this article were based on cost assumptions derived from a study regarding cSSTI, and conclusions could theoretically apply to this type of infections only. If discharge is possible, we have reasons to believe that patients managed at home would require fewer resources than hospitalized patients, regardless of the type of infection. ED could be beneficial in prolonged antibiotic therapies like osteomyelitis or prosthetic joint infections, providing the absence of comorbidities that may preclude the patient's discharge.

Keywords: Complicated skin and soft tissue infections, early discharge, hospital costs, health policy.

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SUMMARY

In order to assess the economic benefits of an early discharge (ED) programme for patients with complicated skin and soft tissue infections (cSSTIs) in terms of hospital and regional authority costs, an economic analysis was conducted comparing two possible alternatives: standard hospital management vs. an ED strategy followed by a period of outpatient management. Utilization of resources and costs were derived from the literature and expert panel evaluation. Patients were classified into four groups: low-intensity non-walking (LINW), low-intensity walking (LIW), high-intensity non-walking (HINW) and high-intensity walking (HIW). The overall costs (inpatient/outpatient) of hospitalization with ED for cSSTIs range from € 2,079 for LIW to € 2,193 for HINW, with the most expensive regimen (HINW) being 50% lower than the costs for 12.6 days of hospitalization alone (€ 4,619). The weighted average Diagnosis Related Group (DRG) reimbursement for cSSTIs (€ 2,042) does not cover the costs of such hospitalization. In conclusion, when a patient's conditions allow for early discharge there is an economic advantage for the hospital with an outpatient management plan, especially for patients requiring low-intensity care. However, this could be disadvantageous in terms of regional costs if outpatient management has to be paid in addition to payment by the DRG.

RIASSUNTO

Obiettivi: *valutare i vantaggi economici di un programma di "ricovero abbreviato"* (Early Discharge - *ED) per i pazienti con infezioni complicate della cute e dei tessuti molli (cSSTI) nella prospettiva dell'ospedale e della Regione.*
Metodi: *l'analisi economica è stata condotta confrontando due possibili alternative: la gestione ospedaliera standard, rispetto ad una strategia di ED seguita da un periodo di gestione ambulatoriale. L'utilizzo delle risorse e i relativi costi sono stati ricavati dalla letteratura e tramite un* board *di esperti. I pazienti sono stati suddivisi in quattro gruppi: a "bassa intensità" di cure (LINW) non deambulanti, a "bassa intensità" deambulanti (LIW), "ad alta intensità" non deambulanti (HINW) e "ad alta intensità" deambulanti (HIW).*
Risultati: *i costi complessivi (ospedalieri/ambulatoriali) di ospedalizzazione con ED per cSSTI varia da € 2.079 per LIW a € 2.193 per HINW; il regime più costoso (HINW) è il 50% inferiore rispetto ai costi per 12,6 giorni di solo ricovero (€ 4.619). Il rimborso DRG medio ponderato per le cSSTI (€ 2.042) non copre i costi di tale ospedalizzazione.*
Conclusioni: *quando le condizioni del paziente consentono un "ricovero abbreviato", un piano di gestione ambulatoriale comporta un vantaggio economico per l'ospedale, soprattutto per i pazienti che richiedono una "bassa intensità" di cure. Tuttavia, questo potrebbe essere svantaggioso dal punto di vista della Regione se i costi della gestione ambulatoriale debbono essere sommati al rimborso della tariffa DRG.*

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