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## Home care for antibiotic therapy in the management of maternal-fetal infection: Action research example

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### Abstract

**Introduction-** Given the progress in medical care in neonatology, the development of neonatal medicine evaluation techniques and management of difficulties in our Moroccan context, the need to increase the alternative structures for complete hospitalization (CH) in this discipline, is clear. **Purpose-** Assess the economic and neonatal outcomes of neonatal infection in case of further outpatient care. **Material and methods-** This is a prospective, single-center including newborns hospitalized for infection between 1 January 2011 and 31 December 2013. Exclusion criteria were respiratory distress, birth defects, direct admission neonatal resuscitation. **Results-** 1060 neonates were included. The parturients had a preterm rupture of membranes PRM in 70% of cases. We had found a tinted amniotic fluid in 23% of cases. Mothers had chorioamnionitis in 20% of cases. We noted the presence of vaginal discharge with vaginal itching in 18% of cases. of mictional burns were found in 10% of cases. Breast laboratory tests (urinalysis, vaginal swabs, blood cultures, CRP) was positive in 3% of cases the mean birth weight was 3300.20 grams +/- 600. The average age was +/- 1.4 days 0.45. Thirty percent of the children were exclusively breastfed. 80% of patients were asymptomatic at admission. The clinical signs were found mainly respiratory distress. Mean CRP was 35,12mg / L +/- 3.5. The average duration of the PRM was 9.66 +/- 57.7 hours. The examination at the end of treatment was without abnormalities in 89.2% of cases. CRP control was below 6 mg / l in 48% of cases. The evolution of life on day 28 was favorable in 100% of cases. The average length of hospital treatment was 2.87 +/- 1.145 days; the average duration of treatment as outpatients was 2.74 +/- 1.31 days. 100% of newborns received treatment by parenteral perfusion according the protocol of the center. The average number of hospital days per patient spared protocol averaged 3.21 +/- 0.78 days. The average amount saved per patient was 82.65 +/- 5.51 Euros. Total amount saved over three years was 83,000 Euros. **Conclusion-** The partial hospitalization seems possible for infected newborns without aggravating their illness. It also contributes significantly to the health economy.

**Keywords:** Partial hospitalisation, Health economy, Maternal fetal infection, Home care antibiotherapy.

### INTRODUCTION

Neonatal infections are frequent diseases, difficult to diagnose with certitude, and potentially serious. Antibiotic therapy will be initiated before any suspicion of infection or not and stopped after biological and bacteriological clinical reassessment to 48 hours of evolution. The deadlines imposed by the realization of bacteriological analyzes are not compatible with a truly wise and efficient use of antibiotics. Despite the improved prognosis related to early antibiotic treatment and advances in supportive care, maternal-fetal infection still accounts for a significant problem of perinatal morbidity and mortality.

WHO recommends an hospitalization with parenteral antibiotics in the case of a neonatal sepsis. In our context, and after an initial observation in 2011 regarding the risks and difficulties inherent in complete hospitalization for the treatment of uncomplicated neonatal infections, a new concept of partial hospitalization in infants with uncomplicated disease was experienced<sup>[1]</sup>.

The objective of our study is to evaluate neonatal and economic issues of the partial hospital care neonatal infection. Initially, we recall neonatal complications that may arise in case of maternal-fetal infection and the usually retained support in this situation. Then, we will present the results of our prospective study in a level 3 hospital. Finally, we will discuss these results by comparing ourselves to literature articles that address this subject.

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## Definition of concepts

- Infection: It is the penetration and development of a pathogen germ in the organism.
- Neonatal infection: It is infection that occurs 0-28 days after birth.
- Early neonatal infection: It's the infection that triggers the first to the seventh day of birth.
- Chorio-amnionitis: When maternal temperature is above 37.5 ° C ≥ 2 separate measures by 2 hours or at 38 ° C once with WBC > 20 000 x 10<sup>9</sup> / L or a malodorous amniotic fluid;
- Premature rupture of membranes (PRM): Rupture of membranes before the onset of delivery.
- Day hospitalization: Is the audit by the hospital expected duration for each day of care in neonatology, it would include the consultation of the professor and the resident, the cost treatment.

## MATERIAL AND METHODS

### Problems, assumptions and objectives of the study

#### *Difficults*

Currently, in the majority of neonatology centers, newborns with infection remain hospitalized until the end of the recommended theoretical duration of treatment. This hospitalization can last days or weeks, and affect the occurrence of nosocomial infections, the psychological status of family, the occupancy of the centers and healthcare spending particularly in our context.

Recognizing this, we asked ourselves the question:

Can we consider that the complementary care day hospital of newborns with an infection is an efficient and reliable alternative to traditional hospitalization, both the neonatal and economic plans?

#### *Assumptions*

Hypothesis 1: The neonatal outcomes are the same regardless of the hospitalization mode.

Hypothesis 2: The risks are higher compared to benefits to be derived after applying this method.

Hypothesis 3: It is recommended that an additional inpatient day hospital in our context.

#### *Objectives*

The objective of the study is to compile a descriptive profile of clinical and economic aspects of the partial hospital treatment of neonatal infection.

Several criteria are designed to assess the maternal-fetal outcomes, neonatal and hospital in these two groups. Moreover, it seems interesting to assess the number of traditional hospital days saved and therefore know the health costs.

## Materials

It's a prospective and observational study. We prospectively taken over a 3-month period (October 1, 2014 to December 31, 2014), 1060 observations of MFIs collected at neonatal unit of the Children's Hospital of Rabat.

Only primitive early onset neonatal infections occurring the first 3 days of life were considered as MFI. Newborns included belong to 3 groups:

- Certain septicemic infection, defined by the presence of a germ in a normally sterile site (central samples: blood and / or CSF)

- Certain non septicemic infection defined by a clinical and / or biological abnormality and positivity of one or more devices samples to a single pathogen, with sterile core samples;

- Probable infection defined by a clinical and / or biological abnormality suggestive of infection, but no germ could be isolated.

Data for this study were collected from hospital records of newborns. Every newborn suspected of infection was assumed according to the protocol used in the service placing the suspicions of MFIs according to three levels of risk:

- Level 1 of infection risk: Neonates with the following risk factors: prolonged rupture of membranes > 12 hours, unexplained fetal distress, meconium amniotic fluid.

- level 2 of infection risk: unexplained preterm delivery, rupture of membranes > 24 hours, maternal fever or a positive gastric fluid on direct examination. In addition to peripheral samples PS, blood count and C-reactive protein (CRP) are performed.

- level 3 of infection risk: febrile birth with another element of infectious medical history and / or two elements of infectious medical history and / or any unexplained clinical abnormalities and / or presence of haematological abnormalities and / or CRP in evocative context. Blood culture is levied in addition to the PS.

Lumbar puncture and cyto-bacteriological examination of urine is done systematically. Antibiotic treatment was started either at birth (level 3) or secondary (levels 1 and 2) on the recognition of a clinical and / or biological and / or bacteriological abnormalities. Since antibiotics are two associations adopted in the service: Ampicillin + gentamicin: full-term and asymptomatic newborns

Ceftriaxone + gentamicin: preterm and symptomatic newborns symptomatic preterm and fullterm

The duration of treatment depends on the type of infection and location of the germ. It is 10 to 14 days in case of certain infections, 5 days in case of likely infection and 15 to 21 days in case of meningeal location.

Excluded were patients who died during hospitalization and / or having respiratory distress, birth defects, birth weight less than 1500 grams and / or directly admitted in neonatal resuscitation.

## Statistical Analysis

SPSS Windows Version 18.0 pour statistical software was used in the statistical analysis. The level of statistical significance was considered when  $p < 0.05$ . Continuous data were presented on average. When the data did not obey normal distribution, data were reported as medians and interquartile (IQR). Comparisons of continuous data was performed using a Student's t test. Discrete data were described in frequency and percentage. Comparisons of categorical characteristics were performed by a Chi<sup>2</sup> test.

Logistic regression analysis was used to study the relationship between the presence of morbidities and predictive variables and potential. Correlations between clinical and maternal and evolutionary characteristics were investigated by Pearson correlation test.

## RESULTS

### Maternal and infectious data

Parturients had an PRM in 70.3% of cases. We had found a green amniotic fluid in 21.6% of cases. It is interesting to see the comparison table of patients infected with meningitis and those without meningitis object of our outpatient care. 72% of mothers are illiterate or low cultural level 50% were primiparous and therefore inexperienced (Table 1).

**Table 1:** Sociodemographic and maternal features

		Infected with meningitis n=60%	Infected without meningitis n=1000%	P
Residency	Rural	24	9	0.003
	Urban	70	85	
		6	8	
Age	≤20 years			<0.001
	21-35 years	37	9	
	>35 years	50	80	
Level of instruction	Illetrate			<0.001
	low	65	40	
	Secondary	22	32	
	University	10	18	
Parity	Primiparus			0.002
	Pauciparus	69	50	
	Multiparus	20	38	
Follow-up of pregnancy	Yes			<0.001
	No	40	85	
Mode of delivery	Caesarian			0.25
	vaginally	20	16	
		80	84	

Mothers had chorioamnionitis in 17.6% of cases. We noted the presence of vaginal discharge with vaginal pruritus in 17.6% of cases. Micturition burns were found in 8.8% of cases. Breast laboratory tests (urinalysis, vaginal swabs, blood cultures, CRP) was positive in 2.7% of cases (Table 2).

**Table 2:** Descriptive statistics of maternal data

Maternal parameters	Frequence	Percentage
PRM	104	70,3
Green amniotic fluid	32	21,6
	13	8,8
Leucorrhoea	26	17,6
Chorioamnionitis	26	17,6
Biologic chekup +	4	2,7

### Neonatal data

1060 newborns were included in the study are divided into 180 premature infants, 830 fullterm and 50 patients in post-term. 30% were hypotrophic and 10 % were macrosomic. The mean birth weight was 3267.30 grams +/- 633.972. The average age was 0.446 +/- 1.24 days (Tables 3, 4).

**Table 3:** Neonatal data

	Infected with meningitis n=60 %	Infected without meningitis n=1000 %	P
Apgar 5min	≥7	80	<0.001
	<7	20	
Sex	M	46	0.35
	F	54	
weight	<1500g	53	<0.001
	1500-2000g	40	
	>2000g	7	
Congenital abnormalities	13	3	0.002

Nineteen percent of infants were from Rabat, 40% from sale and 20% from temara, the rest came from other regions of Morocco.

Thirty percent of the children were exclusively breastfed. Over 79% of patients were asymptomatic at admission. The clinical signs were found mainly respiratory distress (10.1%) (Table 4).

**Table 4:** Clinical signs at admission

Examination	Frequence N	Percentage %
Asymptomatic	106	79.6
Respiratory distress	15	10.1
Icterus	13	8.8
Fever	3	2
Hypoglycemia	8	4.8
Hypotonia	1	0.7

The analysis of our study population also shows that:

- Neonatal adaptation was good in almost all cases
- Newborns are eutrophic frequently
- The anomalies identified were minor type of supernumerary fingers, isolated or pre-tragien tuber.
- Only one death was noted (Table 3)

The average CRP was 32,47mg / L +/- 4.67. The average duration of the PRM was 9.66 +/- 57.7 hours. The newborn was asymptomatic at admission in 79.6% of cases (Table 5).

**Table 5:** Descriptive parameters of neonates

Parameters	Average	SD
Age	1.24	0.446
Birth weight	3267.30	633.972
CRP	32.47	4.67
Hemoglobin	16.89	1.89
White cells	16080.30	1584.84
Neutrophils	8792.77	3558.59
PRM duration	57.7	9.66
Lymphocyt	8320.24	1421.91
Platelets	247188.03	77560.09

The examination at the end of treatment was without abnormalities in 89.2% of cases. CRP control was below 6 mg / l in 48% of cases. The evolution of life on day 28 was favorable in 80% of cases. The rest of the patients were lost to follow up (Table 6).

**Table 6:** Description of the clinical and biological evolution

Parameter	Effective	Percentage %
Evolution	132	89.2
- Normal	132	89.2
- Icterus	11	7.4
- Refusal sucking	1	1
CRP		
- <6mg/l	71	48
- 6<<20 mg/l	75	51
- >20 mg/l	1	0.96
Examination (day28)		
- normal	117	79.05
- abnormal	0	0
- lost	31	20.95

The positivity of CRP at admission was significantly associated with prematurity. The occurrence of meningeal infection was observed significantly higher in preterm than for term infants (Table 7).

**Table 7:** Variables significantly associated with prematurity: univariate analysis

	Relative risk	RR	IC 95%	P
CRP>20	0.37		0.3 – 0.44	0.037
Lombar punct+	1.95		0.4 – 5.2	0.03

### Hospitalization

The average length of hospital treatment was 2.87 +/- 1.145 days; the average duration of treatment as outpatients was 2.74 +/- 1.31 days. One hundred percent of newborns received treatment by perfusion according to the service protocol. The average number of hospital days economized was 3.21 +/- 0.78 days. The average amount economized per patient was 82.65 +/- 5.51 Euros. The total amount saved sue three months was 14,779 Euros (Table 8).

**Table 8:** Hospital duration and cost economized

Paramètre	Moyenne	Ecart type
Hospital treatment duration	2.87	1.145
Average of home care duration	2.74	1.316
Cost (euros)	82.65	5.51

### DISCUSSION

The maternal-fetal infection (MFI) is an important cause of neonatal morbidity and mortality. Early bacterial neonatal or maternal-fetal infections (MFIs) are a constant concern of the pediatrician.

Despite the improved prognosis related to early antibiotic treatment and advances in supportive care, the MFI still accounts for a significant share of perinatal morbidity and heavy mortality (4-20%) more important in cases of prematurity. Neonatal infections are responsible

for 700.000 to 800.000 deaths in the neonatal period that occur worldwide each year [1].

Most newborns in developing countries do not currently receiving hospital care, including lack of availability of antibiotics or because the hospital is not acceptable or feasible for families, which is the case for some regions of Morocco.

The evaluation of the treatment of the simplest schemes for severe neonatal infection was identified as a priority at the global scale project. This test is designed to determine whether outpatient antibiotic treatment for uncomplicated maternal-fetal infection is effective and safe in health institutions in our context. The objective is to increase the availability and quality of care in referral hospitals and contribute to the rational management of care facilities. Tests with a similar design are also underway in Bangladesh, Pakistan and Nigeria, the study is adapted according to their demographic and economic data [3-6]. The current WHO recommendation for the treatment of severe neonatal infection in newborns is hospitalization and parenteral antibiotic treatment with penicillin and gentamicin injections for at least 10 days, requiring 50 injections. In practice, these guidelines are rarely implemented in many low-resource settings, due to the lack of guidance systems or refusal of parents [7].

A technical advisory group organized by Save the Children Saving Newborn Lives has made well-designed studies to assess the simplified antibiotics for the treatment of neonatal sepsis in ambulatory [8,9]. Doses were chosen to optimize the efficiency, safety and feasibility for possible use programmed with similar results in our study.

Our experience has shown that homecare antibiotic therapy in neonates is a simple, reliable and efficient option. Moreover, this practice might be provided in hospitals of level 1 or 2.

Several considerations are important to consider before designing this project, Anita et al. in a test of Pakistan had raised the injection safety and bacterial resistance [10,11]. Our work had not reported incidents of iatrogenic and evolution of life on day 28 had no evidence of re-hospitalizations. Newborns are processed daily to assess the clinical signs of treatment failure. In our series, no patient had developed complications.

As part of the development of the school plan, it is important that the institution conducts a reflection on his abilities and the difficulties he would face or to support newborns infected in optimal conditions quality and safety of care. Meta-analysis of the Cochrane found a significant decrease in hospital care cost daily compared to that of a hospital treatment [12]. The study of Asamai et al come to this same conclusion and shows that the costs of a newborn treated in day hospitals are on average 150 dollars against 480 dollars for those staying in hospital (p <0.001) [13]. Knowing about the cost of a hospital day which is about 80 euros and the partial hospitalization which is about 10 euros, we can estimate that amount for the health economy in our study. There was a difference of about three days of hospitalization with a theoretical full hospitalization. Considering that patients are monitored once a day one day hospital by a doctor and a nurse until the end of the duration of treatment, the amount saved for these 148 patients would be 16,000 euros.

Our clinical trial tries to help deliver information to policy makers on the most appropriate regime to be included in the treatment of neonatal infection in our community context.

### CONCLUSIONS

Our retrospective study shows that this method of hospitalization in neonatology can be recommended. However, it should be verified that the re-hospitalization level during the first month is not increased by this alternative therapy. Our conclusion can however not be

extrapolated to all newborns or to all neonatal units of different hospitals. To evaluate more broadly the benefit of these units, it would be useful to validate this study and complete the data by more patients.

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### Competing Interests

None.

### Author's contributions

MA.Radouani : Collect data, analyze results, writing

Amina Barkat: Analyze results, reading and correcting.

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