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RESEARCH

Clinical, economic, and organisational impact of the novel AAP 2022 neonatal hyperbilirubinemia guidelines in an Italian third-level neonatology unit

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Abstract

Neonatal hyperbilirubinemia (HB) is universally screened in Italy to reduce the risks of subsequent neurological damage. The 2022 American Academy of Paediatrics revised guidelines set higher phototherapy thresholds and offer follow-up recommendations that ultimately reduce HB overtreatment in newborns born at ≥ 35 weeks' gestational age. While assessing the implementation of AAP guidelines at our centre, we compared the clinical and economic outcomes between the AAP 2022 guidelines and current Italian recommendations. We retrospectively applied the American guidelines to newborns managed according to current Italian recommendations, born at our centre between November 2024 and February 2025. Clinical characteristics, bilirubin levels, and interventions were recorded. The Institutional Treasury provided healthcare costs for hospitalisation and interventions. Clinical decisions and subsequent costs were compared. Nine-hundred and four newborns (50% females, median gestational age 39 weeks) were enrolled. Forty-eight (5.3%) patients presented bilirubin-induced risk factors. The bilirubin level informing a clinical decision was performed at a median of 51 (interquartile range 44–58) hours-of-life. AAP guidelines potentially reduced phototherapy by 69.8% ($p < 0.001$), accounting for a 98 bed-days reduction. Post-discharge bilirubin checks increased by 37.9% ($p = 0.004$). A 4-month reduction of 16,591.58 € in variable costs and a significant improvement in resource rationalisation were calculated. *Conclusion*: The AAP 2022 guidelines potentially reduce HB treatment and shift bilirubin surveillance to the outpatient department, enhancing neonatal care efficiency and reducing healthcare costs. These analytical outcomes encouraged the adoption of the AAP guidelines at our centre. Longitudinal surveillance will clarify the safety and actual extent of this change of reference guidelines in our practice.

What is Known:

- *The risk of bilirubin-induced neurological damage (BIND) in healthy term and near-term newborns has been overestimated in the past. The AAP revised its hyperbilirubinemia guidelines, providing higher hourly bilirubin thresholds for newborns without risk factors for BIND.*
- *Despite reports on the safety and efficacy of the AAP 2022 guidelines, their implementation was not officially encouraged in Italy, making their adoption a choice to be evaluated at a facility level.*

What is New:

- *Simulation on retrospective data of AAP 2022 guidelines promises a reduction in healthcare costs and rationalisation of healthcare system resources.*
- *The favourable cost-effectiveness analysis prompted the adoption of AAP 2022 guidelines at our centre. Longitudinal surveillance will help clarify the actual extent of economic impact and to assess real-life safety and efficacy of the guidelines.*

Keywords Evidence-based medicine · Guideline implementation · Healthcare economics · Neonatal jaundice

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Introduction

Unconjugated hyperbilirubinemia is almost universal in newborns due to the increased turnover of foetal haemoglobin, the impaired activity of the hepatic enzyme UGT1A1, and enhanced enterohepatic circulation of bilirubin [1]. As a liposoluble molecule, free (i.e. not albumin-bound) unconjugated bilirubin crosses the blood-brain barrier and accumulates in the central nervous system. Prolonged exposure to elevated unconjugated bilirubin levels may induce a spectrum of neurologic disorders [2]. The most severe is chronic bilirubin encephalopathy (CBE), characterised by choreoathetoid cerebral palsy, gaze palsy, and sensorineural impairment, which occurs in 0.4 to 2.3 cases per 100,000 live births in developed countries [3]. To prevent CBE, multiple institutions have developed guidelines for universal screening of neonatal hyperbilirubinemia using gestation-specific bilirubin thresholds [4]. Our centre currently follows the Italian Neonatal Society recommendations by Romagnoli et al. for bilirubin screening and management [5], in which phototherapy thresholds based on GA parallel those reported in the 2004 AAP guidelines, but without accounting for the risk factors for hyperbilirubinemia [6].

The management of neonatal hyperbilirubinemia presents significant healthcare costs, which include the organisation of pre- and post-discharge check-ups and the extension of hospitalisation when phototherapy is required. Nevertheless, growing evidence indicates the need to revise upward the safe bilirubin thresholds in full-term newborns [7–10]. In 2022, the American Academy of Paediatrics (AAP) published revised guidelines for screening and treatment of hyperbilirubinemia in newborns over 35 weeks of age, introducing higher treatment thresholds for each gestational age from 35 to ≥40 weeks for newborns without neurotoxicity risk factors, albeit keeping lower thresholds for newborns with neurotoxicity risk factors [11]. Despite the potential to reduce the burden of bilirubin surveillance in infants ≥35 weeks' gestation, to date, AAP guidelines have not been formally endorsed by the Italian Neonatal Society and therefore have not reached widespread use in Italy.

Our study tests the hypothesis that the use of the novel AAP 2022 guidelines, compared to the current Romagnoli guidelines, would result in a significant decrease in bilirubin-related interventions and overall healthcare costs at our centre.

Methods

This is a single-centre retrospective observational cohort study. The study is conducted at Spedali Civili Children's Hospital, a tertiary-level centre with approximately 3600 births per year. The nursery has 37 beds for mothers and their newborn babies, caring for approximately 3200 newborns each year. Phototherapy is performed in a sub-intensive care room provided with six beds and attended by one nurse and two healthcare providers.

The study time horizon was set between November 1, 2024, and February 28, 2025; considered appropriate to reach statistical significance for the primary outcome of a reduction in phototherapy rate, and to calculate quarterly cost variations. We enrolled inborn neonates born at 35 weeks' gestation or later, delivered at our centre. Neonates born elsewhere, before 35 weeks of gestational age, or transferred to the nursery after the first 12 h of life, were excluded. To minimise confounders, cases with incomplete bilirubin-related data (i.e. missing data or newborns transferred to other units before the conclusion of bilirubin management) were also excluded.

At our centre, the attending physician follows current Italian recommendations. Newborns with predictable risk factors for the development of significant hyperbilirubinemia (i.e. positive direct antiglobulin test, known haemolytic conditions such as glucose-6-phosphate dehydrogenase deficit or inherited erythrocyte disorders, large scalp hematoma, macrosomic infant of diabetic mother, Down syndrome) have bilirubin tested every 8 h during the first 24 h of life, then every 12 h until 48 h, and subsequently every 24 h until discharge. Newborns without such risk factors are visually inspected every 8 h and, in the absence of overt jaundice, checked with a pre-discharge test at ≥36 h of life. Screening is performed with a transcutaneous (TC) bilirubinometer (JM105, Drägerwerk AG & Co., Lübeck, Germany). In case of values of TC bilirubin within 3 mg/dl, or exceeding the phototherapy threshold, total serum bilirubin is tested with a photometric bilirubinometer on capillary plasma (One Beam, Ginevri SRL, Albano Laziale, Italy). In cases of uncertainty regarding measurement reliability (e.g. bilirubin levels inconsistent with the clinical presentation), total serum bilirubin is determined at our central laboratory using colourimetry (Roche Cobas c702, Diazo reagent "Bilirubin Total Gen.3", Hoffmann-La Roche Ltd, CA, USA).

The last bilirubin value before discharge, or an earlier value informing a clinical decision, is defined as "decision-making bilirubin (DMB)". Clinical decisions, as well as the rationale for the calculation of economic and organisational implications, are summarised in Table 1. Cost analysis was performed based on cost models provided by the hospital treasury (Supplementary Materials). Daily allowances for mother and newborn were detailed for both fixed and variable costs (Table S1). Variable costs were calculated for inpatient phototherapy cycle and outpatient bilirubin checks (Tables S2 and S3). Dietary interventions (increase in breastfeeding frequency, introduction or increase in formula feeding) were also considered a bilirubin-related clinical decision

Table 1 Summary of economic and organisational costs for each bilirubin-oriented clinical decision. *Extra daily allowance calculated if bilirubin check falls on the day after the first check. **Calculated as the number of hospitalisation days between phototherapy indication and discharge for those needing treatment with current recommendations; calculated as an extra 2 days of hospitalisation (median of days of hospitalisation due to phototherapy at our institution) for those requiring treatment with novel guidelines, but not with the current recommendations

Clinical decision	Economic costs	Organisation
Discharge without interventions and/or further tests	Standard	Standard
Dietary interventions	Not considered	Not considered
Discharge without interventions, with post-discharge test	Ambulatorial check: 22.49 €	1 ambulatory slot occupancy
Withhold discharge with a bilirubin test < 24 h from the previous	Extra daily allowance for mom and newborn*: 948.39 €	1 extra hospitalisation day*
Phototherapy cycle	Phototherapy cycle: 148.00 € Extra daily allowance for mom and newborn**: 948.39 €	Extra hospitalisation days**
Re-hospitalisation for phototherapy	Phototherapy cycle 148.00 € Extra daily allowance for mom and newborn: 948.39 €	Extra hospitalisation days

but were not evaluated for economic impact because clinical records lacked precise data on increased formula consumption, rendering cost models unreliable.

Data pertinent to hyperbilirubinemia management (date and time of birth, GA, presence of hyperbilirubinemia neurotoxicity risk factors as per AAP guidelines [11], weight and sex at birth, feeding type and regimen, decision-making bilirubin timing and levels, and subsequent clinical decisions) were obtained from the anonymised patient medical records after hospital discharge. Two investigators (F.M. and S.P.) independently simulated the application of the AAP guidelines to the historical cohort data and DMB levels and recorded the resulting bilirubin management decisions. The investigators reviewed discrepancies by consensus. The current recommendations and novel guidelines-oriented clinical decisions were compared, and the cost model applied.

Ethical considerations

The study protocol was approved by the Central Ethical Committee no. 6 of Regione Lombardia (ref. number NP 6812). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Informed consent to participate and to publish was waived due to the retrospective and anonymised nature of data.

Statistical analysis

Data were collected with REDCap (ASST-Spedali Civili di Brescia). The sample size was calculated using the StatCalc software in Epi Info© version 7.0, assuming an annual referral rate to phototherapy according to the current recommendations at our centre of 2.5% (percentage derived from internal analysis of cases in the year 2023), selecting a margin of error of ±1% and a confidence level of 99.9%, resulting in a total of 922 subjects. Descriptive statistics have been generated using IBM SPSS software version 30.01 (IBM SPSS Inc., Chicago, IL). The Kolmogorov-Smirnov test was used to assess the normality of the distributions. Continuous variables are presented as means ± SD (for normal distributions) or medians and IQR (for skewed distributions) and compared using nonparametric tests (Mann-Whitney *U* (MWU) test for binary grouping, Kruskal-Wallis (KW) test for non-binary grouping). Categorical variables are presented as frequencies or percentages and compared with the chi-squared test (Fisher's exact test in case of groups with <5 subjects).

Results

Of 1096 newborns, 192 were excluded (81 due to GA < 35 weeks, 44 due to nursery admission after the first 12 h of life, 67 due to incomplete data), while 904 newborns (50% female) met the inclusion criteria. The median GA was 39 weeks (IQR 38–40). The mean birthweight was 3180 (±406) g for females and 3310 (±431) g for males. Forty-eight (5.3%) newborns presented with one or more risk factors: 40 (83%) had a positive direct antigen test (60% due to Rhesus incompatibility), 6 (13%) had sepsis or signs of clinical instability, and one presented with a G6PD deficiency. The feeding regimen was exclusive breastfeeding in 260 (29%) infants with 8 (7–9) feedings per day, exclusive formula in 63 (7%) cases with 7 (6–7) feedings, and mixed in 582 (64%) cases with 8 (7–9) feedings.

The first decision-making bilirubin value was measured at 51 (IQR, 45–79) hours, using a TC bilirubinometer in 730 (80%) cases, capillary plasma in 144 (20%) cases, and serum sampling in 30 cases. According to the current recommendations, the differential between the decision-making

bilirubin level and the corresponding hourly threshold for phototherapy (bilirubin gap) was 6.7 (4.8–4.9) mg/dl. Novel AAP guidelines (GL) bilirubin gap was higher for newborns without neurotoxicity risk factors (8.2 [6.2–10.2] mg/dl) and lower in case of risk factors (4.9 [2.8–6.8] mg/dl) (MWU's $z = 6.6$, $p < 0.0001$).

A comparison of the clinical decision using the current recommendations and novel AAP GL is summarised in Fig. 1. Despite a high concordance rate between the two reference documents, pre-discharge interventions markedly decreased with the novel AAP GL ($p < 0.001$), due to a disagreement directed towards non-intervention. A similar trend was observed about readmissions for phototherapy, although the analysis did not reach statistical significance. Of the 29 infants requiring phototherapy according to current recommendations, 21 (72%) had bilirubin below the AAP guidelines thresholds, with half being greatly below the limits (> 2 mg/dl). Only one patient, not requiring phototherapy according to current recommendations, would have been given it because of the use of AAP risk-factor thresholds. In contrast, AAP guidelines led to a substantial increase in post-discharge testing (+37.9%, $p = 0.004$).

The total organisational and economic potential impact of applying novel AAP GLs is summarised in Table 2. Longer hospitalisation was associated with the need for phototherapy (4 [4, 5] vs. 2 [2, 3] nights; MWU's $z = 7.8$, $p < 0.0001$) and pre-discharge testing (+ 24 h of hospitalisation in 26 out of 77 cases). The use of novel AAP GL led to a total reduction of 82 hospitalisation days (− 26 days from pre-discharge testing, − 48 days from avoided phototherapy cycles, and − 8 days from avoided readmission for phototherapy). Taking into account variations in inpatient and outpatient costs, the application of AAP GL resulted in a calculated quarterly gross spare of 80,727.98 €, with a median gross spare of 2044.78 (IQR 1096.39–3941.56) € per infant. Considering only variable costs, a net quarterly spare of 16,591.58 € was calculated, with a median spare of 594.62 (IQR 445.31–1337.25) € per infant. A mean net increase of 5.21 € per patient was calculated for the increased outpatient clinic post-discharge check.

Discussion

The application of AAP guidelines would lead to a significant reduction in bilirubin-oriented clinical decisions before discharge and shift the management of neonatal hyperbilirubinemia towards outpatient care. The cost analysis highlighted potential for monetary savings and resource rationalisation in a single tertiary care setting.

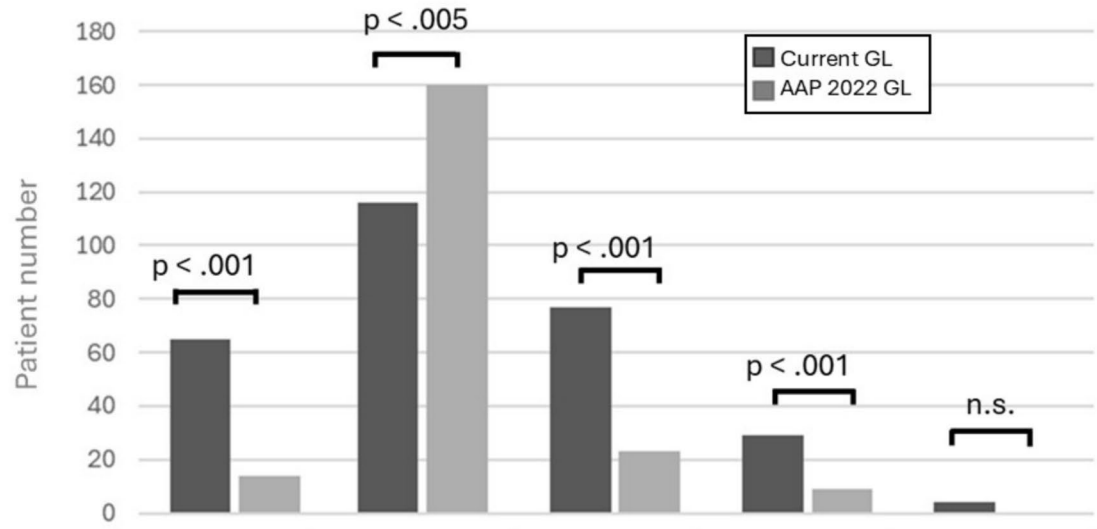
The present study comes with some limitations. First, the retrospective design might have led to an overestimation of the impact of AAP guidelines, as it is not possible to estimate the odds of requiring bilirubin management in infants treated under former guidelines who, as per AAP 2022 guidelines, did not require phototherapy. Nevertheless, a retrospective design allowed us to avoid potential communication failures within our network of secondary centres that could have triggered unnecessary referrals or hospitalisations. Additionally, it bypassed the complexities of comparing costs across pre-post intervention cohorts and eliminated the risk of bias inherent in the blind randomisation of patients between existing and novel guidelines. Secondly, due to seasonal fluctuations in bilirubin levels [12, 13], the quarterly reductions in clinical decisions and costs we observed may not be stable throughout the year. Finally, the sample size calculated on prevalence precision makes the study underpowered to detect differences of low-prevalence secondary outcomes, such as readmission rates.

Despite limitations, the observed reduction in phototherapy showed a large effect size and high statistical significance despite the conservative nature of the cohort. This is consistent with the results of a similar Italian study reporting a 42–68% reduction in the need to initiate phototherapy in a retrospective cohort of 876 newborns admitted for phototherapy [12]. Similar reductions in phototherapy and hospitalisation have been reported by before- and after-cohort studies in the USA [13–16], Europe [17, 18], and Asia [19, 20], which consistently reported the lack of safety issues such as the increase in readmissions for phototherapy, escalation of care, or CBE incidence.

The adoption of guidelines and position papers can be hindered by many personal (i.e., physicians' knowledge and attitudes) and external factors (i.e., organisational and institutional constraints) [21, 22]. While the first can be addressed through education and dissemination strategies, evidence of cost-quality improvement might help overcome the latter. At the time of our institutional reference guideline change, data on the financial and organisational benefits of adopting the AAP 2022 were missing.

Besides limitations, our results highlighted a potential, significant reduction of healthcare costs. This is in line with the results of a recent before-and-after analysis that identified an 865,920.00 € cost saving at a perinatal academic referral centre in France [18].

A careful discussion is needed for the quarterly cost reduction we calculated. The reduction in healthcare costs attributable to bilirubin was evaluated in the context of the facility's routine workload. In addition, only variable costs can be accounted for as a result of reduced activity [31], which, according to our institution's treasury, consisted of 20.7% of the mother's and 4.5% of the newborn's daily allowances, plus the costs of the phototherapy cycle. Consequently, of the estimated gross savings of 80,727.98 €, only 16,591.58 € can be considered actual savings. Conversely, unnecessary healthcare reduction makes fixed costs more efficient, allowing care for another patient with the same resources. This can be calculated as a reduction in the bed



	Dietary interventions	Post-discharge test	Withold discharge for retest	Phototherapy	Readmission for Phototherapy
Current GL (n)	65	116	77	29	4
AAP 2022 GL (n)	14	160	23	9	0
Variation	- 78,4 %	+ 37,9 %	- 70,13 %	- 68,9 %	- 100 %
Concordance Rate	94 %	88 %	92 %	97 %	96 %
Non-int. disagreement	100 %	28 %	97,5 %	95 %	100 %

Fig. 1 Summary of the variations of different clinical indications according to the current recommendations and AAP 2022 guidelines. Chi-squared test; Fisher's exact test (readmission for phototherapy). Concordance rate: percentage of agreement between AAP 2022 and current guidelines. Non-int. disagreement: percentage of non-intervention indication with AAP 2022 guidelines when AAP 2022 and current guidelines disagree

Table 2 Differences in healthcare costs and organisational burdens between current recommendations and the AAP guidelines. *Bed occupancy rate is calculated over 119 days (reference period 1 st Nov. 24–28th Feb. 25). **Slot occupancy rate calculated over 81 days (from Monday to Friday, same reference period). ***Net costs: costs calculated only at a variable cost level (i.e. not considering fixed costs)

		Current GL	AAP 2022 GL	Net difference
				Pre-discharge management
Total hospitalisation days (*n*)		2458	2378	
Beds available per day (*n*)		37	37	
Bed occupancy rate*		55.36%	53.7%	− 3.34%
Mom and newborn daily allowance			948.39 €	
PT cycles		29	9	
PT cycle cost			148.00 €	
	Total costs	2,335,434.62 €	2,254,706.64 €	− 80,727.98 €
	Net costs***	372,589.1 €	355,997.5 €	− 16,591.58 €
				Post-discharge management
Outpatient bilirubin test (*n*)		116	160	
Available daily slots (*n*)		7	7	
Slot occupancy rate**		20.4%	28.2%	+ 37.9%
Ambulatory check costs (variable costs only)			22.49 €	
Total costs		2684.84 €	3598.40 €	+ 913.56 €
			Quarterly spare	− 79,814.42 €
			Net spare	− 15,678.0 €

occupancy rate (BOR), a measure reflecting the saturation of available care capacity [24]. Even though the mean quarterly BOR reduction of 3.34% might seem negligible, it primarily involves sub-intensive beds dedicated to caring for newborns with minor pathologies, who should be transferred elsewhere if full bed occupancy occurs. Moreover, this might reduce personnel overload, increase time available for mom and newborn care, and lead to greater adherence to assistance protocols [25].

Finally, by increasing outpatient controls against inpatient management, AAP 2022 guidelines shift neonatal bilirubinaemia care to the outpatient setting, a combination associated with comparable efficacy at lower cost in different low-risk, acute disease management [23]. The increase in ambulatory costs is limited relative to the savings, even when hypothesising multiple controls for all patients. Moreover, it could be beneficial in reducing parental misperceptions of neonatal jaundice as a serious illness rather than a physiological phenomenon, and in reducing the emotional impact (family organisation issues, physical exhaustion, fears, and sense of guilt) commonly reported by mothers of jaundiced infants managed as inpatients [27–29]. Nevertheless, the 40% increase in outpatient checks must be carefully considered, and strategies to reduce service overload elaborated, for instance, by externalising bilirubin surveillance by providing community care units with a portable screening instrument to be used within a hub-and-spoke network [26].

The results of our study may be generalisable in terms of percentage reduction in phototherapy administration and bilirubin-oriented clinical decision, as demonstrated by studies focusing on the same outcomes. Although different institutions could account for jaundice management costs using different expenditure items, we believe the trend towards cost reduction could be confirmed if applied across contexts operating with lower bilirubin-threshold guidelines.

Conclusions

Applying the novel AAP guidelines promises to substantially reduce healthcare costs and improve the efficiency of neonatal care by shifting the focus of bilirubin surveillance to outpatient clinics. Considering the balance between cost optimisation and the safety profile described in the literature, and the feasibility of adopting the AAP 2022 guidelines, we plan to implement them at our centre as part of our quality-of-care initiatives. Longitudinal observation will clarify the real-life implications of this change of reference guidelines in our practice.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00431-026-07091-2.

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Author contribution F.M, S.P. elaborated the project. F.M, S.P., G.B., C.T., M.A, S.F. collected data. F.M and C.T. planned and performed statistical analysis. D.Z., F.M and F.C. generated healthcare costs tables. F.M. wrote the main manuscript text, prepared figures and tables. F.M.R., B.G., S.V., MdC.R.P, S.A., E.B revised the work critically for important intellectual content. All authors revised the article, approved the version to be published; and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. F.M.R and F.M. equally contributed to the work and share first authorship.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Conflict of interest The authors have no conflicts of interest to disclose.

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