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Elia Balestra ¹, Giorgio Cozzi ², Idanna Sforzi ³, Ilaria Liguoro ⁴, Enrico Felici ⁵, Silvia Fasoli⁶, Silvia Bressan ⁷, Marta Minute ⁸, Laura Portale ⁹, Paolo Dalena ^{1,2}, Riccardo Lubrano ¹⁰, Angela Troisi ¹¹, Kevin Valentino ⁵, Maria Luisa Casciana⁶, Benedetta Ferro⁸, Silvia Bloise ¹⁰, Federico Marchetti ¹¹, Valentina Baltag¹², Egidio Barbi ^{1,2}, Marzia Lazzerini ^{2,13} on behalf of the CHOICE study group

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For numbered affiliations see end of article.

Correspondence to

Dr Paolo Dalena; paolo.dalena@burlo.trieste.it

ABSTRACT

Background There is little experience on the use of the WHO Standards for improving the quality of care (QOC) for children. We describe the use of four prioritised WHO Standard-based Quality Measures to assess the provision of care for children with pain in emergency departments (EDs).

Methods In a multicentre observational study in 10 EDs with different characteristics in Italy, we collected data on 3355 children accessing the EDs between January 2019 and December 2020. The association between children and facility characteristics and quality measures was analysed through multivariate analyses.

Results The proportion of children whose pain was measured was 68.7% (n=2305), with extreme variations across different centres (from 0.0% to 99.8%, p<0.001). The proportion of children treated for pain was 28.9% (n=970) again with a wide range (5.3%–56.3%, p<0.001). The difference between the frequency of children with pain measured and pain treated varied widely between the facilities (ranging from –24.3 to 82). Children with moderate and severe pain were more frequently treated (48.9% and 62.9% of cases, respectively), although with large variations across centres (ranges: 0%–74.8% and 0%–100% respectively, p<0.001). After correction for children's characteristics, the variable more strongly associated with analysed outcomes was the facility which the child accessed for care. Being a facility in Northern Italy was associated with a higher rate of pain measurement (67.3%–95% CI: 39.9% to 94.6%, p<0.001) compared with facilities in South Italy (–22.1% lower (95% CI: –41.7% to –2.50%, p=0.03).

Conclusions The use of few WHO Standard-based measures related to pain can help identifying priority gaps in QOC for children and in monitoring it over time. There is a need for more implementation research to establish which are the most sustainable and effective interventions to improve the QOC for acute pain in children.

BACKGROUND

Europe, North America and Australia are the regions worldwide with lower child mortality.¹

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Previous studies conducted in the European region highlighted gaps in the quality of care (QOC) for children with pain, but limited evidence exists from Italy. WHO published in 2018 a set of standards for improving the QOC for children, but limited evidence is available on their implementation.

WHAT THIS STUDY ADDS

⇒ The utilisation of 4 prioritised WHO Standard-based Quality Measures to assess provision of care for children with pain across 11 Italian emergency departments revealed significant differences across hospitals—in particular on pain measurement—with diffuse substandard practices on pain treatment, persisting even after correction by children characteristics.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The utilisation of few WHO Standard-based Quality Measures related to pain provides a practical means of identifying priority gaps in QOC for children and monitoring it over time and can be used both by researcher and policymakers to plan activities and studies to improve QOC for children.

However, even in high-income countries where child mortality rates are generally low, quality of care (QOC) has been described as substandard in many settings.^{2–7} Improving the QOC for children is a key priority recognised by the WHO, as well as by many other institutions and scientific societies.^{2–4 8–10}

Pain is the most frequently reported symptom in children and adolescents, being experienced by up to 78% of children accessing emergency departments (EDs).^{11 12} Lack of pain treatment in childhood may have

detrimental consequences in older age, both in the short-term—heightening pain perception, stress and fear—and in the long term—leading to the possible development of chronic and complex pain conditions as well as health-care avoidance.^{13–15} Adequate management of paediatric pain is therefore an important public health problem, and successful pain management should be one of the main goals of emergency medicine in children.^{11 16}

However, despite children having the right to appropriate pain management,^{10 11 16} and despite several national and international guidelines of pain management having been developed,^{16–18} evidence shows a tendency for underassessing and undertreating pain, either in EDs or in hospitalised children.^{19–22} For example, a recent survey in the UK highlighted that a pain assessment was documented in only 57.5% of children during their ED visit, with a site variability ranging from 1.4% to 100%.¹⁹ Other studies documented that children are more exposed to inadequate pain control than adults, especially in younger age.^{21 22}

In 2018, WHO developed a framework on paediatric QOC and list of ‘standards for improving the QOC for children and young adolescents at facility level’.²³ However, given that WHO standards for improving the QOC for children and young adolescents in health facilities are relatively recent,²³ there is little experience in their application. In 2019, in dialogue with WHO, we established a multicountry study called Child HOspItal CarE (CHOICE), with the objective of conducting research on the implementation of the WHO Standards,²³ with a special focus in high-income and middle-income countries. Previous products of the CHOICE study, including WHO Quality Measures prioritised and the validation of data collection tools, have been reported elsewhere.²⁴

This paper is part of a journal collection reporting key findings of the CHOICE study, related to lessons learnt on the implementation of the WHO Standards²³ in Italy. The present paper reports on the use of few prioritised WHO Standards-based Quality Measures to assess paediatric pain management in EDs with different characteristics in Italy, and factors affecting it. Findings of this study may be of interest to both researchers and policymakers by providing new evidence on QOC on pain management in ED in a high-income country such as Italy, a topic on which only few studies are available.²⁴ Other manuscripts included in the journal collection are reporting on other paediatric conditions (acute respiratory infections - ARI - and acute diarrhoea - AD) and on other domains of QOC (experience of care, resources), for a total of 175 WHO Standard-based Quality Measures.

METHODS

Study design

This was a multicentre observational study, and it is reported according to the STrengthening the Reporting of Observational studies in Epidemiology (STROBE)

Statement.²⁵ The STROBE Checklist is provided in online supplemental table 1.

Study population

Data were collected in 10 paediatrics EDs, distributed across the Italian geographical territory (North, Centre and South) and with different characteristics in terms of volume of work, facility level (referral facilities vs lower levels) and type (university vs non university hospital), as detailed in online supplemental table 2.

Children and young adolescents aged from 1 month to 15 years accessing the EDs during a period of 2 years (from January 2019 to December 2020) were included. Children classified as needing urgent or emergency care (ie, labelled as either ‘red’ or ‘yellow code’ at the triage) were excluded, not being the focus of this paper. Children with fever, unable to take oral drugs, treated for pain at home in the last 2 hours before medical evaluation in the ED or with any neuropsychiatric or genetic condition affecting pain (eg, cerebral palsy, mental delay, Prader-Willi syndrome, familial dysautonomia) were also excluded.

Study variables and data collection

Within the CHOICE study, a set of WHO Quality Measures to assess ‘provision of care’ in paediatric ED was prioritised by a team of experts, through a Delphi process (details provided in online supplemental table 3). Among these, four were pertinent to pain management in children and were calculated as the frequency of children with: (1) pain measured, that is, children for whom the pain level was reported in the discharge letters (in a numerical rating score from 0 to 10); (2) pain treated, that is, children for whom a drug was prescribed and administered; (3) pain with score \geq 4 treated, that is, children with a registered pain level \geq 4 for whom a drug was prescribed and administered; (4) pain with score \geq 7 treated, that is, children with a registered pain level \geq 7 for whom a drug was prescribed and administered. Based on the above four measures, we also calculated differences in the percentage frequencies of children with pain measured and pain treated, in the overall sample and in cases with a pain score of \geq 4 and \geq 7. Data on socio-demographic variables of children were also collected.

All centres had dedicated protocols for pain measurement and management. We considered as pain treatment all the oral, intravenous, rectal, intranasal and sublingual drugs. We did not include ice, topical medications or nerve blocks or use of sucrose or nitrous during procedures. No timeframe limitation for painkiller administration was considered. Procedural pain management (eg, fracture reductions, stitches) was not included in the study.

Data were collected from discharge letters, which in Italy are the official written reports provided at discharge from the ED, for each single patient, by the doctor in charge. Pain management was assessed among children/young adolescents accessing the EDs with any

type of complaint. Discharge letters were selected at random among those identified as relevant within the study period. The data extraction tool was designed as a standardised Excel document with precise guidelines for completion and pre-set tables for input. It underwent practical testing by an impartial data collector across 660 cases, and subsequent enhancements were made post testing, including more comprehensive and explicit instructions integrated into the tool. Trained researchers extracted data, under the supervision of an independent data analyst and of a senior paediatrician.

Data analysis

The minimum sample size for inclusion for each hospital was 115 cases, based on an expected minimum frequency for each indicator of 4% and an absolute precision of 97.5%. For year 2020, given the drastic reduction of accesses to paediatric EDs due to the COVID-19 pandemic,²⁶ the sample was set as the maximum number of available cases with the given case definition in each facility. In order to examine the variations in the frequencies of quality measures between the data collected in the 2 years, the non-parametric Wilcoxon-Mann-Whitney test was applied.

First, we conducted a descriptive analysis of patients' characteristics and of results of the four quality measures of interest. We also analysed pain scores reported, types of drugs prescribed and type of hospitalisation—whether short duration of stay, defined as a stay of 6–48 hours, or formal hospitalisation. All EDs used the common pain rating scales validated for children,²⁷ all ranging from a score of 0 (no pain) to 10 (worst possible pain): the FLACC (Face, Legs, Activity, Cry, Consolability) Score for children under the age of 3 years, a visual numeric scale for children aged between 3 and 7 years, numerical scales for older collaborating children.²⁷ Acknowledging that there is not a general consensus regarding the optimal cut-off values,²⁷ pain severity in classes was assessed based on the scores provided in the discharge letters, as follows: pain was considered as mild with a self-reported pain score of 0–3, moderate with a score of 4–6 and severe with a score of 7–10.

We performed an additional analysis of the frequency of all quality measures for centres which measured pain in at least 75% of cases (best performers). Data were presented as percentage frequencies, by centre and on the overall sample. To compare results of the quality measures across different facilities, we used the χ^2 test.

In order to assess the association among key quality measures and children individual characteristics, we conducted univariate and multivariate logistic regression analyses. For univariate and multivariate logistic regression analysis, two quality measures of major interest were identified: (1) children with pain measured and (2) children with pain treated. Two separate logistic regression models were estimated, considering the two quality measures as binary outcome variables, and as explanatory variables demographic characteristics (age,

sex), clinical characteristics of the patients (pain level, hospitalisation, short stay observation, type of diagnosis), the facility and the year in which the child was treated. For the model on pain treated, the facility named CC1 was taken as the reference value. For the logistic model related to pain measurement, facility CC7 was excluded and facilities CC1, CC2, CC3 and CC4 were merged into one level because they presented extreme results (0% for CC7 and values above 95% for CC1, CC2, CC3 and CC4). Because facility CC1 could not be taken as reference for this analysis, CC8 was chosen as the reference because of its geographical proximity to CC1. Frequencies, OR and adjusted OR (AdjOR) were calculated, with 95% CI and p value of significance.

Last, to assess the association between two key quality measures (ie, pain measurement and pain treatment) and characteristics of each facility, when adjusted for characteristics of the population in each facility, we performed a multivariate analysis with a general linear model using Gaussian family with identity link function. The independent variables included in this model as key characteristics of each facility were: geographical location, university centre, number of paediatricians, number of residents, number of nurses. For the characteristics of the population in each facility, we included: per cent of children in age and sex classes, per cent of children with pain level ≥ 7 . For the selection of the optimal models, backward elimination method was applied, based on Akaike information criterion. Findings were presented with β coefficients with 95% CI and p value of significance.

A p value of <0.05 was taken as statistically significant. R V.4.1.2 was used for data analysis.

RESULTS

Characteristics of the sample

A total of 3355 cases of children accessing care in the 10 paediatric EDs were assessed (online supplemental table 4). About three-quarters of children belonged to the age group between 5 and 15 years ($n=2429$, 72.4%), with children between 2 and 5 years accounting for 17.7% ($n=594$) and children below 2 years accounting for 9.9% ($n=332$). There were slightly more boys ($n=1909$, 56.9%) than girls ($n=1446$, 43.1%, $p<0.01$). Trauma was the most frequent reason for accessing the ED with 1206 cases (35.9%), followed by gastrointestinal problems (747 cases, 22.3%), musculoskeletal/headache/inflammatory complaints (671 cases, 20.0%) and infections (359 cases, 10.7%).

A total of 358 children (10.7%) underwent a short hospital stay in the ED, with a considerable variation across centres, ranging between 1.9% and 32.5%, while 156 children (4.6%) were admitted (ranging between 0.7% and 13.3% across centres). Overall, among children in whom pain was measured ($n=2305$, 68.7%), 1178 children (51.1%) reported mild pain (pain score 0–3), 786 (34.1%) moderate pain (4–6) and 341 (14.8%) severe pain (7–10).

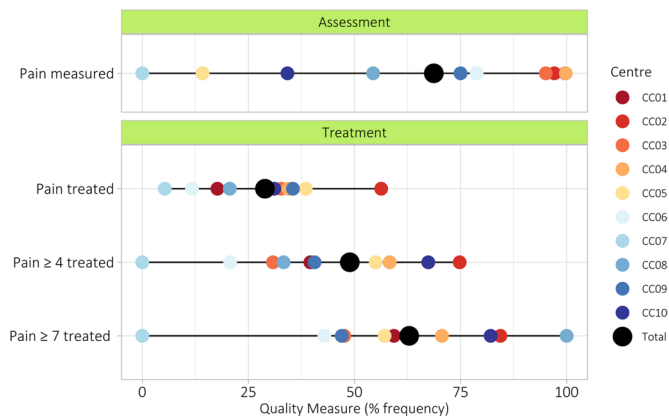


Figure 1 Results on the four prioritised WHO Standard-based Quality Measures for pain in children (2019–2020). Note: facilities were identified in the legend as CC (CC1–CC10); for pain treated, the total records were included.

Quality measures

The distribution of the quality measures across the 2 years was not statistically different (p values ranged from 0.21 to 0.72), therefore results for the 2 years were analysed together.

All quality measures considerably varied across centres (figure 1, (online supplemental table 5A)). The overall rate of children whose pain was measured was 68.7% ($n=2305$), ranging across different centres from 0.0% to 99.8% ($p<0.001$). The overall rate of children treated for pain was 28.9% ($n=970$), varying across centre from 5.3% to 56.3% ($p<0.001$).

Moderate (score of 4–6) and severe pain (score of 7–10) were more frequently treated (48.9%, $n=1641$ and 62.9%, ($n=2110$, of cases, respectively) than mild pain, although again with considerable variations across centres (ranging from 0% to 74.8% across centres for $\text{pain}\geq 4$ and from 0% to 100% for $\text{pain}\geq 7$, $p<0.001$).

The difference between the frequency of children with pain measured and pain treated varied widely between the facilities, with values ranging from -24.3 to 82 (figure 2). Only two centres had a difference close to zero (CC10, 3.1 and CC07, -5.3). When limiting the sample to cases with pain levels ≥ 4 and ≥ 7 , the negative values and the ranges increased (from -51.6 to 64 and from -48.7 to 53.2, respectively, figure 2).

The high heterogeneity among centres was confirmed also when considering only facilities that assessed the pain in least the 75% of children (online supplemental table 5B): $\text{pain}\geq 4$ was treated in 47.1% of cases ($n=1580$, ranging from 20.7% to 74.8%), while $\text{pain}\geq 7$ in 62.9% ($n=2110$) ranging from 41.9% to 83.5%.

Drugs used to treat pain

Among the 1000 children (29.8%) who were treated with drugs for pain, paracetamol ($n=499$, 49.9% of treated children, 14.9% of total children) and ibuprofen ($n=338$, 33.8% of treated children, 10.1% of total children) were the most frequently used drugs (online supplemental table 6). However, in five centres (CC2, CC6, CC7, CC8

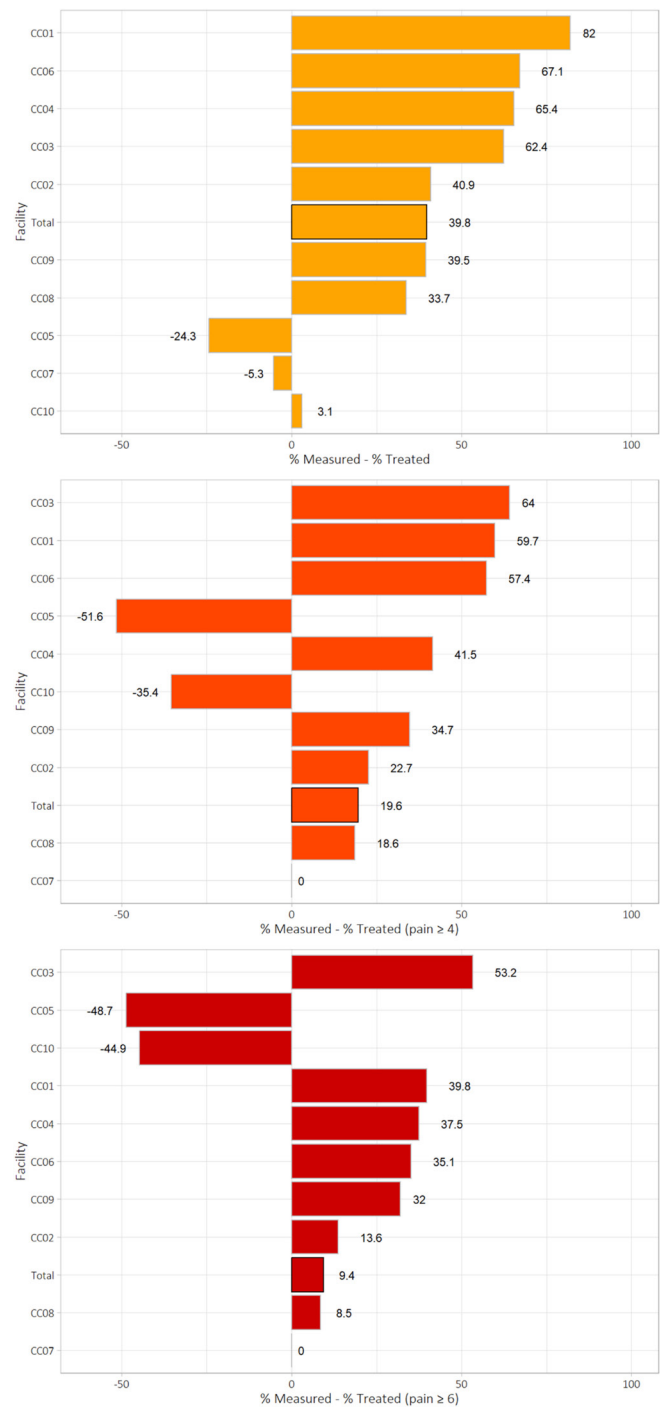


Figure 2 Difference between frequency of children with pain measured and pain treated.

and CC9), paracetamol was the most commonly used drug, while in other five centres (CC1, CC3, CC4, CC5 and CC10), ibuprofen was the most used.

Ketorolac was used only in few cases (22 cases, 0.7% of total children) and only 4 centres prescribed it (CC2, CC5, CC7, CC8). Opioids were prescribed only in five cases overall, in the form of tramadol (two cases), intranasal fentanyl (two cases) and paracetamol plus codeine (one case).

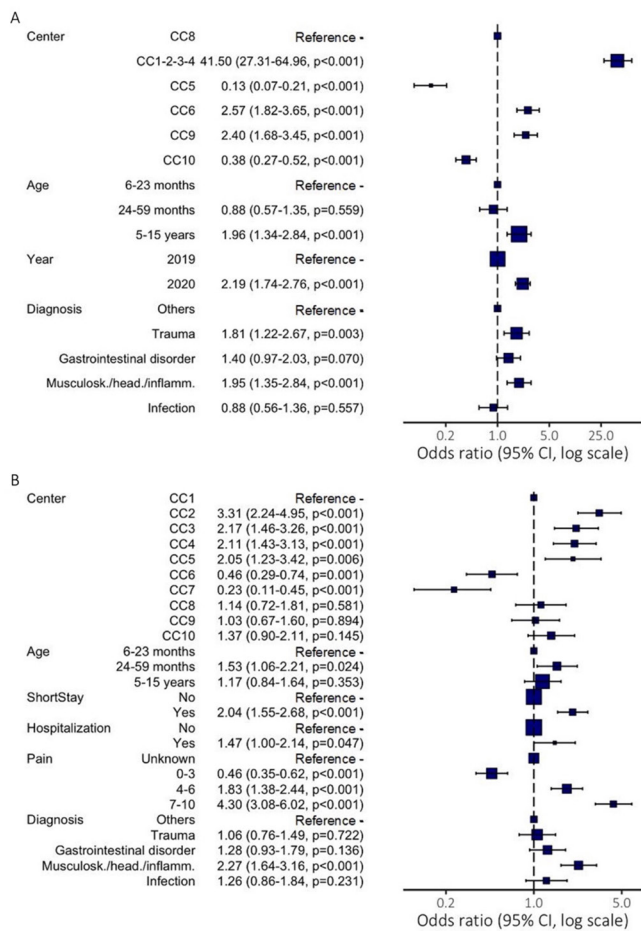


Figure 3 Variables significantly associated with pain measured (A) and pain treated (B). Notes: facilities were identified as CC (CC1–CC10). For (A), facility CC7 was excluded and facilities CC1, CC2, CC3 and CC4 were merged into one level because they presented extreme results (0% for CC7 and values above 95% for CC1, CC2, CC3 and CC4). Since facility CC1 could not be taken as reference, for this analysis, CC8 was chosen as the reference because of its geographical proximity to CC1. Musculosk./head./inflamm., musculoskeletal/headache/inflammatory complaints.

Multivariate analysis

At the multivariate analysis, after correction for children’s characteristics, the variable more strongly associated with analysed outcomes was the facility itself (figure 3 and online supplemental table 7).

Specifically, for pain measured, the variable more strongly associated with the outcome, when corrected for other variables, was the centre itself, with CC1, CC2, CC3 and CC4 having much higher odds of measuring pain than the reference CC8 (AdjOR range 27.31 to 64.96, p<0.001), CC6 and CC9 having higher odds (AdjOR 2.57 and 2.40 respectively, p<0.001 for both), while CC5 and CC10 having lower odds (AdjOR 0.13 and 0.38 respectively, p<0.001 for both) (figure 3A, see online supplemental table 7 for details). Other factors significantly associated with increased odds of pain measurement were: accessing EDs in 2020 (AdjOR 2.19, 95% CI: 1.74 to 2.76,

p<0.001), being older than 5 years (AdjOR 1.96, 95% CI: 1.34 to 2.84, p<0.001) and accessing ED for trauma or musculoskeletal/headache/inflammatory complaints (AdjOR 1.81, 95% CI: 1.22 to 2.67, p=0.003 and AdjOR 1.95, 95% CI: 1.35 to 2.84, p<0.001).

Similarly, regarding pain treatment (figure 3B and online supplemental table 7), the variable more strongly associated with the outcome, when corrected for other variables, was the facility. Four centres associated with higher odds of treating children with pain (CC2, CC3, CC4 and CC5, AdjOR range between 2.05 and 3.31 p<0.001 for CC2, CC3 and CC4, p=0.006 for CC5), two with lower odds (CC6 and CC7, AdjOR 0.46, 95% CI: 0.29 to 0.74, p=0.001, and 0.23, 95% CI: 0.11 to 0.45, p<0.001, respectively).

The odds of pain treatment increased alongside pain severity, with AdjOR equal to 0.46 for pain between 0 and 3 (95% CI: 0.35 to 0.63, p<0.001), AdjOR equal to 1.83 for pain between 4 and 6 (95% CI: 1.38 to 2.44, p<0.001) and AdjOR equal to 4.30 for pain between 7 and 10 (95% CI: 3.08 to 6.02, p<0.001).

Other factors significantly associated with increased odds of pain treatment were: children aged between 24 and 59 months (AdjOR equal to 1.53, 95% CI: 1.06 to 2.21, p=0.024); short stay and hospitalisation (AdjOR equal to 2.04, 95% CI: 1.55 to 2.68, p<0.001, and 1.47, 95% CI: 1.00 to 2.14, p=0.047, respectively), diagnosis of musculoskeletal/headache/inflammatory complaints (AdjOR equal to 2.27, 95% CI: 1.64 to 3.16, p<0.001).

The analysis of the associations between pain management with the facility characteristics (table 1) showed that the geographical location was the key factor associated with both pain measurement and treatment. Specifically, being a facility in Northern Italy associated with a higher rate of pain measurement, by 67.27% on average (95% CI: 39.9% to 94.6%, p<0.001), while being a facility in South Italy associated with less pain treatment (table 1), with average rate 22.1% lower (95% CI: -41.7% to -2.50%, p=0.03).

DISCUSSION

This study shows that the use of four WHO Standard-based Quality Measures, as prioritised by the CHOICE Project, can help identify key gaps in the domain of provision of care for children with pain. Furthermore, it clearly highlights how the appropriate measurement and treatment of pain in children accessing the ED in Italy is still an unreach goal. While large heterogeneity of practices was observed in relation to pain measurement—with only four centres measuring pain in at least 95% of children—pain treatment was poor in all centres. In most centres, there was a large difference between rate of measurement and rate of treatment. Although this difference often narrowed in patients with moderate or severe pain, it really reflects a main gap in QOC that can also affect patient motivation to access health services. Multivariate analysis showed that, independently from

**Table 1** Linear regression models

Variables associated with pain measurement rates					
	Estimate	95% CI (lower)	95% CI (upper)	t val.	Pr(> t)
(Intercept)	8.53	-24.99	42.06	0.54	0.597
Geographical location—North	67.27	39.95	94.60	5.22	<0.001***
Geographical location—South	19.12	-17.77	56.02	1.10	0.288
Number of ft nurses in ED in 2019/2020	80	-0.27	1.86	1.58	0.133
Variables associated with pain treatment rates					
(Intercept)	46.2	27.5	64.9	5.26	<0.001***
Geographical location—North	-11.1	-26.1	4.02	-1.56	0.139
Geographical location—South	-22.1	-41.7	-2.50	-2.40	0.030*
Children accessing the ED per year—hundreds	-0.0992	-0.180	-0.0187	-2.63	0.019*
Total residents in paediatrics ft in hospital in 2019/2020	0.269	0.114	0.425	3.70	0.002**

Associations between characteristics of the EDs with pain measurement and treatment.

*P<0.05.

**P<0.01.

***P<0.001.

ED, emergency department; ft, full time.

children's clinical characteristics, the centre where the child was managed was the variable more strongly associated with all the investigated outcomes, and this aligns with all other findings of the CHOICE study.^{28 29} These findings, and the geographical gradient observed, raise an important concern on equity in access to high quality care, which is a fundamental right for all patients.^{8 16} Furthermore, the lack of significant change in practices over time (year 2020 vs 2019), suggesting that gaps in provision of care for children were pre-existing to the COVID-19 pandemic, a finding that has been observed also by the other CHOICE studies on ARI²⁸ and AD,²⁹ and further calls for action.

Overall results of this study in Italy, showing a suboptimal pain treatment in paediatric EDs, add evidence specific to the Italian setting, and align with previous evidence from other settings,^{20–22 30–32} showing that still, despite a large body of the literature underlying the importance of pain treatment,^{9–22 33} most facilities need to improve their practices. Overall, study findings clearly call for actions to standardise pain management practices across facilities so that each child and their families can have access to high QOC.

However, a relevant finding of this study is also that, even in the centres with the best percentages of pain treatment, the use of pain scales and the percentage of children with pain receiving treatment does not reach the full percentage. We believe that this is due to the well-known fact that the use of pain scales should not be considered as a real and affective proxy of pain treatment. As a matter of fact, pain scales are a very poor proxy of real pain and their uncritical use can even be confusing and lead to overtreatment, with a significant percentage of children with high pain scores refusing treatment. In

fact, pain scales use should be limited to study settings and a holistic measure of pain, that is, a full pain assessment, should be used.³⁴ On the other hand, the differences in the figures of treatment between centres remain impressive and strongly suggest pain under treatment in some areas. The future trends suggested by this study are therefore the need to develop a better assessment tool than the simple numerical rating score, on one side, and focused programmes developed to improve pain recognition and management among the centres attending the study.

This study suggests that paracetamol and ibuprofen are the two most frequently used drug to treat pain in Italy, while it confirms that opioid use in Italy is not common,³⁵ differently from what is documented in the USA.^{36 37} While each child deserves to be treated for pain, appropriateness of opioid prescription in paediatric EDs should be carefully evaluated,³⁸ in the light of several studies documenting opioid overuse and related risk for adverse effects. The CHOICE study aims at supporting facilities in translating evidence into action, according to what current literature suggests as best pharmacological, including non-pharmacological strategies to improve case management for children with pain.^{17 18 39} Partners of the CHOICE project agreed as a first step for improving QOC to develop a comprehensive set of slides, to be disseminated and used across all included hospitals, including: results collected with the assessment; current evidence on most appropriate measurement and treatment options for pain in children; drug dosages, administration routes, adverse effects, and contraindication; other reflective material to support behaviour change in different settings. The impact of these interventions will be addressed in further studies.

The study has the strength of using objective measures for assessing pain management, from official data sources (discharge letters), thus allowing simple data extraction and comparison of quantitative data across facilities and over time, as well as replication of data collection in other settings. On the other side, findings of this study may have been affected by under-reporting of pain measurement and treatment in medical files, thus overestimating gaps in QOC in some centres. Completeness of patients' discharge letters is not a trivial issue, since information for the family and for the family doctors, both on children assessment and treatment, may be critical to allow clinical follow-up of children; additionally, correct information is a fundamental right of patients.¹⁸

Another limitation is that we excluded children already receiving pain medications since, from a pragmatic perspective, we assumed that a percentage of them would be admitted for reasons different from pain (such as, fever, respiratory or abdominal symptoms...) or search for a diagnosis; with a high likelihood of not being in pain since only a minority of patients do not respond to first-line painkillers. We recognise that in this group we may have overlooked children seeking care for persisting pain, but this would have been a minority and pain the chief complaint at admission.

A further limitation is that we considered as pain treatment only all the oral, intravenous, intranasal and sublingual drugs.

We did not include ice, topical medications, nerve blocks or use of sucrose or nitrous during procedures. Similarly, we could not evaluate when the pain was measured and when the drug was administered, because this information is usually missing in the discharge letters from PED in Italy. As a rule, pain should be measured at the triage, and medication should be provided after pain measurement; however, this study clearly shows that the practice is substandard in most centres.

The relatively small sample of facilities must be recognised among limitations of this study; however, few studies exist on this topic from Italy. The main purpose of the CHOICE study was to collect lessons on the implementation of selected quality measures from the WHO Standards,¹⁶ with the aim of extending it to future larger-scale implementation efforts. The results of the CHOICE study cannot be directly generalised to other facilities, while methods adopted could be easily replicated and translated in other contexts. Future research could focus on how to further optimised indicators of QOC for children with pain, how to implement sustainable data collection, and how to support data use in practice. The WHO standards should be upheld, and their implementation should be routinely monitored over time. There is a general need for systems to monitor QOC across countries and over time,⁴⁰ with the ideal purpose to link, as done in this study, quality measures to the individual children and facility characteristics. In the current absence of a national monitoring system, multicentre research collaborations could represent an effective way to

promote the implementation of the WHO Standards and to identify interventions to improve QOC for children.

Author affiliations

¹University of Trieste, Trieste, Italy

²Institute for Maternal and Child Health IRCCS Burlo Garofolo, Trieste, Italy

³Department of Pediatric Emergency Medicine and Trauma Center, Meyer Children's Hospital IRCCS, Florence, Italy

⁴Santa Maria della Misericordia University Hospital, Udine, Friuli-Venezia Giulia, Italy

⁵Azienda Ospedaliera Nazionale Santi Antonio e Biagio e Cesare Arrigo Alessandria, Alessandria, Piemonte, Italy

⁶Department of Pediatrics, Carlo Poma Hospital, Mantova, Italy

⁷Department of Women's and Children's Health, University of Padova, Padova, Italy

⁸Department of Pediatrics, Treviso Hospital, Treviso, Italy

⁹Department of Clinical and Experimental Medicine, University of Catania, Catania, Italy

¹⁰Department of Pediatrics Sapienza University of Rome, Santa Maria Goretti Hospital, Latina, Italy

¹¹Department of Pediatrics, Santa Maria delle Croci Hospital, Ravenna, Italy

¹²Department of Maternal, Newborn, Child and Adolescent Health and Ageing, World Health Organization, Geneva, Switzerland

¹³London School of Hygiene & Tropical Medicine, London, UK

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Collaborators Alessandria: Marta Gagliardi, Chiara Grisaffi, Bari: Fabio Cardinale, Annunziata Lucarelli, Lucia Grazia Tricarico, Mariateresa De Sario, Alessandra Pisani; Catania: Maria Carla Finocchiaro, Marta Arrabito, Gian Luca Trobia, Francesca Patanè, Vita Antonella Di Stefano; Firenze: Stefano Masi, Marco Greco, Emiliano Talanti, Andrea Iuorio, Anna Madera, Paola Stillo, Rosa Santangelo, Nicolò Chiti; Latina: Vanessa Martucci, Mariateresa Sanseviero, Alessia Marcellino; Mantova: Silvia Sordelli, Mariangela Labruzzo; Padova: Silvia Galiazzo, Francesca Tirelli; Palermo: Massimo Lo Verde, Domenico Cipolla, Sarah Contorno, Roberta Parrino, Giuseppina De Rosa; Ravenna: Sara Dal Bo, Alessandra Iacono, Vanna Graziani, Carlotta Farneti, Francesco Oppido, Giulia Sansovini; Treviso: Stefano Martellosi, Chiara Stefani, Marcella Massarotto, Paola Crotti, Giada Sartor, Riccardo Pavanello, Paola Moras; Trieste: Ilaria Mariani, Benmario Castaldo, Marta Magnolato, Michele Maiola, Alessandro Amaddeo, Alice Del Colle, Massimo Dagnelut; Udine: Maristella Toniutti, Michela Pandullo, Sara Rivellini, Chiara Pilotto, Paola Cogo.

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Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants. Approval for data collection was obtained by the ethical committee of the Friuli Venezia Giulia Region for the coordinating centre (Study ID: 2976, RC 15/2019 Prot. 0035348, 3 December 2019) and by ethical committees of all participating hospitals. Anonymity in data collection was ensured by not collecting any information that could disclose participants' identity. Participants gave informed consent to participate in the study before taking part.

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ORCID iDs

Elia Balestra <http://orcid.org/0000-0002-5492-0166>
 Giorgio Cozzi <http://orcid.org/0000-0002-6427-1366>
 Idanna Sforzi <http://orcid.org/0000-0002-3445-8963>
 Ilaria Liguoro <http://orcid.org/0000-0002-9177-0400>
 Enrico Felici <http://orcid.org/0000-0002-5997-7057>
 Silvia Bressan <http://orcid.org/0000-0002-6736-5392>
 Marta Minute <http://orcid.org/0000-0002-1329-5704>
 Laura Portale <http://orcid.org/0009-0006-7257-4929>
 Paolo Dalena <http://orcid.org/0000-0003-2920-9572>
 Riccardo Lubrano <http://orcid.org/0000-0001-8237-955X>
 Angela Troisi <http://orcid.org/0000-0001-9457-3974>
 Kevin Valentino <http://orcid.org/0000-0001-5127-1685>
 Silvia Bloise <http://orcid.org/0000-0002-2853-8318>
 Federico Marchetti <http://orcid.org/0000-0002-1257-7312>
 Egidio Barbi <http://orcid.org/0000-0002-6343-846X>
 Marzia Lazzarini <http://orcid.org/0000-0001-8608-2198>

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