

Prevalence of unplanned extubation and associated factors in a neonatal intensive care unit

Prevalência de extubação não planejada e fatores associados em uma unidade de terapia intensiva neonatal

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ABSTRACT | INTRODUCTION: Endotracheal intubation is a common procedure in Neonatal Intensive Care Unit (NICU) and Unplanned Extubation (UE) is a severe related event, which increases neonatal morbidity. **OBJECTIVE:** To verify the prevalence of UE and associated factors in newborns submitted to mechanical ventilation (MV). **MATERIALS AND METHODS:** This is a cross-sectional retrospective study, including 38 newborns and 72 UE. The collected parameters were: gender, weight at the time of extubation, diagnosis, time of UE, associated conditions and conduct. The statistical analysis included the Fisher's exact test and odds ratio (Statistica®). **RESULTS:** A total of 72 UE were recorded in 38 newborns, with a rate of 1.561 intubated patients/day and UE prevalence of 4.6%. Weight less than 1,500g was observed in 20 newborns (52.6%) and prematurity in 25 (65.8%) and when it was less than 2500g it was associated with a 6-fold increased risk of recurrent UE. In 15 newborns (39.5%) there was more than one event per patient. The conditions associated with increased UE risk were motor agitation of the newborn (50%), endotracheal tube (ETT) manipulation (28.3%) and routine procedures (21.7%). Reintubation was necessary in 58 cases (80.5%), being immediate in 20 (34.5%). **CONCLUSION:** The prevalence of UE was high and strongly associated with motor agitation and manipulation of ETT. Its recurrence was more frequent in newborns weighing less than 2,500 g. Therefore, prevention measures should include adequate management of the motor agitation in newborns and implementation of protocols for handling the ETT.

Keywords: Unplanned extubation. Prematurity. Patient Safety.

RESUMO | INTRODUÇÃO: Intubação endotraqueal é procedimento comum nas Unidades de Terapia Intensiva Neonatais e tem como evento adverso a extubação não planejada, um incidente grave, associado a morbidade neonatal. **OBJETIVO:** Verificar a prevalência de extubação não planejada e fatores associados em recém-nascidos submetidos à ventilação mecânica na unidade de terapia intensiva neonatal por condições respiratórias, cardíacas ou por pós-operatório. **MATERIAIS E MÉTODOS:** Estudo transversal, retrospectivo realizado entre março a dezembro de 2017. Os dados foram coletados da ficha de notificação do serviço e incluíram: sexo, peso no momento do evento, comorbidades do paciente, data e hora de ocorrência, condições associadas e conduta pós-extubação. **RESULTADOS:** Em 38 recém-nascidos em ventilação mecânica foram registrados 72 eventos, a prevalência da extubação não planejada de 4,6%. Entre os fatores identificados, peso inferior a 1.500g foi observado em 20 recém-nascidos (52,6%) e prematuridade em 25 (65,8%). Em 15 recém-nascidos (39,5%) houve mais de um evento/paciente. Peso inferior a 2.500g esteve associado a um risco 6 vezes maior de recorrência do incidente. As condições associadas aos eventos foram agitação motora do recém-nascido (50%), manuseio da cânula endotraqueal (28,3%) e durante procedimentos de rotina do recém-nascido (21,7%). Reintubação foi necessária em 58 casos (80,5%), sendo imediata em 20 (34,5%). **CONCLUSÃO:** A agitação motora e o manuseio da cânula endotraqueal, portanto, foram os fatores mais associados aos eventos, a recorrência foi mais frequente em recém-nascido com peso inferior a 2.500g. Medidas de prevenção devem incluir o manejo adequado da agitação motora do recém-nascido e implementação de protocolos de manuseio da cânula endotraqueal.

PALAVRAS-CHAVE: Extubação não planejada. Prematuridade. Segurança do paciente.

Introduction

Severely ill newborns routinely require endotracheal intubation and mechanical ventilation, a procedure associated with longer survival¹. However, this condition exposes patients to unplanned extubation, a serious and common adverse effect in neonatal intensive care units (NICUs). Unplanned extubation (UE) is defined as any withdrawal of the endotracheal tube, at an unplanned moment, accidentally removed by the patient or unintentionally by the health team², which can have serious consequences for the patient's life. Among the most frequent complications are hypoxemia, hypercapnia, atelectasis, pneumothorax, airway damage, hemodynamic changes and the need for reintubation in urgent and less controlled situations².

Newborns are considered a population at risk of unplanned extubation due to difficulties in securing the endotracheal tube, small face, short-length trachea, and use of cuffless endotracheal tubes^{1,2}. Among the most common associated conditions are motor agitation of the newborn and procedures performed by health professionals, such as bed bathing, transport, endotracheal tube change, and position change¹⁻⁴. It is known that Prolonged mechanical ventilation^{5,6} and the frequency and time of handling the newborns by the team and the parents are also factors that increase the risk of unplanned extubation^{1,2,7,8}.

It is estimated that the rate of unplanned extubation among adult patients varies between 0.10-3.61 / 100 intubated patients / day, while in pediatric ICUs it is around 0.11-2.70 / 100, being 2 to 3 times higher in NICUs. In the US, the estimated incidence of such occurrence is 0.14-6.6 / 100 and in Brazil, a study carried out in Campinas (São Paulo) indicated an incidence of 5.34 / 1005. It is the fourth most frequent

adverse event in NICUs, surpassed only by medication errors, health-associated infections and skin lesions.

The objective of this research was to verify the prevalence and factors associated with unplanned extubation in newborns admitted to the NICU of the participating institution, subjected to mechanical ventilation for respiratory, cardiac or postoperative conditions. And to increase vigilance and preventive actions for this frequent incident, contributing to patient safety actions.

Material and methods

Cross-sectional, retrospective study carried out in a NICU of a University Hospital. Data from neonates who required endotracheal intubation and mechanical ventilation in the period from March to December 2017, those who had unplanned extubation events in that period were included. Newborns who had planned extubation during this period were excluded. The data collected were extracted from a standardized specific unplanned extubation form, utilized in the hospital, completed by the team at the time the event occurred. It contained information on gender, weight at the time of extubation, patient comorbidities, date and time of unplanned extubation, possible conditions associated with the event and behavior after the fact. Planned extubations were excluded. In the statistical analysis, Fisher's exact test was applied, and the odds ratio was calculated to estimate the odds ratio for recurrent unplanned extubation. Statistica software (Statsoft®) was used, considering the significance level of 5% and the test power of 90%. The study was approved by the Institution's Human Research Ethics Committee, according to opinion number 2,426,709 (CAAE 7980141710000096).

Results

The NICU, at the University Hospital, a tertiary unit with 10 ICU beds and 10 intermediate-risk beds presented an occupation during the study period of 8,170 patients / day and 125 newborns were intubated, with a rate of intubated patients / day of 1,561. In 38 newborns, 72 unplanned extubation events were recorded. Considering the frequency of intubated patients per day, a prevalence of 4.6 / 100 was observed.

Of the 38 newborns, 18 were male (47.4%) and 20, (52.6%). Of these, 13 (34.2%) weighed less than 1,000g at the time of the event, 7 (18.5%) between 1,000 and 1,500g, 4 (10.5%) between 1,500 and 2,500g and 14 (36, 8%) weighing more than 2,500 g. Prematurity was observed in 25 cases (65.8%) and 11 newborns (28.9%) presented some type of malformation. All were on mechanical ventilation due to respiratory, cardiac, or postoperative conditions. Most of the newborns (95.0%) were intubated by the orotracheal route and the rest (5.0%) by the nasotracheal route. During the study period, the rate of patients on mechanical ventilation per month was 13, with a range of 7 to 23 days, (Table 1).

Of the 38 newborns, 23 had an unplanned extubation event (60.5%) and 15 had more than one (39.5%), of these, two events in five cases; three out of four cases; four out of four cases; five in only 1 case and 7 events in 1 more case. A total of 72 unplanned extubation events. Excluding these last two cases of recurrent unplanned extubation, whose newborns presented cervical malformations that made intubation difficult, the corrected prevalence in the unit would be 3.8 / 100.

In 28 cases, there were one or two unplanned extubation events (73.6%), 19 of them (67.8%) in newborns weighing less than 2,500 g at the time of the event ($p < 0.01$). The risk of more than one episode of unplanned extubation was six times higher in these infants who weighed less than 2500 g (OR = 6.6, 95% CI = 1.7 - 24.8). Considering the 72 events, 29 (40.3%)

occurred in newborns who weighed less than 1,000g at the time of extubation, 10 (13.9%) between 1,000 and 1,500g, 6 (8.3%) between 1,500 g and 2,500 g and 27 (37.5%) weighing more than 2,500 g.

In 60 events (83.3%) it was possible to analyze the cause of extubation, which occurred during the manipulation of the endotracheal cannula (fixation, change or repositioning) in 17 cases (28.3%), during procedures performed by health professionals (weighing, passage of the nasogastric tube, placement of drains, collecting a blood sample or performing imaging tests) in nine cases (15.0%), during the clinical examination in four cases (6.7%) and during motor agitation of the newborn in 30 cases (50.0%), (Table 2).

In seven cases (9.7%) extubation occurred in the first 48 hours of mechanical ventilation, in 17 cases (23.6%) between 2 and 7 days, 8 (11.1%) between 8 and 14 days; 15 (20.8%) between 15 and 30 days; 18 (25.0%) between 31 and 60 days and 9 (12.5%) with more than 60 days. Half of the cases occurred in the first 21 days of ventilatory support. Of the 72 extubation cases, 29 (40.3%) occurred in the morning (from 7:00 a.m. to 12:59 p.m.), 21 (29.2%) in the afternoon (between 1:00 p.m. and 6:00 p.m. 59 pm) and 22 (30.5%) at night (from 7:00 p.m. to 6:59 a.m.).

Reintubation was required in 58 of the events (80.5%). In 20 of them (34.5%) reintubation was immediate, in the remaining cases (65.5%) the newborns were stabilized before reintubation, with oxygen via nasal catheter (22.4%), ventilation with positive pressure (17.2%), continuous positive airway pressure (CPAP) (12.0%) and non-invasive ventilation (NIV) (19.0%). There was no association between the need for reintubation and the weight of the newborn ($p = 0.22$). Of the 14 events (19.5%) in which there was no reintubation, 2 (14.3%) were treated with inhaled oxygen, 4 (28.6%) with ventilation with positive pressure, 4 (28.6%) with CPAP and 4 (28.6%) with NIV. One newborn died, equivalent to 2.6% of the cases and 1.4% of the episodes of unplanned extubation, (Table 3).

Table 1. Characteristics of the 38 newborns in newborns admitted to the NICU

| Characteristics | n (%) |
|---------------------------------|------------|
| Gender | |
| Female | 20 (52,6%) |
| Male | 18 (47,4%) |
| Weight (gram) | |
| Less than 1000 | 13 (34,2%) |
| 1000 e 1499 | 7 (18,5%) |
| 1500 e 2499 | 4 (10,5%) |
| Bigger than 2500 | 14 (36,8%) |
| Diagnostic | |
| Gestational age | |
| Prematurity | 25 (65,8%) |
| Full term | 13 (34,2%) |
| Congenital malformation | 11 (28,9%) |
| Endotracheal tube | |
| Orotracheal | 36 (95,0%) |
| Nasotracheal | 2 (5,0%) |
| Number of unplanned extubations | |
| 1 | 23 (60,5%) |
| 2 | 5 (13,1%) |
| > 2 | 10 (26,4%) |

Table 2. Characteristics of 72 unplanned extubation events in newborns admitted to the NICU

| Characteristics | n (%) |
|--|-------------|
| Gender | |
| Female | 39 (54,2%) |
| Male | 33 (45,8%) |
| Weight | |
| Less than 1000 | 29 (40,3%) |
| 1000 e 1499 | 10 (13,9%) |
| 1500 e 2499 | 6 (8,3%) |
| Bigger than 2500 | 27 (37,5%) |
| Endotracheal tube | |
| Orotracheal | 72 (100,0%) |
| Nasotracheal | 0 (0,0%) |
| Diagnostic | |
| Gestational age | |
| Prematurity | 47 (65,3%) |
| Full term | 22 (34,7%) |
| Congenital malformation | 24 (33,3%) |
| Condition associated with unplanned extubation | |
| Tube Exchange/Fixation/Repositioning | 17 (28,3%) |
| Routine procedures | 9 (15,0%) |
| Clinical examination | 4 (6,7%) |
| Psychomotor agitation of the newborn | 30 (50,0%) |

Table 3. Characteristics of 72 unplanned extubation events related to mechanical ventilation days, in newborns admitted to the NICU

| Characteristics | n (%) |
|---|------------|
| Day on mechanical ventilation of unplanned extubation | |
| 1 - 48 hours | 7 (9,7%) |
| 2 - 7 days | 17 (23,6%) |
| 8 -14 days | 8 (11,1%) |
| 15 - 30 days | 15 (20,8%) |
| 31 - 60 days | 18 (25,0%) |
| > 60 days | 9 (12,5%) |
| Unplanned extubation day period | |
| Morning | 29 (40,3%) |
| Afternoon | 21 (29,2%) |
| Night | 22 (30,5%) |
| Management after unplanned extubation | |
| Reintubation * | 58 (80,5%) |
| Immediately | 20 (34,5%) |
| After nasal oxygen | 13 (22,4%) |
| After positive pressure ventilation | 10 (17,2%) |
| After CPAP | 7 (12,0%) |
| After VNI | 11 (19,0%) |
| Non-reintubation | 14 (19,5%) |
| Nasal oxygen | 2 (14,2%) |
| Positive pressure ventilation | 4 (28,6%) |
| CPAP | 4 (28,6%) |
| VNI | 4 (28,6%) |
| Death | 1 (1,4%) |

* Some newborns underwent more than one procedure before non-immediate reintubation;
 VM: Mechanical ventilation; NIV: Non-invasive ventilation; CPAP: *Continuous Positive Air Pressure*

Discussion

Among the most recent recommendations⁸, the acceptable rate of unplanned extubation should be less than 2/100 intubated patients / day, while Merkel et al.⁹, suggest that the ideal should be less than 1/100 and that the adoption of security measures can reduce this rate to 0.41 / 100, considering that it is a potentially preventable incident^{8,9}. In this sample, the prevalence found was 4.6 / 100 and 3.8 / 100 when correcting (excluding the 2 newborns with cervical malformations and high recurrence of unplanned extubation), being higher than the recommended one, but within variations reported in the literature. There was no difference in the frequency of occurrence of the incident according to sex, but there are few studies that evaluate this aspect. Aydon, Zimmer and Sharp¹⁰ reported a more prevalent unplanned extubation rate in newborn males, with a ratio of 3:1. Other authors have also observed a higher prevalence in males³.

The literature points to an association between birth weight and unplanned extubation. In the 30-year systematic review by Silva et al.¹¹ of 34,105 potentially relevant articles on the subject, 15 of 192 studies initially considered were selected for a more detailed evaluation. Among them, Brown¹² found a higher frequency of unplanned extubation in newborns weighing less than 1,000g (42% versus 23%), while Harimoto et al.¹³ reported that 87% of unplanned extubation occurred in newborns weighing less than 2,500g, a rate similar to that observed in the present study (62.5%). Some authors, however, found no association between unplanned extubation and birth weight or weight at the time of extubation¹⁴. The events in our database were distributed in a bimodal manner: a peak in a population of very low birth weight newborns (<1000g) (34.2%) and another in newborns over 2,500g (36.8%), possibly reflecting an association with prematurity and inadequate sedation, similar to those observed in other studies^{5,7}. There were also recurrent events (39.5%), with a 6-fold higher risk in neonates weighing less than 2,500g, an association also described by Kleiber and Hummel¹⁵ in 47% of their cases.

Length of stay on ventilation has been identified as one of the main risk factors for unplanned extubation^{2,5,7}. The highest event rate is around 10.5 days of mechanical ventilation^{2,7}, Carvalho et al.⁵ pointed out that each day of mechanical ventilation increases the risk of unplanned extubation by 3%. The nasotracheal intubation procedure, although considered safer by some authors, is rarely used due to complications such as necrosis of the nasal flaps and nasopharyngeal hemorrhage. Likewise, balloon cannulas, used in pediatric ICUs and potentially safer, are not used in neonatology due to the risk of tracheal necrosis^{16,17}.

Among the factors that favor unplanned extubation events in neonates are some characteristics of the newborn, such as a short trachea, neurological immaturity, and a small face. Other factors are the need to maintain care of fixation due to constant wetting, which can be caused both by salivation and by the use of humidified incubators, and ease of extubation, due to the short length that defines effective intubation, meaning that millimeters of displacement can determine extubation²⁻⁵.

Intubation of newborns with malformations is usually more difficult, since they can present greater resistance to the endotracheal tube passage. Another determining factor for a higher prevalence of unplanned extubation is the greater number of procedures these newborns undergo, either through diagnostic or therapeutic measures. Newborns with cystic hygroma and Prune Belly syndrome had the highest extubation recurrence (7 and 5 events, respectively) in this sample. In the literature, congenital malformation is rarely treated in the analysis of unplanned extubation events¹⁸.

In the systematic review carried out by Silva et al.¹¹, the main conditions associated with unplanned extubation were motor agitation of the newborn (13-89%), manipulation and fixation of the endotracheal tube (17-30% and 8-31%, respectively) and bedside procedures (27.5-50%). In the present study, motor agitation in the newborn was associated with unplanned extubation in half of the cases, while endotracheal tube management was responsible for 28.3% of the cases.

Some of the measures to prevent unplanned extubation include sedation and non-pharmacological interventions. There are no adequately designed studies to evaluate the use of sedation to prevent extubation. The few studies have controversial results and, in pediatric and adult ICUs, sedation was not associated with effective prevention of unplanned extubation^{5,11,14,15,18-20}. Furthermore, it is important to note that motor agitation can be a clinical manifestation of hypoxemia⁹. Studies in which there is routine use of sedation in neonates under mechanical ventilation describe lower rates of motor agitation during tube manipulation and interventions⁷, which qualifies sedation as a protective factor against unplanned extubation. However, this strategy involves side effects. Many drug classes do not have analgesic effects, even more so, some can even increase the pain. Several opioids are an exception, which, in addition to reducing newborn motor agitation, also act as analgesics in face of painful stimuli and invasive procedures. Nevertheless, these drugs are associated with respiratory depression, urinary retention, nausea, vomiting, decreased intestinal transit, and physical dependence^{21,22}.

Alternatively, containment is a frequently used non-pharmacological measure. In the studied NICU, pharmacological sedation is not used routinely, and the newborns are accommodated in a nest, made up of folded glutes and placed in an oval shape around the patient, providing comfort and limiting risky movements for extubation. In the literature, results regarding containment measures are not consistent either, although some authors still recommend the use of gloves on the newborn's hands, especially in newborns weighing less than 2,500g, avoiding endotracheal tube extraction^{12,17,20}. Constant vigilance is also effective, since it allows the early identification of motor agitation, and can prevent unplanned extubation, which is inversely proportional to the professional / patient ratio¹⁰.

The association between unplanned extubation and the management of the neonate during routine procedures is present in most studies. They include blood collection, weighing, position change, among others. In the studied NICU, the lower rate of unplanned extubation associated with team procedures is

possibly due to an internal protocol, which always mandates one or more health professionals while handling the newborn, be they doctors or nurses. Blood collection, for example, is usually done in two, the doctor collects and the assistant restrain the patient. Some authors point out the need for at least two team members to perform procedures on intubated newborns. This recommendation is aligned with the safety bundles regarding this subject^{9,10}.

In procedures involving endotracheal tube management, such as changing fixation, aspirating secretions and newborn repositioning, the rate of unplanned extubation is elevated due to direct manipulation of the endotracheal tube, which can cause inadvertent mobility. Veldman et al.¹⁴ point to inadequate endotracheal tube fixation as one of the main causes of extubation. Many methods of fixation have already been proposed and include the use of adhesive tapes, umbilical cord clamps, sutures, and endotracheal tube fixation devices adapted to the neonate's head. Lai et al.²⁴, in a review that included all controlled clinical trials from 1966 to 2013, concluded that given the heterogeneity of the methods used, both in fixation and in study design, there is a lack of conclusive evidence on what is the best way of fixing the endotracheal tube in newborns, and that procedure standardization and team experience are associated with safer intubations.

The use of adhesive tapes is common in the NICU, but with a small face and sensitive skin, care must be taken with its excessive use in newborns, limited only to the centimeters necessary for fixing between lip rhymes²²⁻²⁴. In the studied NICU, the fixation method used is an adhesive tape cut in the shape of an H, with the endotracheal tube positioned in the center, with the upper part of the H fixed in the upper nasolabial region and the lower part in the endotracheal tube.

Silva et al.¹¹ reported that 39% of unplanned extubation occur in the first 48 hours of mechanical ventilation, and 51.2% of cases occur in the first 7 days. In this study, these frequencies were 9.7% and 34.7%, respectively. Even so, it was observed that unplanned extubation events occurred with a similar distribution in the morning, afternoon and night periods, while the systematic review indicated

26.8% of the cases between 7 and 10 in the morning and 17 % between 4pm and 7pm^{9,11}. The morning period is considered of higher risk due to the greater number of procedures performed, such as clinical, laboratory and imaging exams, hygiene and wellness procedures, therapeutic and ventilatory procedures, including CET care².

Immediate complications of unplanned extubation usually include deterioration of cardiorespiratory function, with bradycardia (39-46%) and cardiopulmonary resuscitation (5-13%), while late complications include an increase in mechanical ventilation time (from 52 to 345 h) and increased length of stay (9 to 51 days), in addition to the risk of subglottic necrosis, pneumonia associated with mechanical ventilation and pulmonary Broncho dysplasia. The estimated need for reintubation varies widely between studies, ranging from 3% to 100% of cases¹¹ and was present in this sample in 80% of events, being immediate in 20 cases (34.5%).

Modifying the culture of patient safety is essential, especially focused on scientific evidence and the acknowledgement that unplanned extubation is an avoidable adverse event and a potential risk for the newborn. Aydon, Zimmer and Sharp¹⁰, in a recent publication, recommend the implementation of a bundle for the cannula care, that includes: a) standardized methods of endotracheal tube fixation; b) guidelines for the prevention and management of unplanned extubation; c) endotracheal tube position documentation according to the newborn's weight and age; d) frequent and continuous monitoring of the endotracheal tube and the conditions for its setting; e) disclosure of the incidence and factors associated with unplanned extubation to the team; f) documented checklist of procedures prior to unplanned extubation; g) participation of 2 professionals for the management of intubated newborns; h) continuous team training on the effects of unplanned extubation and prevention strategies.

Merkel et al.⁹ reported a reduction in the unplanned extubation rate from 2.38 to 0.41 / 100 when using a bundle that included, in addition to the aforementioned measures, the placement of notices about the position of the endotracheal tube near the

patient and red stripes identifying those newborns with a higher risk of unplanned extubation, such as those weighing less than 1,000g, previous unplanned extubation, history of intubation difficulty, abnormalities of the face and / or airways that make intubation difficult, and severe respiratory conditions, in which inadvertent endotracheal tube displacement can have serious consequences for the newborn.

Although it is considered a very serious adverse event, unplanned extubation is not associated with an increase in mortality^{2,14}, with one case of death being observed in our sample. Its morbidity, however, is not well established and the authors highlight the heterogeneity of the studies carried out on the subject and the low event documentation, which makes it difficult to analyze and understand its real impact. What is known, in fact, is that simple safety measures are highly effective in reducing unplanned extubation and should be implemented in the NICU to ensure the best care for newborns in mechanical ventilation^{9-11,23}.

The study limitations are related to the absence of data on the newborn's gestational age and the days being supported by mechanical ventilation; this information was not routinely documented in our form during the studied period, this was corrected by the service team, after the investigation period.

Conclusion

The prevalence of unplanned extubation in the studied NICU is higher than the recommendation found in the literature. The frequency of unplanned extubation was higher in newborns weighing less than 2500 g, in premature infants, and in those with associated congenital malformations. The recurrence of unplanned extubation was mainly associated with body weight lower than 2500 g and the presence of congenital malformations. The main causes were newborn psychomotor agitation and inadequate fixation of the endotracheal cannula. Thus, simple safety measures related to organizational culture are highly effective in reducing unplanned extubation and should be implemented to ensure the best care for the newborn on mechanical ventilation.

Author contributions

Mattos MCL and Silva GA participated in the design, search, data collection, statistical analysis of the research data, interpretation of results, and writing of the scientific article. Andreaza MG participated in the design, data collection, statistical analysis of the research data and the interpretation of the results. Rodrigues FS and Oliveira IC participated in the search, statistical analysis of the research data, interpretation of results and writing of the scientific article. Cat MNL participated in the conception, design, statistical analysis of the research data, interpretation of the results.

Competing interests

No financial, legal or political conflicts have been declared involving third parties (government, companies and private foundations, etc.) for any aspect of the work presented (including, but not limited to, grants and funding, participation in advisory council, study design, manuscript preparation, statistical analysis, etc.).

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