



CLINICAL RESEARCH ARTICLE



Federal regulations and neonatologists' views on care of seriously ill infants: changes over time

 Emily Polidoro¹, Andrea S. Weintraub¹ and Katherine F. Guttman¹  

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BACKGROUND: The Baby Doe Regulations (BDR) regulate provision of life-sustaining treatment to seriously ill neonates. In 2020, the Trump administration expanded upon these through the Executive Order on Protecting Vulnerable Newborn and Infant Children (EO-PVNIC). Neonatologists were surveyed in 1988 to determine their opinions on the regulations. We sought to compare views of neonatologists from 1988 and 2021 in relation to three hypothetical cases and about the impact of the BDR and to evaluate perceptions of the EO-PVNIC.

METHODS: We modified and distributed the 1988 survey to members of the American Academy of Pediatrics Section on Neonatal Perinatal Medicine. We used Chi-squared tests to compare responses in 1988 to responses in 2021.

RESULTS: We received 445 survey responses. Neonatologists today felt less compelled to provide aggressive care to the hypothetical patients, felt less constrained by the regulations, and were more likely to report that parental wishes would impact their actions.

CONCLUSIONS: There have been shifts in neonatologists' perceptions of the Baby Doe Regulations toward less aggressive medical treatment for seriously ill neonates and more shared decision-making. Further research is required to identify how practices have been impacted over these decades.

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IMPACT:

- Neonatologists in the 1980s largely objected to the Baby Doe regulations, fearing the regulations would restrict their ability to provide optimal care to seriously ill neonates.
- Though still in place, current perceptions of these and newer regulations are unknown.
- Perspectives on the Baby Doe regulations have changed since their enactment and with the addition of newer, more restrictive regulations.
- Neonatologists today may favor less aggressive management in the face of poor prognosis.
- Neonatologists may also favor more shared decision-making now as compared to the past.

INTRODUCTION

Advances in neonatal medicine have led to considerable improvement in survival of very low birth weight and extremely premature infants. Despite this, some patients admitted to the neonatal intensive care unit face prolonged hospitalization, serious medical and neurologic morbidity, and poor long-term prognosis. Neonatologists must often make difficult decisions surrounding the withdrawal or withholding of aggressive medical intervention in these situations, largely in a legal vacuum, as there are no international norms informing restraint of intensive care for critically ill infants.¹

Amid concerns about the care of a pair of critically ill neonates, the Baby Doe Regulations (BDR), which require that each state's Child Protection Agency meet certain requirements in order to receive federal funding, were enacted via amendment to the Child Abuse Prevention and Treatment Act in the early 1980s.² These regulations have been interpreted by many to stipulate that all infants <1 year of age must receive maximal medical therapy

(including medications, feeding, and hydration) unless treatment is deemed futile in terms of survival and/or the infant is actively dying or in a chronic and irreversible coma.^{3,4} These regulations have most recently been expanded upon with the 2019 Trump Administration Executive Order on Protecting Vulnerable Newborn and Infant Children (EO-PVNIC), which states that withholding treatment on the basis of quality of life may violate Federal law.⁵

Over time, medical care across specialties has progressively moved toward shared decision-making. In pediatrics, this involves collaboration between doctors and parents and the application of the Best Interest Standard when conflict arises.^{3,4} At the time of their implementation, a 1988 survey of American neonatologists revealed that many feared the BDR might force medical decision-making that was not aligned with the patient's best interest or with families' wishes.⁶ The American Academy of Pediatrics has interpreted the BDR to allow for withdrawal of treatments (such as nutrition or hydration) when the benefit of such treatment no

¹Division of Newborn Medicine, Department of Pediatrics, The Icahn School of Medicine at Mount Sinai, New York, NY, USA. ✉email: katherine.guttman@mssm.edu

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longer outweighs the burden.⁷ However, several scholars and at least one court have taken issue with this position^{3,4,8} and the EO-PVNIC on Protecting Vulnerable Newborn and Infant Children seems to directly rebut such an interpretation,⁹ leaving even less room for agreement between the Best Interests Standard and Federal law.

Since Kopelman's landmark survey, professional opinions of these regulations have not been revisited. Further, there have been no legal challenges to the BDR at the national level, so legal precedent has not been set. Despite this, neonatologists have continued to practice according to their personal interpretation of the Best Interests Standard.⁴ Not only might this practice be in conflict with Federal law^{3,10} but it may also interfere with the Best Interests Standard.⁴ Clearly the inconsistencies between practice, law, and ethical norms could lead to different standards and goals of care.

In order to better understand how neonatologists' views regarding the care of critically ill infants and the relevant federal regulations have evolved in the past three decades, we replicated the 1988 Kopelman survey, with the addition of questions soliciting opinions about the EO-PVNIC, among members of the American Academy of Pediatrics Section on Neonatal-Perinatal Medicine. We sought to (1) compare the views of neonatologists from 1988 and 2021 in relation to three hypothetical cases, (2) compare the views of neonatologists from 1988 and 2021 about the impact of the BDR, and (3) evaluate perceptions of the EO-PVNIC.

METHODS

The 1988 survey by Kopelman and colleagues queried neonatologists' opinions about the extent of clinical care obligations in the context of the BDR in three scenarios (a full-term infant with Trisomy 13 in congestive heart failure at 3 weeks of age; a 550 g preterm infant born at 25 weeks gestation who develops a large intraparenchymal hemorrhage; and a blind, full-term infant with advanced congenital hydrocephalus, a ventriculoperitoneal shunt, and life threatening ventriculitis), as well as sentiments on eight general statements about the BDR. Participants' survey responses were on a 5-point Likert scale (strongly agree, agree, uncertain, disagree, strongly disagree, and not applicable). For the purposes of analysis, Kopelman et al.⁶ omitted "not applicable" responses, combined "strongly agree" and "agree", and combined "disagree" and "strongly disagree" to create a final 3-point Likert scale (agree, uncertain, disagree). With permission from the Drs. Kopelman, we modified their survey to include opinions about the extent of clinical care obligations in the context of the EO-PVNIC and updated the gestational age of the preterm infant in scenario 2 to 23 weeks to better reflect anticipated outcomes in 2021 (Appendix 1). We also solicited personal demographic information (age, gender identity, level of training, Neonatal Intensive Care Unit acuity level, geographic location, and religious and political party affiliations) from study participants.

Our survey was distributed electronically via RedCap to neonatology attendings and fellows through the American Academy of Pediatrics Section on Neonatal-Perinatal Medicine. Individual survey responses were downloaded, coded, and entered into SPSS Statistics Version 23 (IBM, Armonk, NY). Demographic characteristics are reported using descriptive statistics. We used the Likert scale from the original 1988 study for our 2021 survey. Chi-squared tests were used to compare 2021 and 1988 opinions for each clinical scenario and statement. The project was approved as exempt human subjects research by the Institutional Review Board of the Icahn School of Medicine at Mount Sinai.

RESULTS

The survey was distributed to approximately 4000 members of the American Academy of Pediatrics Section on Neonatal-Perinatal Medicine between March and April of 2021. Four hundred and forty-five responses were received (response rate 2021 = 11% vs. response rate 1988 = 49%). The majority of study participants in 2021 self-identified as female, Christian, and Democratic and practiced in urban Level 4 Neonatal Intensive Care Units (Table 1).

Table 1. Demographics of the 2021 study population ($N = 445$).

Characteristic	<i>n</i>	%
Male	179	40.2
Academic level		
Attending	391	88
Fellow	47	11
Clinical setting		
Level 1	4	1
Level 2	14	3
Level 3	162	36.4
Level 4	263	59
Setting		
Urban	317	71.2
Suburban	102	23
Rural	21	4.7
Other	4	1
Geographic region of US		
Northeast	124	28
Southeast	100	22.5
Midwest	80	18
Southwest	62	14
West	72	16.2
Non-continental	3	0.7
Religion		
None	94	21
Christian	255	57.3
Jewish	41	9.2
Muslim	7	1.6
Hindu	17	3.8
Sikh	1	0.2
Other	7	1.6
Political party affiliation		
Democratic	282	63.4
Independent	82	18.4
Republican	36	8.1
Other	8	1.8
Aware of BDR	316	71
Aware of EO-PVNIC	320	72

Comparisons between perspectives regarding hypothetical cases

The comparison of current study participants' opinions about the BDR, in the context of the three clinical scenarios, with historical data from 1988,⁶ is presented in Table 2. For the case of the full-term infant with Trisomy 13 in congestive heart failure, fewer current study participants agreed that the "BDR required cardiac catheterization to be performed" ($p < 0.001$), and more agreed that "parents' wishes would influence their decision" ($p < 0.001$) when compared with their peers' opinions from 1988. For the case of the extremely preterm infant with intraparenchymal hemorrhage, more current study participants agreed they would "consider stopping ventilator support at this time" ($p < 0.001$) and that "parents' wishes would influence their decision" ($p < 0.001$) when compared with 1988 survey participants. Significantly fewer current study participants felt that the BDR would "require them to continue ventilator support" of the patient ($p < 0.001$) and that their "decision would be based solely on the medical facts"

Table 2. Comparison between neonatologists' opinions in 2021 and 1988.

	Agree 2021 (%)	Agree 1988 (%)	Disagree 2021 (%)	Disagree 1988 (%)	<i>p</i>
Case 1. Term infant with Trisomy 13, congestive heart failure at 3 weeks of age					
Good medical judgment requires cardiac cath after anti-congestive treatment is begun	7.1	10	75.3	86	0.05
The BDR require that the cardiac cath be performed	12.8	22	76.9	61	<0.001
The parent's wishes would influence my decision	87.1	77	28.8	15	<0.001
The EO-PVNIC require that the cardiac cath be performed	23.1	—	63.5	—	
Case 2. 23 week gestation, 550 g with large cerebral intraparenchymal hemorrhage					
I would consider stopping ventilator support at this time	86.4	75	5.4	16	<0.001
The parents' wishes would influence my decision	95.9	87	2.7	8	<0.001
The BDR require me to continue ventilator support	13.9	30	76.2	52	<0.001
My decision would be based on medical facts and the parents' wishes would not enter into it	4.7	8	91.4	86	0.012
My approach to care of such infants is impacted by the federal regulations	15.4	23	68.6	68	NS
The EO-PVNIC requires me to continue ventilator support	24.7	—	59.8	—	
Case 3. Full-term infant with advanced congenital hydrocephalus, blind, and minimally responsive, with shunt infection and life-threatening ventriculitis					
According to the BDR, I am compelled to treat the infant	14.1	47	78.2	39	<0.001
It is in the infant's best interest to treat them	8.8	9	79.6	77	NS
My approach to treatment of such an infant is impacted by the federal regulations.	17.3	33	66.1	58	<0.001
According to the EO-PVNIC, I am compelled to treat the infant	24.9	—	63.5	—	
Statements					
The BDR has resulted in improved care for all infants	15.2	5	53.4	81	<0.001
The BDR were needed to protect the rights of handicapped infants	29.1	14	54.7	76	<0.001
The EO-PVNIC is needed to further protect the rights of handicapped infants	8.9	—	77	—	
The BDR did not affect parental rights to consent to or refuse treatments based on what is in infant's best interest	44.5	19	34.3	66	<0.001
The EO-PVNIC will not affect parental rights to consent to or refuse treatments based on what is in infant's best interest	35.4	—	45	—	
The BDR allow adequate consideration of suffering	34.5	29	51.2	60	<0.001
The EO-PVNIC allows adequate consideration of suffering	16.2	—	65.1	—	
The BDR have exacerbated the shortage of NICU beds	7.8	17	61.4	51	<0.001
The EO-PVNIC will exacerbate the shortage of NICU beds	18.5	—	47.4	—	
Most critically ill infants are over treated when the chances for their survival are very poor	38.6	56	41.1	31	<0.001
If the Federal government requires life-saving treatments of severely handicapped infants, then it should guarantee payment for that treatment	87	82	2.7	12	<0.001
If the Federal government requires life-saving treatments of severely handicapped infants, then it should guarantee payment for their rehab care	88.4	82	3.2	12	<0.001

2021 and 1988 cohorts are compared using Chi-squared test.

($p < 0.001$) when compared with peers' opinions from 1988. For the case of the blind, minimally responsive full-term infant with advanced congenital hydrocephalus and life-threatening ventriculitis, significantly fewer current study participants believed that the BDR would "compel them to treat" the infant ($p < 0.001$) and that their "approach to treatment of such infants is impacted by federal regulations" ($p < 0.001$) when compared with peers' opinions from 1988.

Comparisons between perspectives on the impact of the BDR

General opinions about the BDR were more positive among current study participants than in the historical cohort from 1988. Significantly more current participants agreed that the "BDR have

improved care for all infants" ($p < 0.001$), were needed to "protect the rights of handicapped infants" ($p < 0.001$), "did not affect parental rights to consent or refuse treatment" ($p < 0.001$), and "allowed adequate consideration of suffering" ($p < 0.001$) than neonatologists in the earlier cohort. Neonatologists today were less likely to agree with the statement "Most critically ill infants are over treated when the chances for their survival are very poor" than were neonatologists in 1988 ($p < 0.001$).

Perspectives on the EO-PVNIC

The overwhelming majority (77%) of current study participants *did not* believe that the EO-PVNIC was needed to further protect the rights of handicapped children. When considering medical

decision-making in the three clinical scenarios in the context of the EO-PVNIC, the majority of study participants (63.5%) *disagreed* that the EO-PVNIC “would require cardiac catheterization to be done” for the patient with Trisomy 13 in congestive heart failure. Nearly 60% of study participants *disagreed* that the EO-PVNIC “would require continued ventilator support” for the 23-week preterm infant with intraparenchymal hemorrhage. The majority (63.5%) *disagreed* that the EO-PVNIC “would compel them to treat” the blind, minimally responsive full-term infant with advanced congenital hydrocephalus and life-threatening ventriculitis. A comparison of current participants’ sentiments about repercussions of EO-PVNIC with the historical cohort’s perceptions of the BDR did not find any significant differences between the groups.

DISCUSSION

In replicating the landmark 1988 Kopelman survey,⁶ and in the context of more recent Federal regulations and evolving perceptions of clinical care obligations, we present a contemporary overview of neonatologists’ opinions on complex medical decision-making for seriously ill newborns. We found that, in general, neonatologists today felt less compelled to provide aggressive care to the three hypothetical patients from the Kopelman survey and were more likely to report that their actions would be impacted by parental wishes. Participants today generally felt less constrained by the BDR. Overall, and consistent with prior reports, these perceptions appear to reflect both greater likelihood of considering withdrawal of aggressive treatment and a shift toward shared decision-making, which seems to transcend federal regulations.¹⁰

Both practices in neonatal intensive care and the federal regulations governing them have evolved since 1988. Changes in neonatologists’ perceptions are impacted by a multitude of factors, including their breadth of clinical experience, experience with the regulations themselves, changes in ethical norms, improved prenatal/perinatal diagnosis and care, as well as a shifting demographic in medicine itself. While we cannot extrapolate the exact reasoning for this evolution in perceptions, we did find some substantial changes that warrant exploration. Our data show that the reservations about the BDR expressed by the historical cohort have diminished significantly over time (Table 2). However, current study participants have similar concerns today regarding the EO-PVNIC to those expressed by their peers in 1988 regarding the BDR (Table 2). This may suggest that physicians become more comfortable with new regulations over time, even when initially controversial. Physicians and policy-makers may need to guard against such a tendency, since interpretation of federal regulations may change with each new administration, with the potential for uncharted changes in enforcement in the future. We identified that, while present day neonatologists are as concerned that the EO-PVNIC will not allow adequate consideration of neonatal suffering as their peers were in 1988 regarding the then untested BDR, they are less concerned that the EO-PVNIC will interfere with serving the infant’s best interest. Perhaps this cohort’s prior experiences with the BDR have shaped some of their responses to the EO-PVNIC, leading some to believe that these new regulations are unlikely to change practice. However, neither the BDR nor the EO-PVNIC have been examined in court on a national level. Such a challenge would have the potential to dramatically shift the interpretation and enforcement of both laws.

Over the past 30 years, withdrawal of aggressive medical care for neonates with guarded neurologic prognoses has been more frequently considered and undertaken.¹¹ Our results are consistent with this trend, with neonatologists in our cohort more likely to believe that aggressive treatment is not in some seriously ill newborns’ best interest and more likely to consider withdrawal of aggressive support as compared to their 1988 peers. In parallel to

prior work, we found a greater acceptance of parental wishes for seriously ill patients when prognosis is poor (case 1 and 2, Table 2).¹² Though many challenges to implementation of shared decision-making still exist, our results echo literature which demonstrates that, especially in the face of uncertainty, physicians are increasingly likely to engage in shared decision-making in the United States.¹³ This trend is culturally mediated, with physicians in some other countries tending toward a more paternalistic approach.¹⁴

Since the BDR were passed, the ethics and medical communities have accepted the Best Interests Standard as the governing principle for management of critically ill neonates.^{4,12} Despite early concerns that the BDR might require physicians to act in ways that were not in the best interest of the patient,³ the American Academy of Pediatrics interpreted the BDR as consistent with the Best Interests Standard.⁷ Our results suggest that this interpretation has been at least somewhat accepted by the medical community. For example, we found decreased concern that the BDR would interfere with parents’ ability to consent/refuse care in accordance with the best interest of their child.

Our study has several important limitations. Our survey response rate was low, and significantly lower than the 1988 response rate, which raises reasonable concerns about non-response bias. Response rates to physician surveys have declined steeply in recent years, with job demands and email/survey fatigue as the most commonly cited reasons.^{15–17} There is no scientifically validated, minimally acceptable survey response rate, and a low response rate, in and of itself, is not an indicator of response bias.¹⁸ Survey response rates are not strongly associated with survey quality.¹⁹ The opinions of neonatologists who chose not to respond to our survey may be different in important ways than those who did respond. We cannot know the perspectives of those who chose not to respond to our survey. In addition, we only surveyed members of the American Academy of Pediatrics Section on Neonatal–Perinatal Medicine whose views may not represent the views of all neonatologists. We cannot say how the opinions of neonatologists who answered our survey have actually impacted their practice. Many of the current participants have only practiced in the era when the BDR were the law, which certainly impacts awareness of how the BDR may have changed the norms of practice. Finally, our results lack the perspectives of key stakeholders including most importantly parents, but also nurses, and policy-makers.

In conclusion, over the past 30 years, there have been significant shifts in neonatologists’ perceptions of the BDR with current neonatologists reflecting upon the BDR more favorably than their predecessors. Opinions have trended toward both less aggressive medical treatment for seriously ill neonates with poor prognoses and more shared decision-making with parents. Although many have reservations about the new EO-PVNIC, most neonatologists we surveyed are not concerned about the impact of this legislation on their clinical practice. Further research, including in-depth review of Neonatal Intensive Care Unit care over time as well as surveys of parents and policy-makers, is required to know exactly how neonatal practices have been impacted over these decades and to make recommendations for future policy and advocacy initiatives.

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AUTHOR CONTRIBUTIONS

E.P. conceptualized and designed the study, designed the data collection instruments, collected data, carried out the initial analysis, and drafted the initial manuscript. A.S.W. conceptualized and designed the study, designed the data collection instruments, collected data, carried out the initial analysis, and reviewed and revised the manuscript. K.F.G. conceptualized and designed the study, designed the data collection instruments, collected data, and reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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COMPETING INTERESTS

The authors declare no competing interests.

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Correspondence and requests for materials should be addressed to Katherine F. Guttman.

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