



International Neonatal Consortium

Culture of Communication Parallel Stakeholder Surveys:

Summary of Results

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on behalf of the Communications WG



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* Part IV was specific to Neonatologists & Nurses ONLY



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Part I: Demographic Data

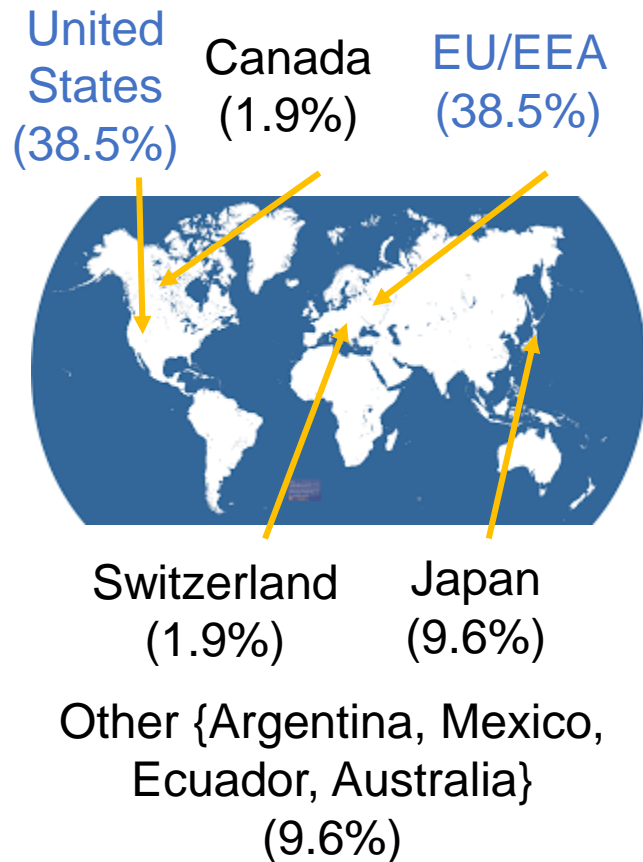
Communications Survey

	# Respondents	Average time in the survey
Physician / Researchers	52	14 mins
Nurse / Nurse Practitioners	188	14 mins
Parent / Family Members	83	8 mins

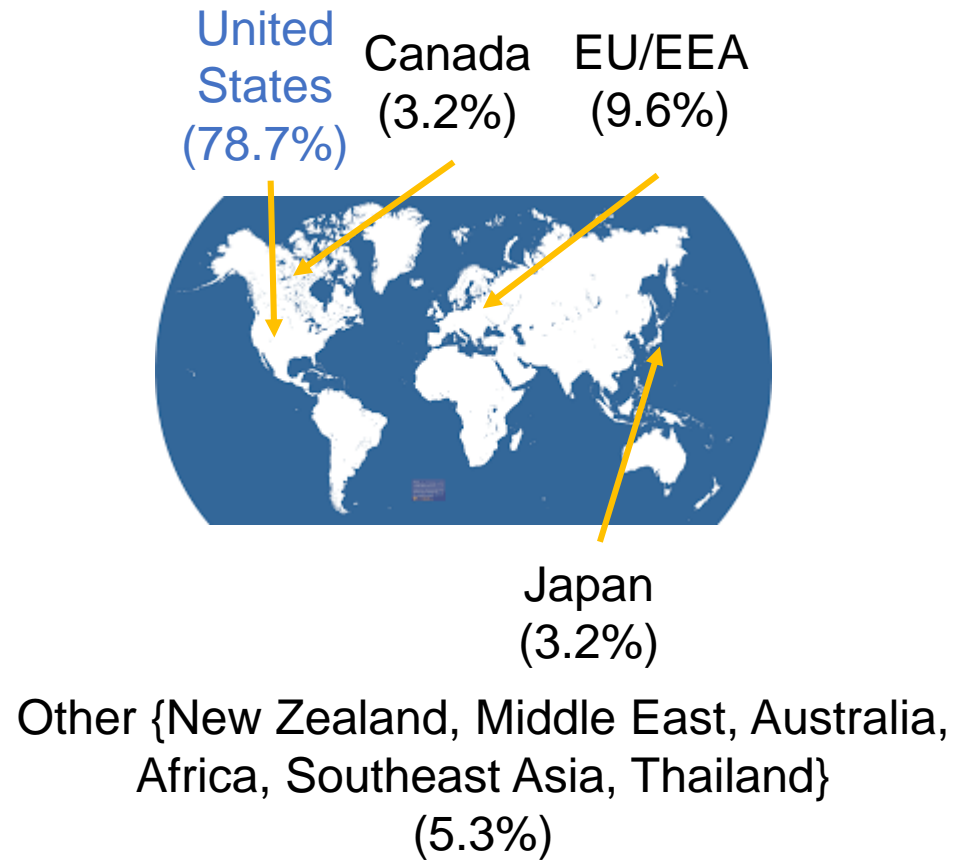
Survey closed 23-November-2018

Which region do you live in?

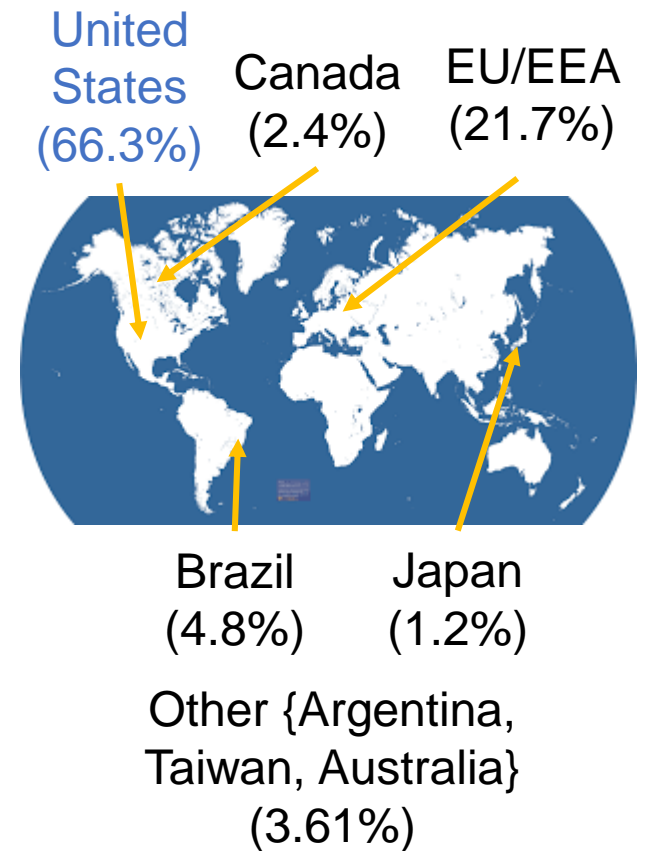
Neonatologists



Nurses



Parents



Which country in the EU/EEA do you live in?



Neonatologists (N=21)

Country	n (%)
Belgium	2 (9.5%)
France	3 (14.3%)
Germany	3 (14.3%)
Spain	1 (4.8%)
Sweden	2 (9.5%)
UK	10 (47.6%)

Nurses (N=19)

Country	n (%)
Cyprus	2 (10.5%)
Denmark	1 (5.3%)
Netherlands	2 (10.5%)
Portugal	1 (5.3%)
Spain	1 (5.3%)
UK	12 (63.2%)

Parents (N=22)

Country	n (%)
Belgium	1 (4.6%)
Germany	1 (4.6%)
Ireland	16 (72.7%)
Portugal	2 (9.1%)
Spain	1 (4.6%)
UK	1 (4.6%)

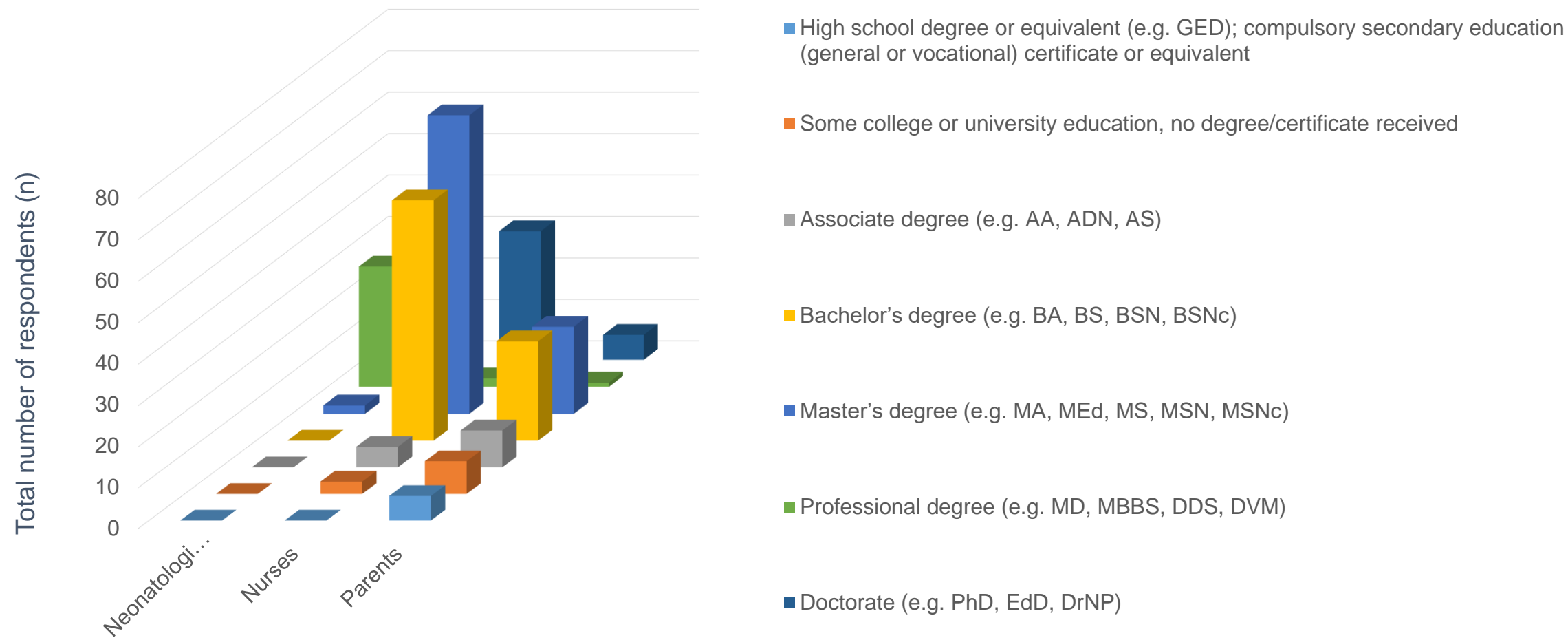
Which geographic region in the US do you live in?



Region	Neonatologists N = 20 n (%)	Nurses N = 147 n (%)	Parents N = 53 n (%)
Midwest	6 (30.0%)	34 (23.1%)	11 (20.7%)
Northeast	7 (35.0%)	38 (25.8%)	7 (13.2%)
Southeast	5 (26.0%)	28 (19.1%)	16 (30.2%)
Southwest	1 (5.0%)	19 (12.9%)	8 (15.1%)
West	1 (5.0%)	28 (19.1%)	11 (20.8%)

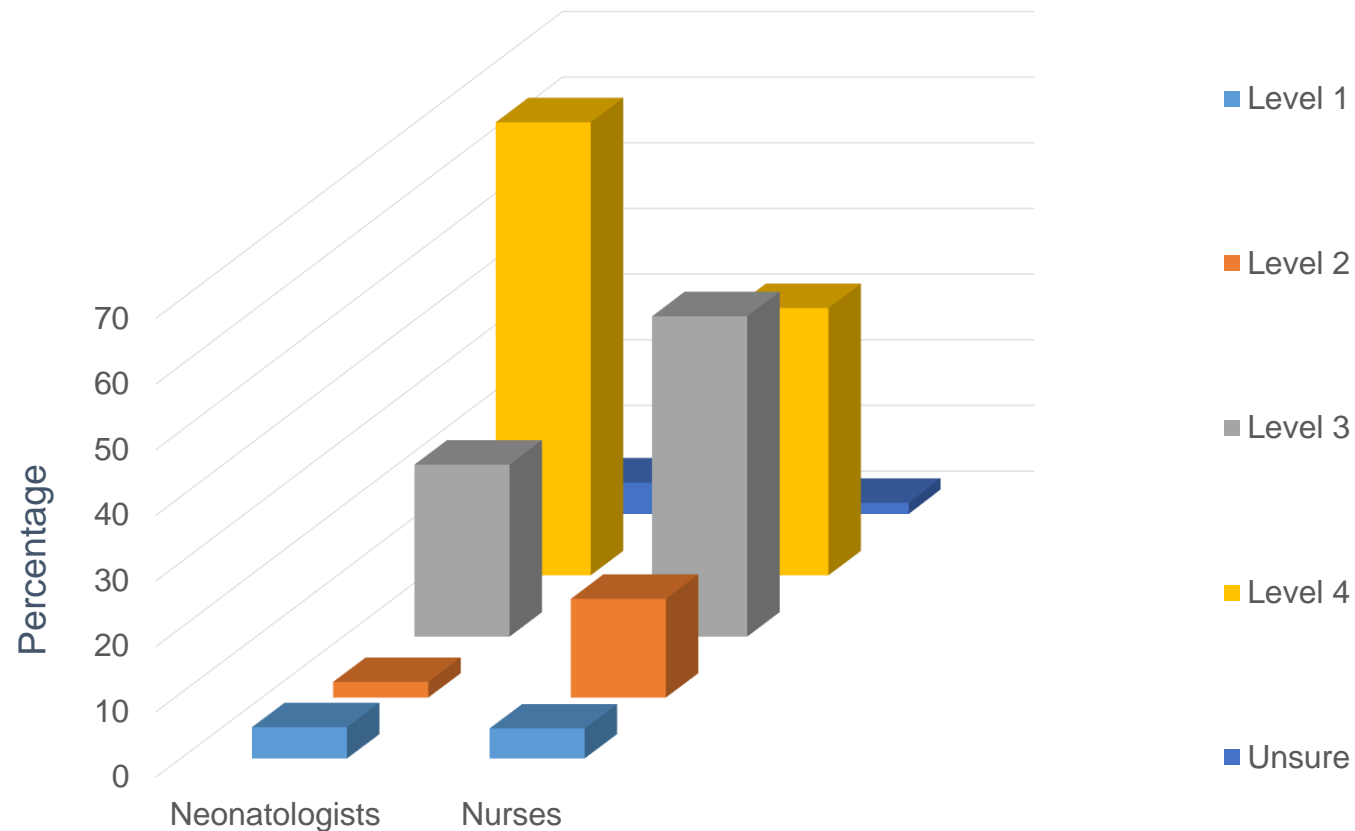
Midwest (IA, IL, IN, KS, MI, MN, MO, ND, NE, OH, SD, WI); Northeast (CT, DC, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VT); Southeast (AL, AR, FL, GA, KY, LA, MS, NC, SC, TN, VA, WV); Southwest (AZ, NM, OK, TX); West (AK, CA, CO, HI, ID, MT, NV, OR, UT, WA, WY)

What is the highest degree or level of school you have completed?*



* Special instructions: *If you're currently enrolled in school, please indicate the highest degree you have received.*

What level of care does your hospital/NICU deliver?*



Definitions

Level 1: Newborn care for babies at low risk, e.g. newborn nursery

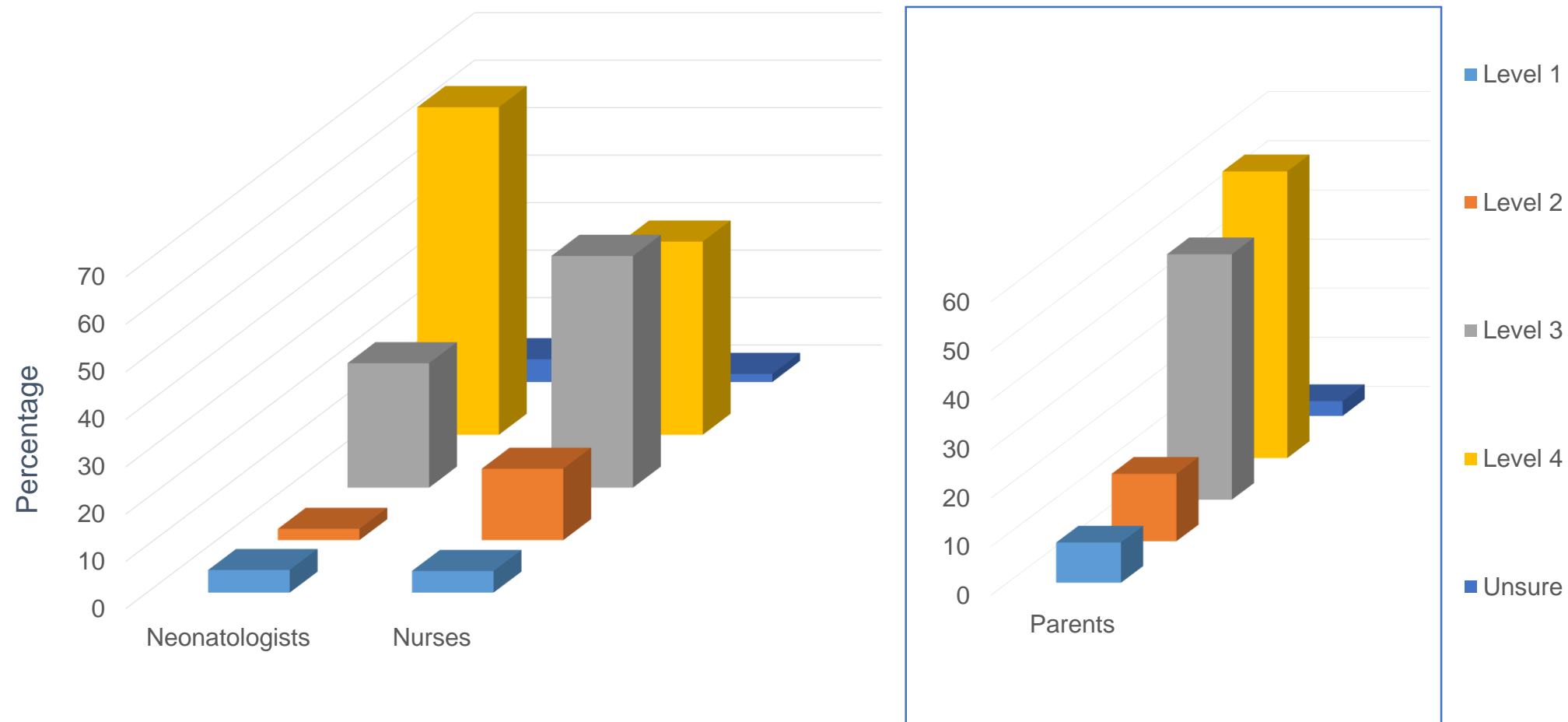
Level 2: Specialty care for stable or moderately ill newborns born > 32 weeks gestation who are born with problems that are expected to resolve rapidly

Level 3: Specialty care for newborns who are born at <32 weeks gestation, weigh <1500 grams at birth, or have medical or surgical conditions necessitating complex care

Level 4: Include the capabilities of a Level 3 nursery with additional capabilities in the care of the most complex and critically ill newborns, and have pediatric medical and pediatric surgical specialty consultants continuously available 24 hours a day

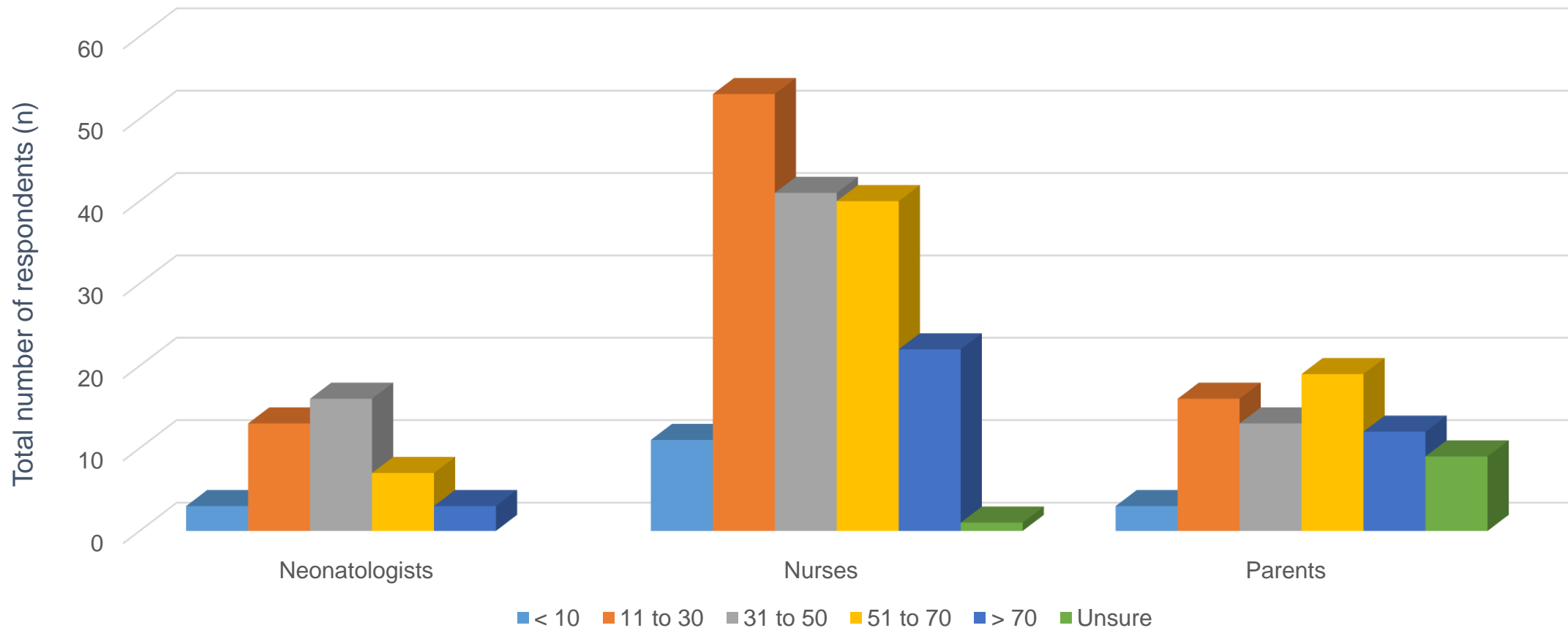
* Special instructions: *If you work in more than 1 hospital/NICU, please select the level based on where you spend the most time.*

What level of care does your hospital/NICU deliver where your child was cared for?*



* Special instructions: *Select all that apply.*

How many beds are available in your hospital/NICU?*



* Special Instructions: (Neonatologists & Nurses ONLY) *If you work in more than 1 Neonatal Unit, please select the number of beds based on where you spend the most time;* (Parents ONLY) *Please answer this question based on the hospital/NICU you are most familiar with.*



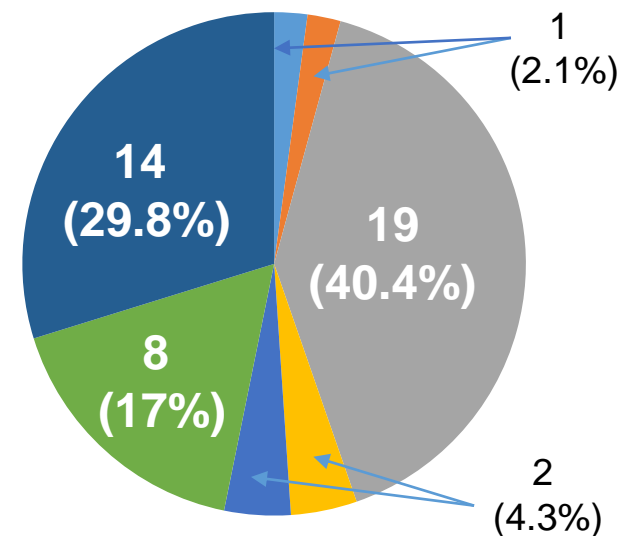
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Demographic Data (Neonatologist / Nurse-specific)



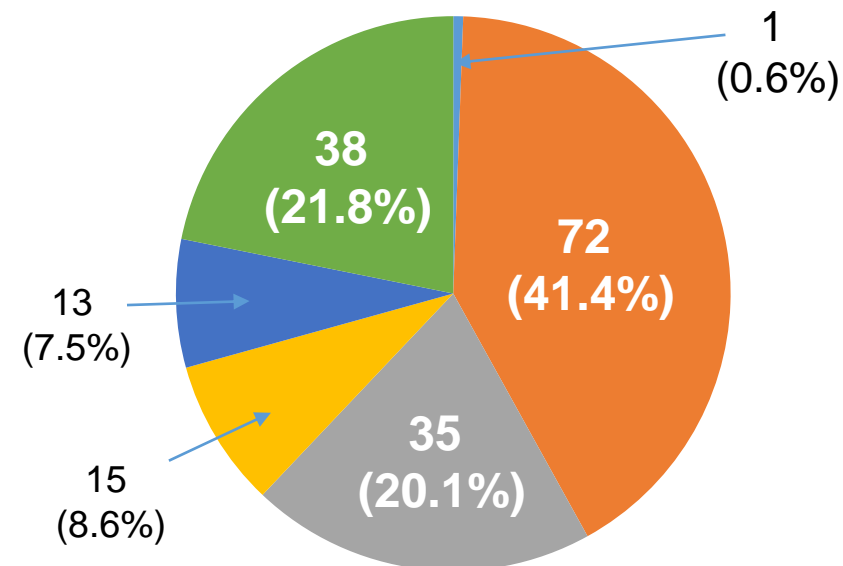
Please indicate your current position held at your hospital/NICU

Neonatologists



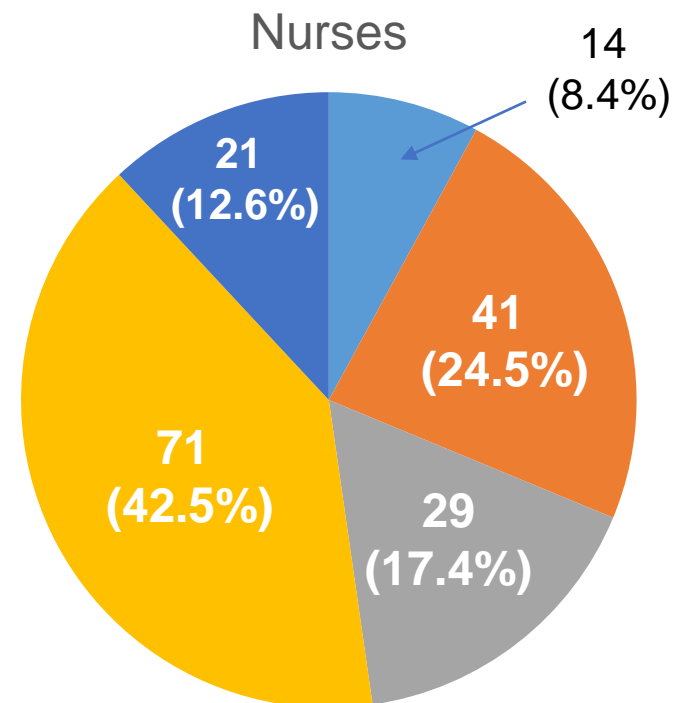
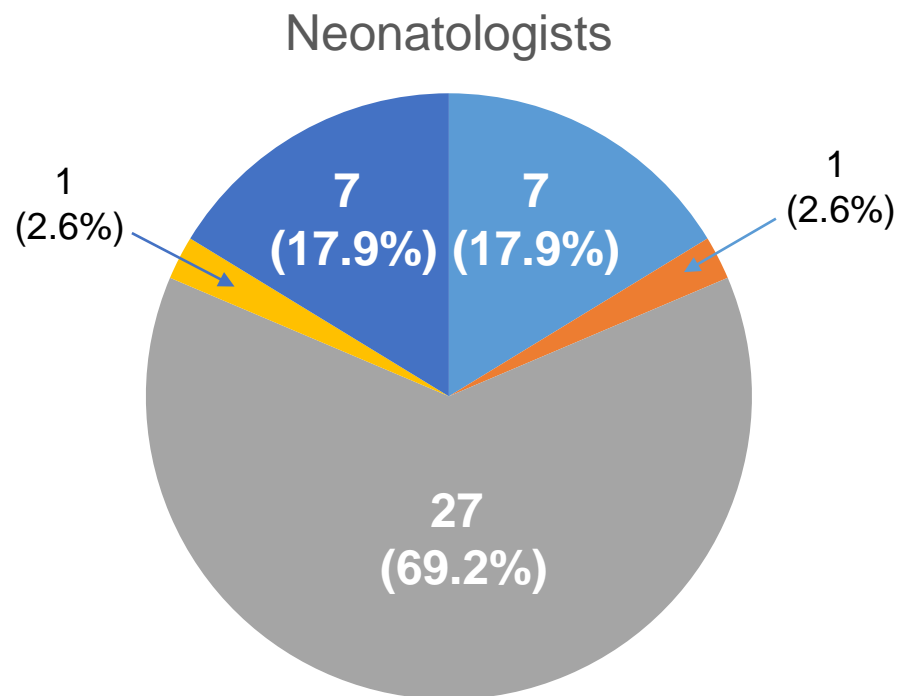
- Pediatric Resident
- Neonatal Fellow
- Neonatal Attending Physician
- Pediatrician
- Research/Clinical Study Coordinator
- Research Physician
- Other

Nurses



- Licensed Practicing Nurse
- Neonatal Nurse
- Neonatal Nurse Practitioner
- Nurse Manager
- Research/Clinical Study Coordinator
- Other

What profile best describes the role you play in contributing to neonatal research in your hospital/NICU?*



- Designated research team
- Direct patient care only
- Both patient care and research responsibilities
- Direct patient care (Informal research responsibilities)
- Other

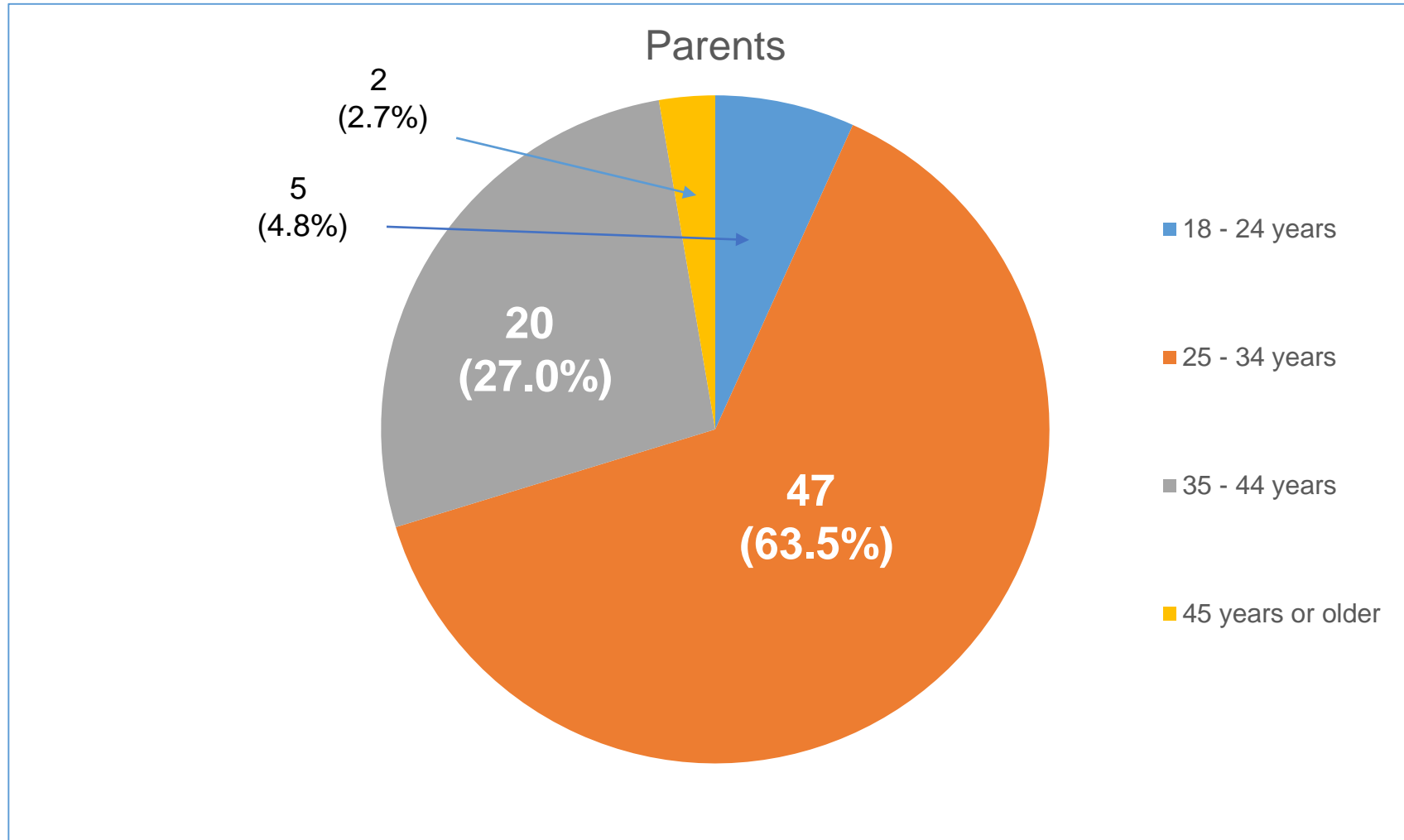
* Special Instructions: *Select all that apply.*



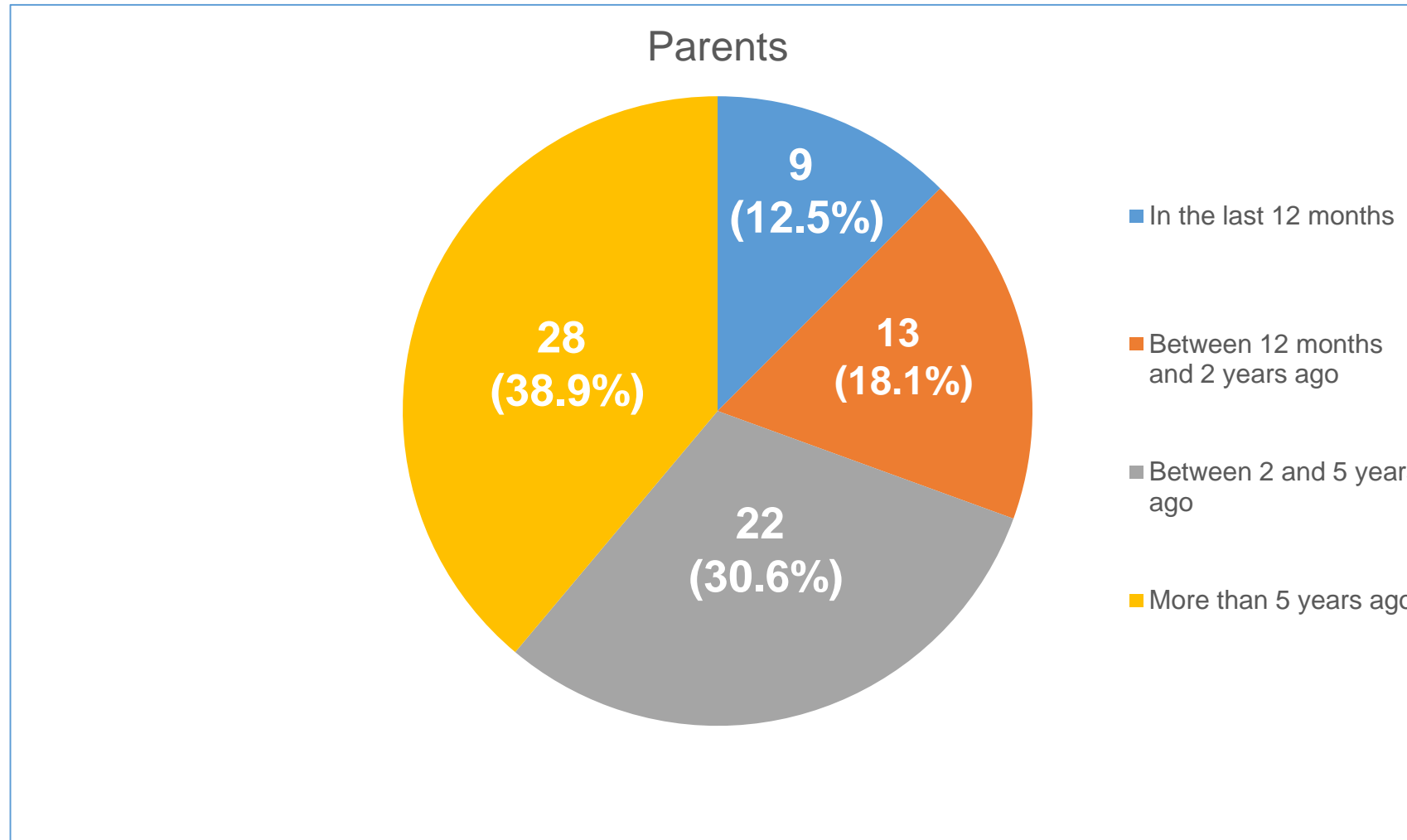
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Demographic Data (Parent-specific)

What was your age at the time your child was cared for in the Neonatal unit?



How long ago was your child cared for in the Neonatal Unit?



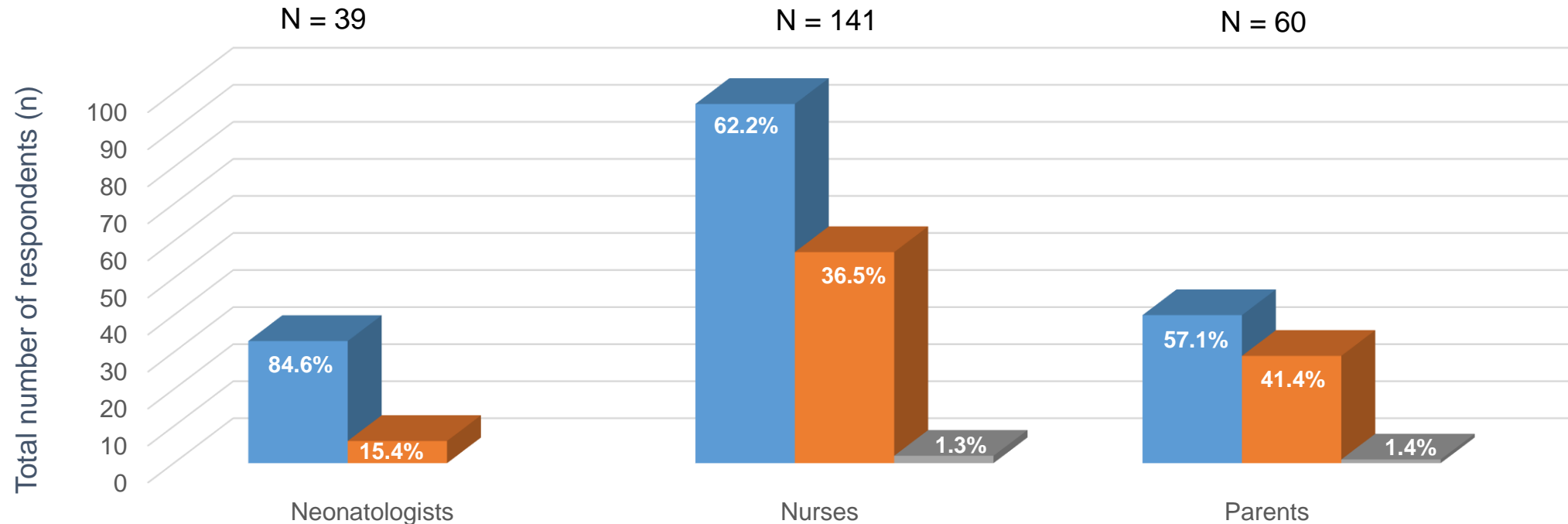


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Part II: Role of Research in the Neonatal Intensive Care Unit (NICU)



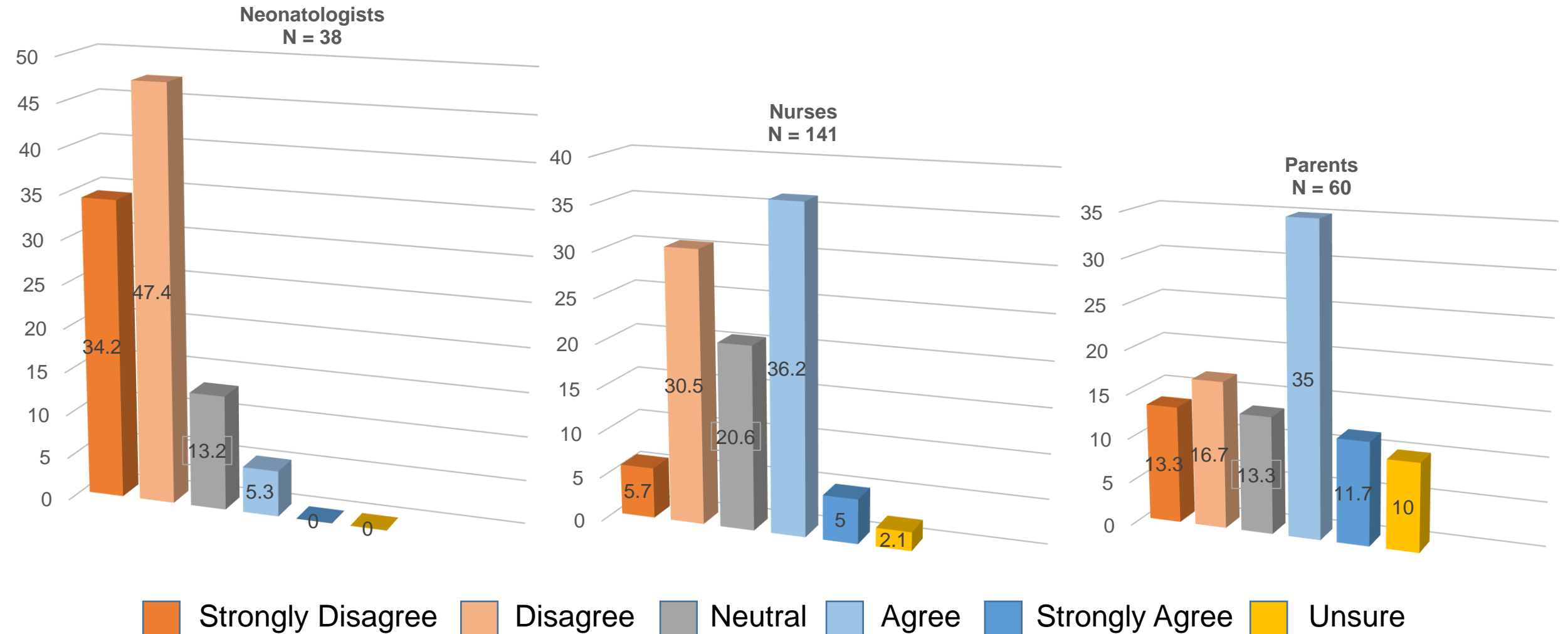
Which of the following statements best represents your beliefs about the necessity of drug studies in sick newborns?*



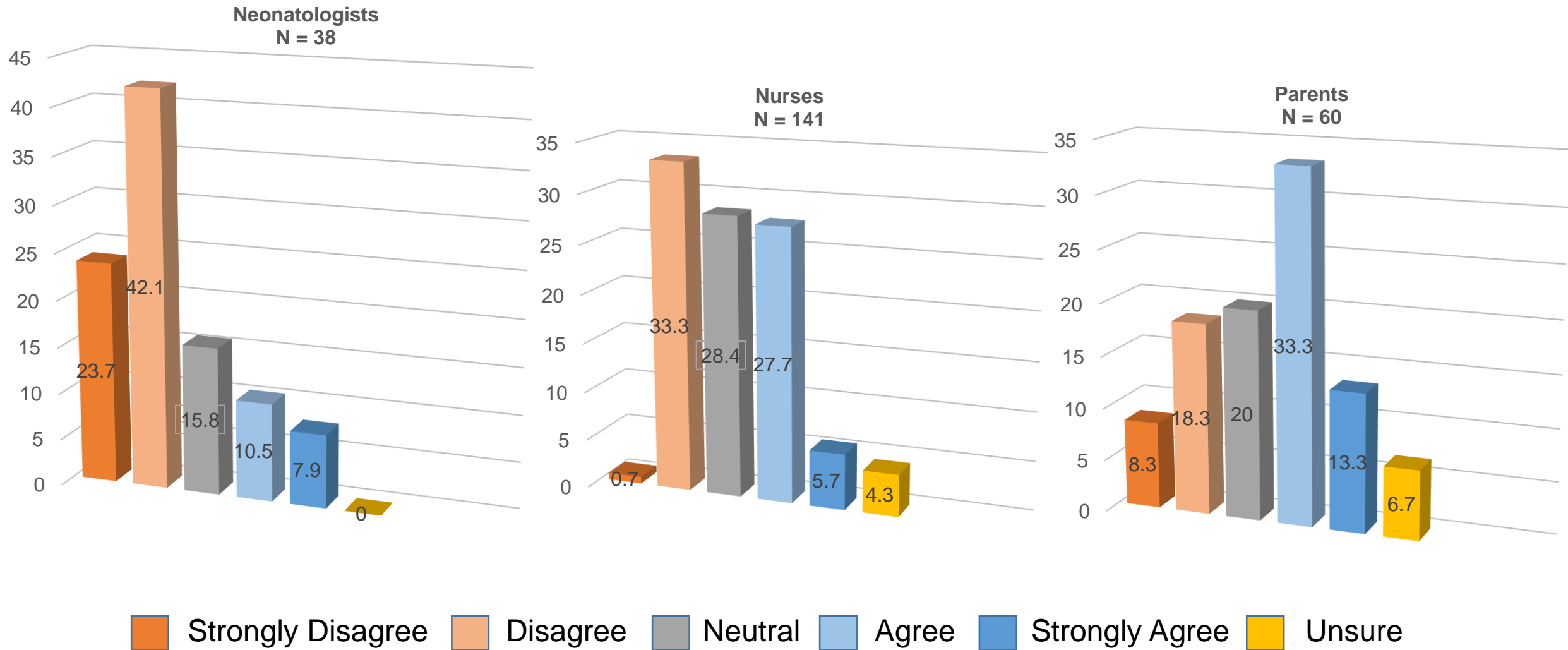
- A study is necessary to determine if a drug is safe and effective in sick newborns even after the drug's efficacy and safety have been demonstrated in adults
- An additional smaller study is necessary to determine dosing and to evaluate the safety of a drug in sick newborns after the drug's safety and efficacy have been demonstrated in adults
- No drug studies are necessary in sick newborns once the drug's efficacy and safety have been demonstrated in adults

* Special Instructions: *Select only one answer.*

The medications currently available in the NICU are sufficient to meet the medical needs of sick newborns (% respondents)

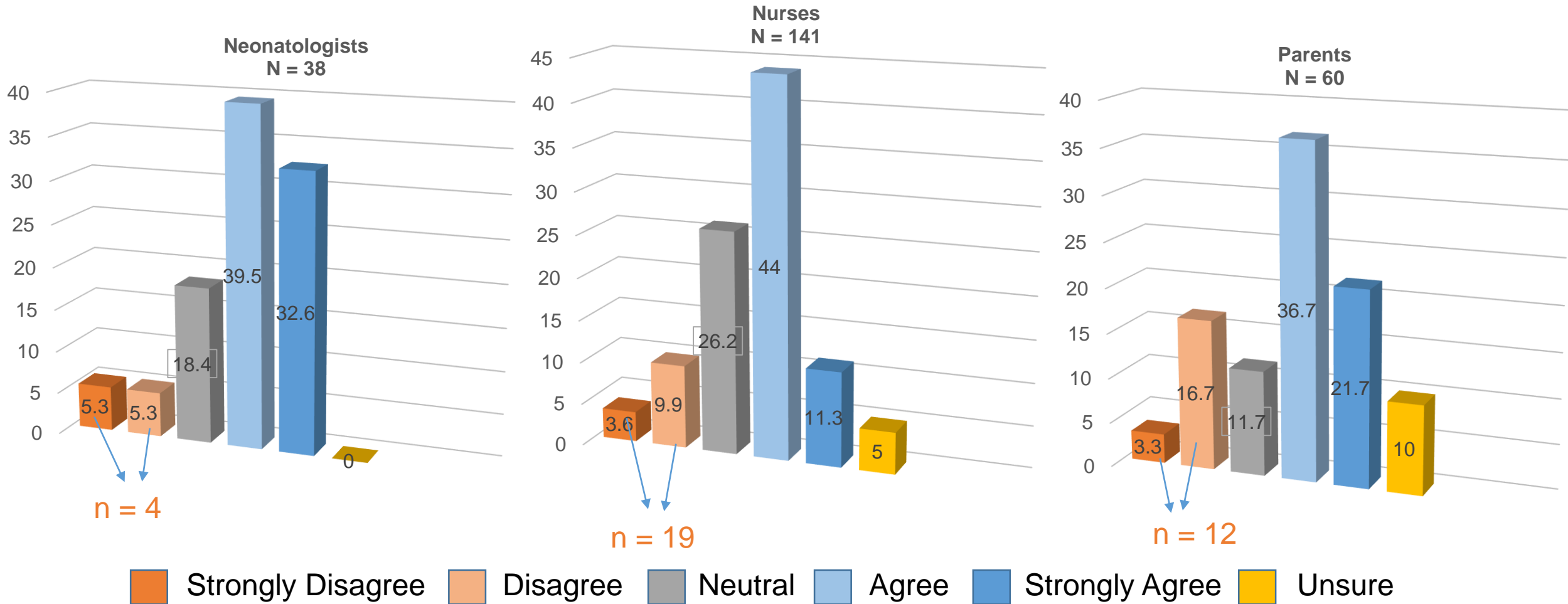


Academic studies* are sufficient to guide medication use in a NICU (% respondents)



* Academic studies were defined as research conducted in the NICU not sponsored by drug companies

Pharmaceutical studies* are needed to guide medication use in a NICU (% respondents)



* Pharmaceutical studies were defined as research conducted in the NICU by drug companies

You indicated that you either Strongly disagree or Disagree with the statement that Pharmaceutical studies are needed to guide medication use in a NICU:

Neonatologists (n = 4)

I do not feel that pharmaceutical studies are safe for sick newborns		1	2	1		
I do not feel there are specific benefits of pharmaceutical studies for sick newborns		2		2		
I do not feel there is a need to study drugs using vulnerable sick newborns as study participants		4				
I feel that pharmaceutical studies should be conducted in older children because sick newborns are a vulnerable population	2	2				
I feel that current treatment options are sufficient and no pharmaceutical studies are necessary in sick newborns	1	3				
None of the above statements accurately reflects my view of pharmaceutical research in sick newborns			1	2	1	

 Strongly Disagree
  Disagree
  Neutral
  Agree
  Strongly Agree
  Unsure

You indicated that you either Strongly disagree or Disagree with the statement that Pharmaceutical studies are needed to guide medication use in a NICU: Nurses (n = 19)

I do not feel that pharmaceutical studies are safe for sick newborns	1	3	6	6	3	
I do not feel there are specific benefits of pharmaceutical studies for sick newborns	3	4	4	4	2	2
I do not feel there is a need to study drugs using vulnerable sick newborns as study participants	3	9	3	3		1
I feel that pharmaceutical studies should be conducted in older children because sick newborns are a vulnerable population	2	9	2	4	1	1
I feel that current treatment options are sufficient and no pharmaceutical studies are necessary in sick newborns	5	10	3	1		
None of the above statements accurately reflects my view of pharmaceutical research in sick newborns	1	1	5	6	6	

 Strongly Disagree
  Disagree
  Neutral
  Agree
  Strongly Agree
  Unsure

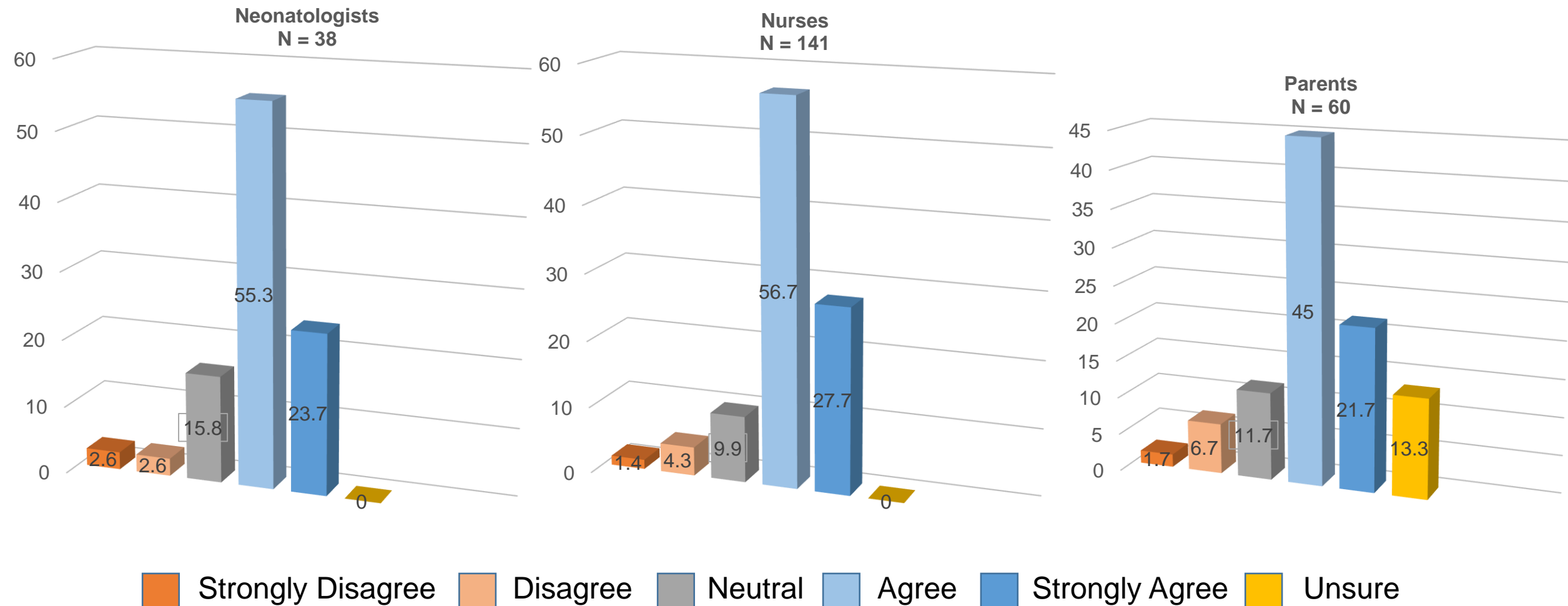
You indicated that you either Strongly disagree or Disagree with the statement that Pharmaceutical studies are needed to guide medication use in a NICU: Parents (n = 14)*

I do not feel that pharmaceutical studies are safe for sick newborns	1	1	6	3		3
I do not feel there are specific benefits of pharmaceutical studies for sick newborns		6	2	4		2
I do not feel there is a need to study drugs using vulnerable sick newborns as study participants	2	5	2	2	2	1
I feel that pharmaceutical studies should be conducted in older children because sick newborns are a vulnerable population	1	4	2	6		1
I feel that current treatment options are sufficient and no pharmaceutical studies are necessary in sick newborns		8	3	1		2
None of the above statements accurately reflects my view of pharmaceutical research in sick newborns		4	4	1	2	3

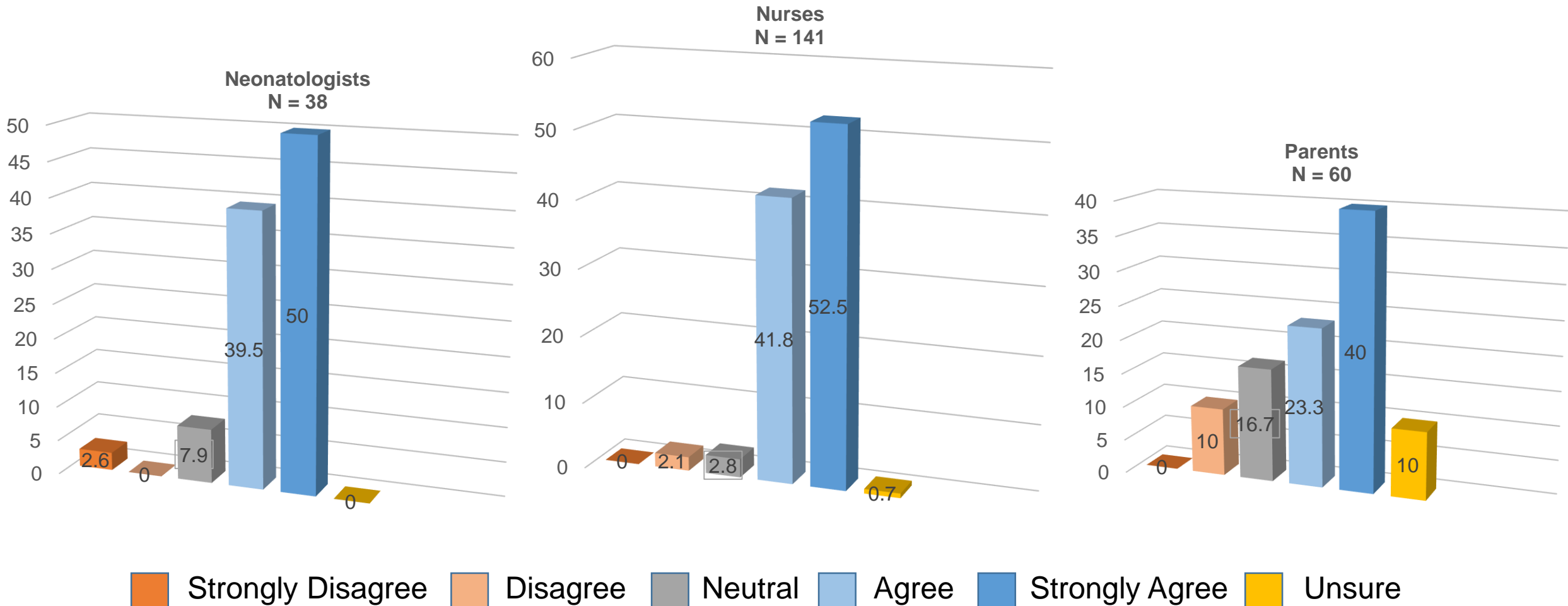
 Strongly Disagree
  Disagree
  Neutral
  Agree
  Strongly Agree
  Unsure

* Discrepant # of respondents. Only 12 parents should have been able to access this question, however, there were 14 who completed the question.

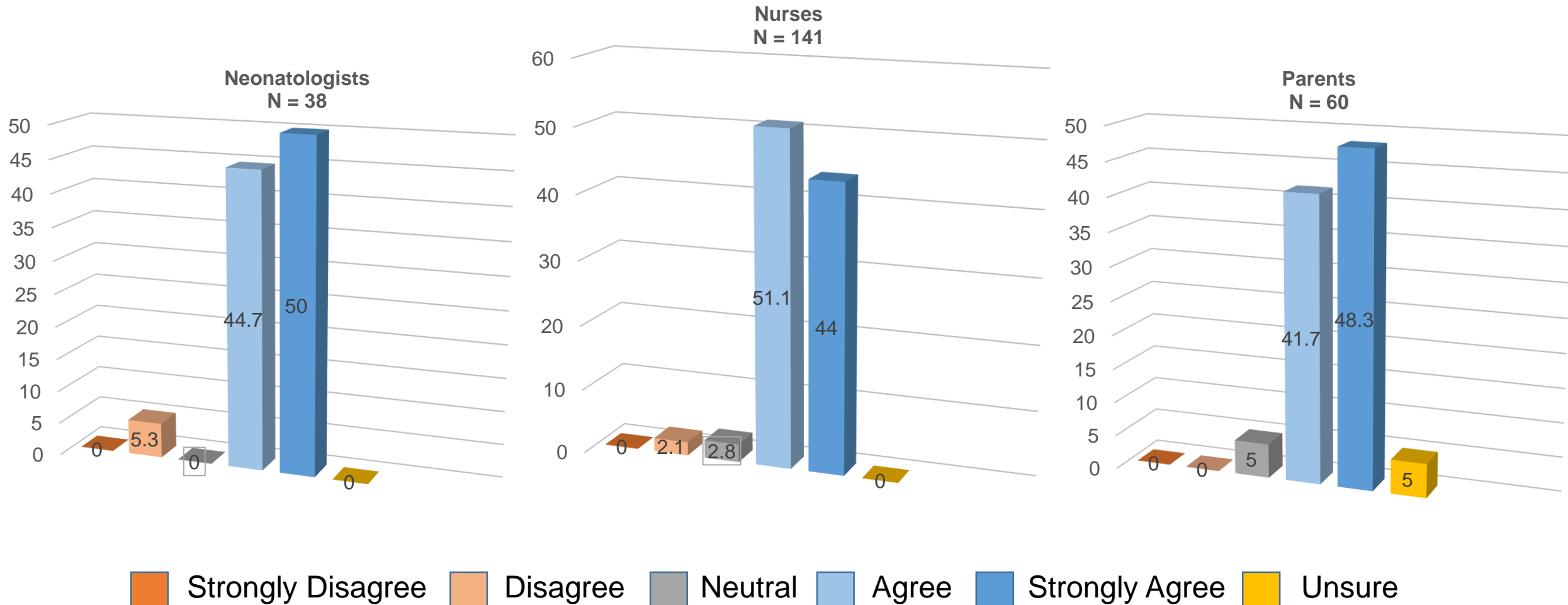
In my NICU, we use a standard approach (e.g., protocol-driven) to the delivery of neonatal care (% respondents)



Standard approaches (e.g., protocol-driven) to neonatal care can improve neonatal outcomes (% respondents)

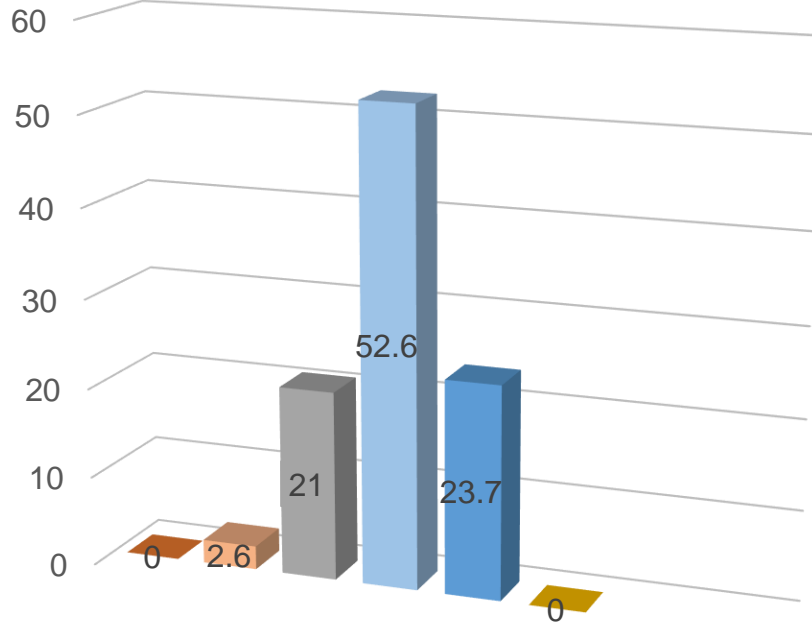


Research protocols are required to develop the appropriate standard approaches (e.g., protocol-driven care) to improve a baby's outcome (% respondents)

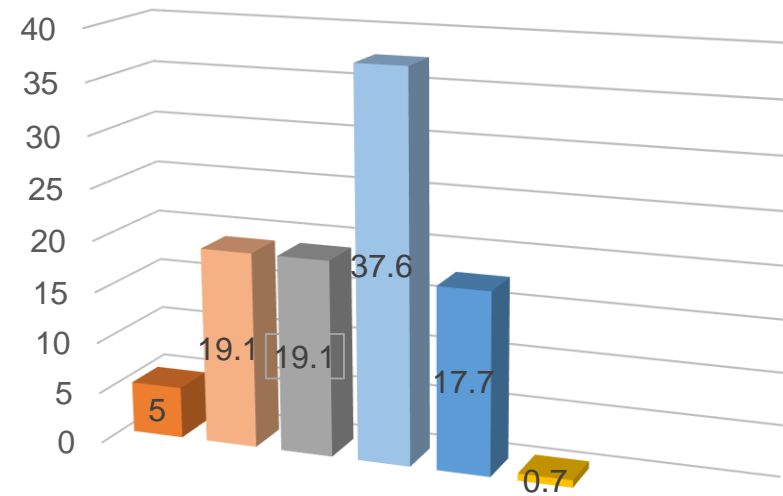


In my NICU, research is a central component of the NICU mission, vision and or goals (% respondents)

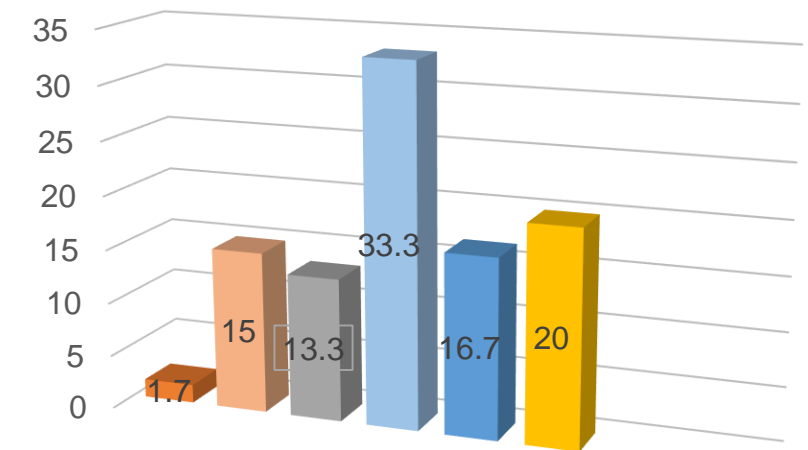
Neonatologists
N = 38



Nurses
N = 141

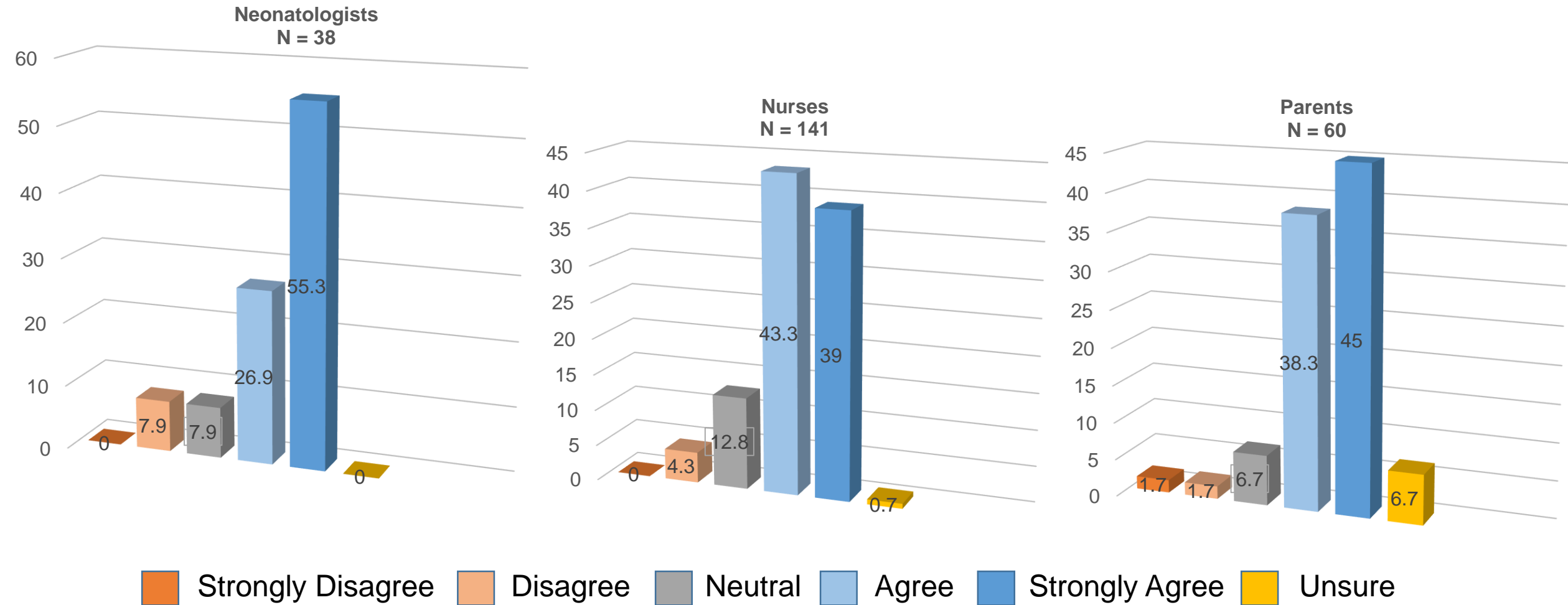


Parents
N = 60



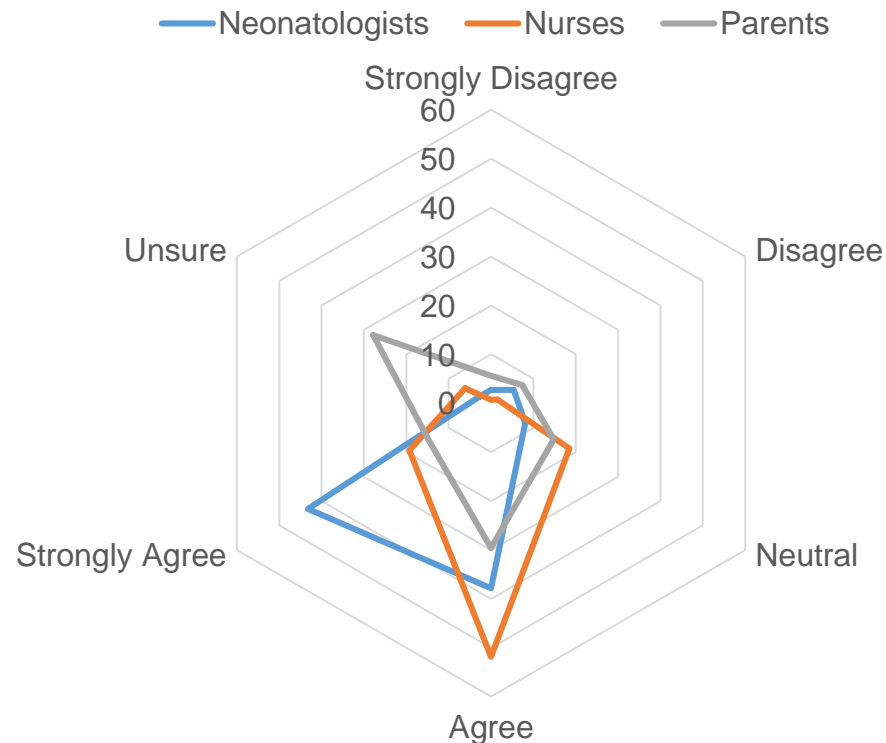
Strongly Disagree Disagree Neutral Agree Strongly Agree Unsure

Research should be a central component of the NICU mission, vision and or goals (% respondents)



We would like to assess your awareness of the availability of supervision for studies that involve sick newborns* (1)

There are sufficient protections in place to ensure the rights and safety of a sick newborn enrolled in a research study (%)

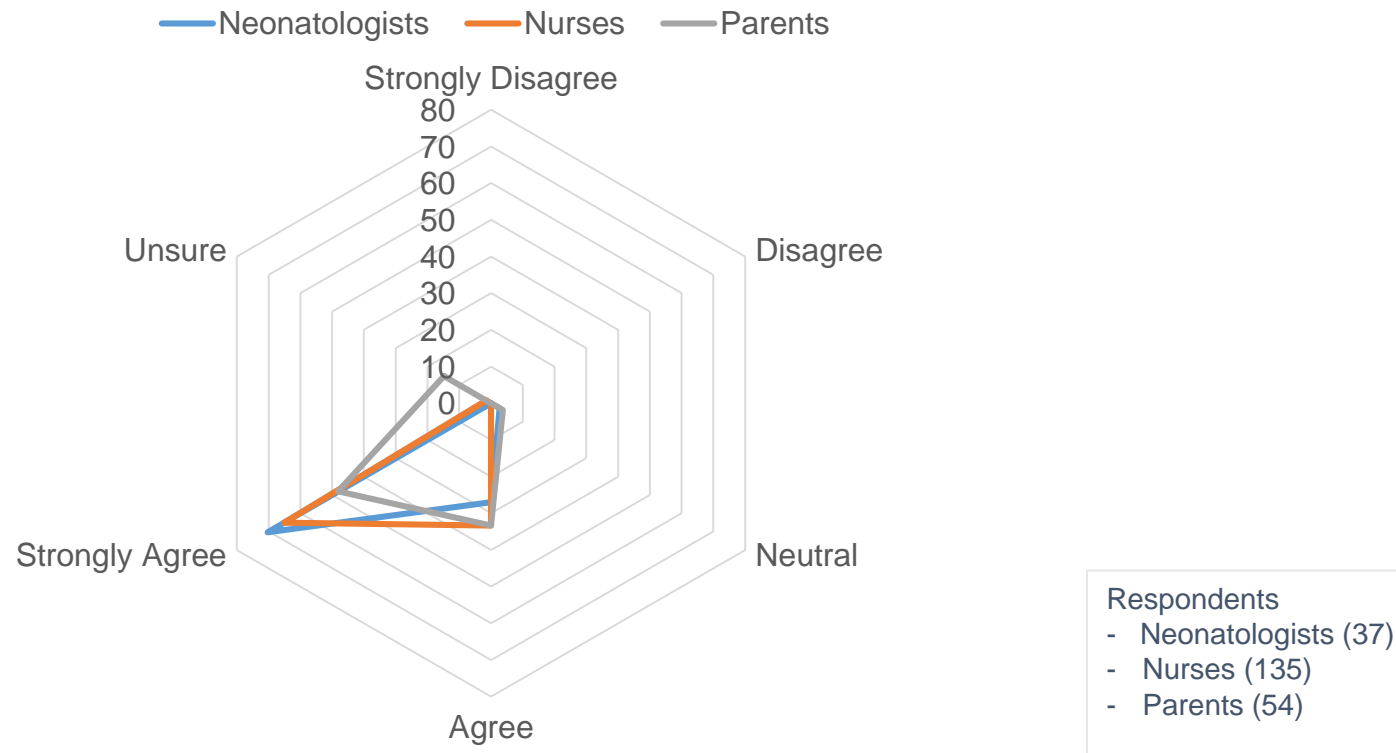


Respondents
- Neonatologists (37)
- Nurses (135)
- Parents (54)

* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to assess your awareness of the availability of supervision for studies that involve sick newborns* (2)

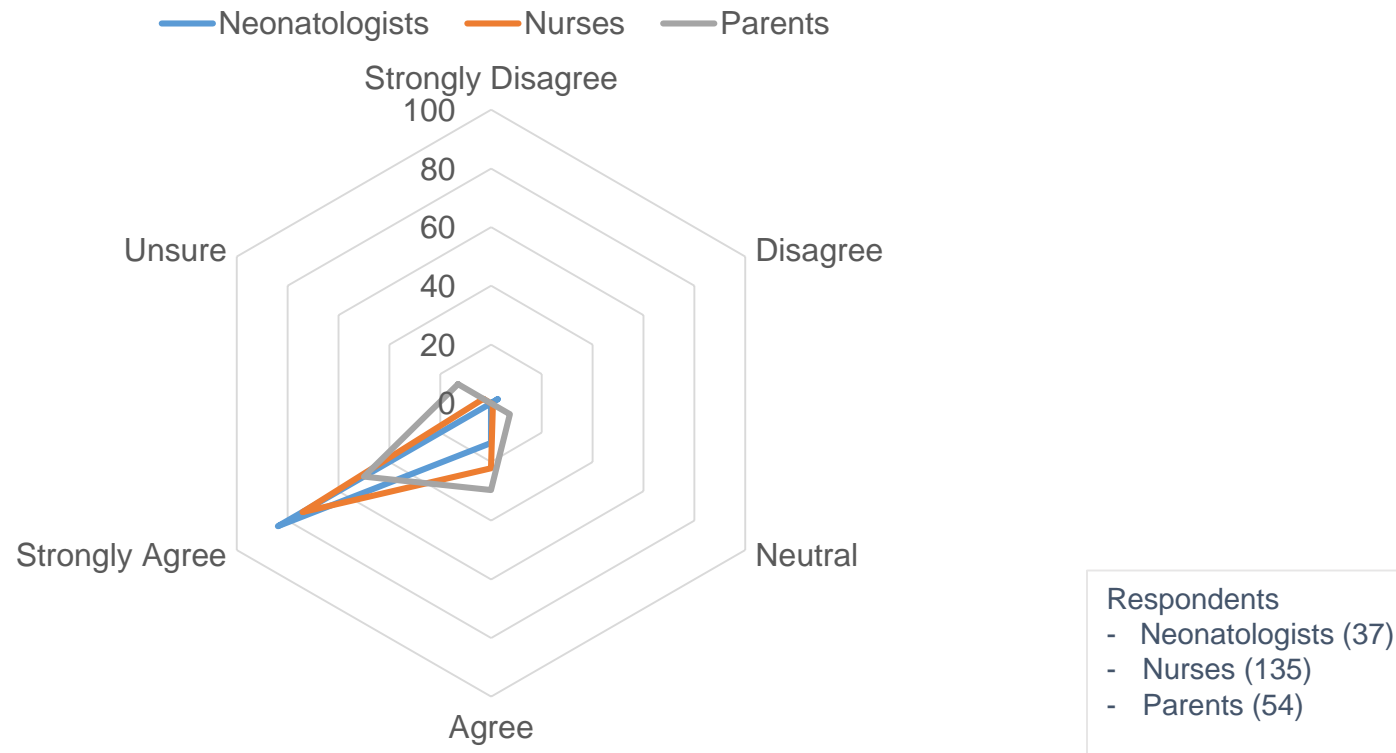
The investigator has the responsibility to ensure the rights and safety of a sick newborn enrolled in a research study are protected (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to assess your awareness of the availability of supervision for studies that involve sick newborns* (3)

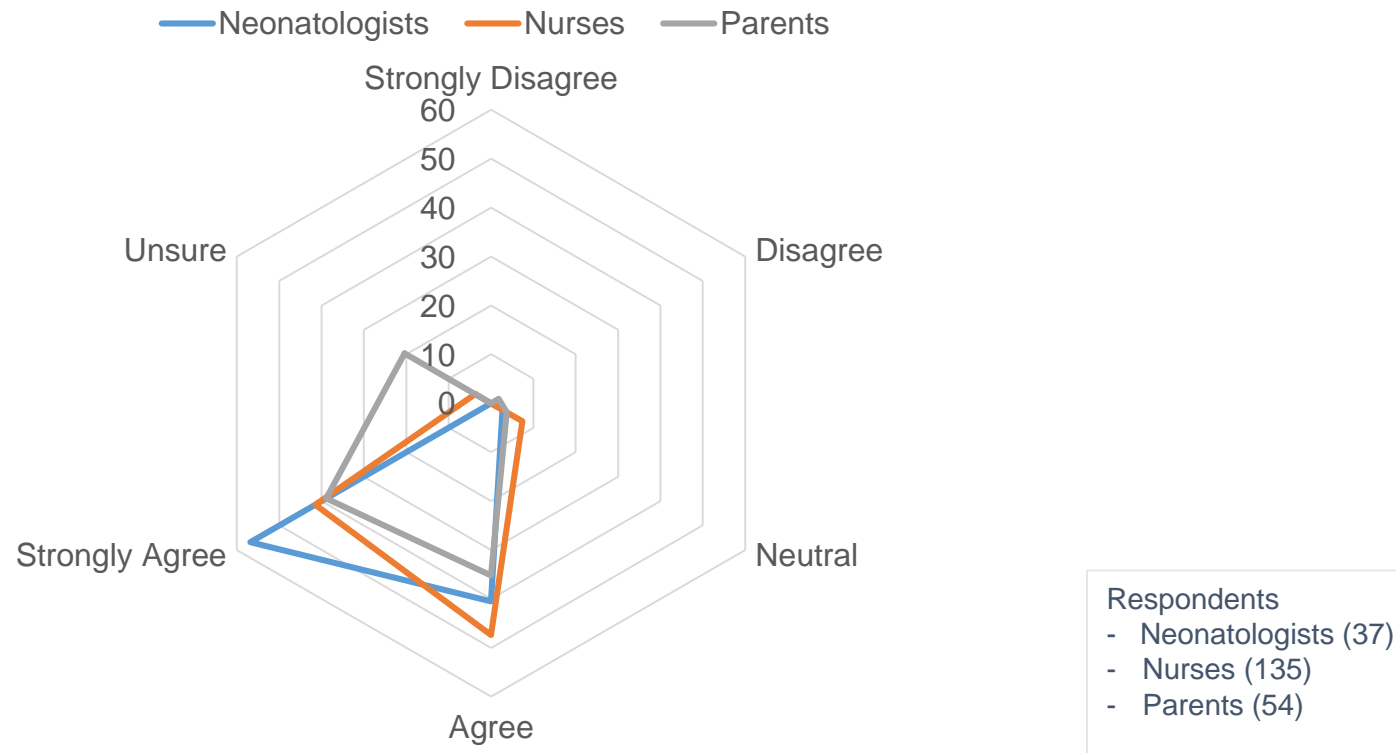
Institutional review board (IRB)/ethics review board (ERB) approval of the research protocol is required to start a neonatal research study (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to assess your awareness of the availability of supervision for studies that involve sick newborns* (4)

Independent monitoring[#] of a neonatal research study provides input on whether an on-going study should continue (%)

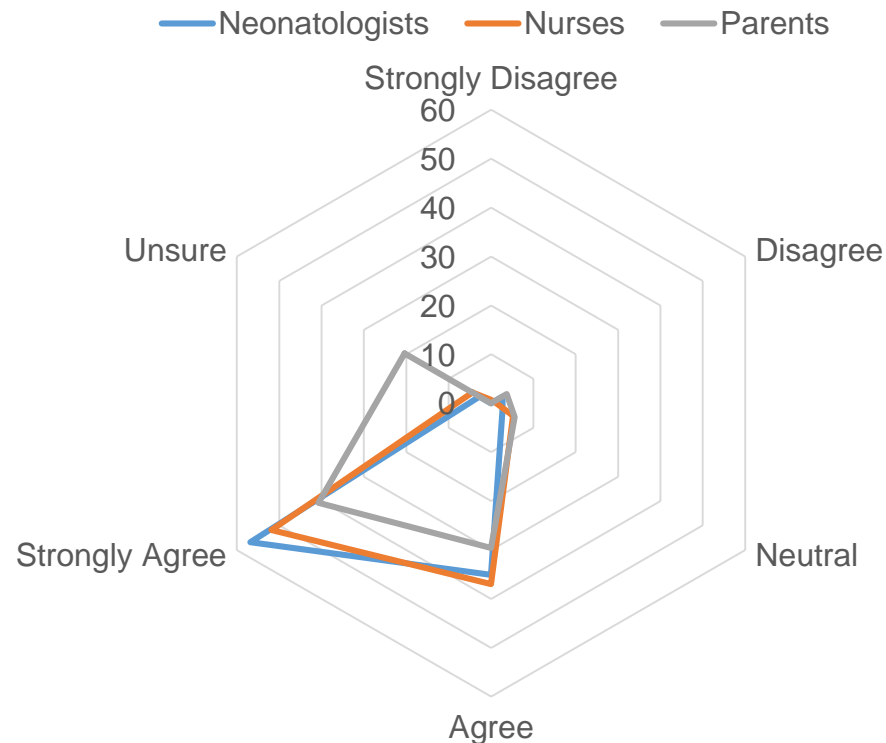


* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

[#] Independent monitoring was defined as a group of experts whose role is to review efficacy and safety data during a clinical study

We would like to assess your awareness of the availability of supervision for studies that involve sick newborns* (5)

Routine adverse event reporting is used to identify safety concerns in a neonatal research study (%)

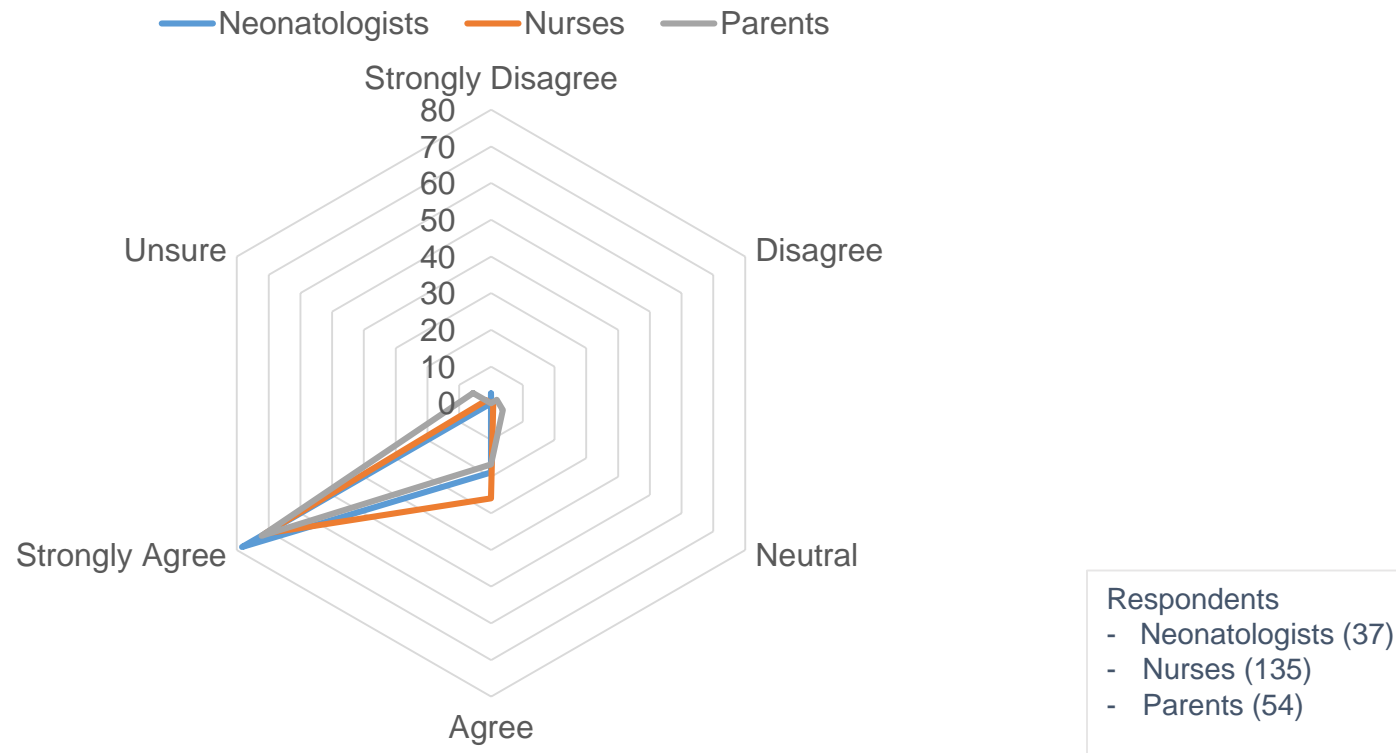


Respondents
- Neonatologists (37)
- Nurses (135)
- Parents (54)

* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to assess your awareness of the availability of supervision for studies that involve sick newborns* (6)

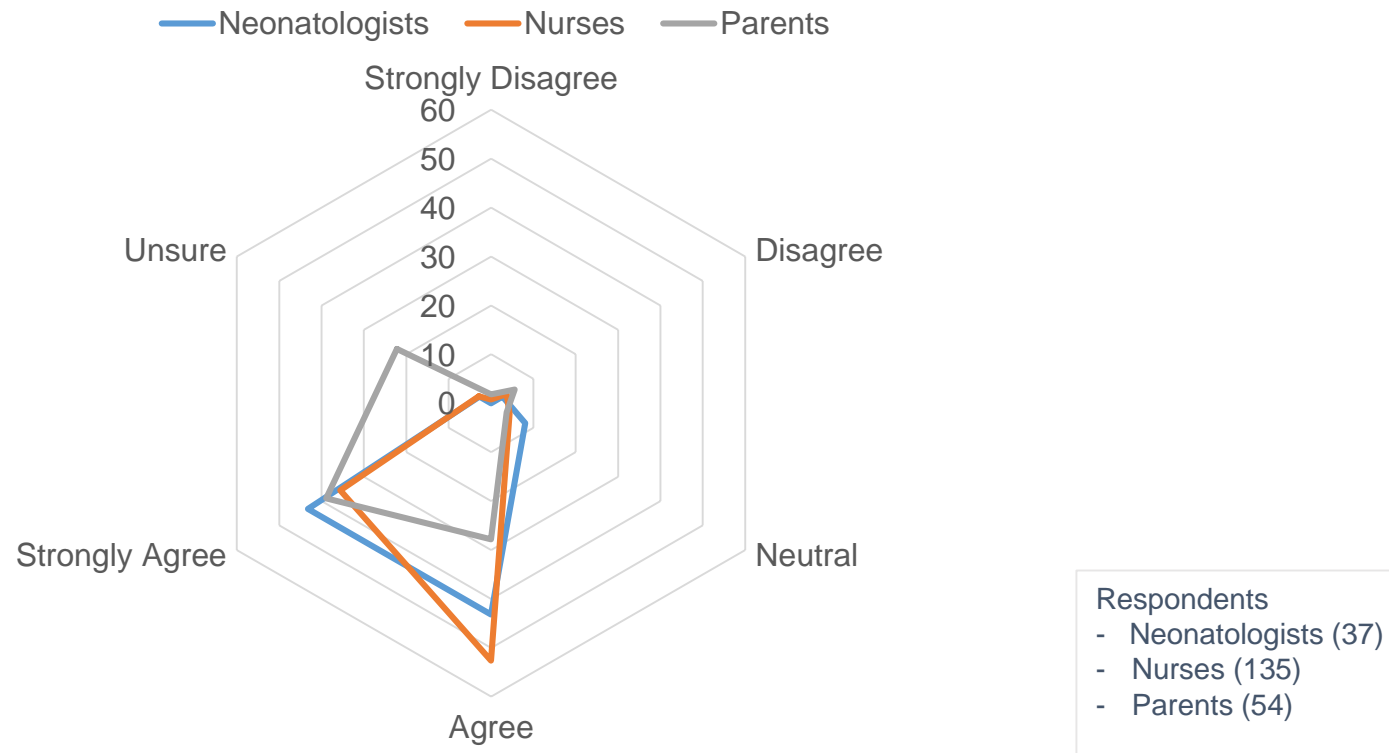
Parental informed consent is required to effectively communicate the purpose of the study and what a baby's involvement will entail (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to assess your awareness of the availability of supervision for studies that involve sick newborns* (7)

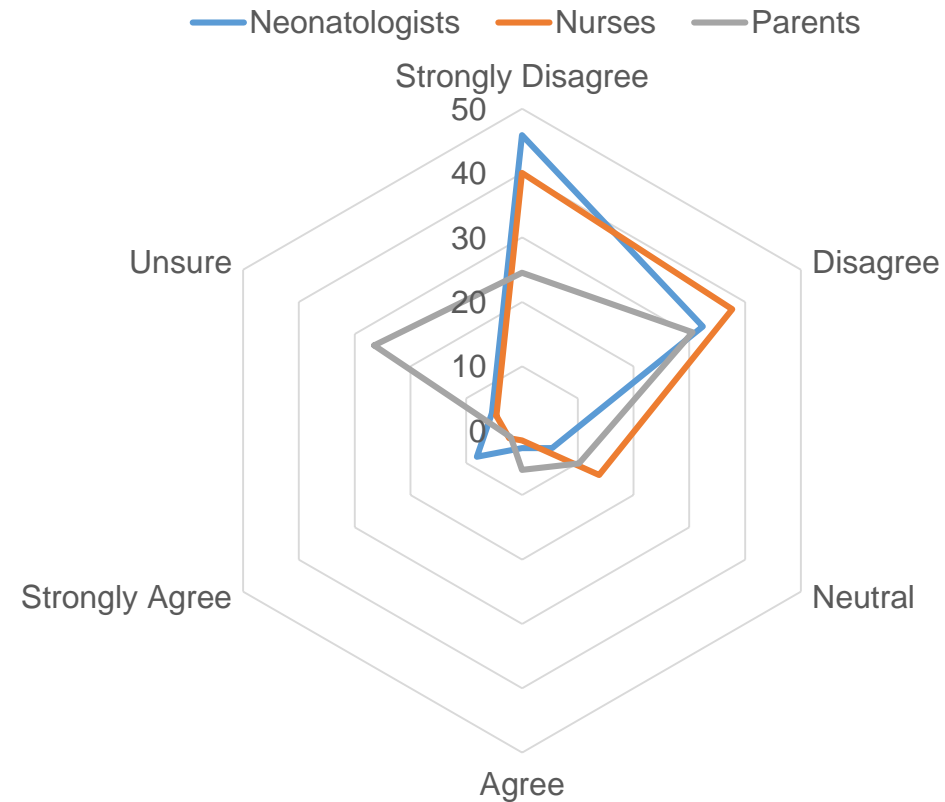
Bedside clinicians (e.g., neonatologists, nurses) who are not on the research team contribute to the oversight of neonatal research studies in the NICU (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to understand your perspective and understanding of special protections (rules for good study practice) in place for sick newborns who are participating in research* (1)

No special protections are provided (%)

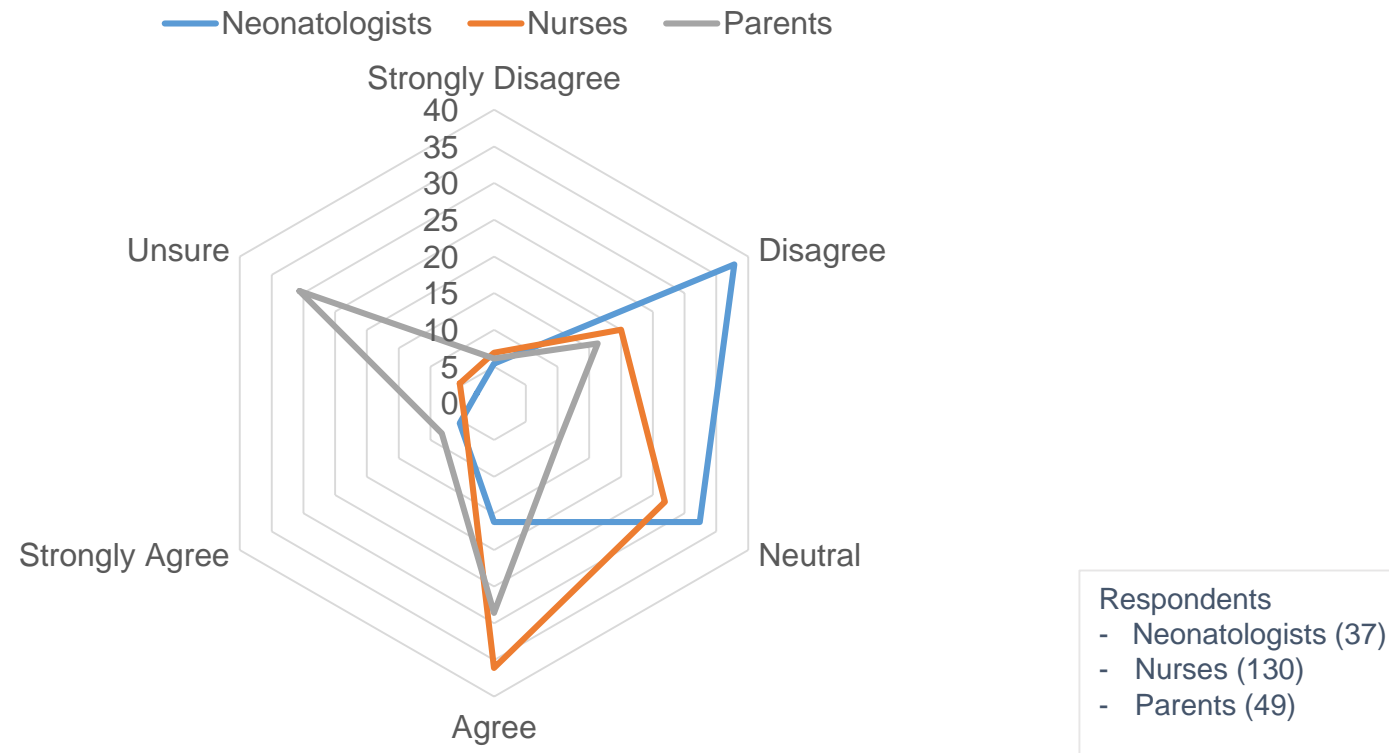


Respondents
- Neonatologists (37)
- Nurses (130)
- Parents (49)

* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to understand your perspective and understanding of special protections (rules for good study practice) in place for sick newborns who are participating in research* (2)

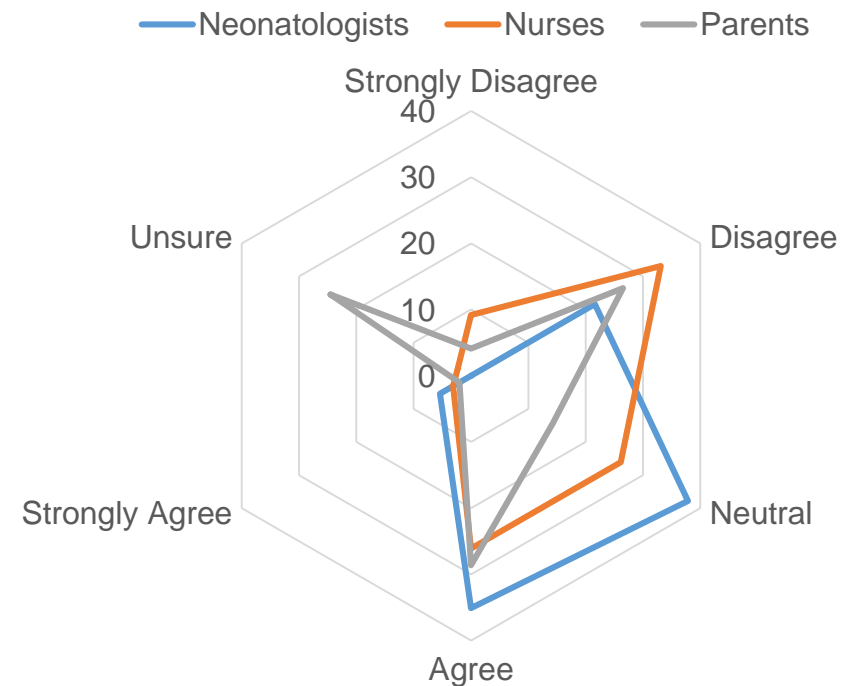
Preclinical research (e.g., animal studies) provides an assessment of safety that is adequate to proceed to conducting a drug study in neonates (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to understand your perspective and understanding of special protections (rules for good study practice) in place for sick newborns who are participating in research* (3)

Clinical research conducted in adults or older children provides an assessment of safety that is adequate to proceed to conducting a drug study in neonates (%)

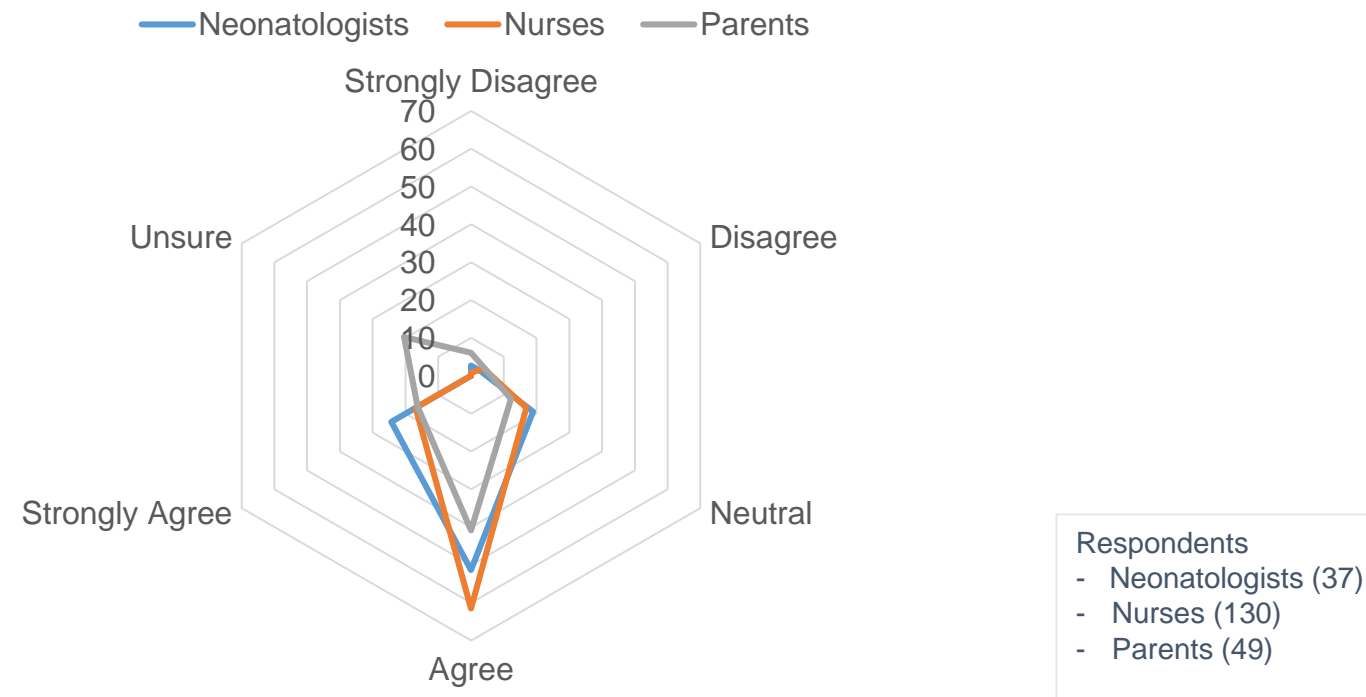


Respondents
- Neonatologists (37)
- Nurses (130)
- Parents (49)

* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to understand your perspective and understanding of special protections (rules for good study practice) in place for sick newborns who are participating in research* (4)

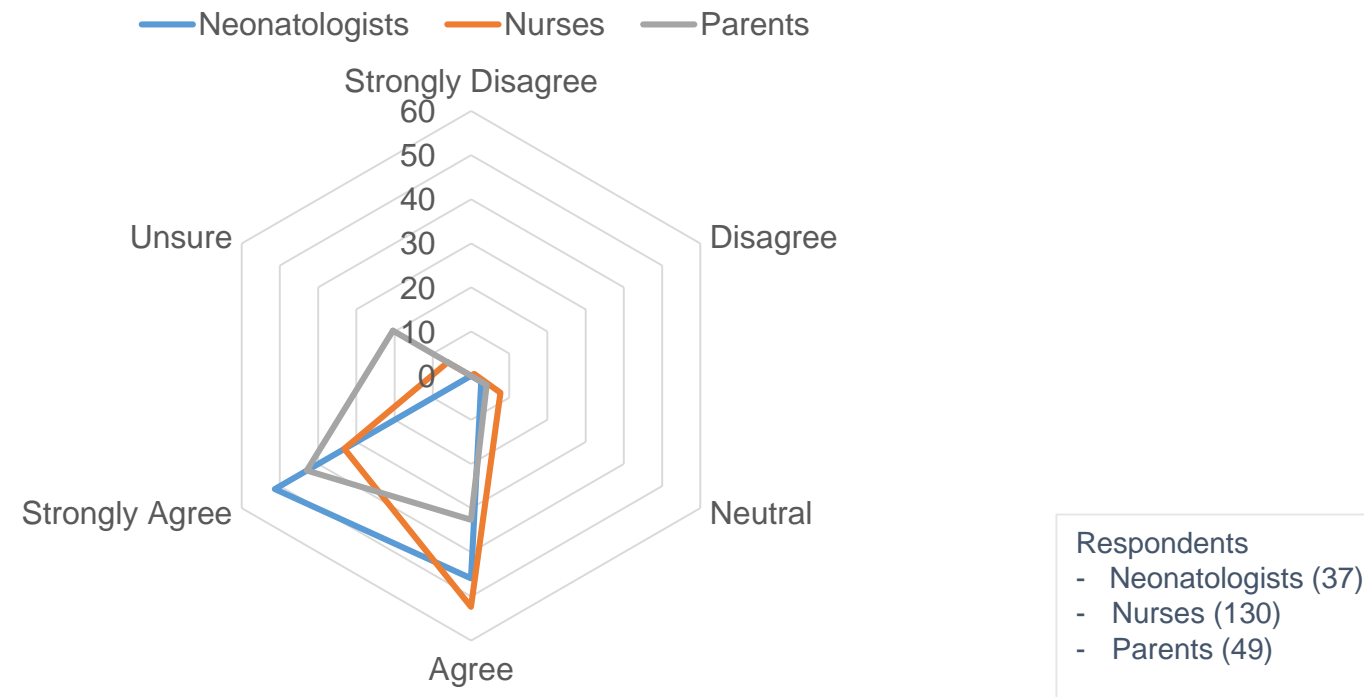
Scientific and ethical review of the research protocol by neonatal experts provide assurance that the benefits of study participation outweighs the risk to the neonatal patient (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to understand your perspective and understanding of special protections (rules for good study practice) in place for sick newborns who are participating in research* (5)

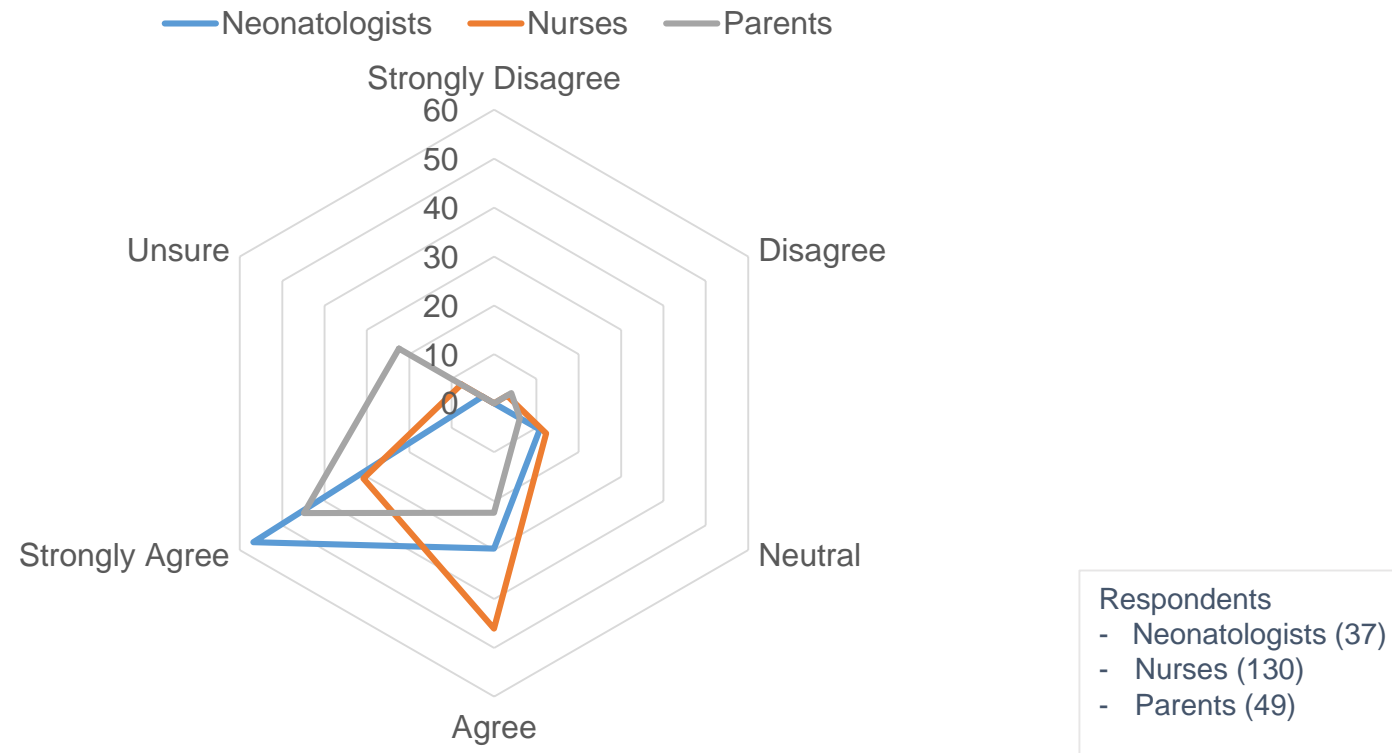
A committee (e.g., data monitoring committee) independent from the study funder is required to provide oversight to protect neonates involved in clinical studies (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to understand your perspective and understanding of special protections (rules for good study practice) in place for sick newborns who are participating in research* (6)

There are special protections to minimize risk, burden (e.g., limiting the amount of blood drawn) and discomfort of neonates involved in clinical studies (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*



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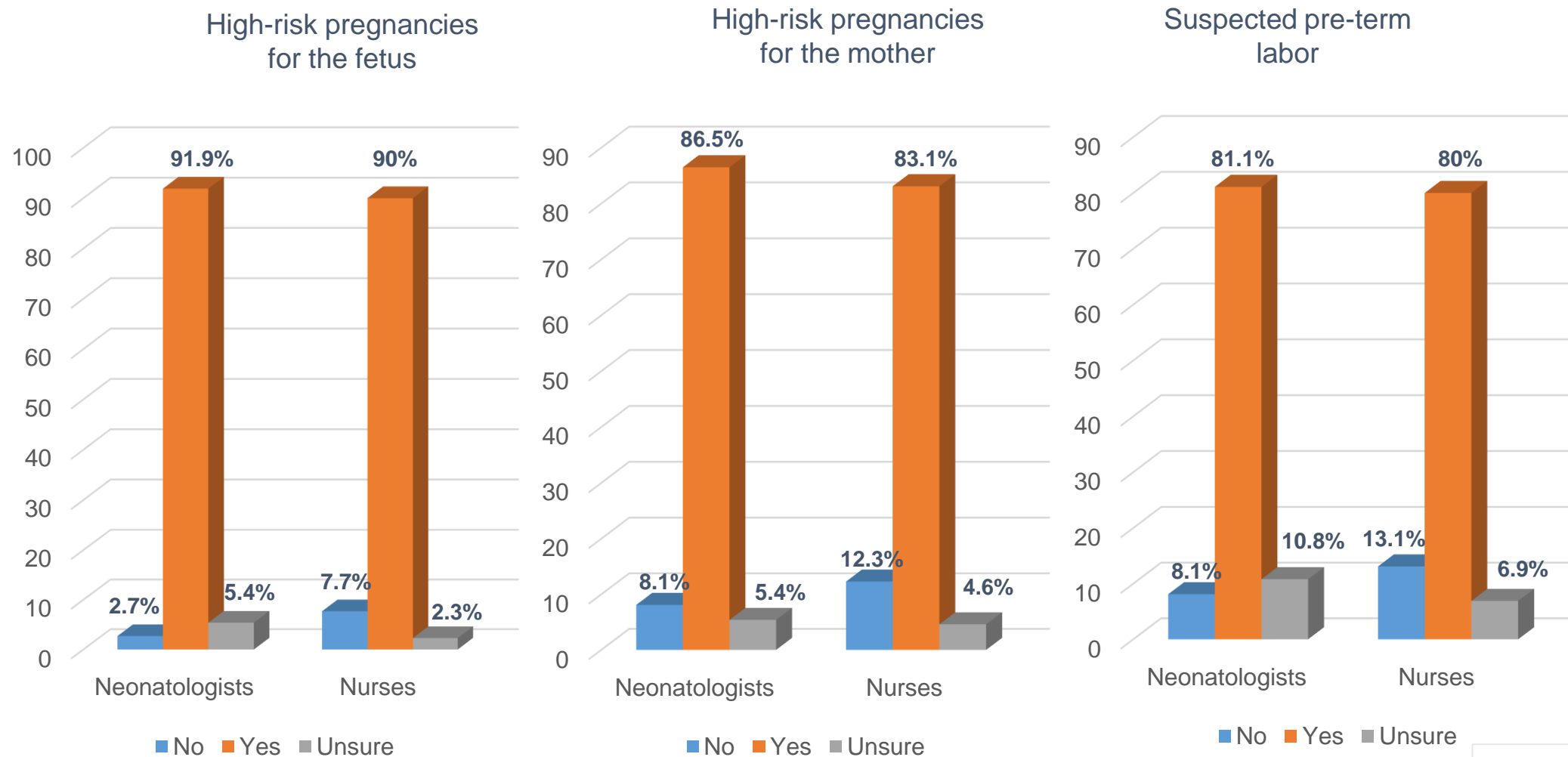
Part III: Current communication flow in the Neonatal Intensive Care Unit (NICU)



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Current communication flow in the Neonatal Intensive Care Unit (NICU) (Neonatologist / Nurse-specific)

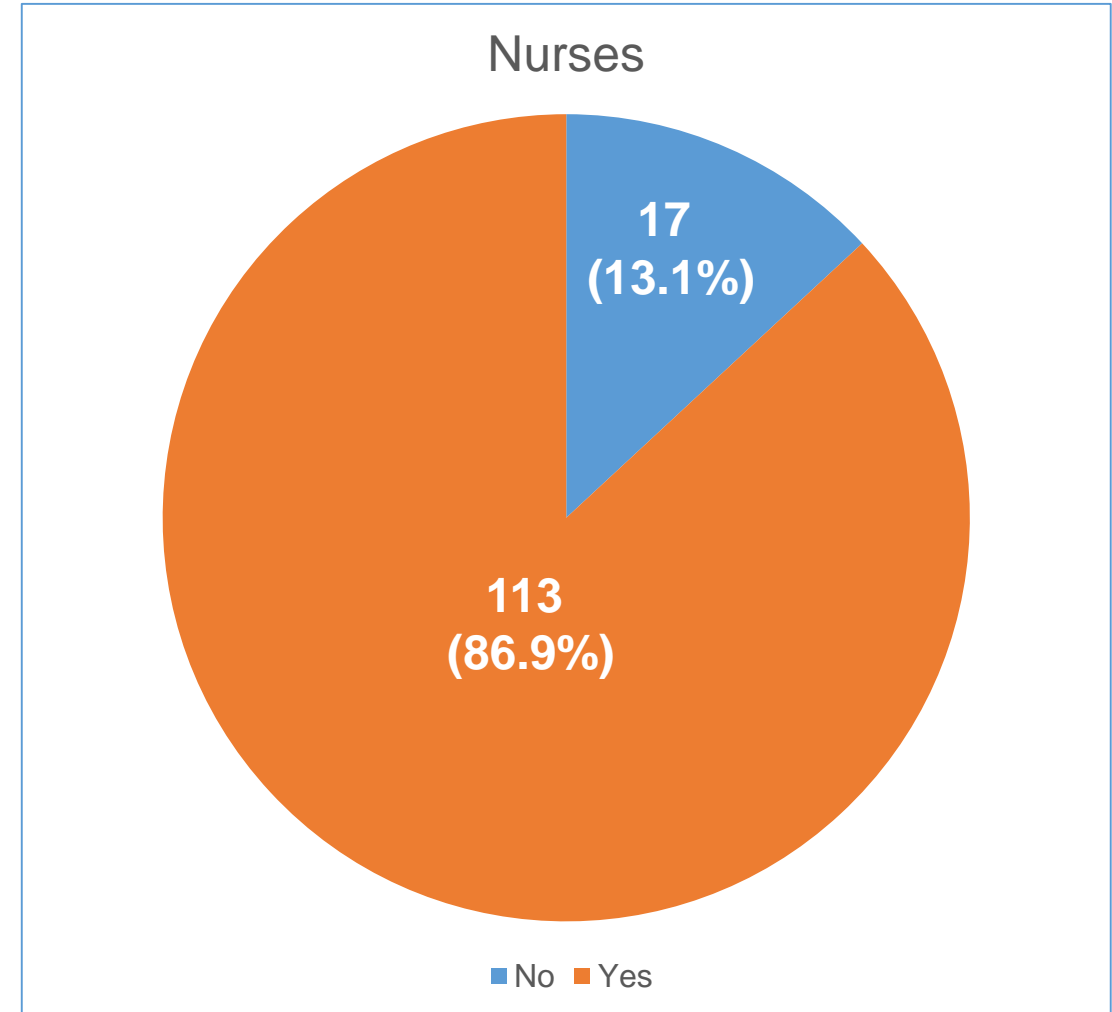
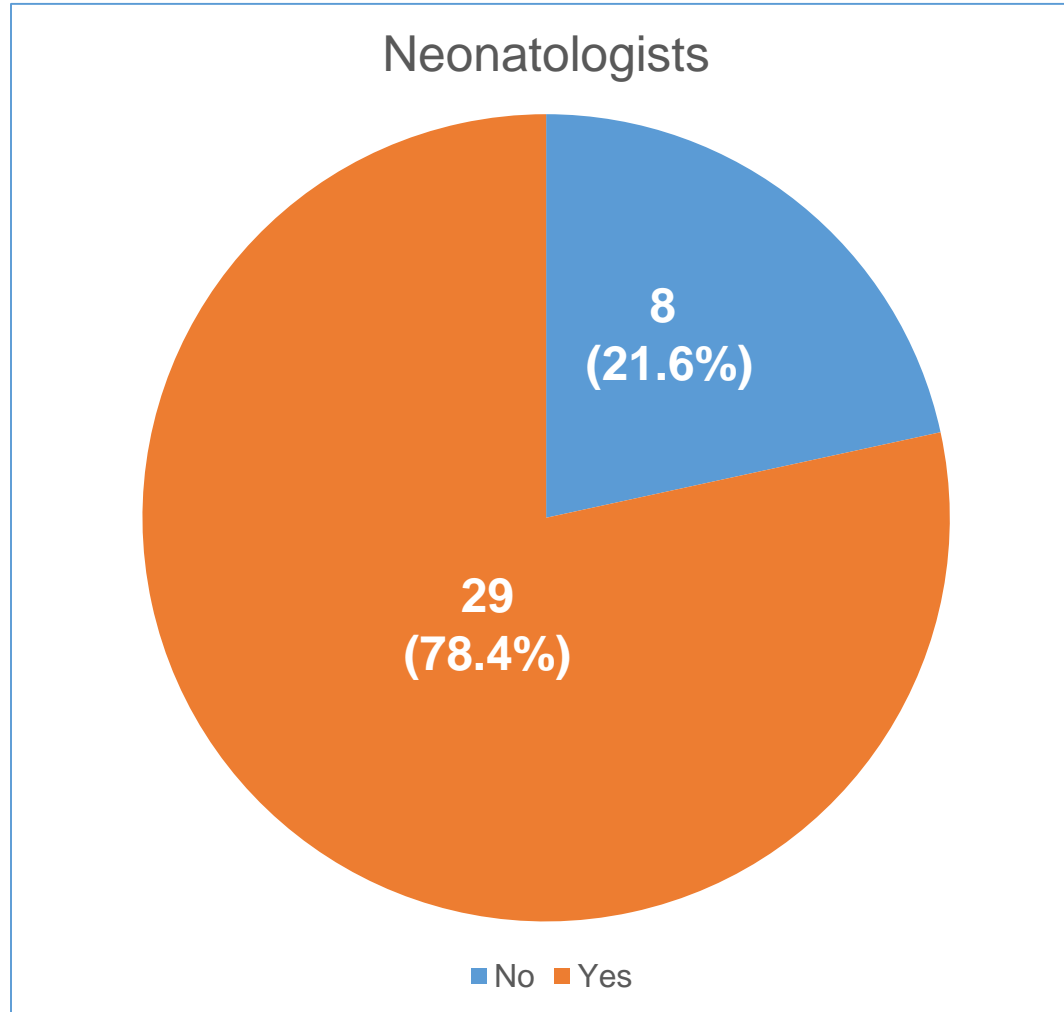
Does your institution offer prenatal visits to the NICU or with NICU staff?



* Special Instructions: *Select only one answer.*

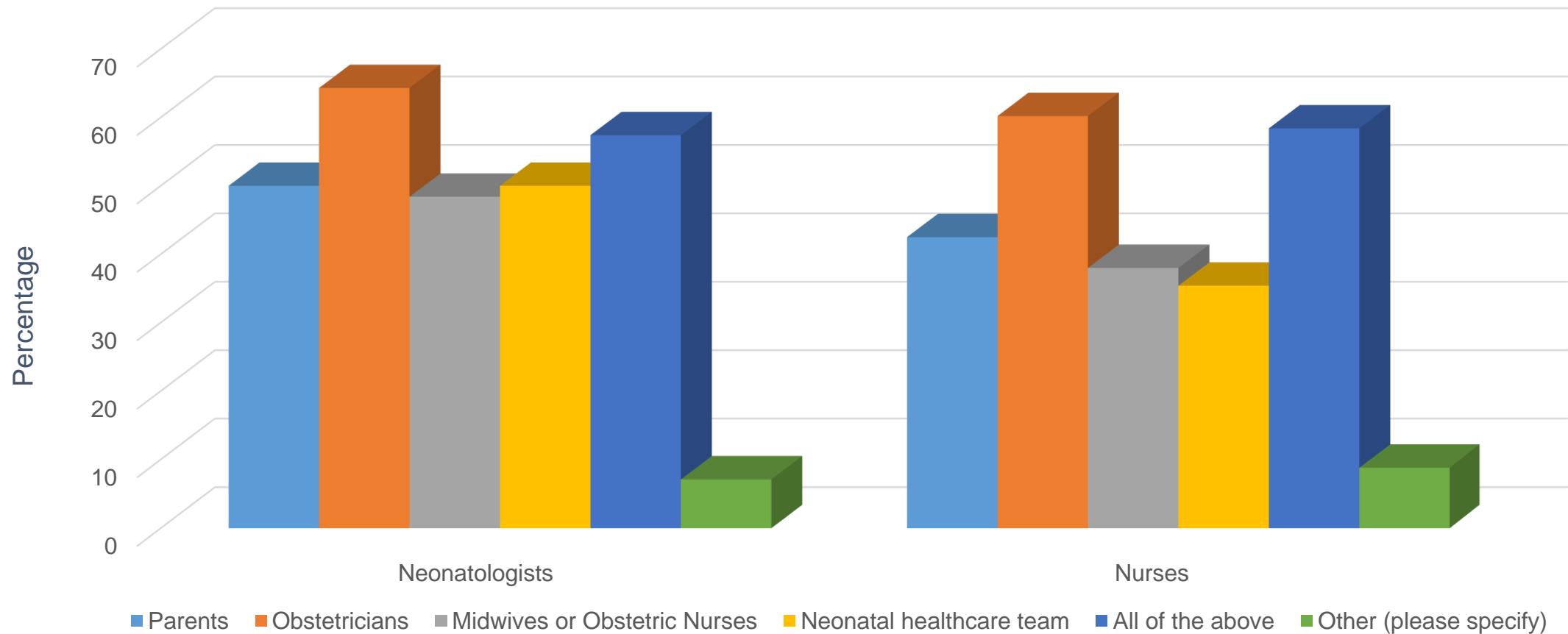
Respondents
- Neonatologists (37)
- Nurses (130)

Does your NICU have a standard approach for prenatal consultations with a neonatal healthcare team member* from the NICU?



* Neonatal healthcare team provider was defined as Neonatologist, NNP, Nurse, Fellow, or Resident

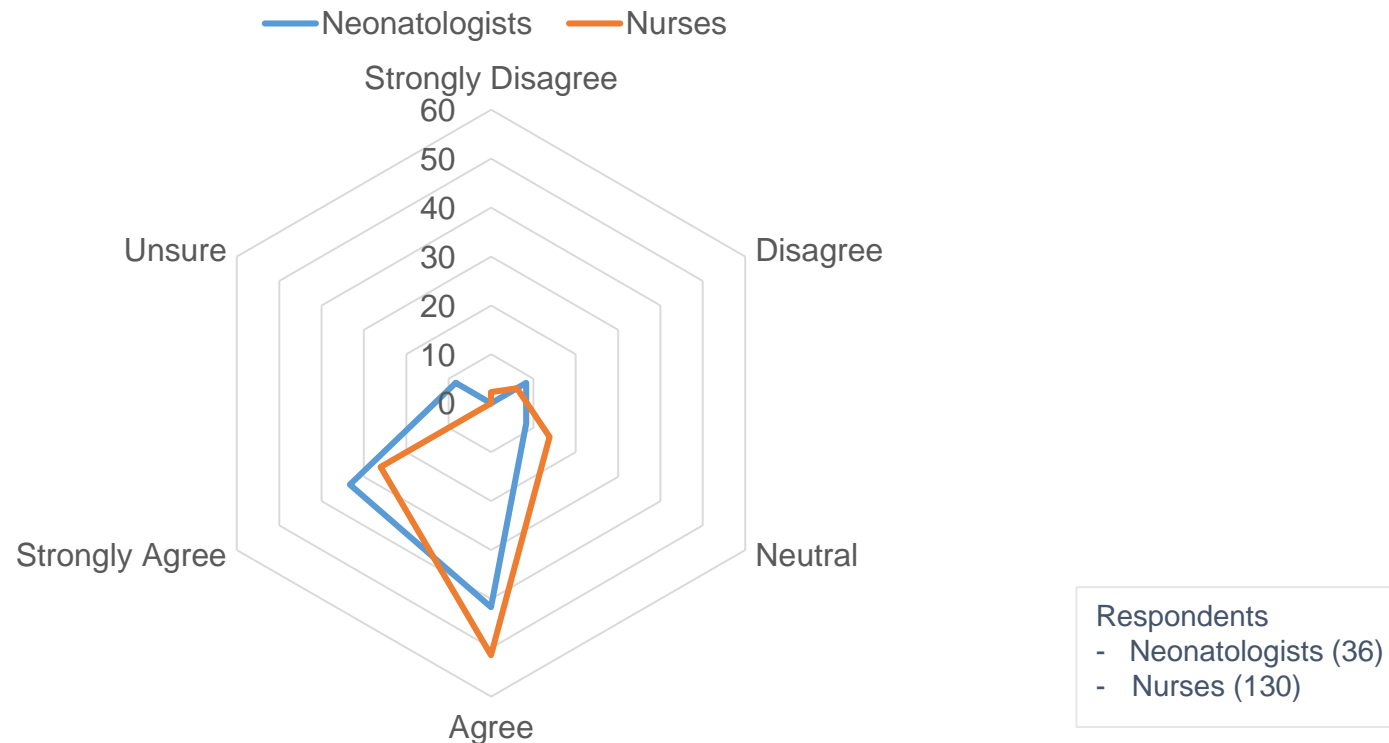
At your institution, who can request these standard prenatal consultations?*



* Special Instructions: *Select all that Apply.*

We would like to understand your perspective on decision-making within your NICU* (1)

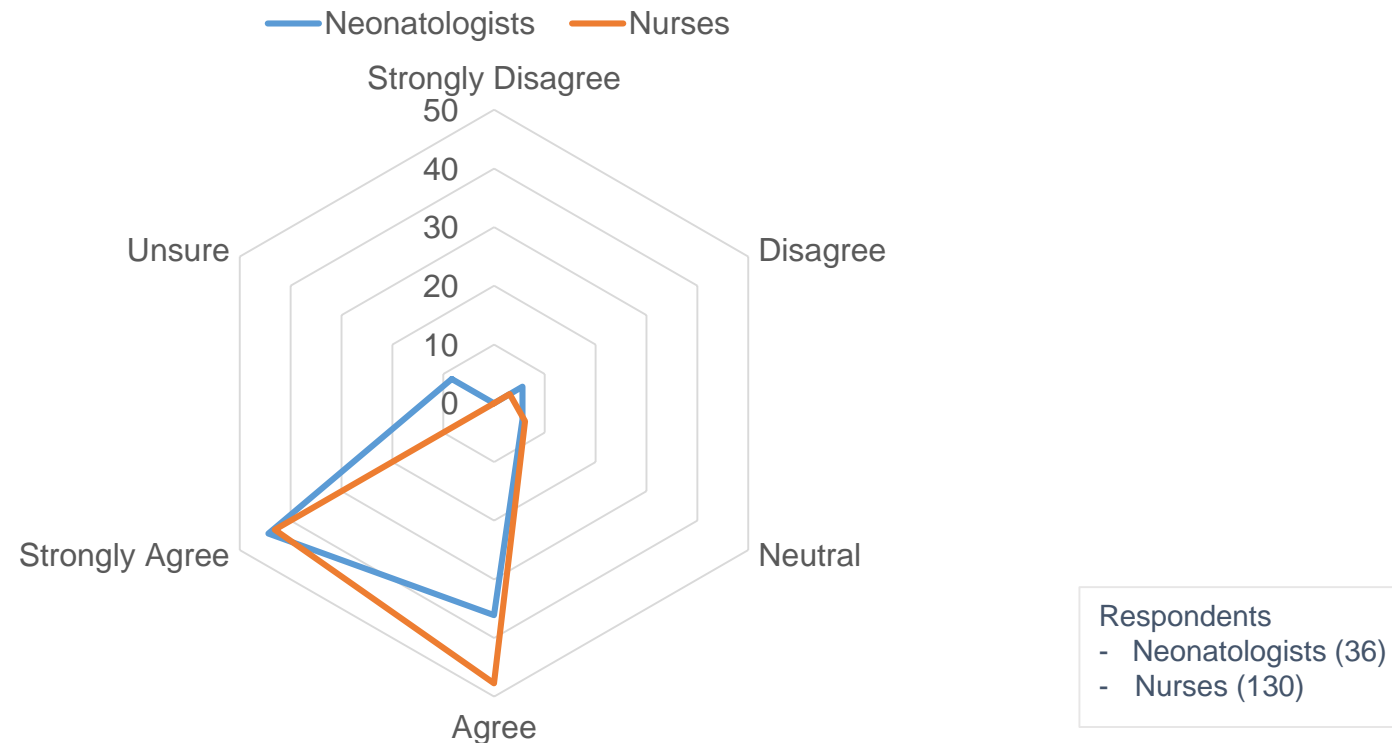
When families are fully engaged, my NICU includes families in developing the plan of care for their sick newborn (%)



* Special instructions: Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).

We would like to understand your perspective on decision-making within your NICU* (2)

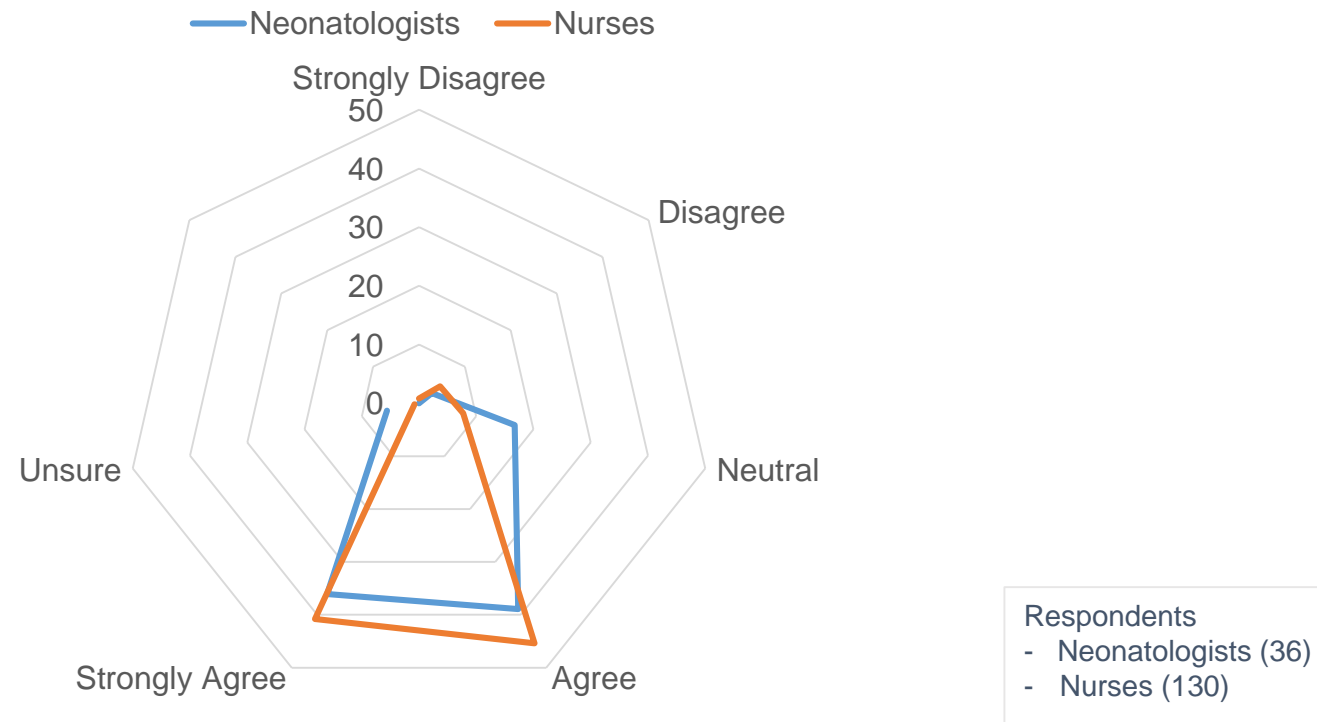
In my NICU I feel free to speak up if I believe a decision may negatively affect the care of a sick newborn (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

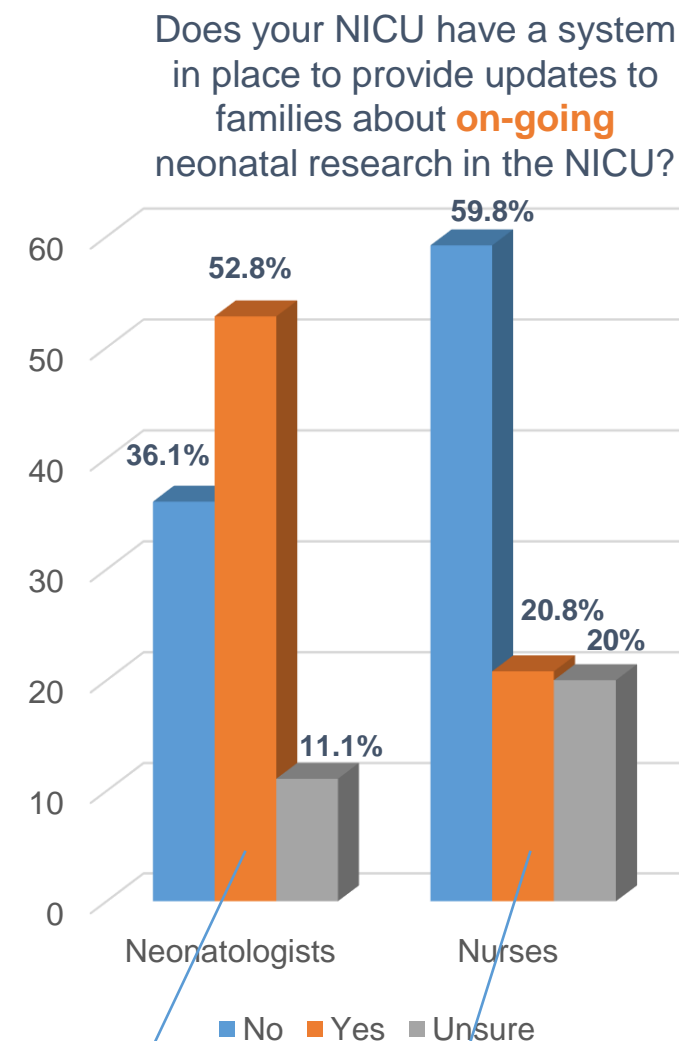
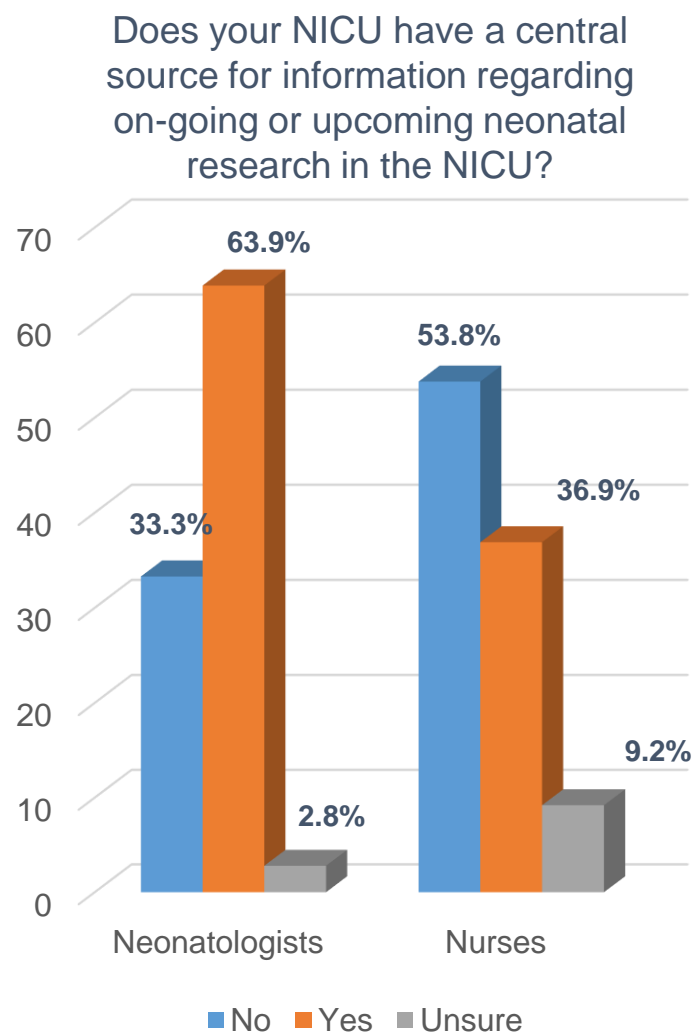
We would like to understand your perspective on decision-making within your NICU* (3)

In my NICU I feel free to question the decisions of those with more authority/experience than mine (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

We would like to understand your institutions current methods of communication regarding research involving neonates* (1)

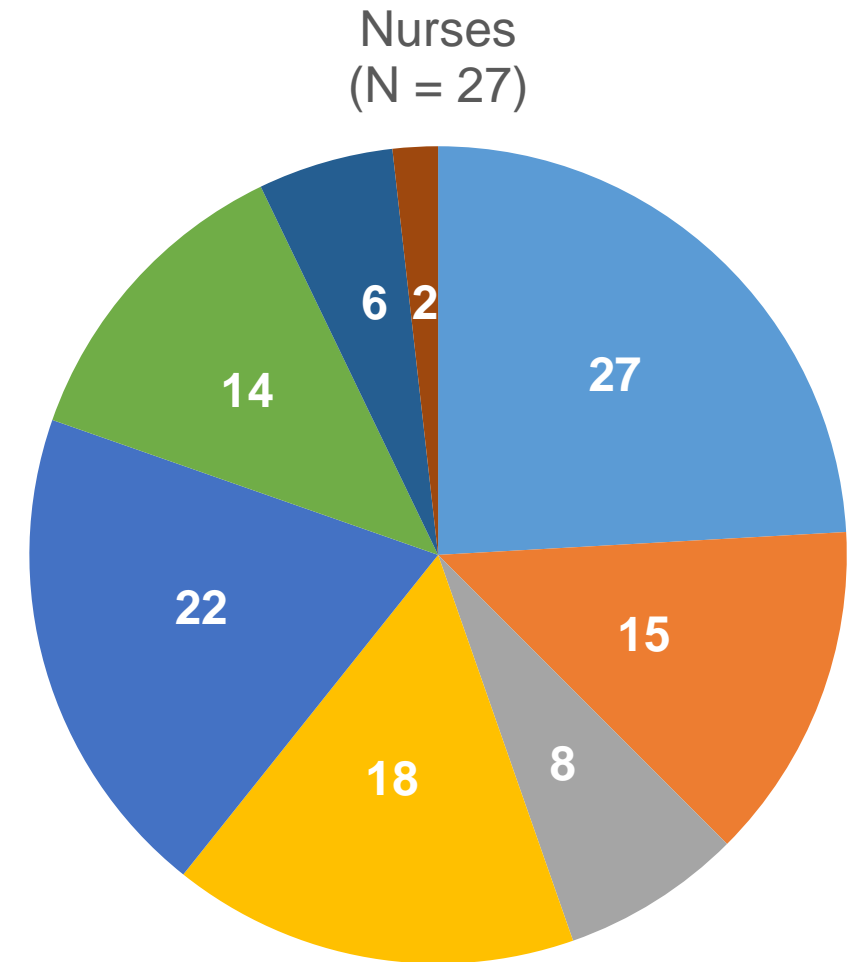
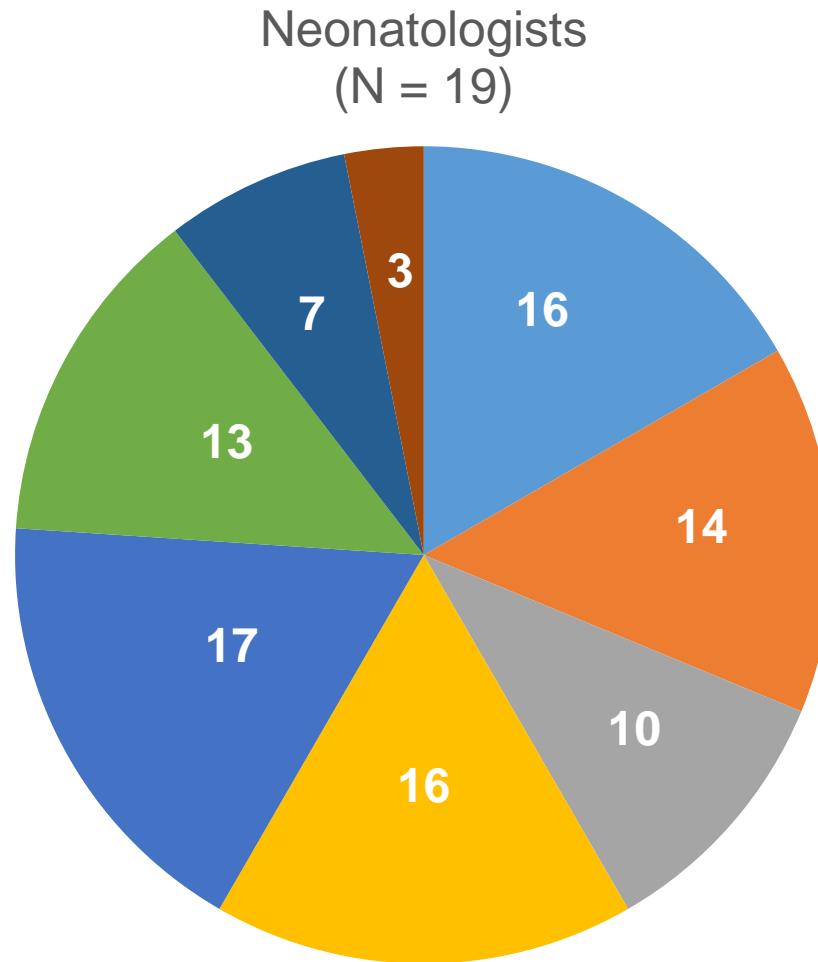


* Special Instructions: *Select only one answer.*

Respondents
- Neonatologists (36)
- Nurses (130)

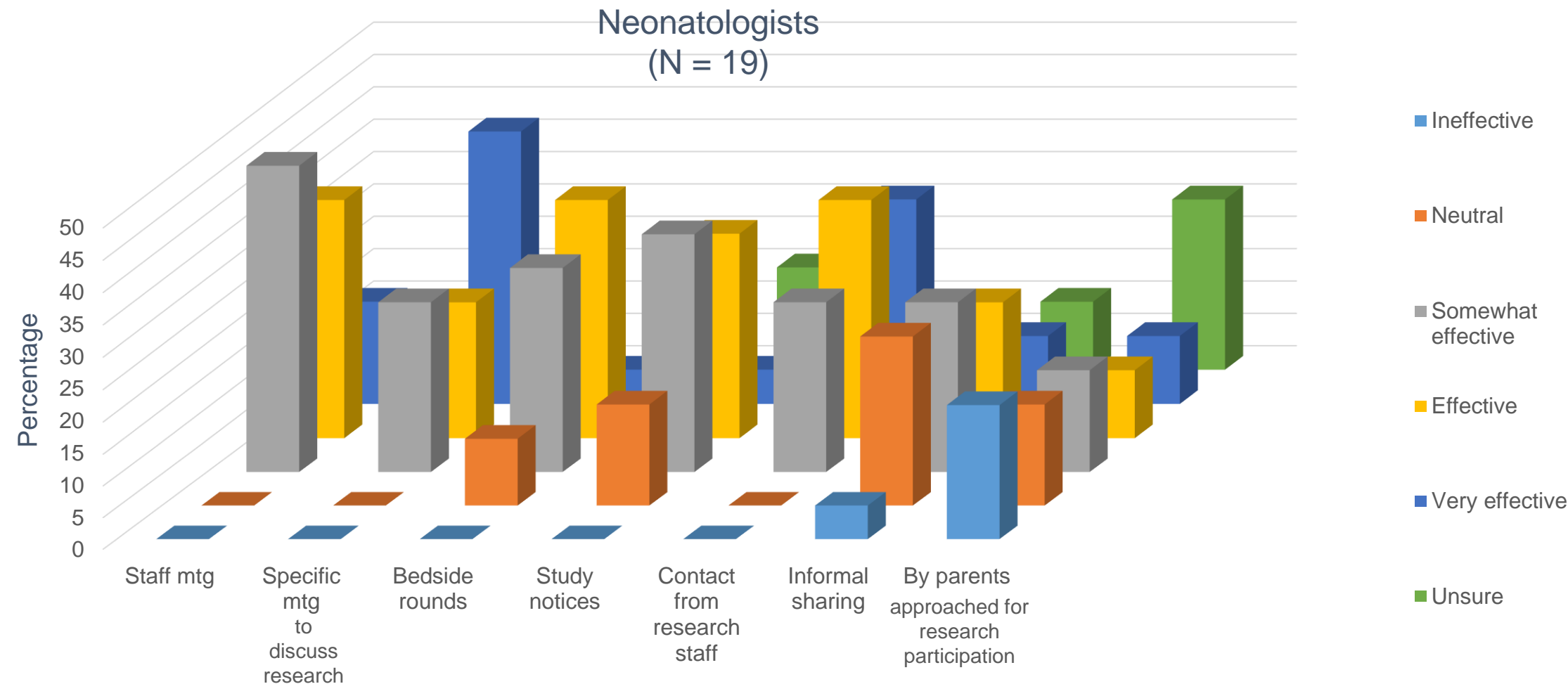
What is the system used to inform staff of **ongoing** research in your NICU?*

- Staff meetings
- Specific meetings to discuss research activity
- Bedside rounds
- Study notices in the NICU
- Contact from research team
- Informal sharing between staff
- By parents who have been approached for the study
- Other (please specify)



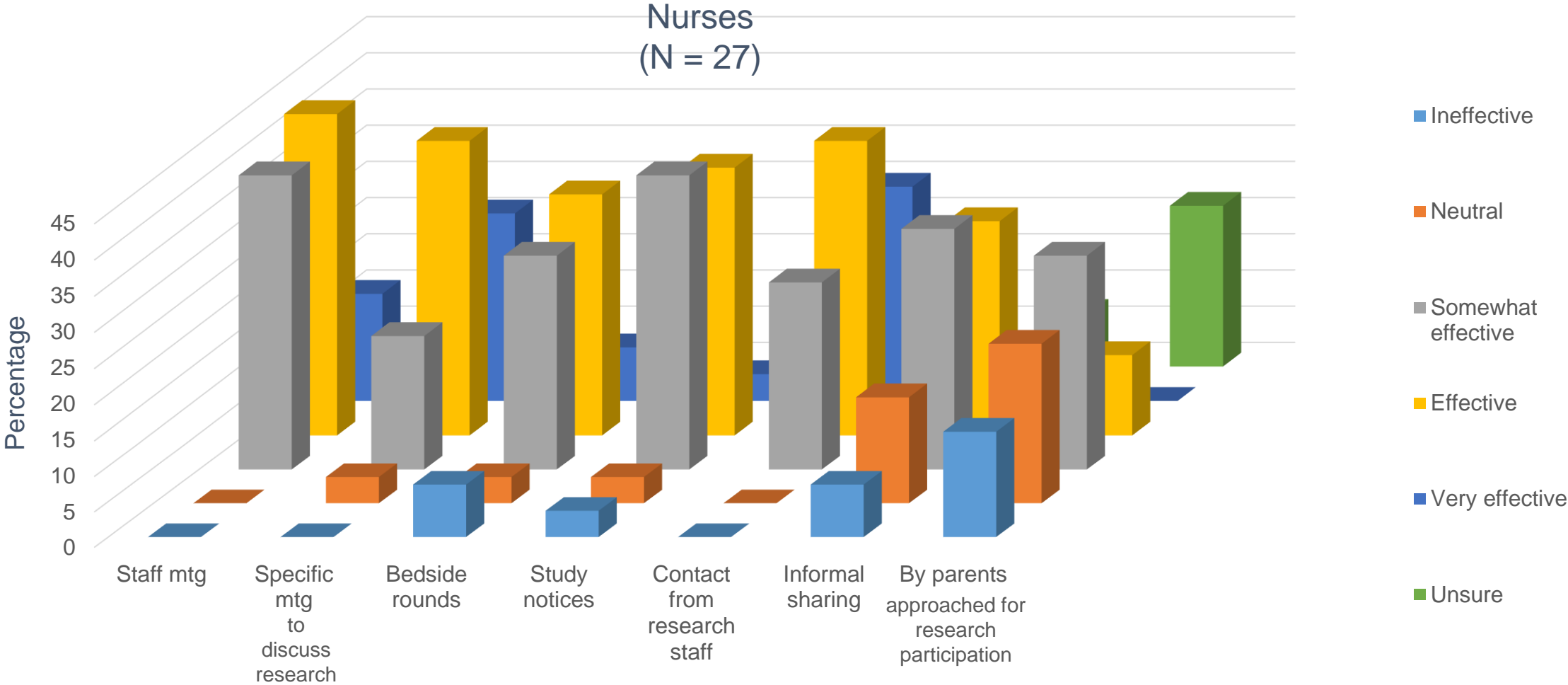
* Special Instructions: *Select all that apply.*

Please rate the effectiveness of the systems that are used in your NICU/hospital to inform staff of **ongoing** research in your NICU* (1)



* Special instructions: Please rate the level of effectiveness on a scale of 1 (Ineffective) through 5 (Very effective).

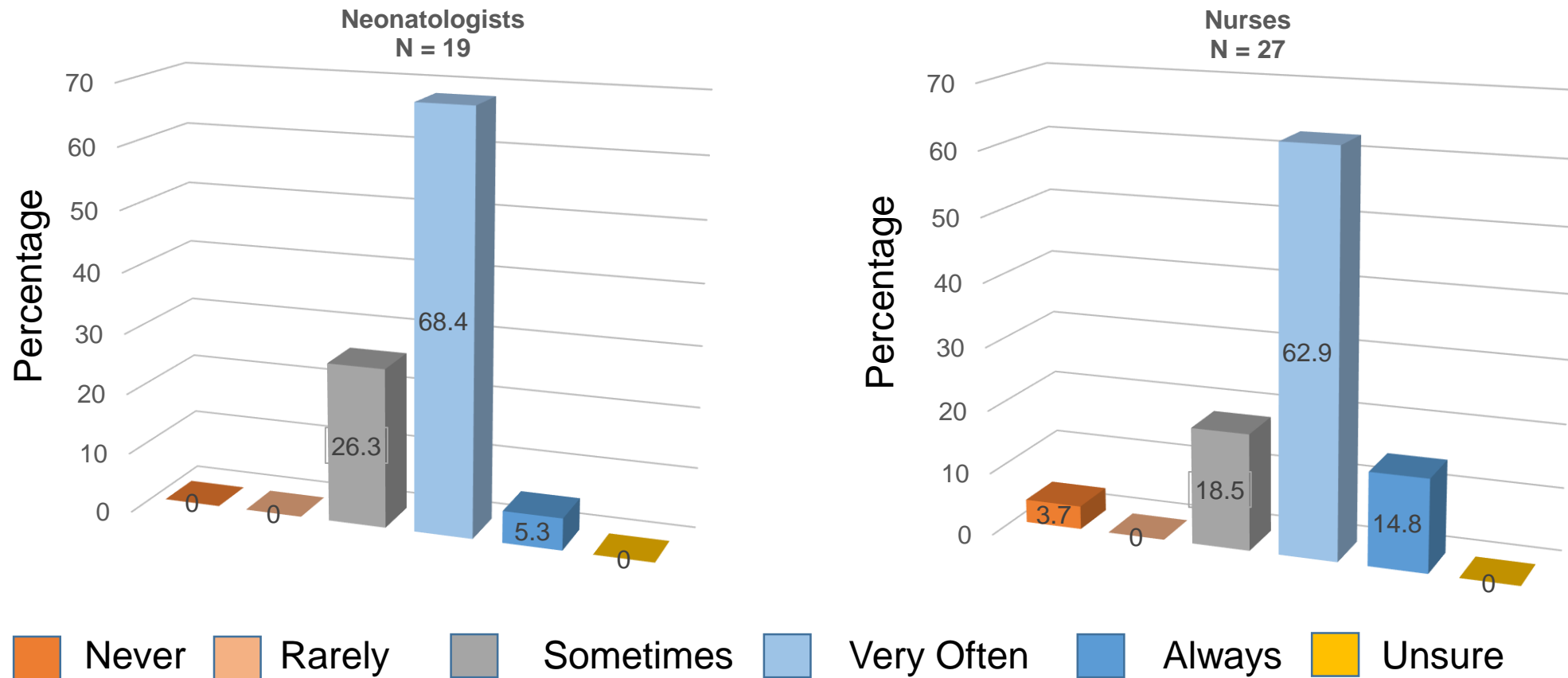
Please rate the effectiveness of the systems that are used in your NICU/hospital to inform staff of **ongoing** research in your NICU* (2)



* Special instructions: Please rate the level of effectiveness on a scale of 1 (Ineffective) through 5 (Very effective).

Please rate your level of agreement with the following statements regarding your NICU/hospitals recruitment in clinical studies.* (1)

Our NICU is successful in recruiting neonates into clinical studies (%)

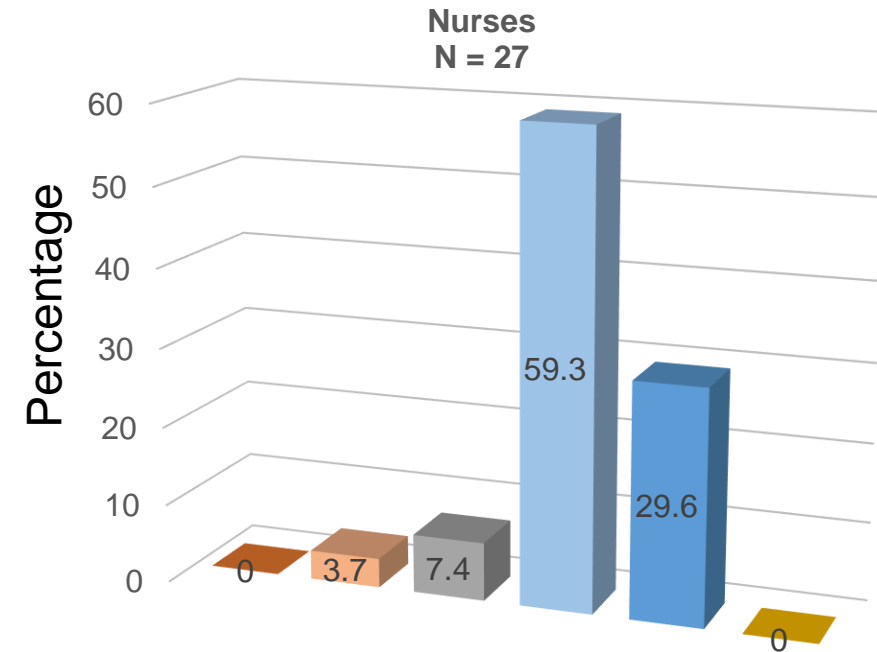
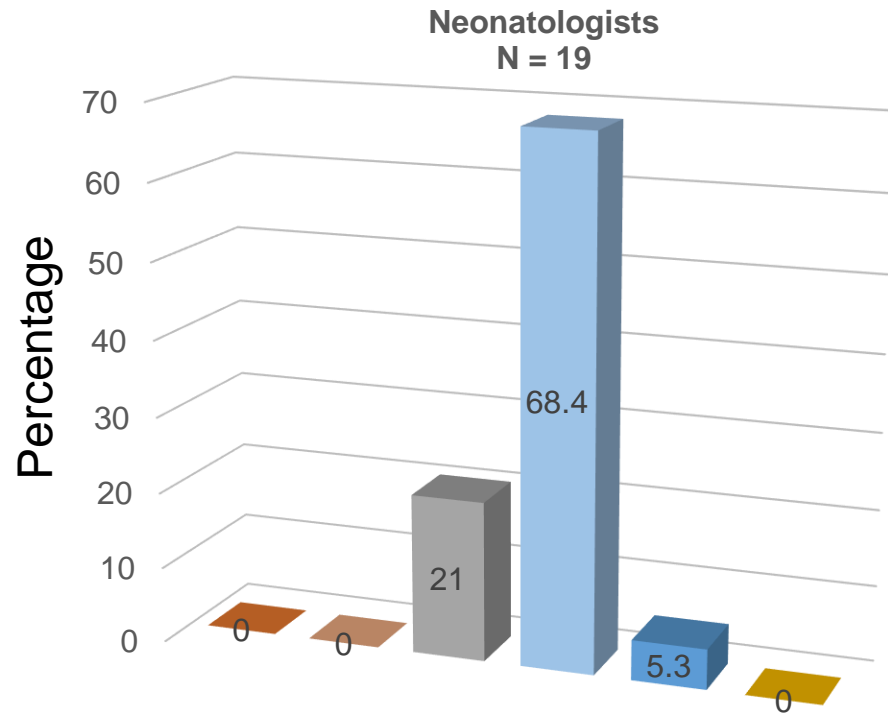


* Special instructions: Please rate the level of effectiveness on a scale of 1 (Never) through 5 (Always).

Data from cohort of respondents who responded that their NICU has a system to inform staff of on-going studies

Please rate your level of agreement with the following statements regarding your NICU/hospitals recruitment in clinical studies.* (2)

Our NICU is successful in completing commitments for academic research studies (%)



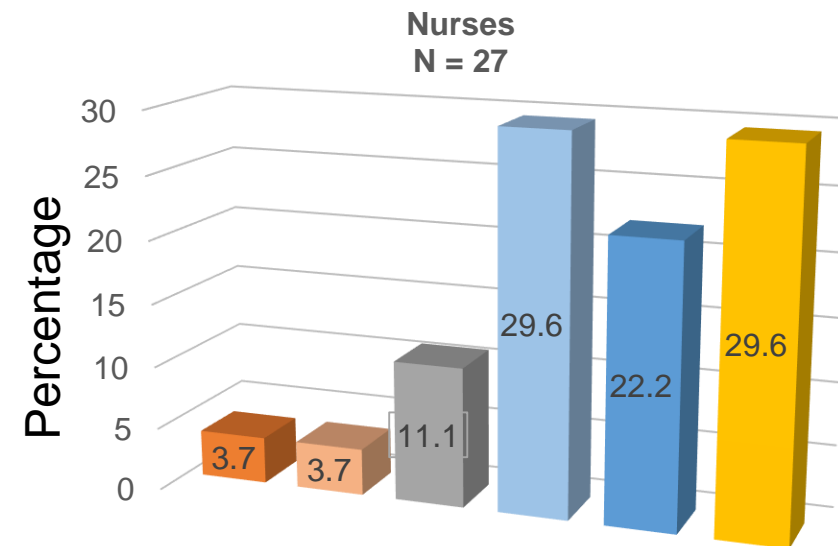
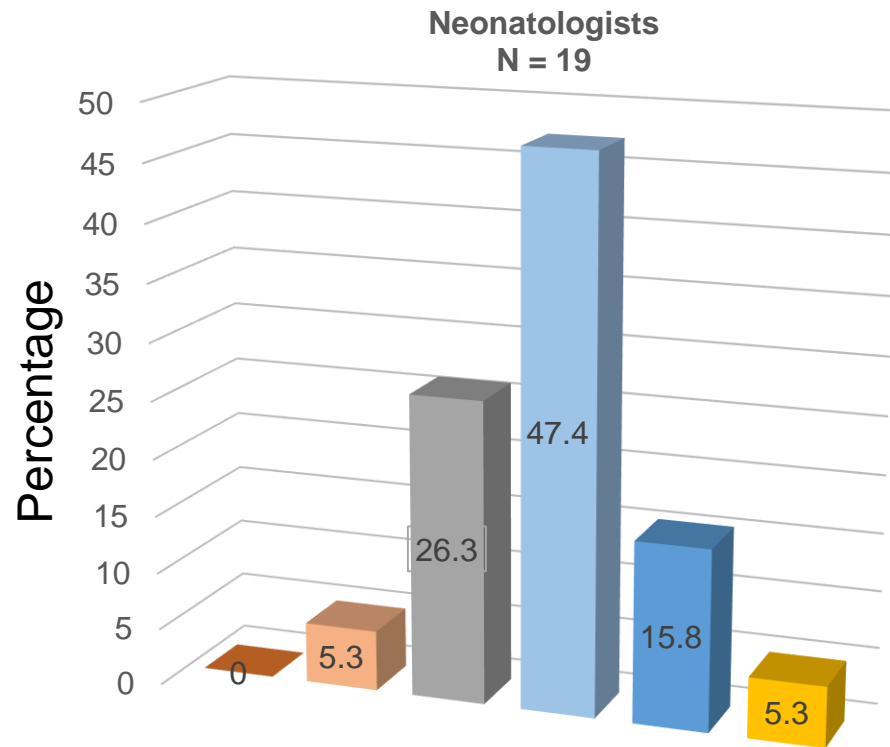
Never Rarely Sometimes Very Often Always Unsure

* Special instructions: Please rate the level of effectiveness on a scale of 1 (Never) through 5 (Always).

Data from cohort of respondents who responded that their NICU has a system to inform staff of on-going studies

Please rate your level of agreement with the following statements regarding your NICU/hospitals recruitment in clinical studies.* (3)

Our NICU is successful in completing commitments for drug development studies (%)



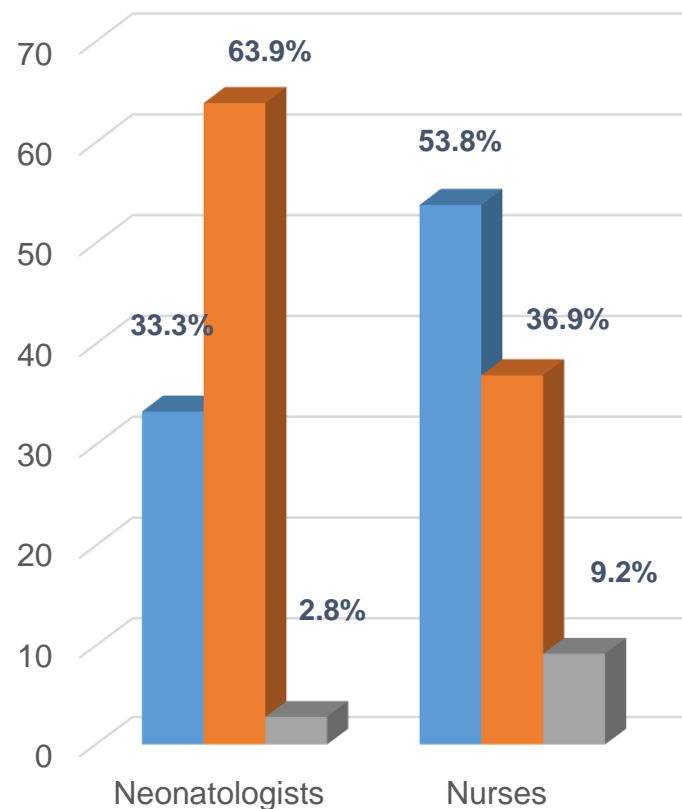
Never Rarely Sometimes Very Often Always Unsure

* Special instructions: Please rate the level of effectiveness on a scale of 1 (Never) through 5 (Always).

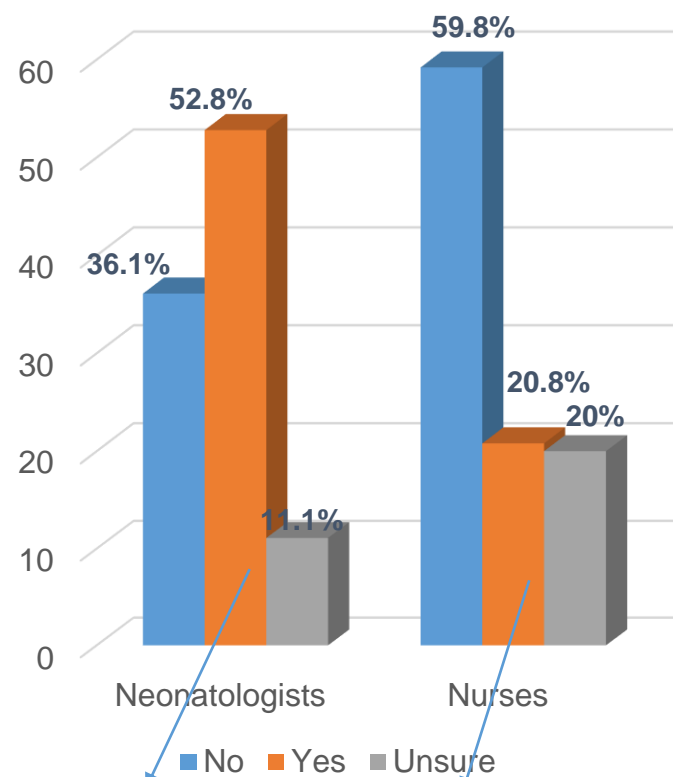
Data from cohort of respondents who responded that their NICU has a system to inform staff of on-going studies

We would like to understand your institutions current methods of communication regarding research involving neonates*

Does your NICU have a central source for information regarding on-going or upcoming neonatal research in the NICU?



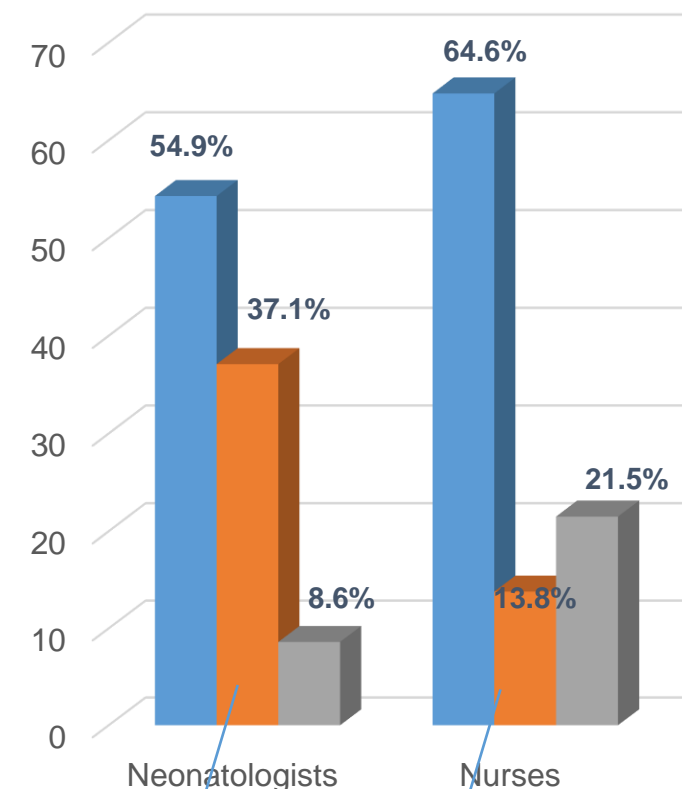
Does your NICU have a system in place to provide updates to families about **on-going** neonatal research in the NICU?



19

27

Does your NICU have a system in place to provide updates to families about **upcoming** neonatal research in the NICU?



13

18

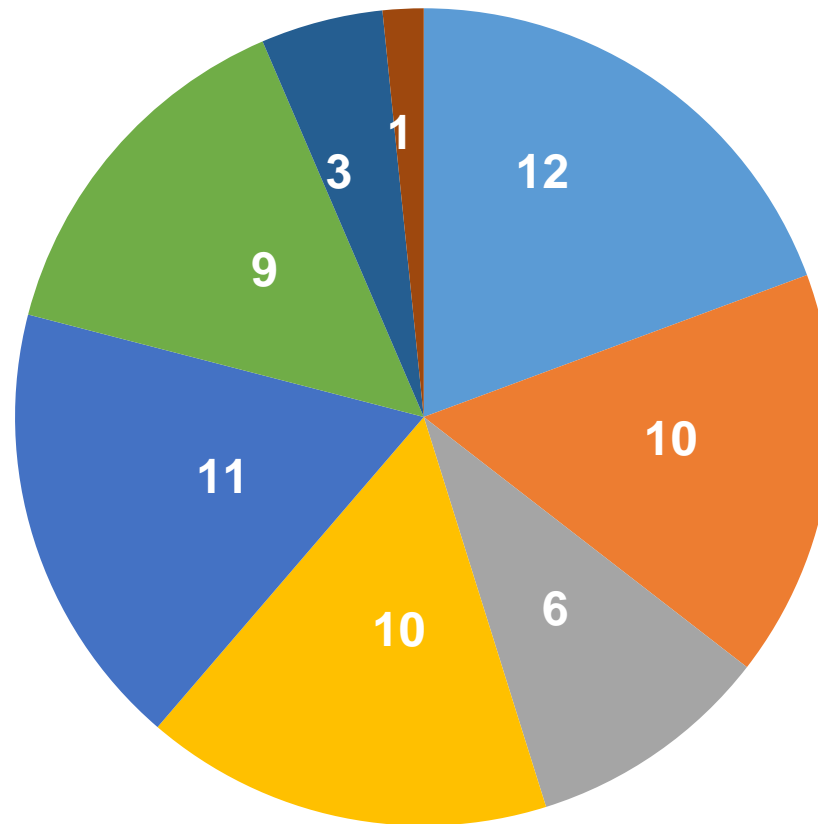
Respondents
- Neonatologists (35)
- Nurses (130)

* Special Instructions: *Select only one answer.*

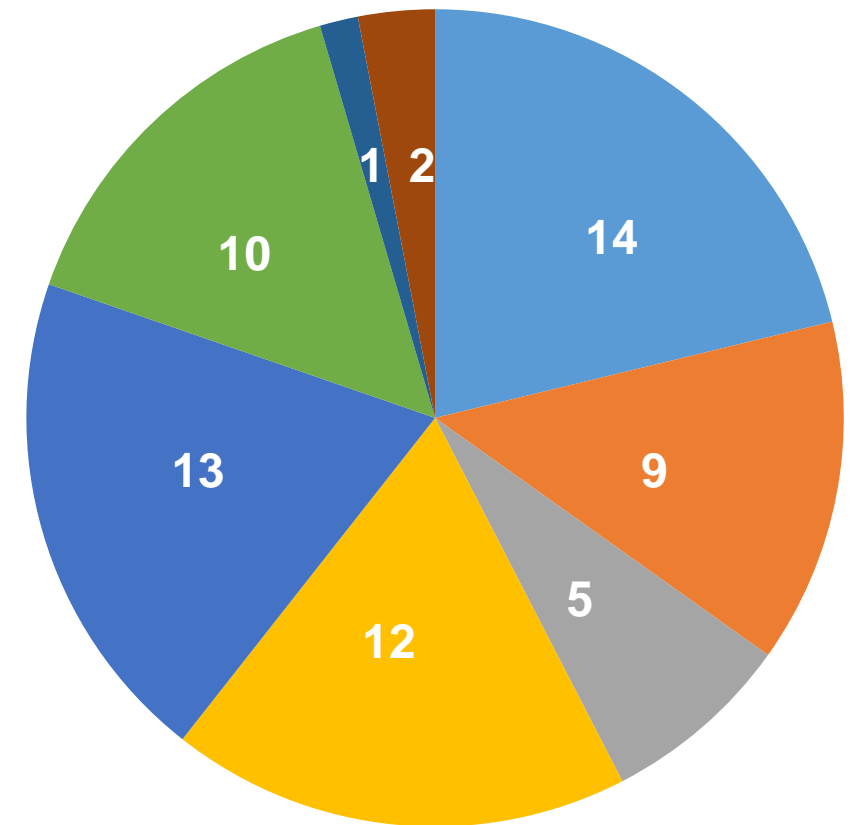
What is the system used to inform staff of **upcoming** research in your NICU?*

- Staff meetings
- Specific meetings to discuss research activity
- Bedside rounds
- Study notices in the NICU
- Contact from research team
- Informal sharing between staff
- By parents who have been approached for the study
- Other (please specify)

Neonatologists
(N = 13)

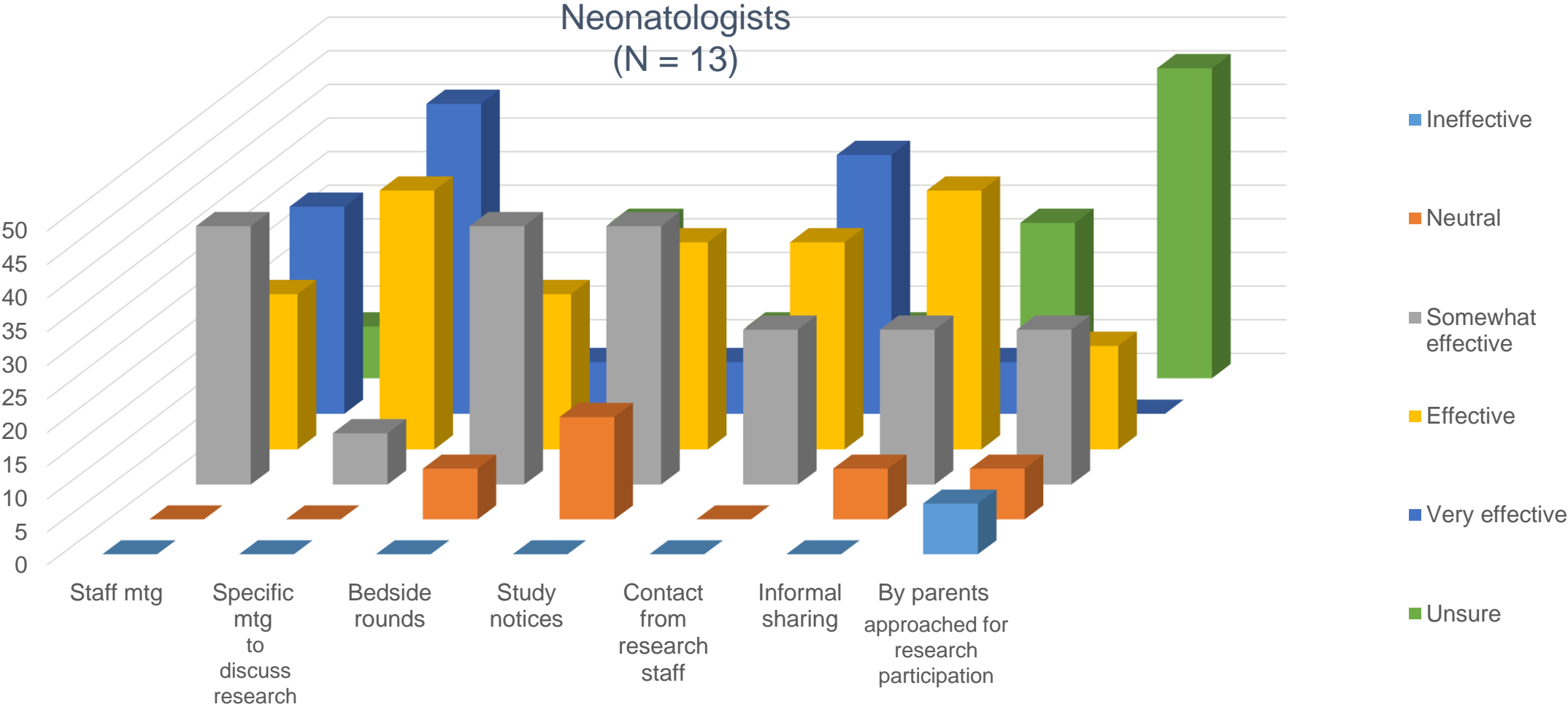


Nurses
(N = 18)



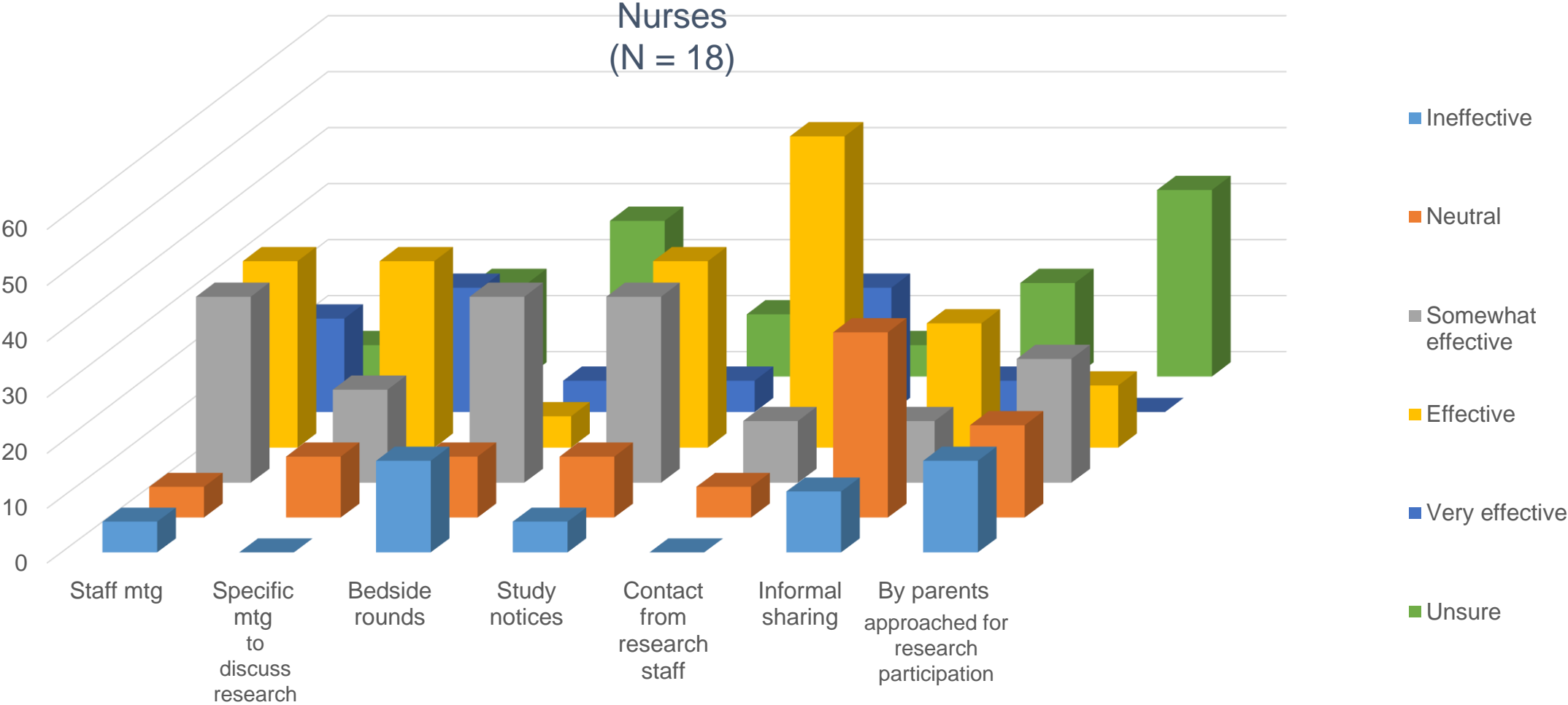
* Special Instructions: *Select all that apply.*

Please rate the effectiveness of the systems that are used in your NICU/hospital to inform staff of **upcoming** research in your NICU* (1)



* Special instructions: Please rate the level of effectiveness on a scale of 1 (Ineffective) through 5 (Very effective).

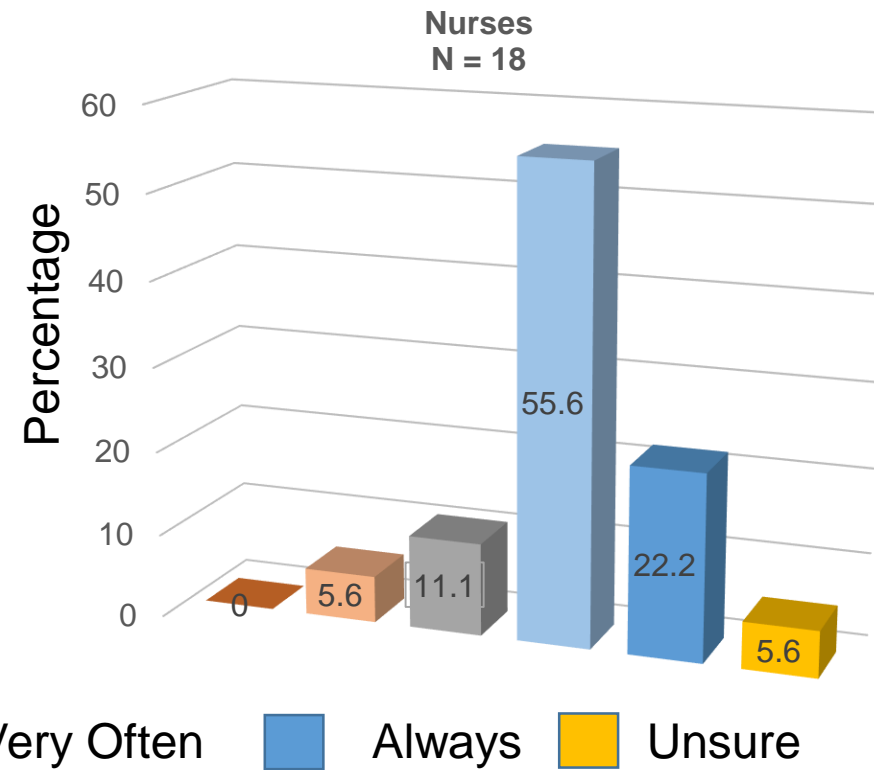
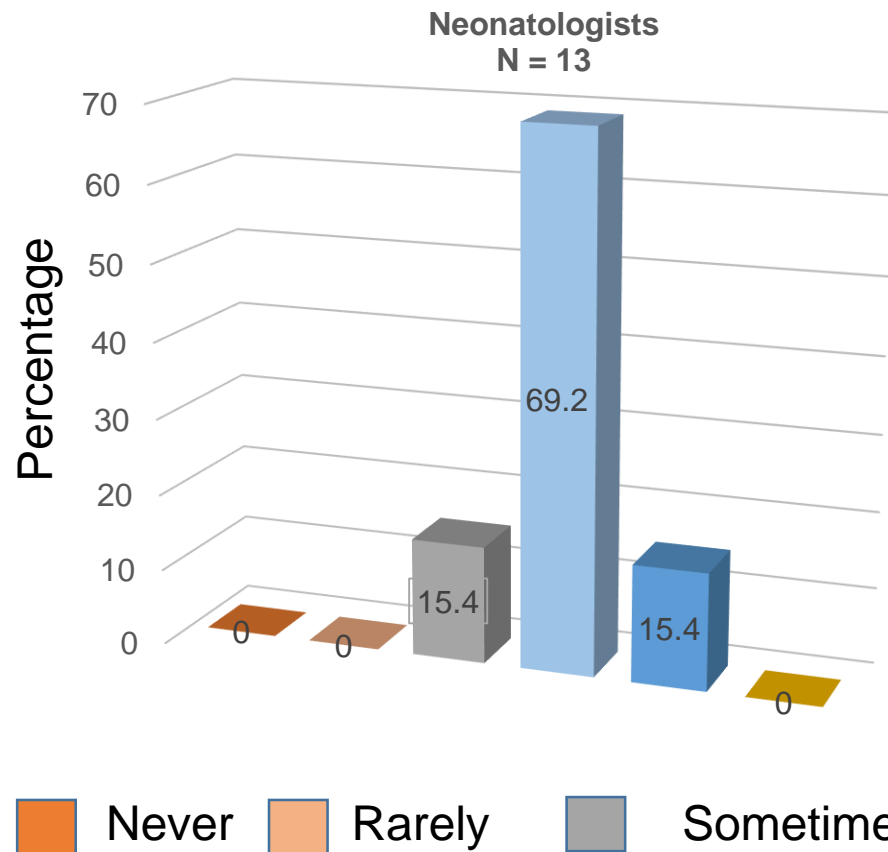
Please rate the effectiveness of the systems that are used in your NICU/hospital to inform staff of **upcoming** research in your NICU* (2)



* Special instructions: Please rate the level of effectiveness on a scale of 1 (Ineffective) through 5 (Very effective).

Please rate your level of agreement with the following statements regarding your NICU/hospitals recruitment in clinical studies.* (1)

Our NICU is successful in recruiting neonates into clinical studies (%)

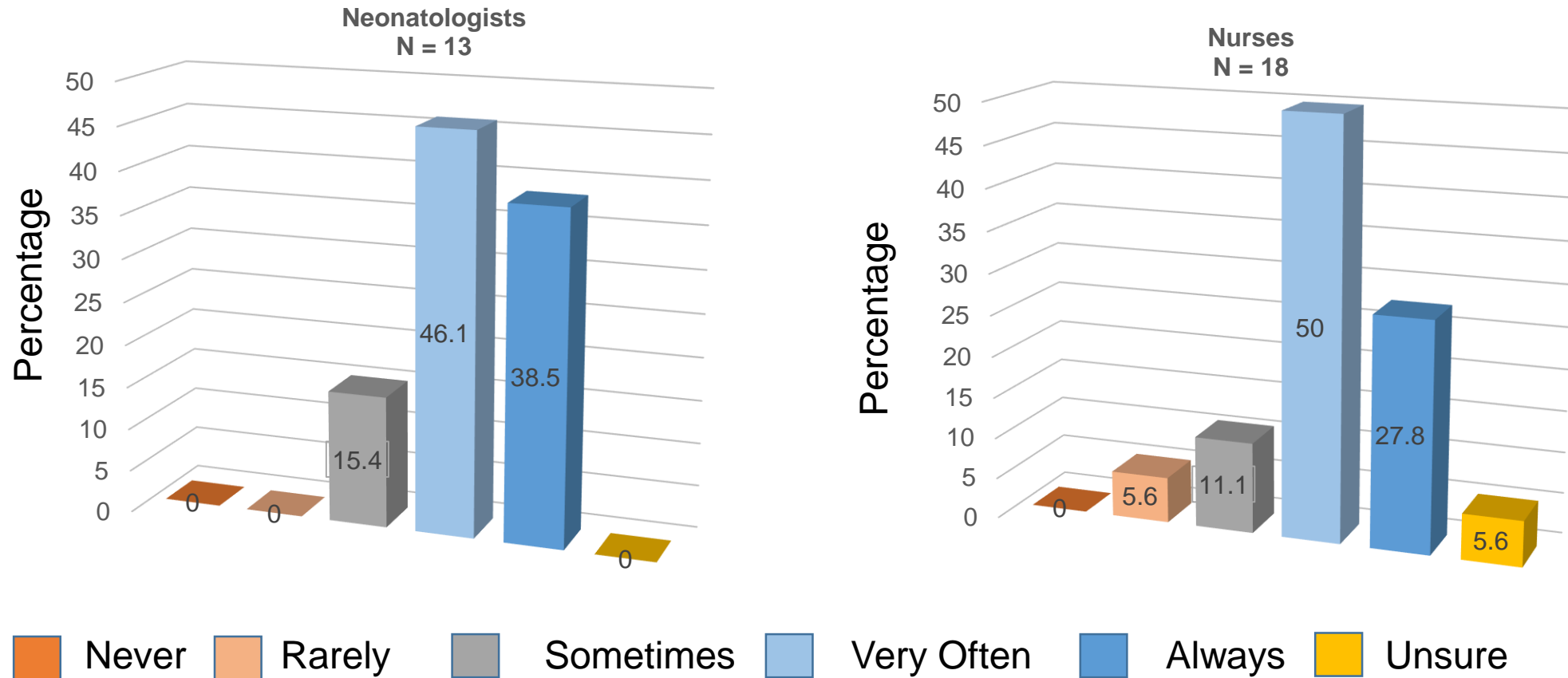


* Special instructions: Please rate the level of effectiveness on a scale of 1 (Never) through 5 (Always).

Data from cohort of respondents who responded that their NICU has a system to inform staff of upcoming studies

Please rate your level of agreement with the following statements regarding your NICU/hospitals recruitment in clinical studies.* (2)

Our NICU is successful in completing commitments for academic research studies (%)

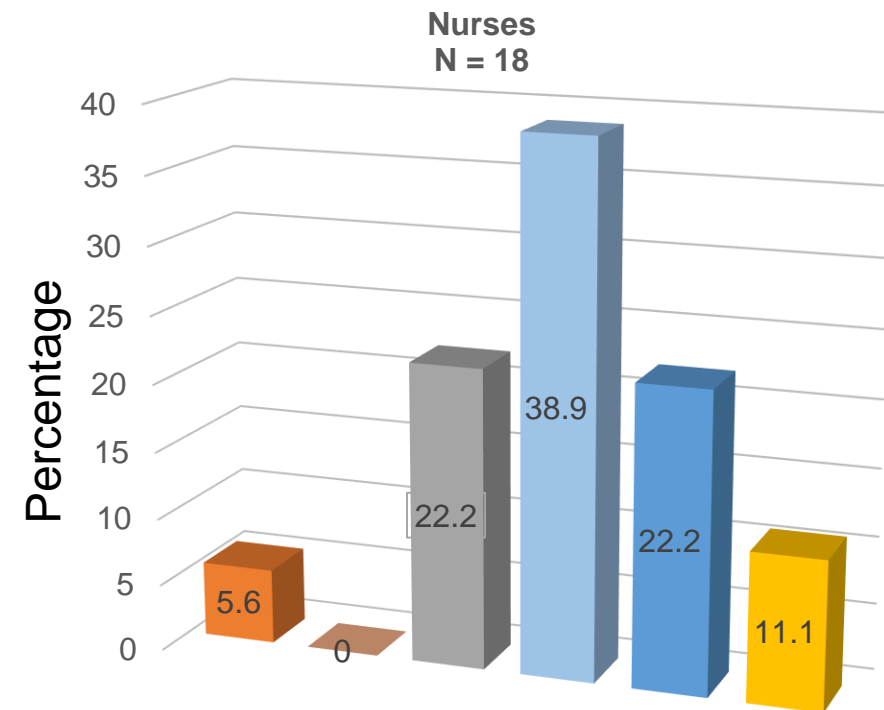
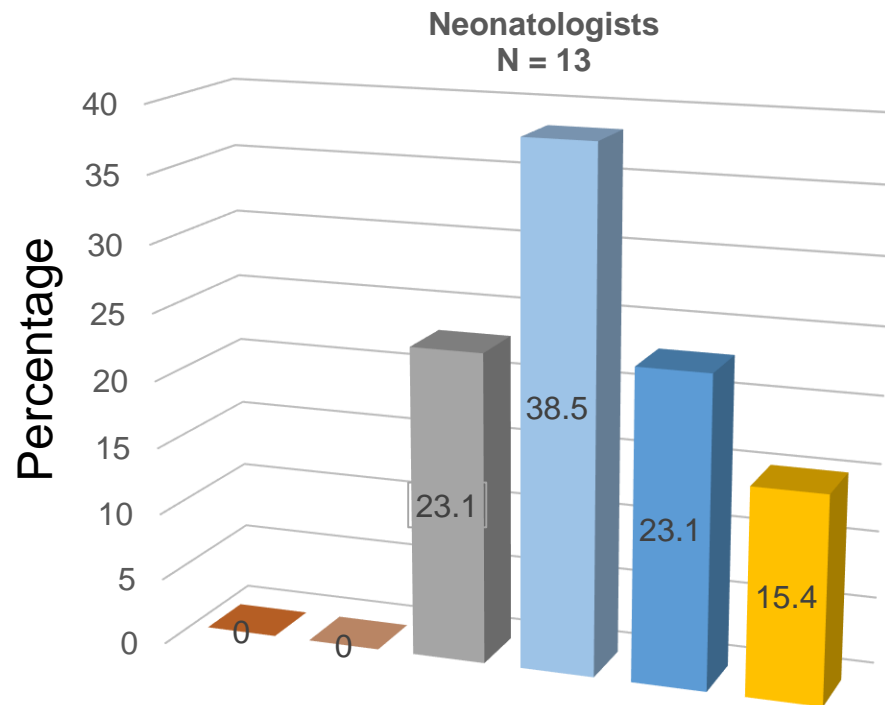


* Special instructions: Please rate the level of effectiveness on a scale of 1 (Never) through 5 (Always).

Data from cohort of respondents who responded that their NICU has a system to inform staff of upcoming studies

Please rate your level of agreement with the following statements regarding your NICU/hospitals recruitment in clinical studies.* (3)

Our NICU is successful in completing commitments for drug development studies (%)



Never Rarely Sometimes Very Often Always Unsure

* Special instructions: Please rate the level of effectiveness on a scale of 1 (Never) through 5 (Always).

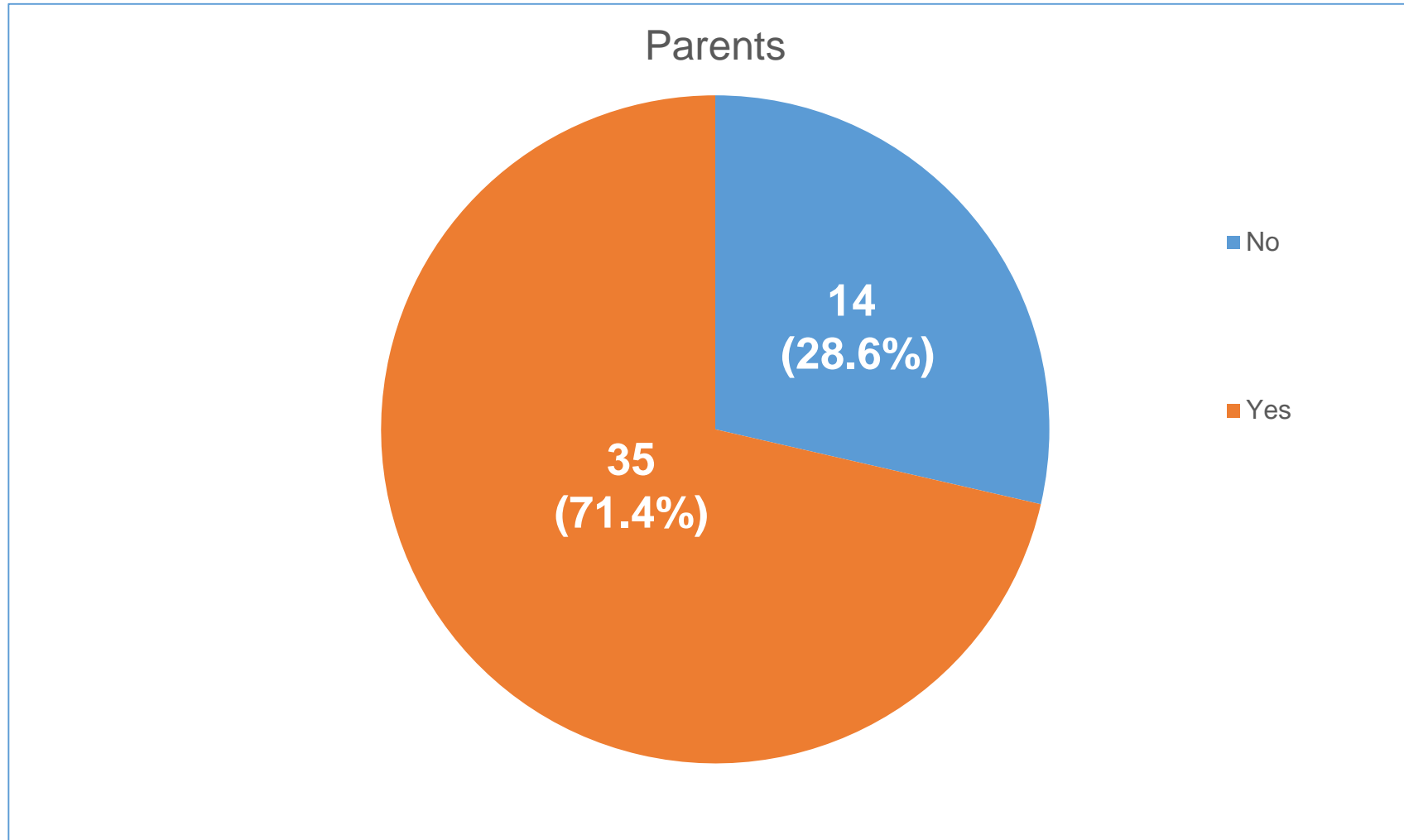
Data from cohort of respondents who responded that their NICU has a system to inform staff of upcoming studies



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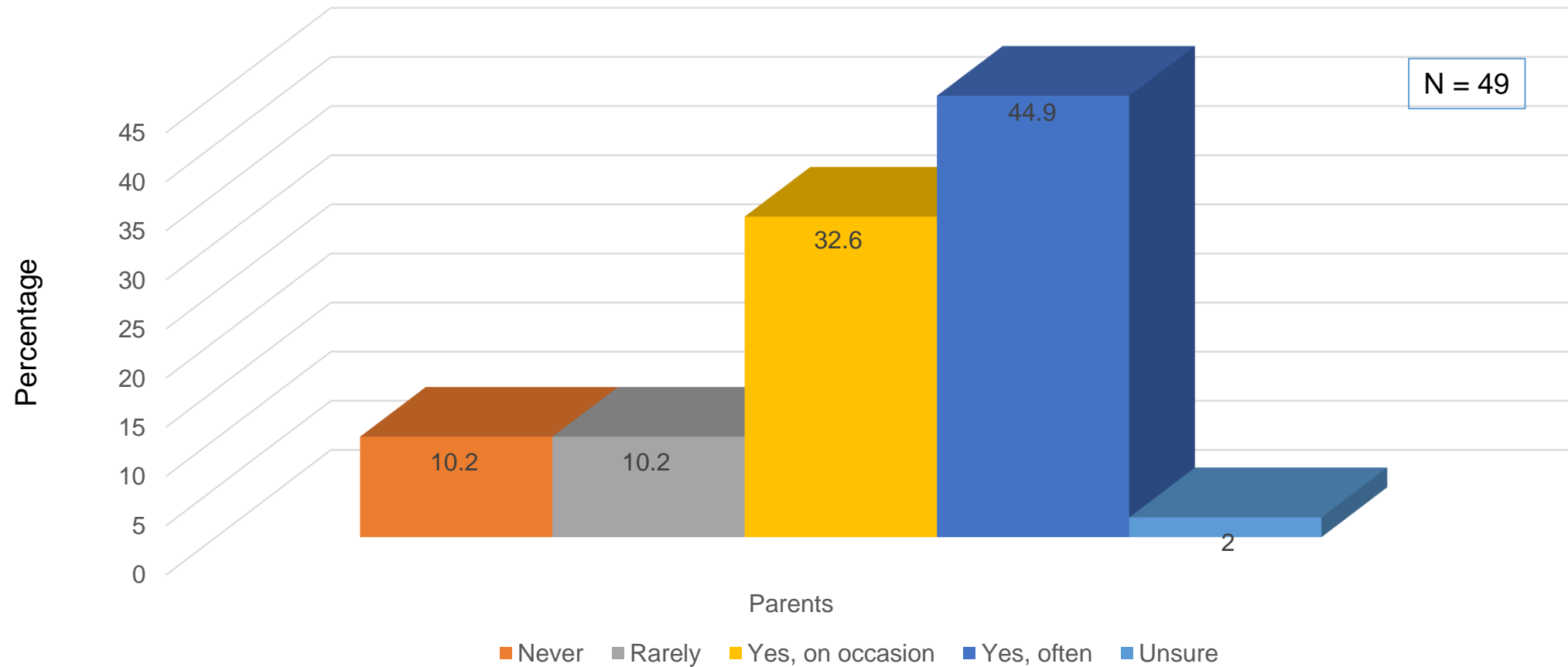
Current communication flow in the Neonatal Intensive Care Unit (NICU) (Parent-specific)

Did the hospital/NICU where your baby was cared for offer you prenatal consultations with a neonatal healthcare team member* prior to your baby's delivery?

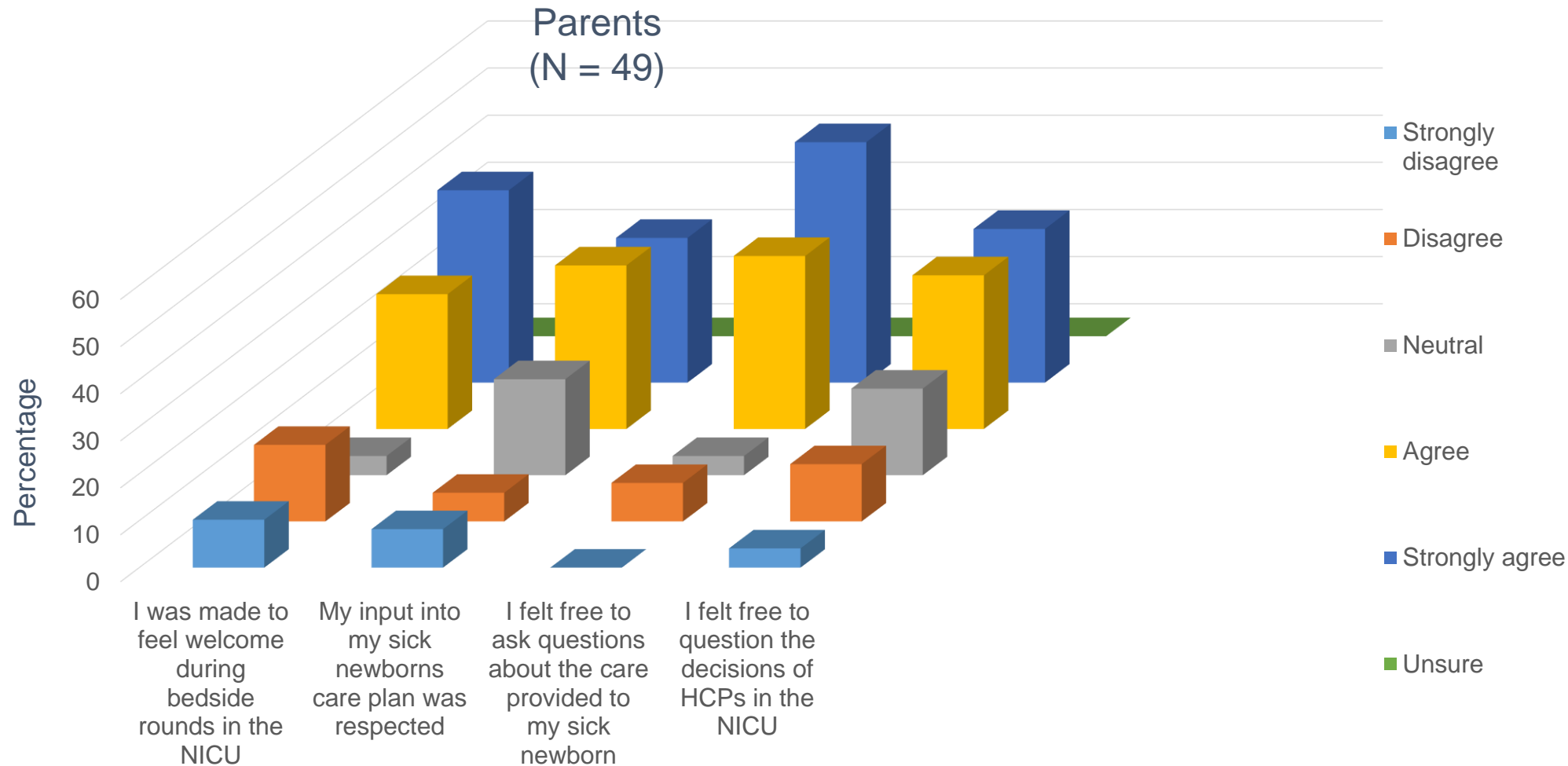


* Neonatal healthcare team provider was defined as Neonatologist, NNP, Nurse, Fellow, or Resident

After your baby was born, were you offered meetings with the neonatal team caring for your sick newborn during his/her stay in the hospital/NICU?



Rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).





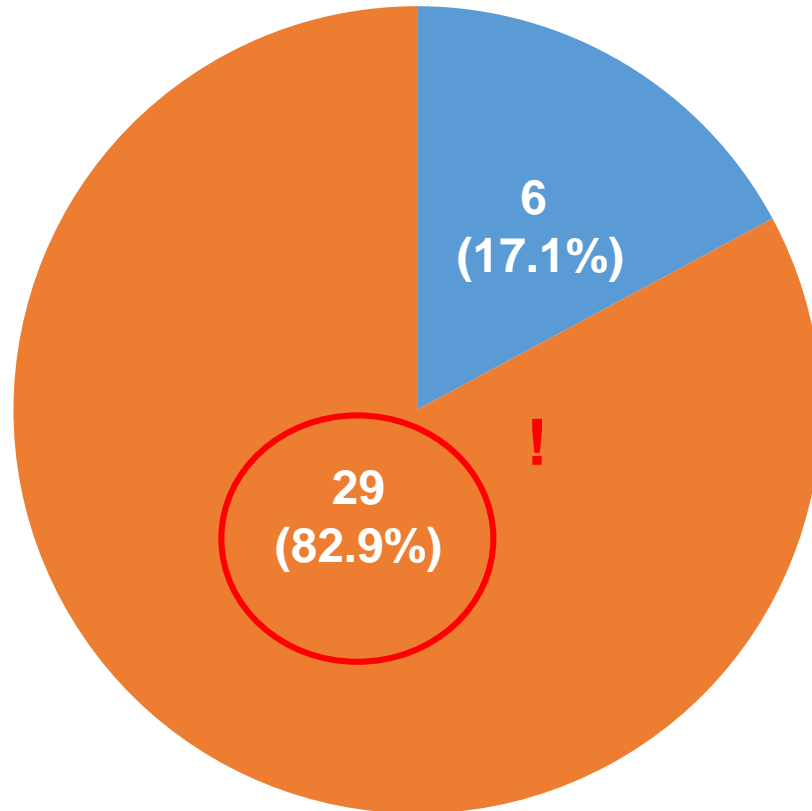
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Part IV: Education and training of neonatal personnel on the role of neonatal research (Neonatologists & Nurses ONLY)



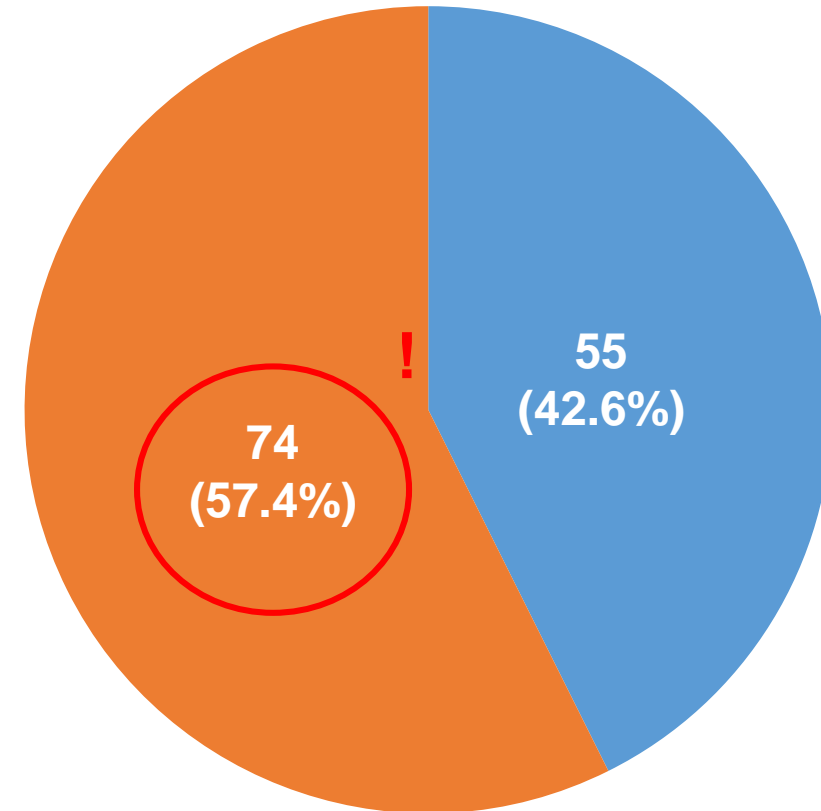
Does your NICU/hospital train personnel on the role of clinical studies and the study consent process before they approach parents and ask for study consent?

Neonatologists



■ No ■ Yes

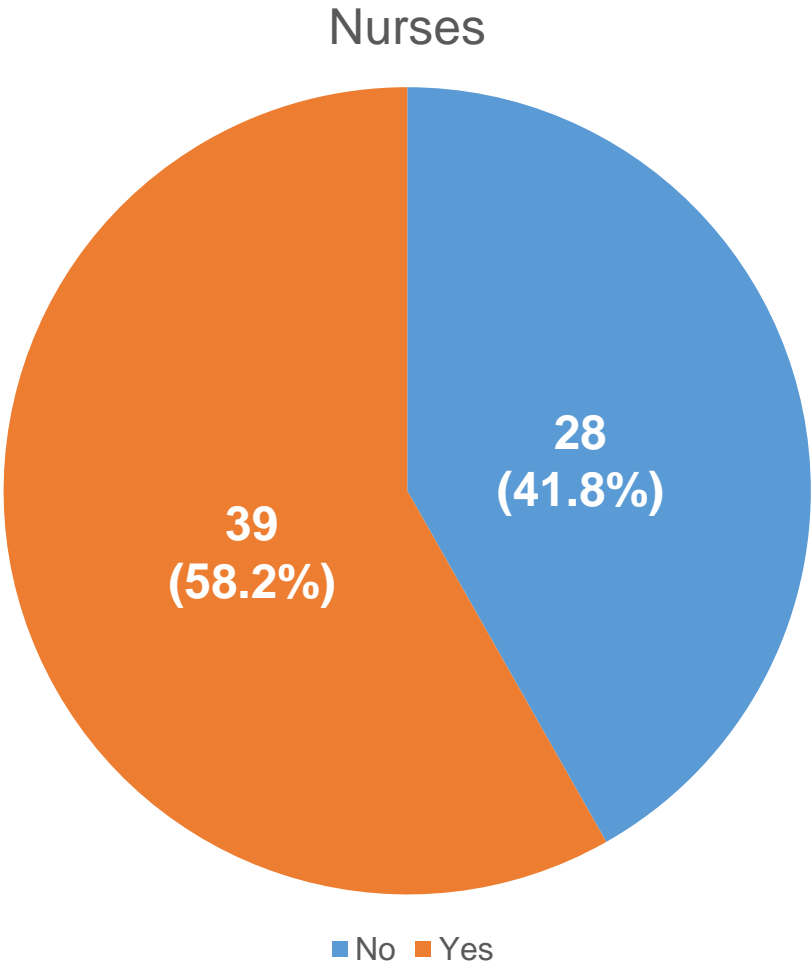
Nurses



■ No ■ Yes

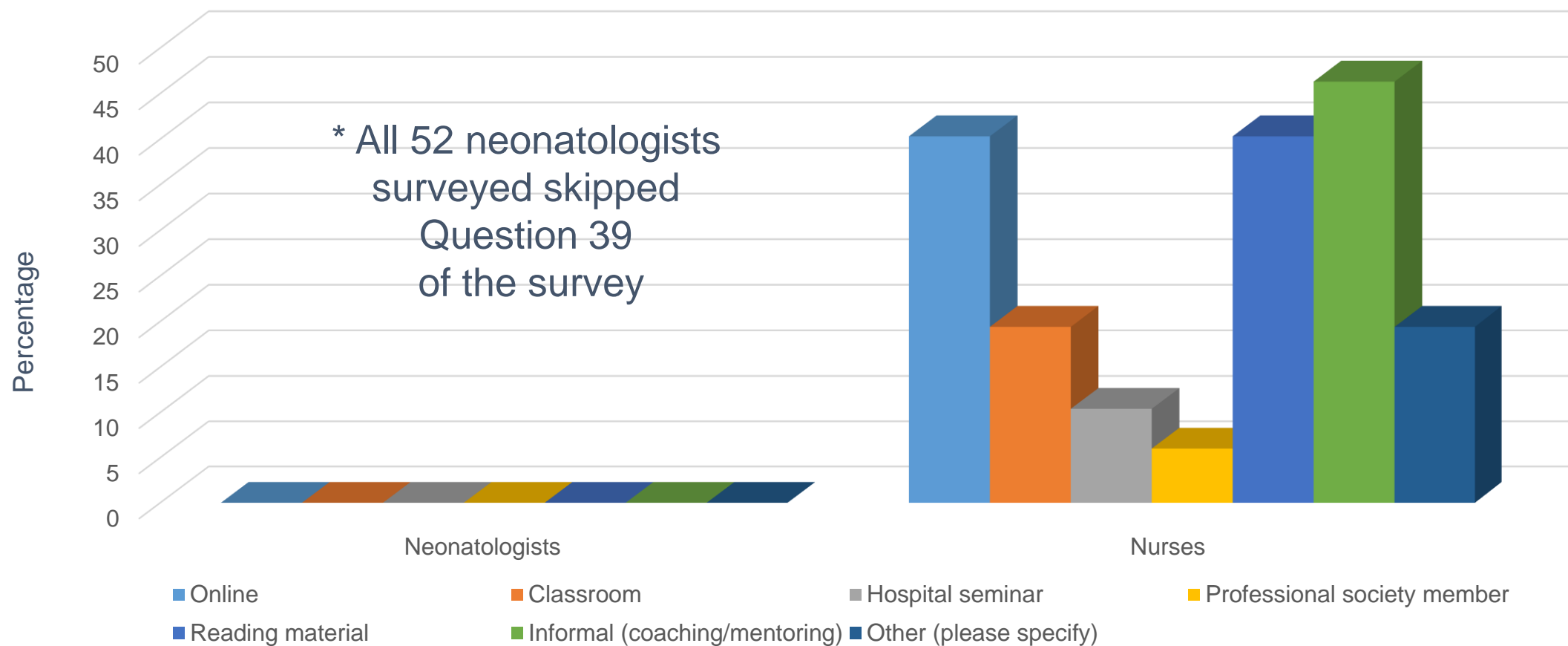
Does your NICU/hospital provide **this** training to all members of the team responsible for the patient enrolled in research?

* All 52 neonatologists surveyed skipped Question 38 of the survey



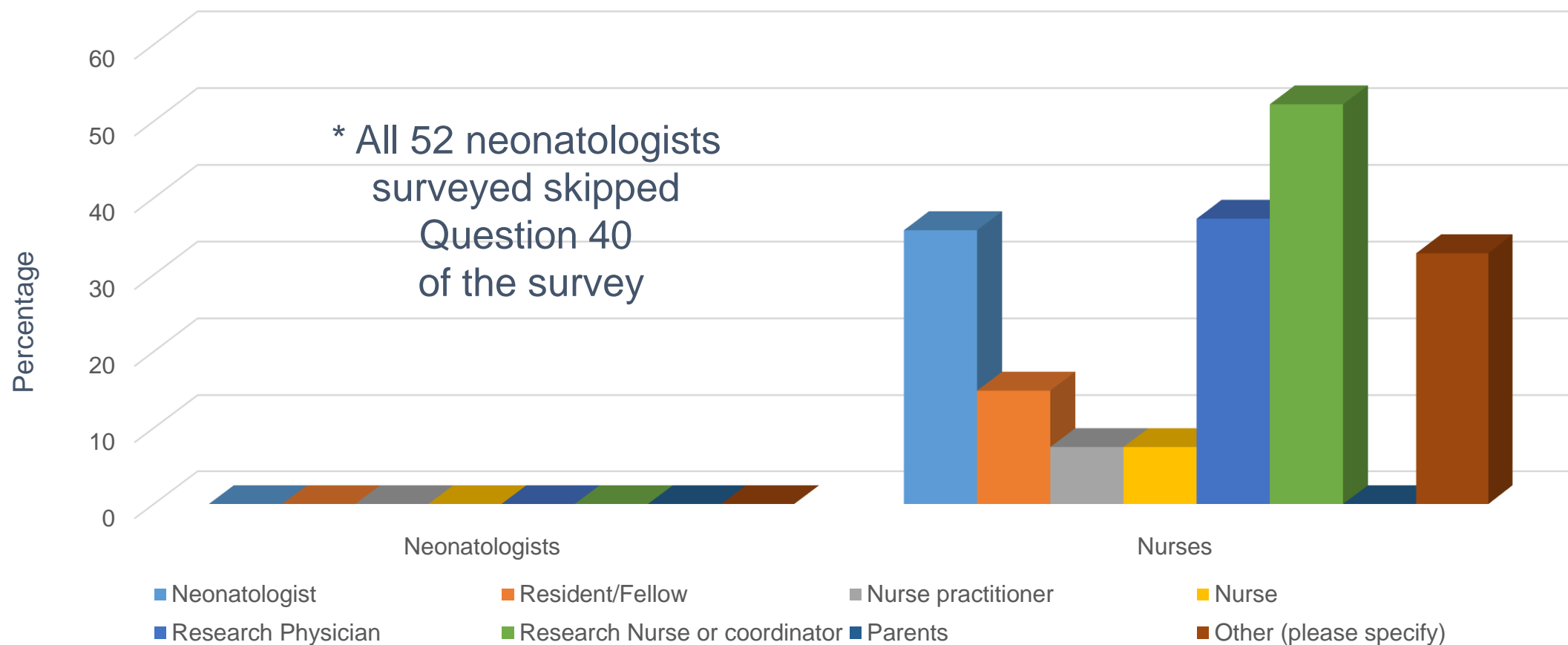
Only 67 of a potential 74 nurses who responded that their NICU/hospital “trains personnel on the role of clinical studies and the study consent process before they approach parents and ask for study consent” provided a response to this question

What training format is offered?*



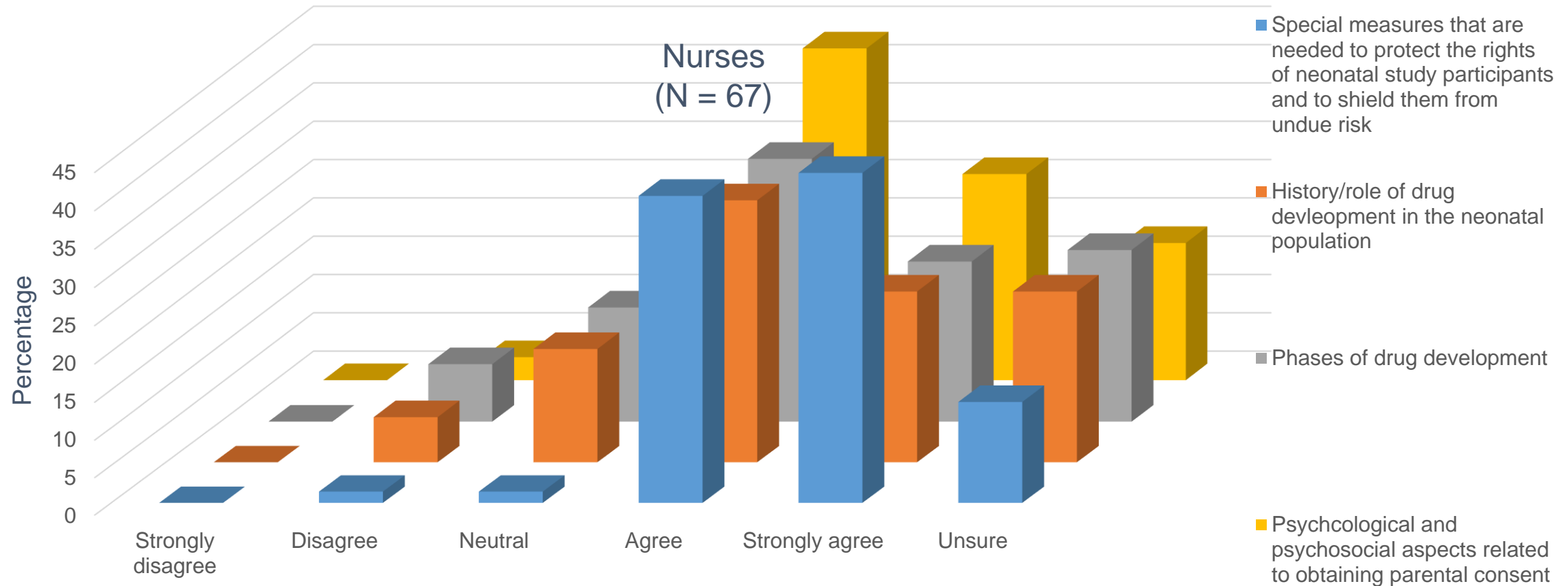
* Special Instructions: *Select all that Apply..*

Who teaches/leads the training?*



* Special Instructions: *Select all that Apply..*

Please rate your level of agreement that the following concepts are included in the NICU/hospital training curriculum*

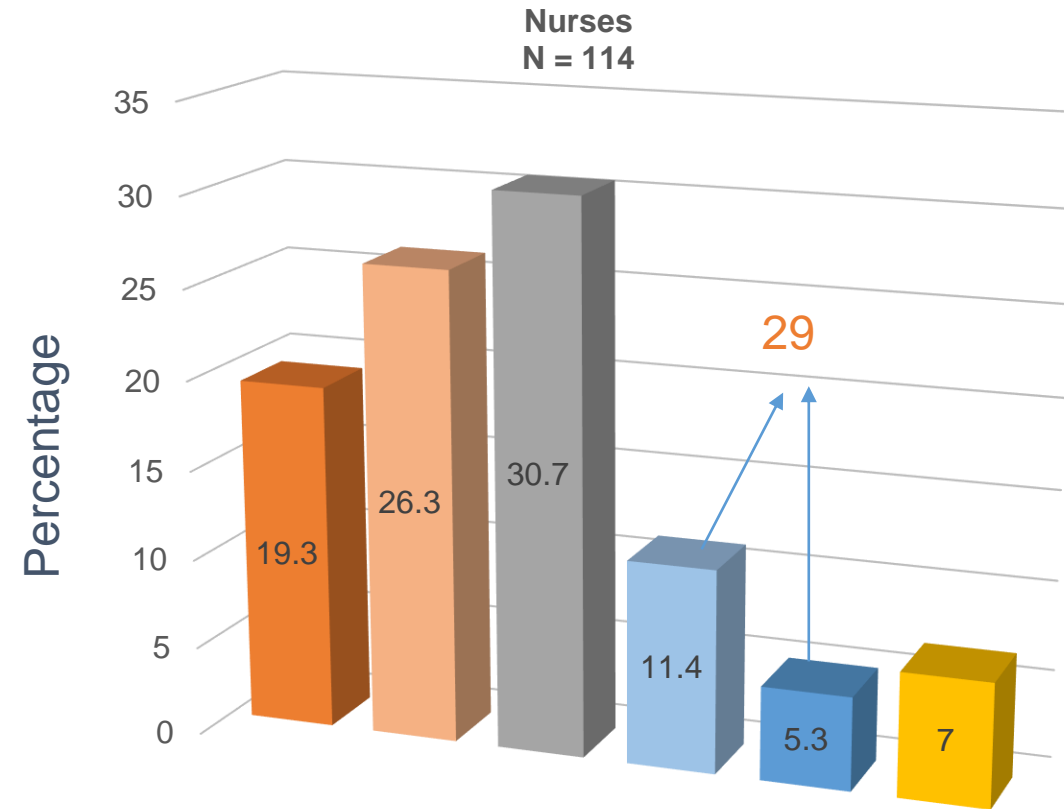


* All 52 neonatologists surveyed skipped Question 41 of the survey

* Special instructions: Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).

I am asked to provide input into study conduct in my hospital*

* All 52 neonatologists surveyed skipped Question 42 of the survey



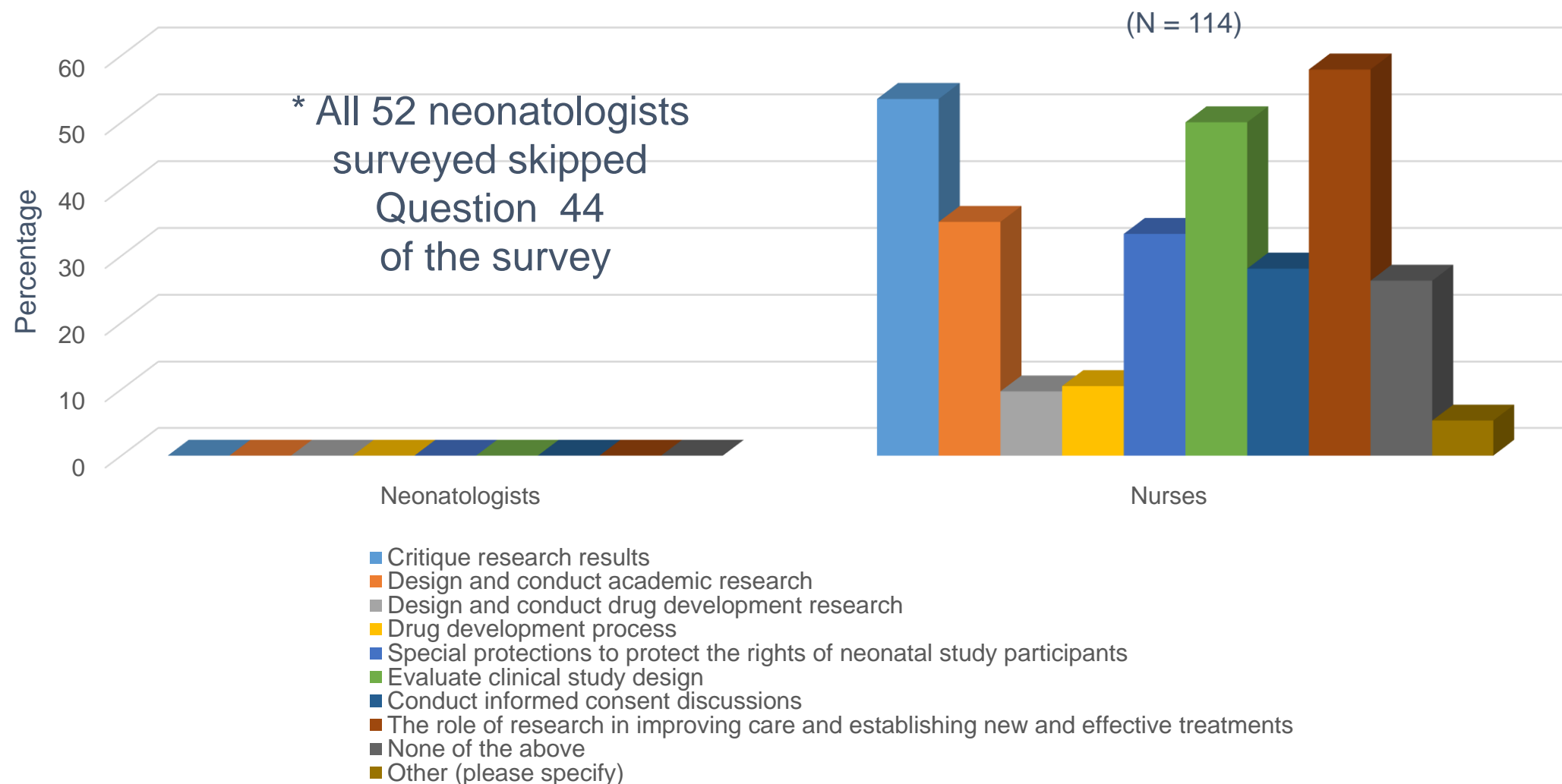
Strongly Disagree Disagree Neutral Agree Strongly Agree Unsure

* Special instructions: Please rate your level of agreement with the following statement on a scale of 1 (Strongly disagree) through 5 (Strongly agree).

If you indicated agreement (Agree or Strongly Agree) with the last Question, what is the input that was solicited?

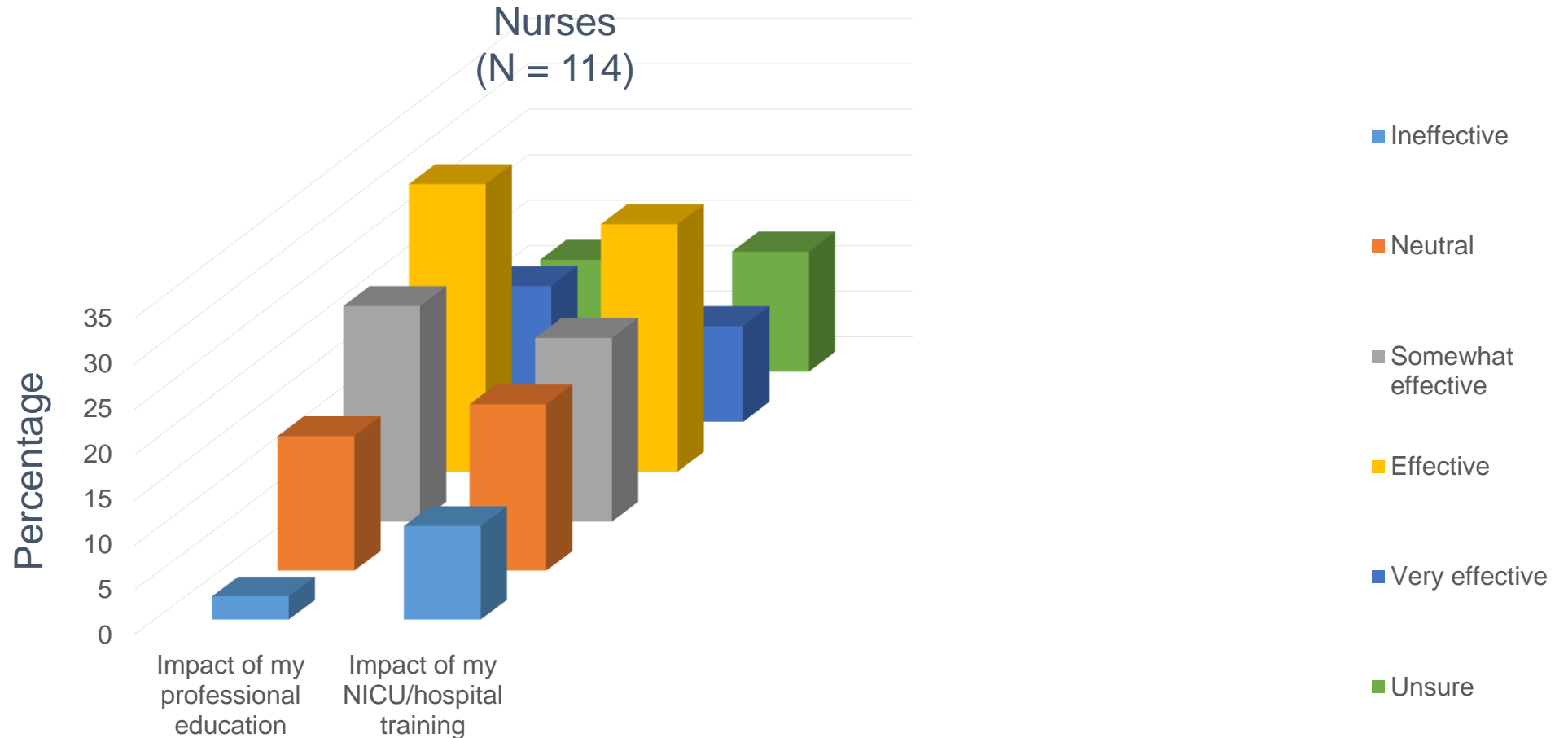
- Input from the nurse bedside prospective and data collection prospective
- As bedside nurse, we follow guidelines to stay within standards of the study! We have resources if we have questions about the study.
- **PLACEHOLDER for verbatims**

What type of training did you receive in your professional education on pediatric/neonatal research?*



* Special Instructions: *Select all that Apply.*

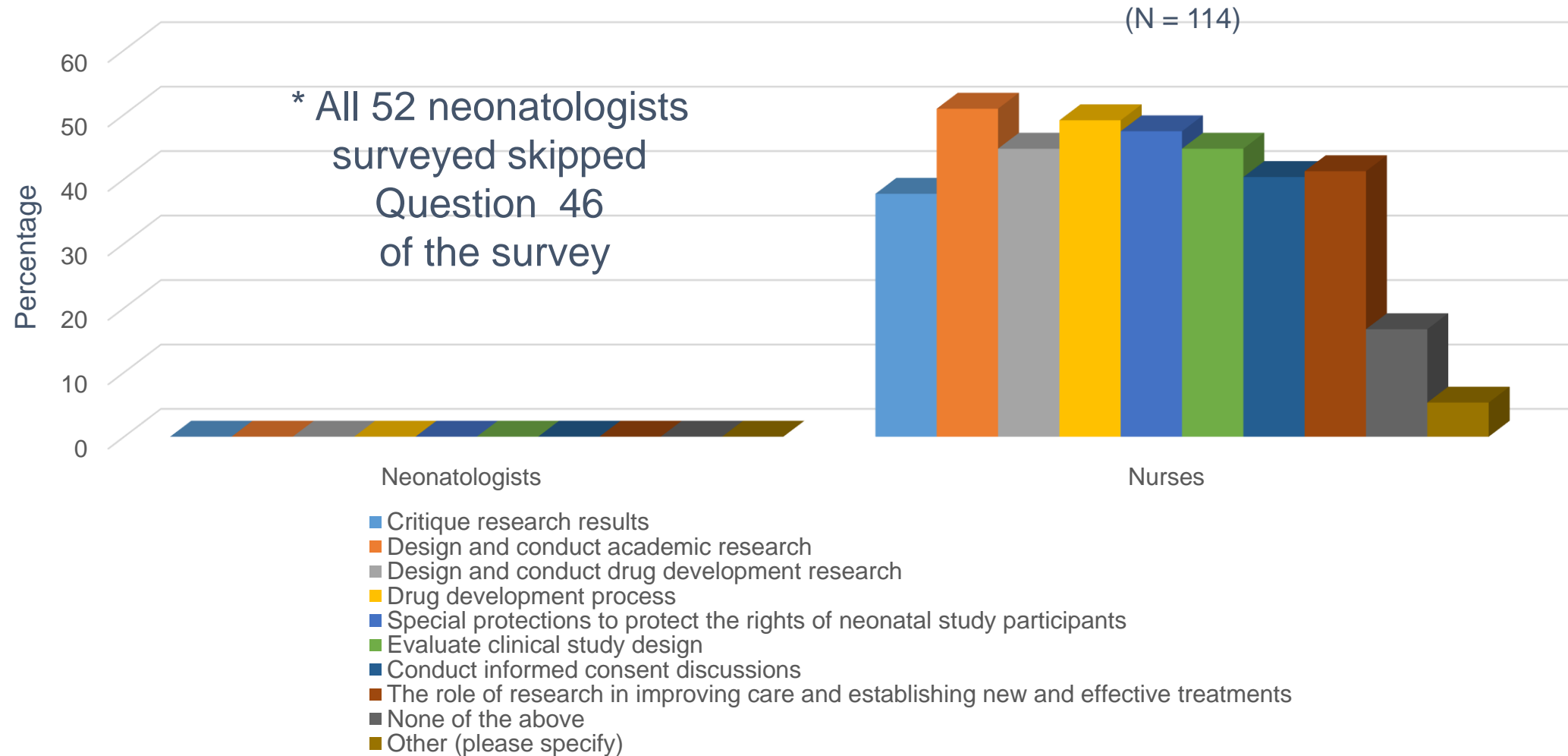
Please rate the effectiveness of your training (professional education or NICU/Hospital) on your ability to participate in the research activities in your NICU*



* All 52 neonatologists surveyed skipped Question 45 of the survey

* Special instructions: *Please rate the level of effectiveness on a scale of 1 (Ineffective) through 5 (Very effective).*

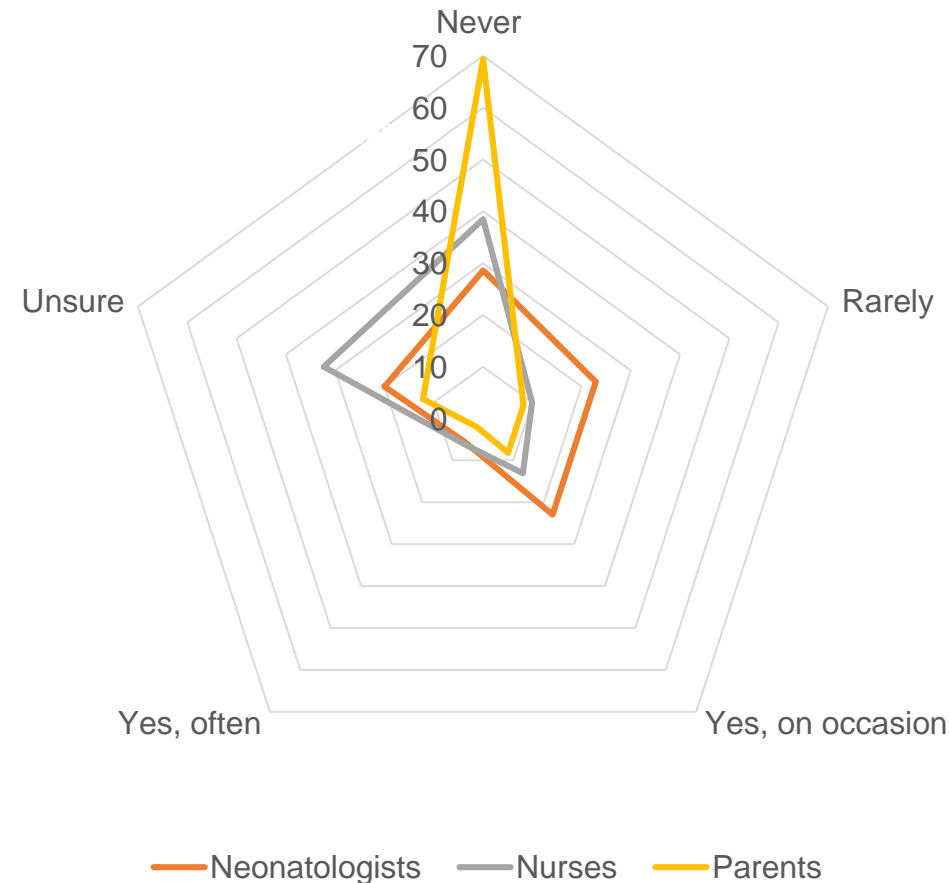
Please identify areas where additional professional education or hospital-based training on pediatric/neonatal research is needed for you to provide support to research activities in your NICU*



* Special Instructions: *Select all that Apply.*

Has your institution included NICU graduate families (whose sick newborns participated in research) in research education/training programs for current NICU parents? *

*** Moved from Part III ***



Respondents
- Neonatologists (35)
- Nurses (130)
- Parents (49)

Question for parents used different wording: *In the hospital/NICU where your baby was cared for, did NICU graduate families participate as teachers in education/training programs for current NICU parents?*



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Part V: Research Consent Process





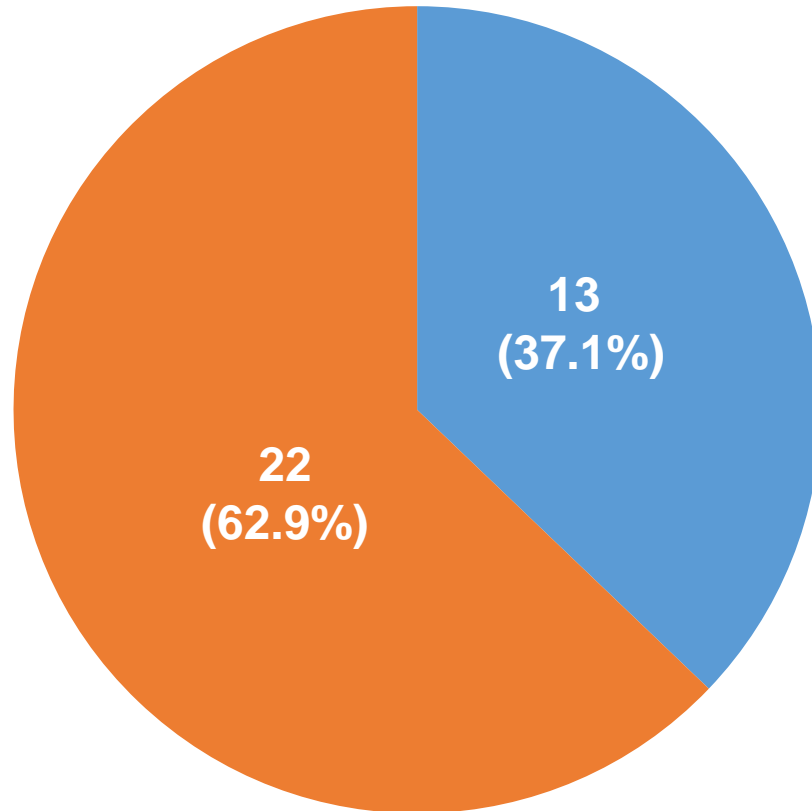
International Neonatal Consortium

Part V: Research Consent Process (Neonatologist / Nurse-specific)



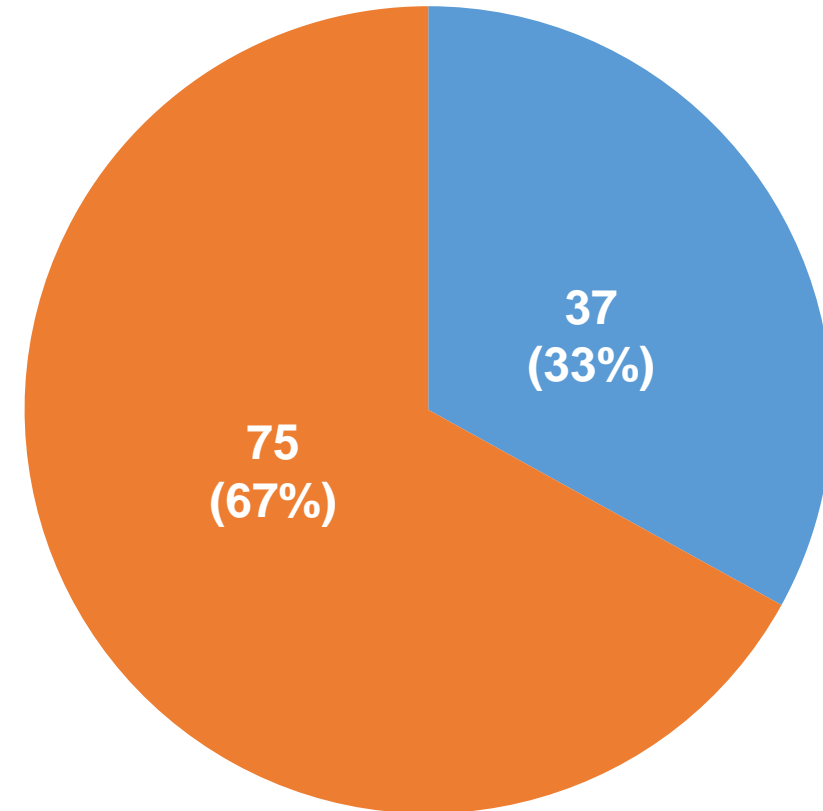
In your NICU, is consent required for delivery of routine clinical care (e.g. blanket consent, admission consent)?

Neonatologists



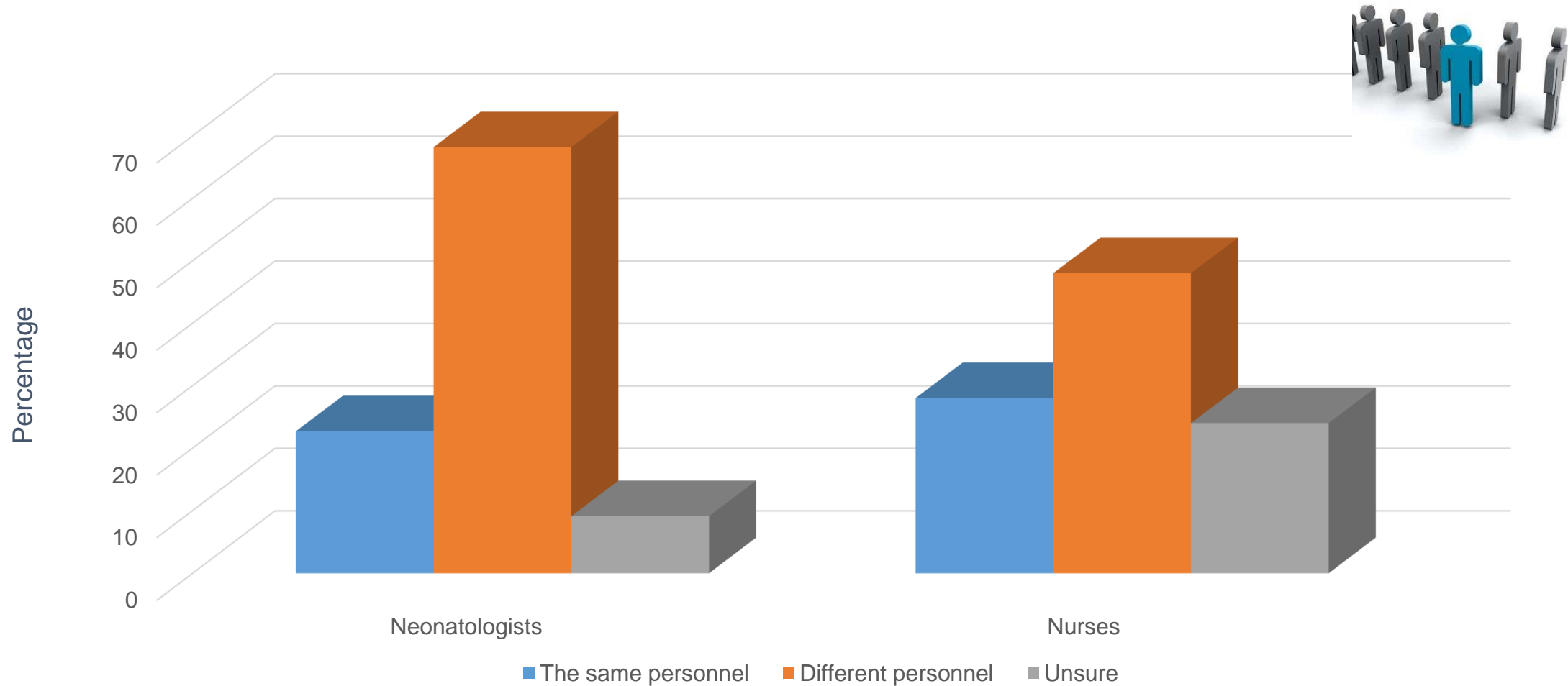
■ No ■ Yes

Nurses

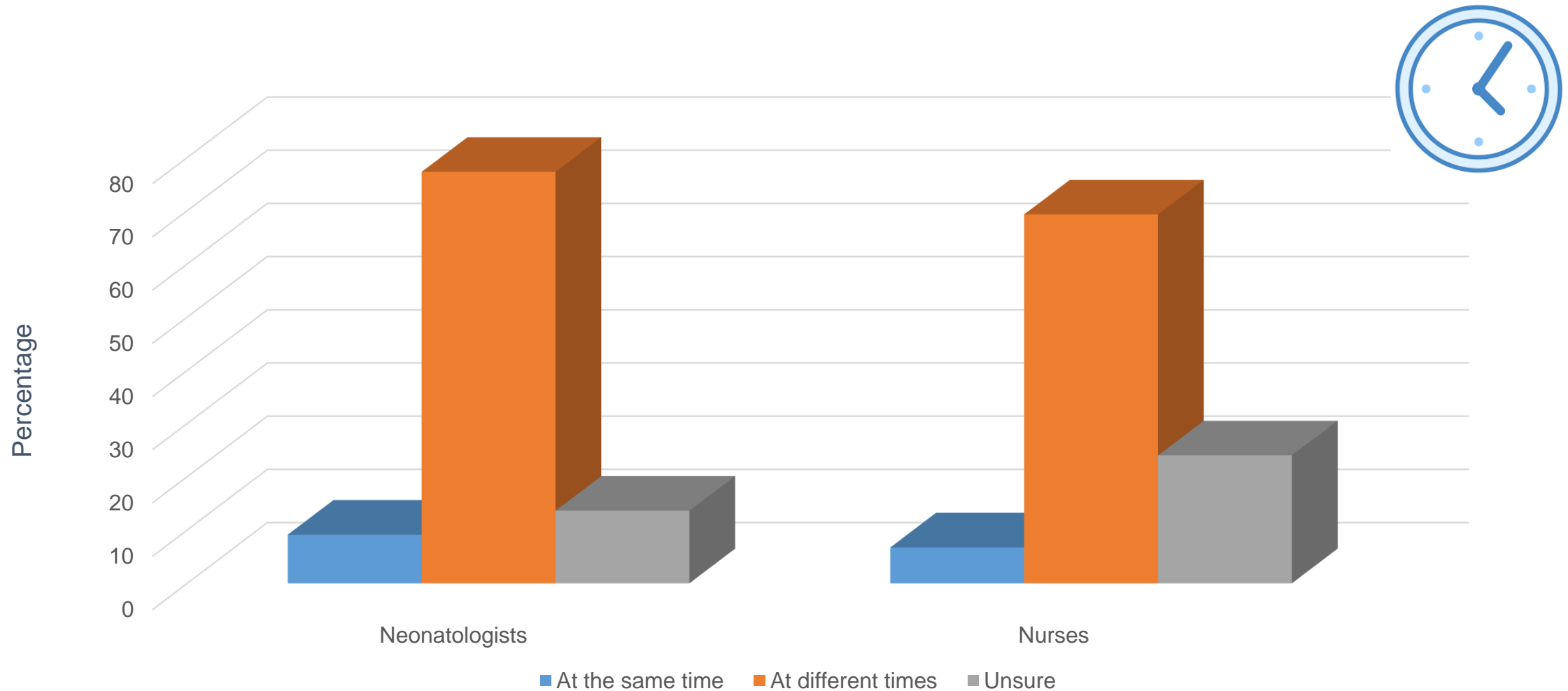


■ No ■ Yes

In your NICU, is consent for delivery of routine clinical care and consent for participation in research obtained by ...

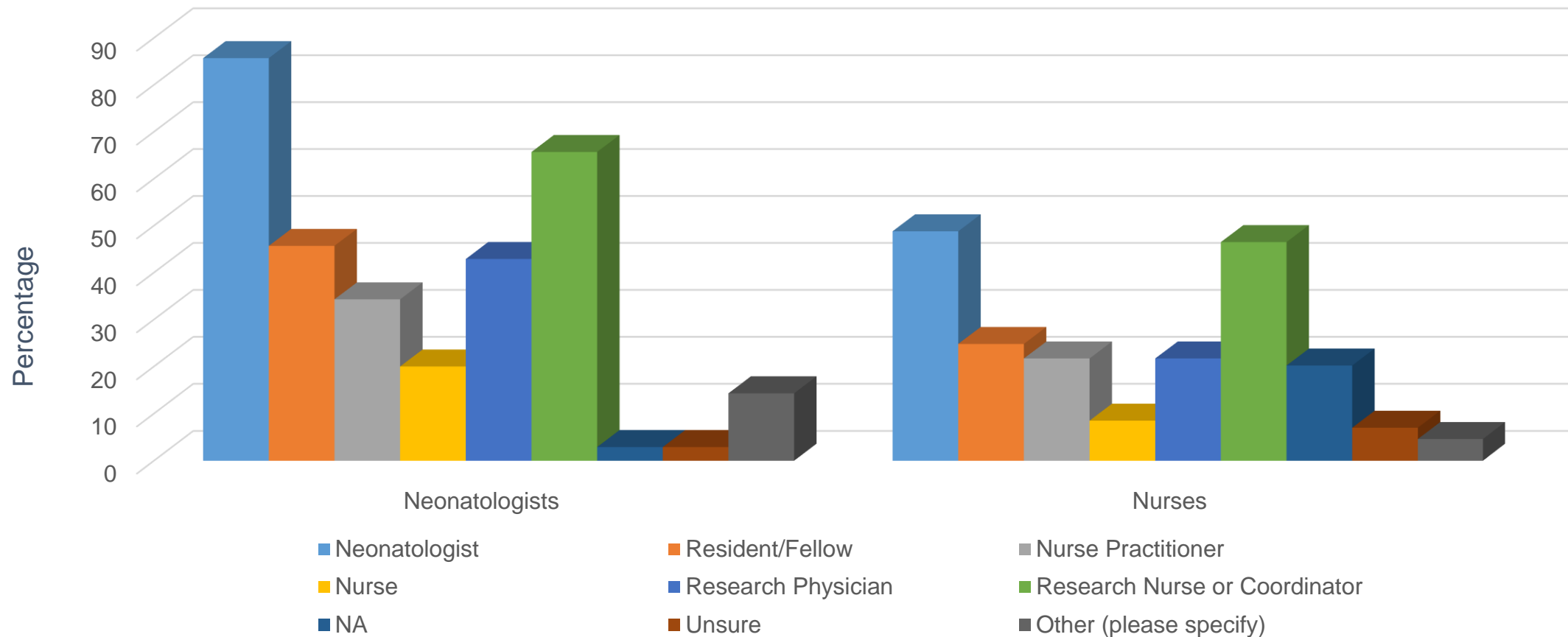


In your NICU, are consents for delivery of routine clinical care and consent for participation in research obtained ...



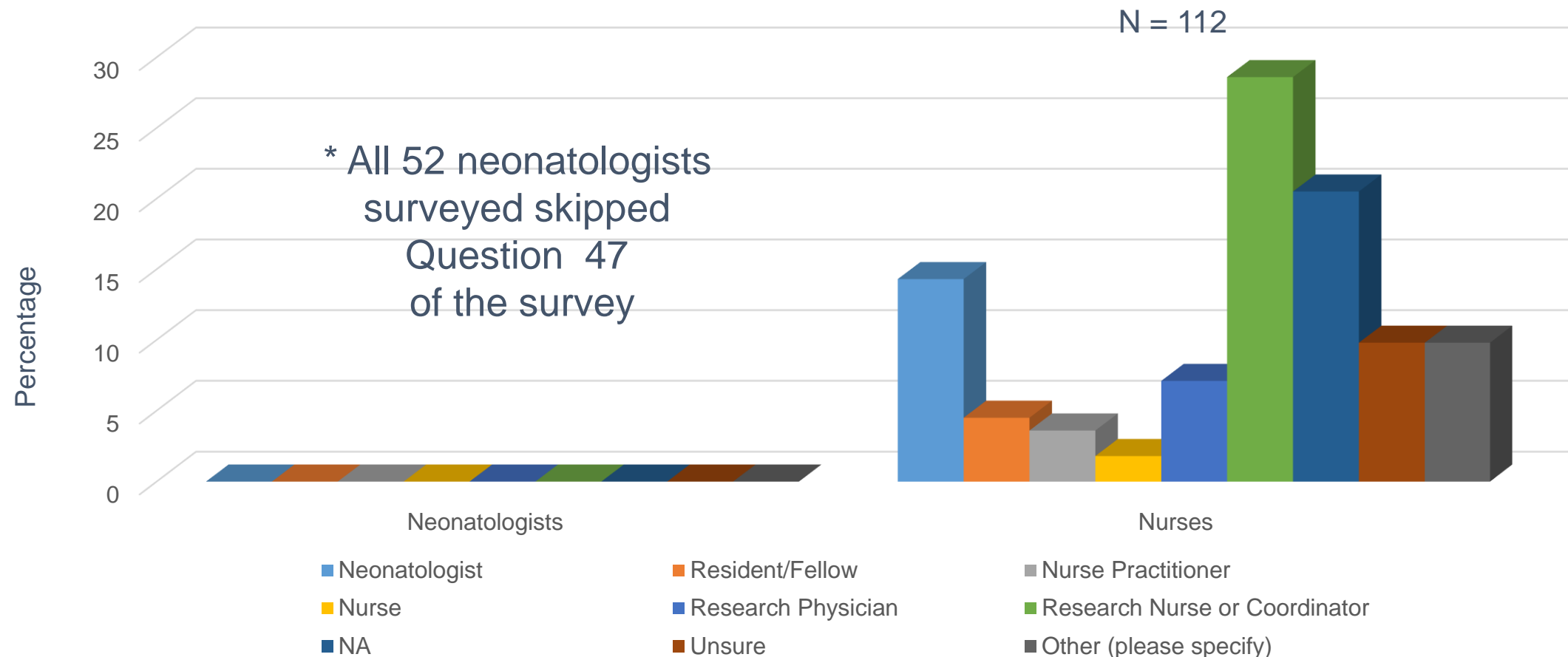
In your NICU, who (personnel) is responsible for approaching parents and asking them about enrolling their sick newborn in a clinical study?*

***** Moved from Part IV *****



* Special Instructions: *Select all that Apply*; NA = Our NICU is not a research center.

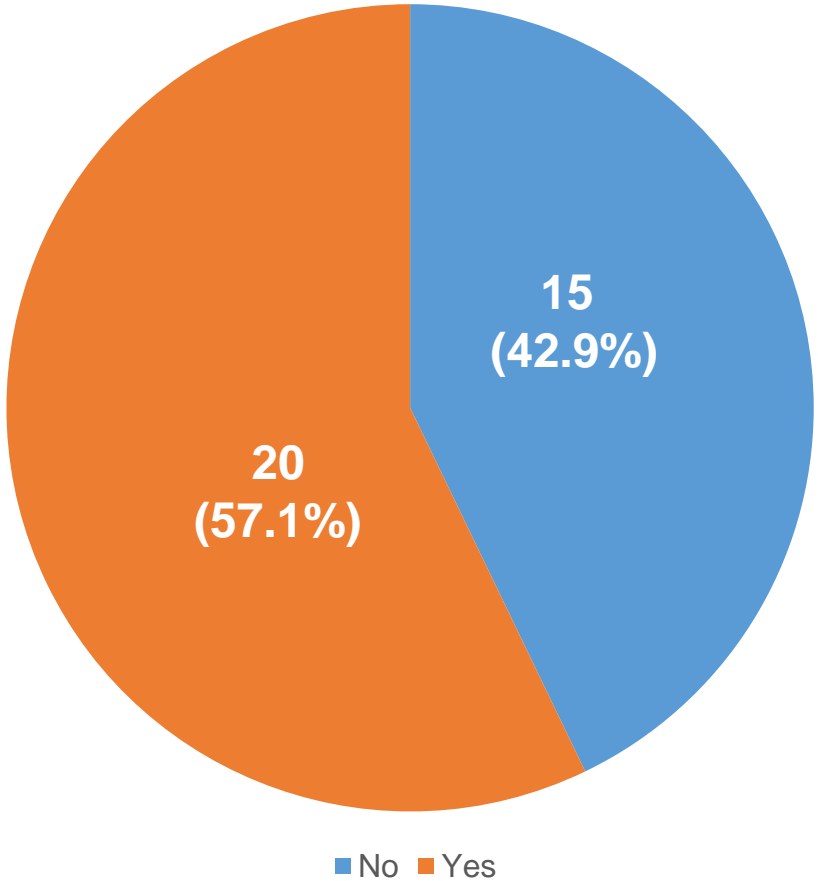
In your NICU, who (personnel) is responsible for obtaining consent from parents to enroll their sick newborn in a clinical study?*



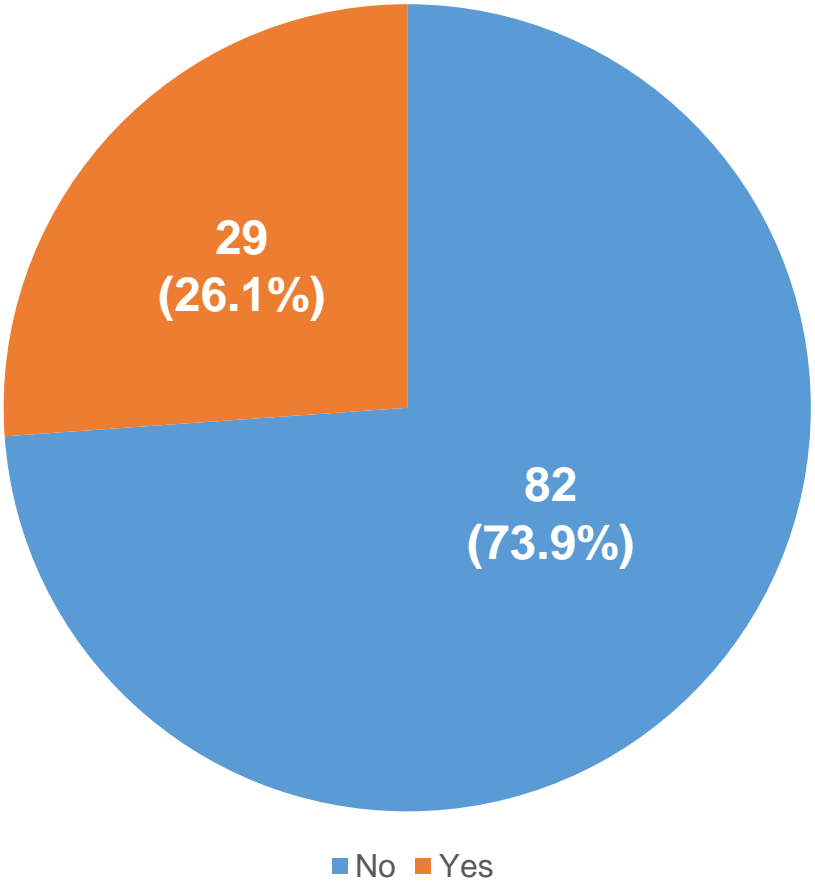
* Special Instructions: *Select all that Apply*; NA = Our NICU is not a research center.

Are sick newborns in your NICU recruited to more than one study at time?

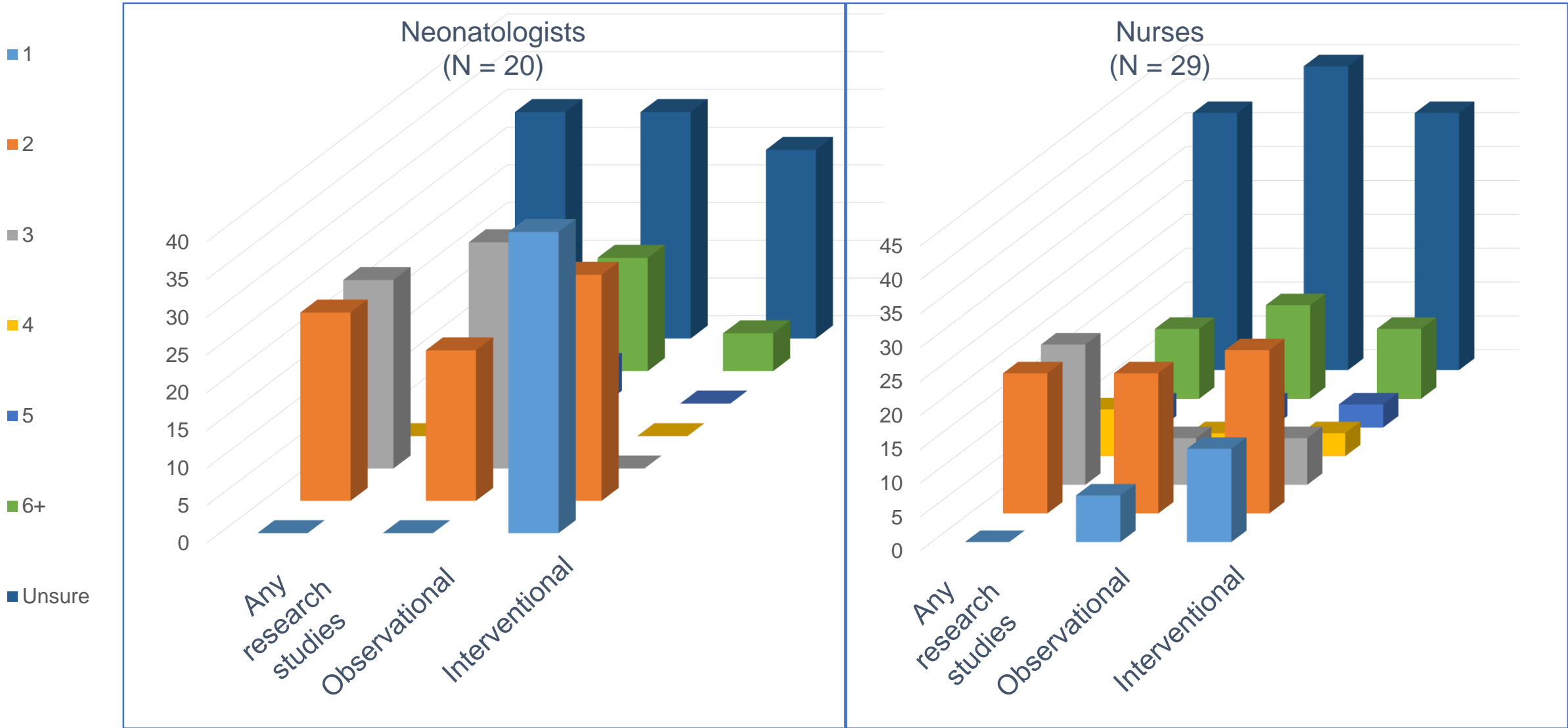
Neonatologists



Nurses



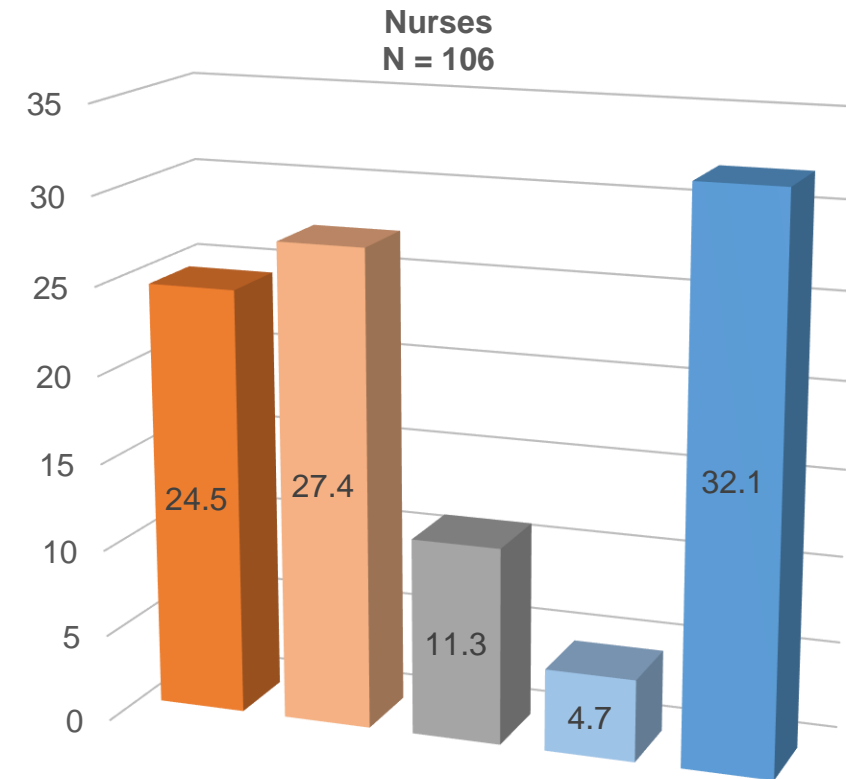
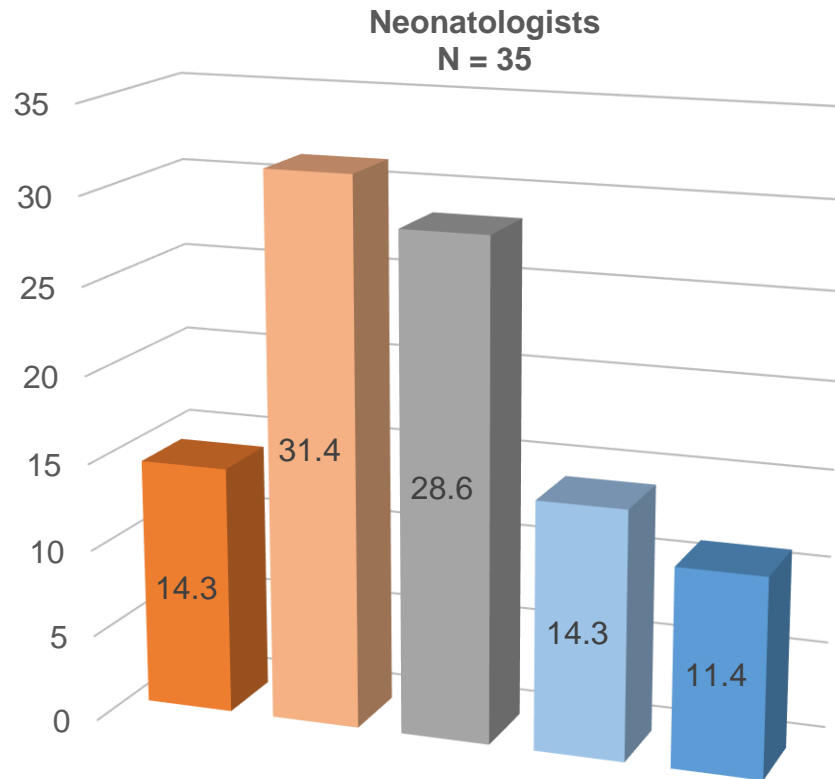
Please quantify the maximum number of studies a family would be approached with at any one time?



Observational was defined as “where the researcher has no control over the variables”; Interventional was defined as “where patients are assigned to a treatment group”.

Please rate your NICU/hospital on the timing of approach or consent of families for research on a Scale of “Never” to “Always” (1)

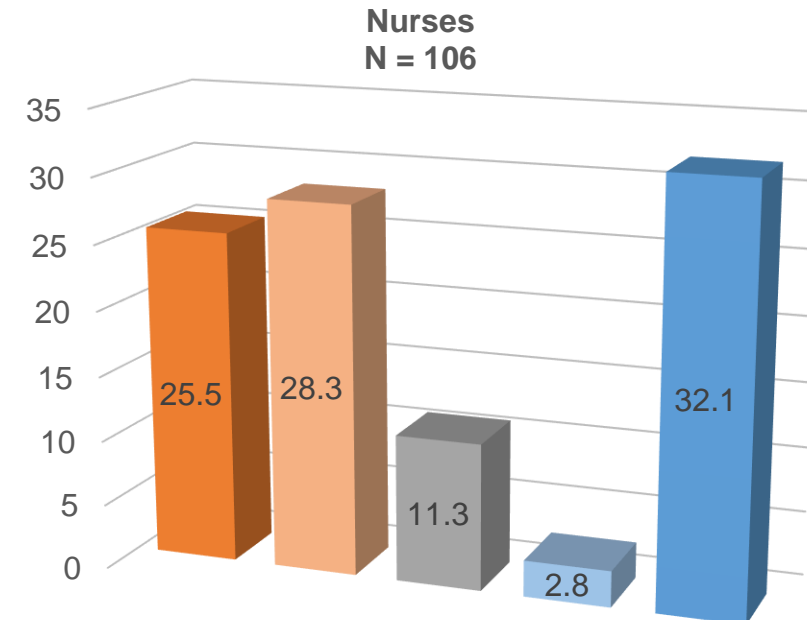
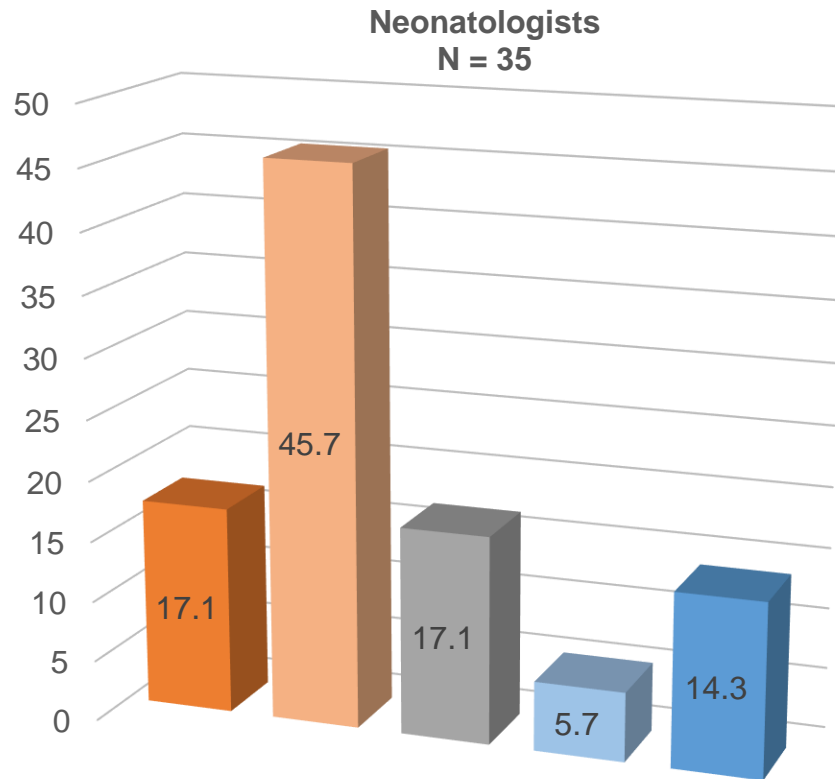
When a mother is admitted with adequate time, families are approached to discuss research before the birth of a sick newborn (%)



Never Sometimes Usually Always Unsure

Please rate your NICU/hospital on the timing of approach or consent of families for research on a Scale of “Never” to “Always” (2)

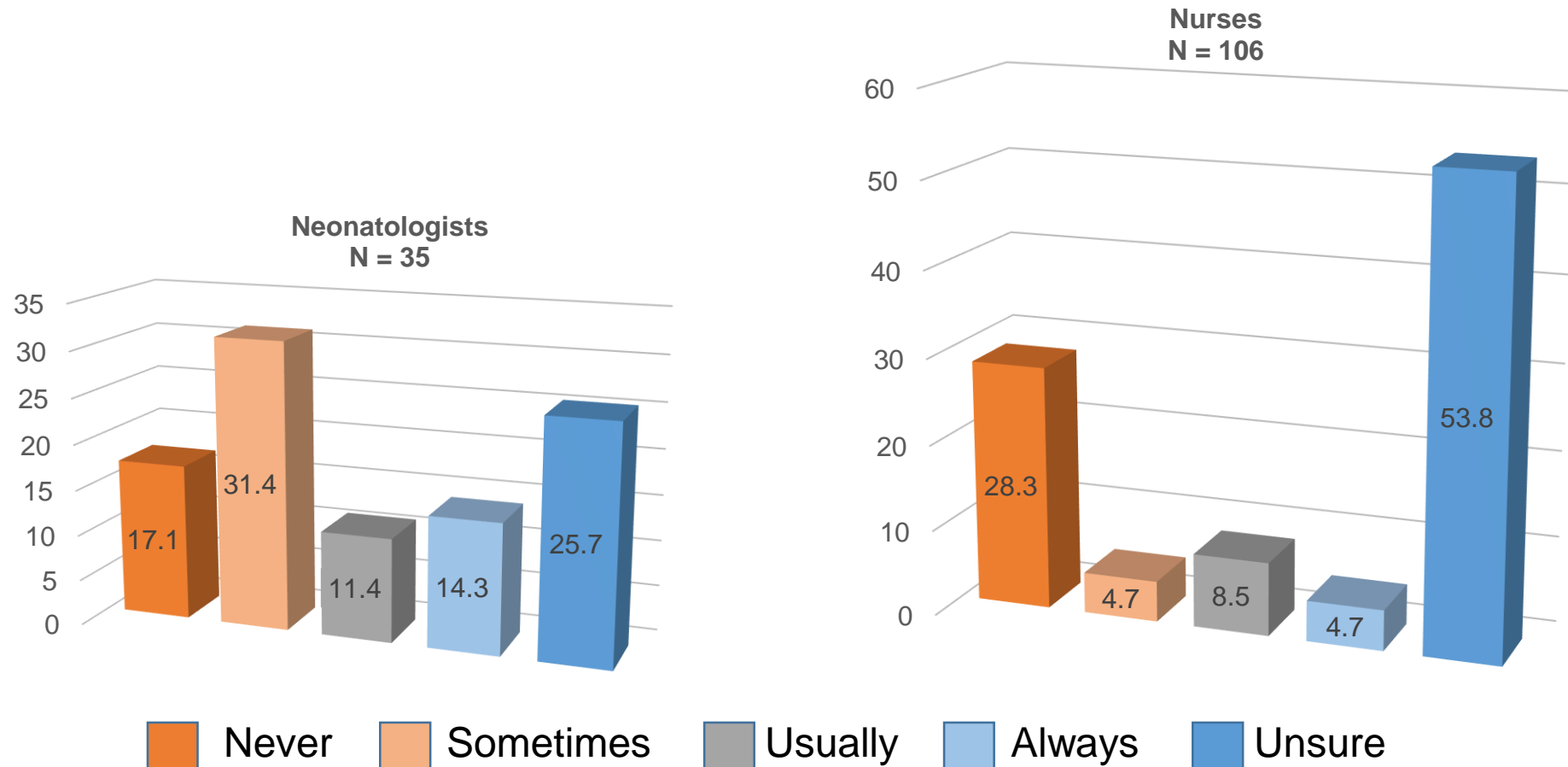
When a mother is admitted with adequate time, consent for study participation is sought from families before the birth of a sick newborn (%)



Never Sometimes Usually Always Unsure

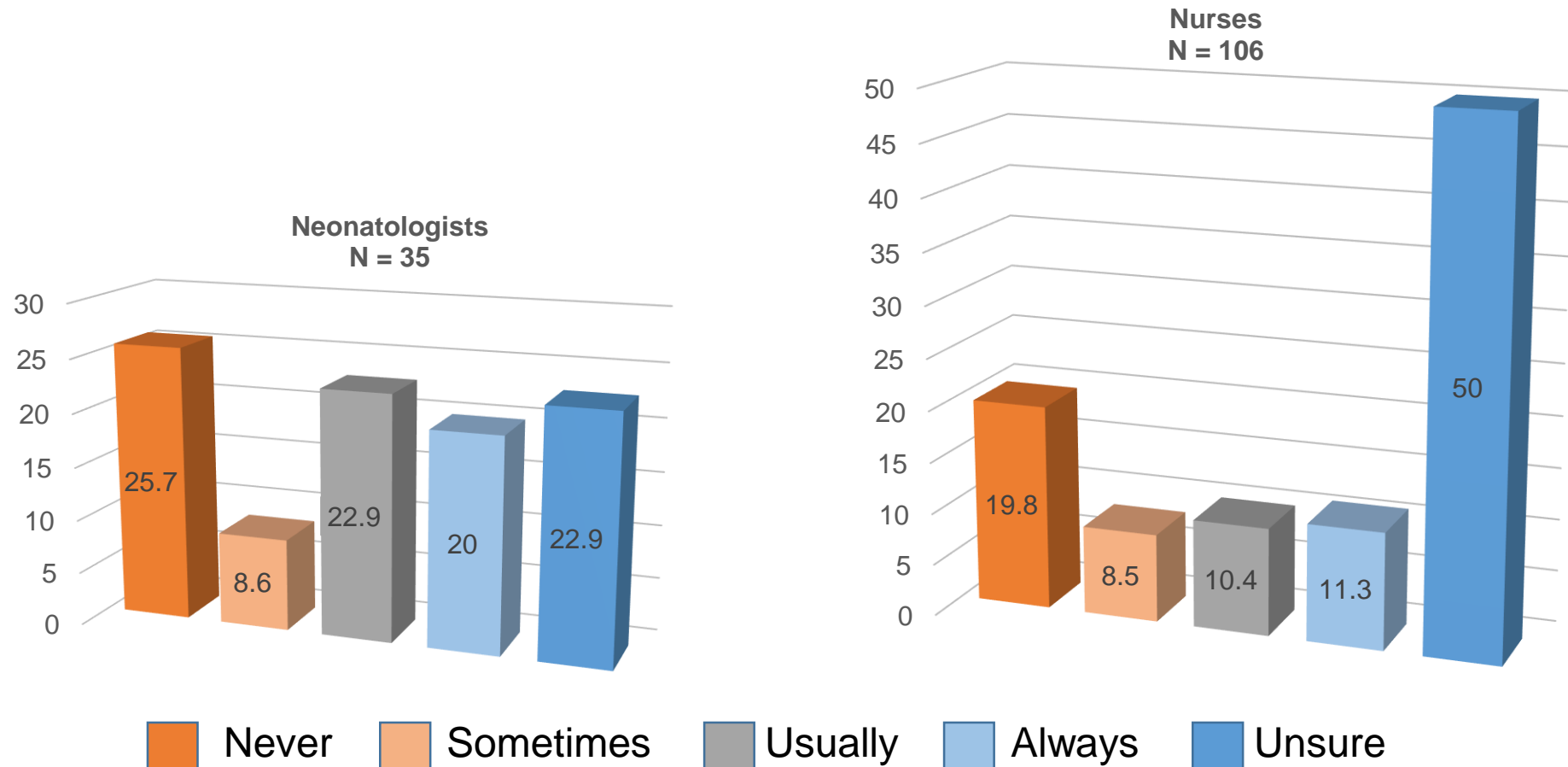
Please rate your NICU/hospital on the timing of approach or consent of families for research on a Scale of “Never” to “Always” (3)

When consent is obtained prior to birth for participation in a study, re-consent is obtained after the birth of a sick newborn (%)



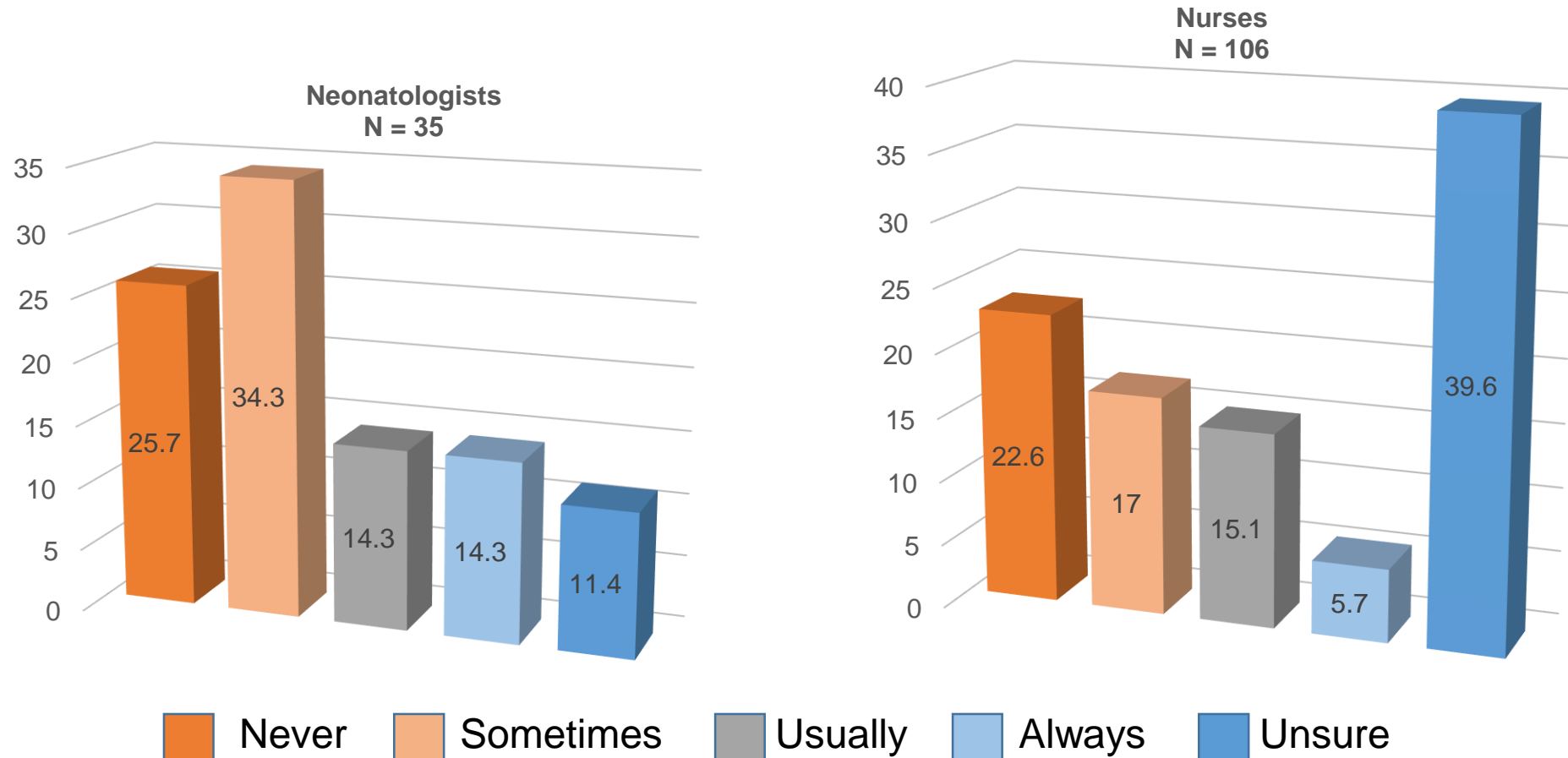
Please rate your NICU/hospital on the timing of approach or consent of families for research on a Scale of “Never” to “Always” (4)

Continuous consent (baby in study, therapy administered, ongoing assessments) is incorporated into research protocols (%)



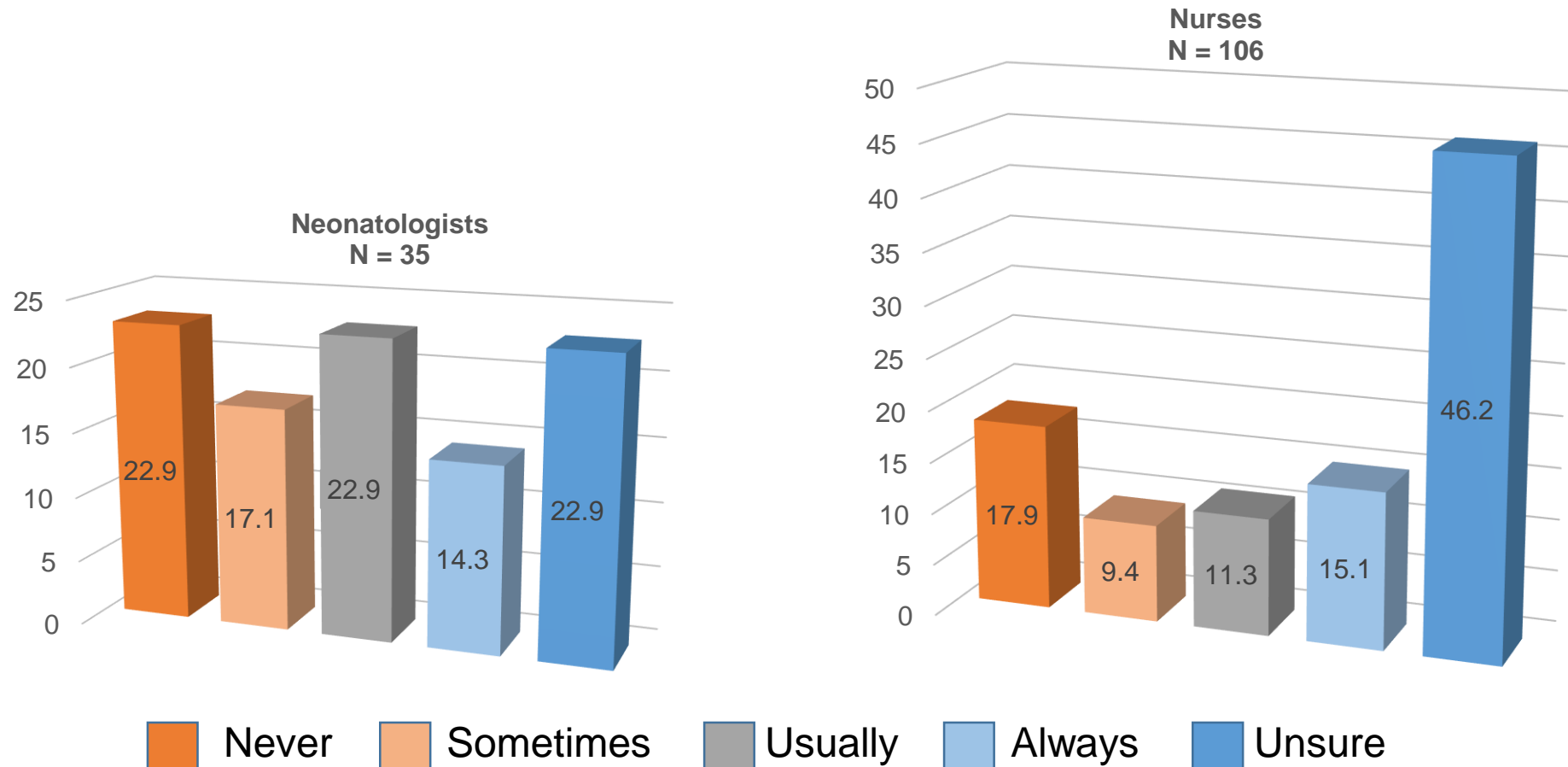
Please rate your NICU/hospital on the timing of approach or consent of families for research on a Scale of “Never” to “Always” (5)

Consent is obtained in advance of anticipated events (e.g., stable 24 week preemie who may have a fever at a later time) (%)



Please rate your NICU/hospital on the timing of approach or consent of families for research on a Scale of “Never” to “Always” (6)

Affirmation of consent is required as a routine part of research (e.g., stable 24 week preemie previously consented now spikes fever requiring antibiotics) (%)



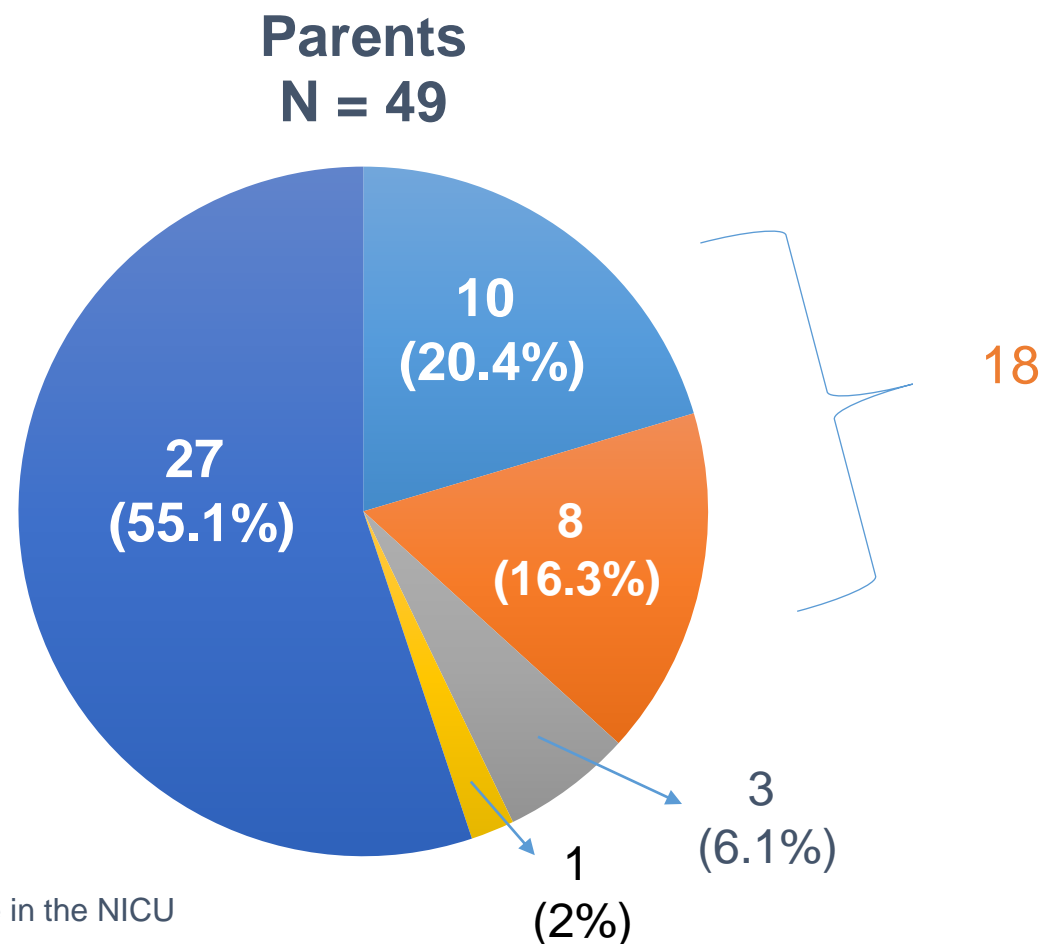


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Part V: Research Consent Process (Parent-specific)



Please indicate how your baby was involved in research while hospitalized in the Neonatal Unit.



■ My baby was enrolled in a research study while in the NICU

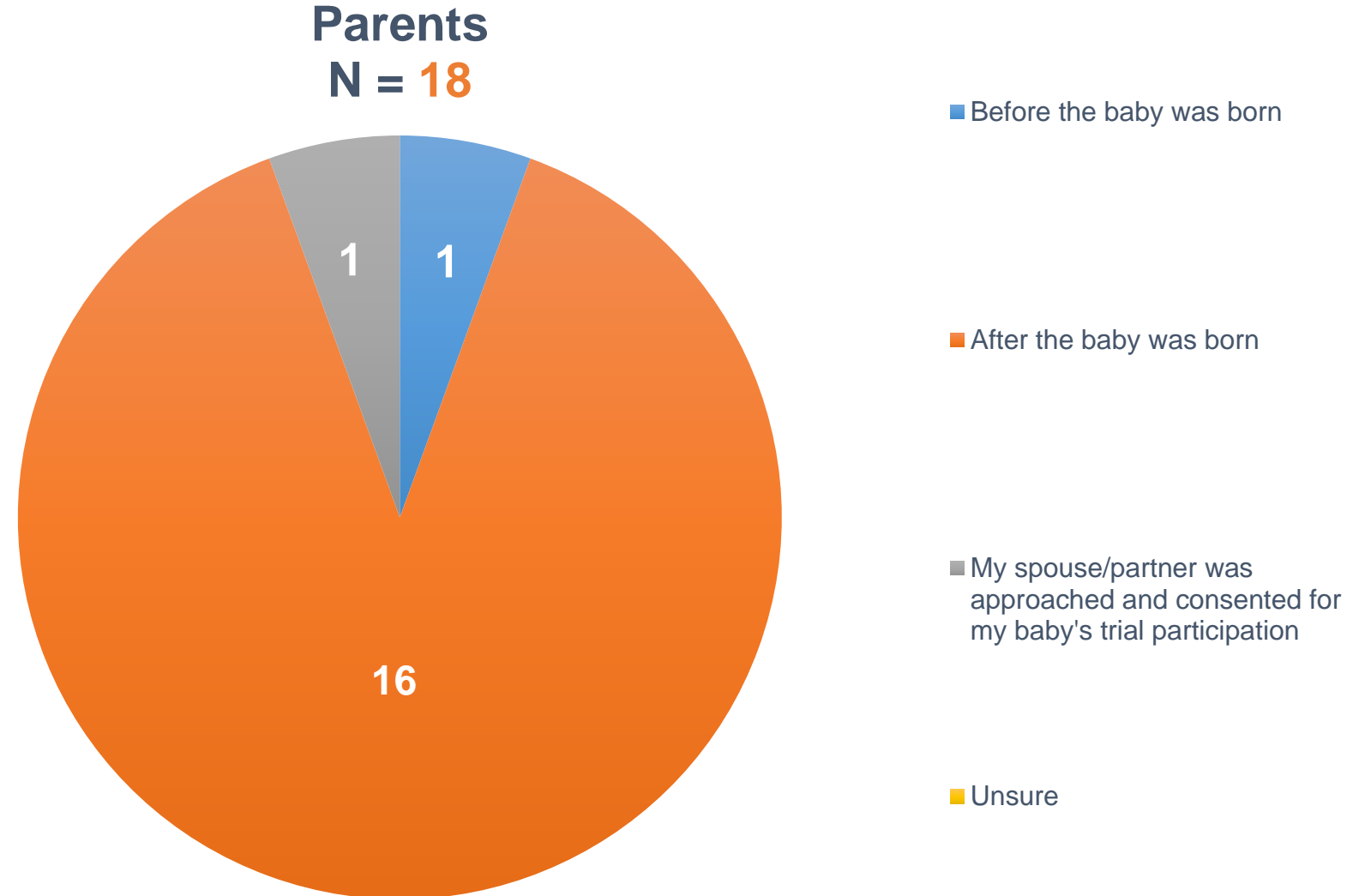
■ My baby was enrolled in > 1 research study while in the NICU

■ I was asked for my baby to participate in a research study in the NICU, however, we declined participation after screening

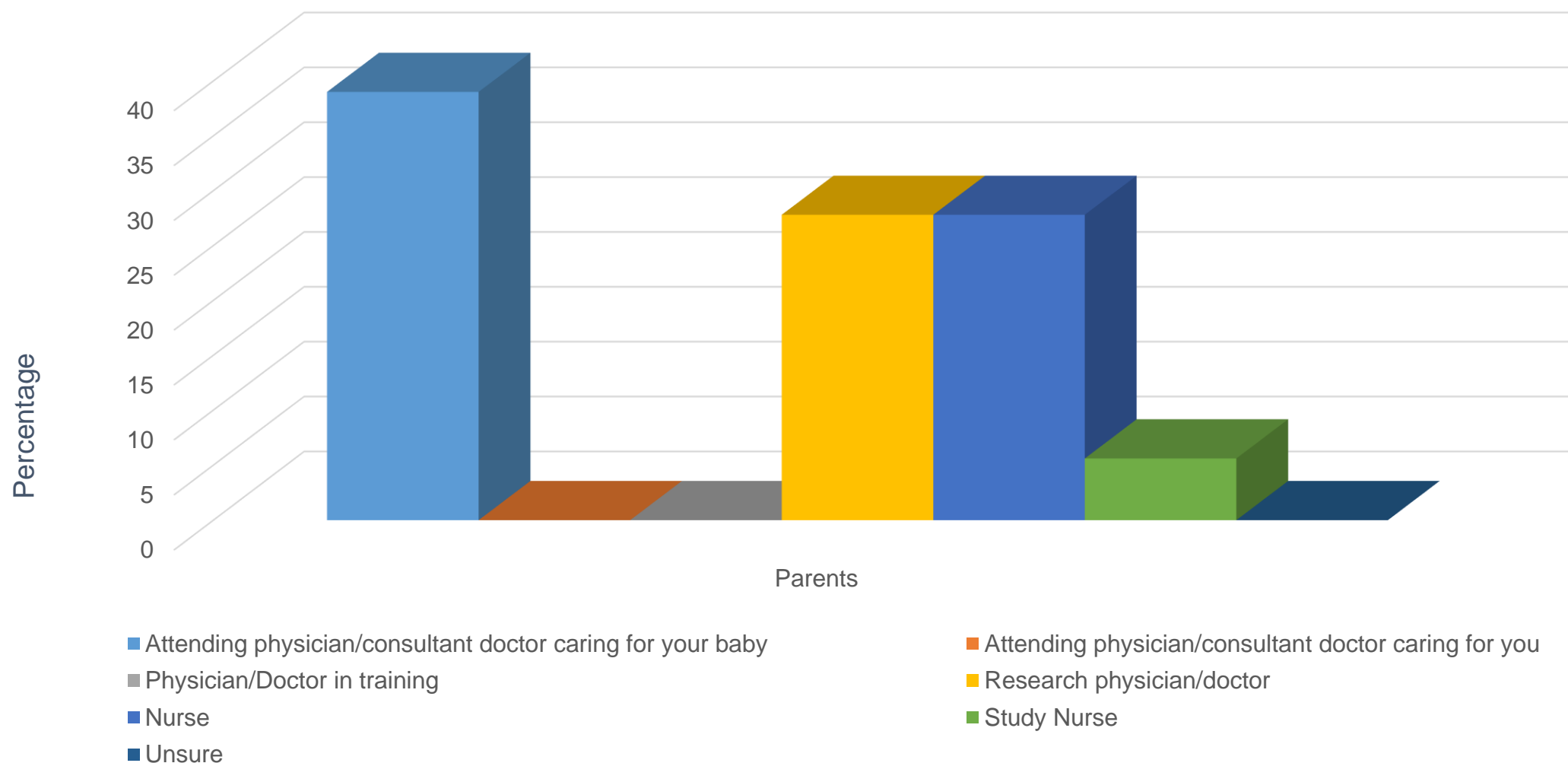
■ I provided consent for my baby to participate in a research study in the NICU, however, my baby did not qualify for study participation after screening

■ I was never asked for my baby to participate in a research study while in the NICU

When were you approached to consent for your baby to participate in a study?



Who first approached you to ask for consent for your baby to participate in a study?

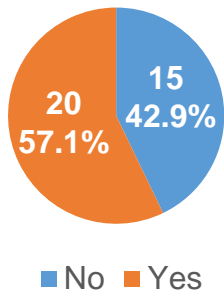


* Special Instructions: *Select all that Apply*; NA = Our NICU is not a research center.

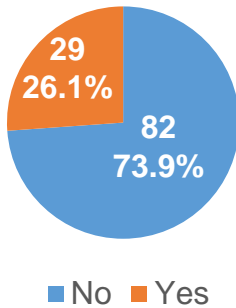
Were you approached for your baby to participate in more than one study?

Are sick newborns in your NICU recruited to more than one study at time?

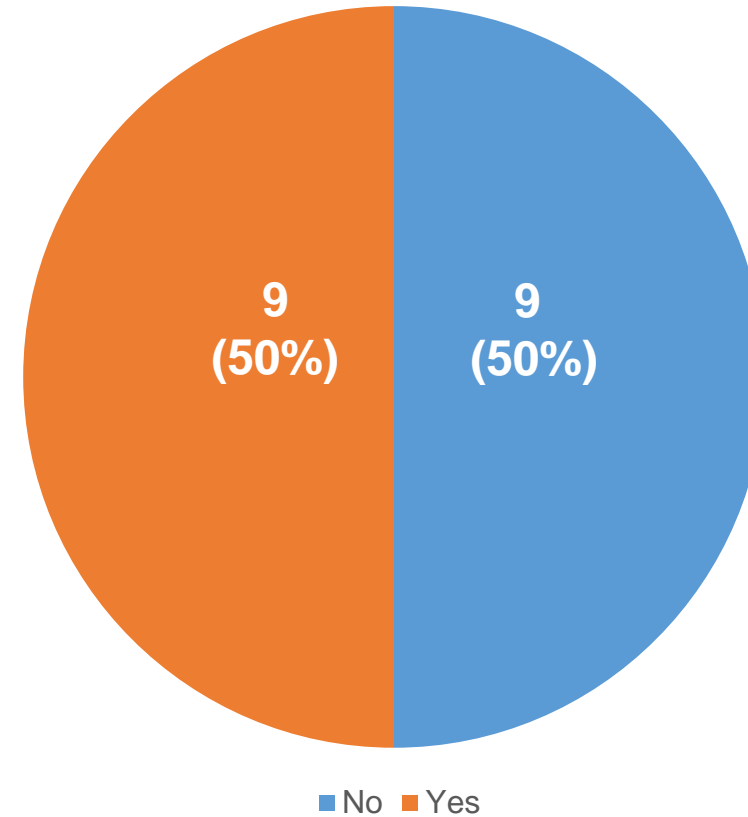
Neonatologists



Nurses



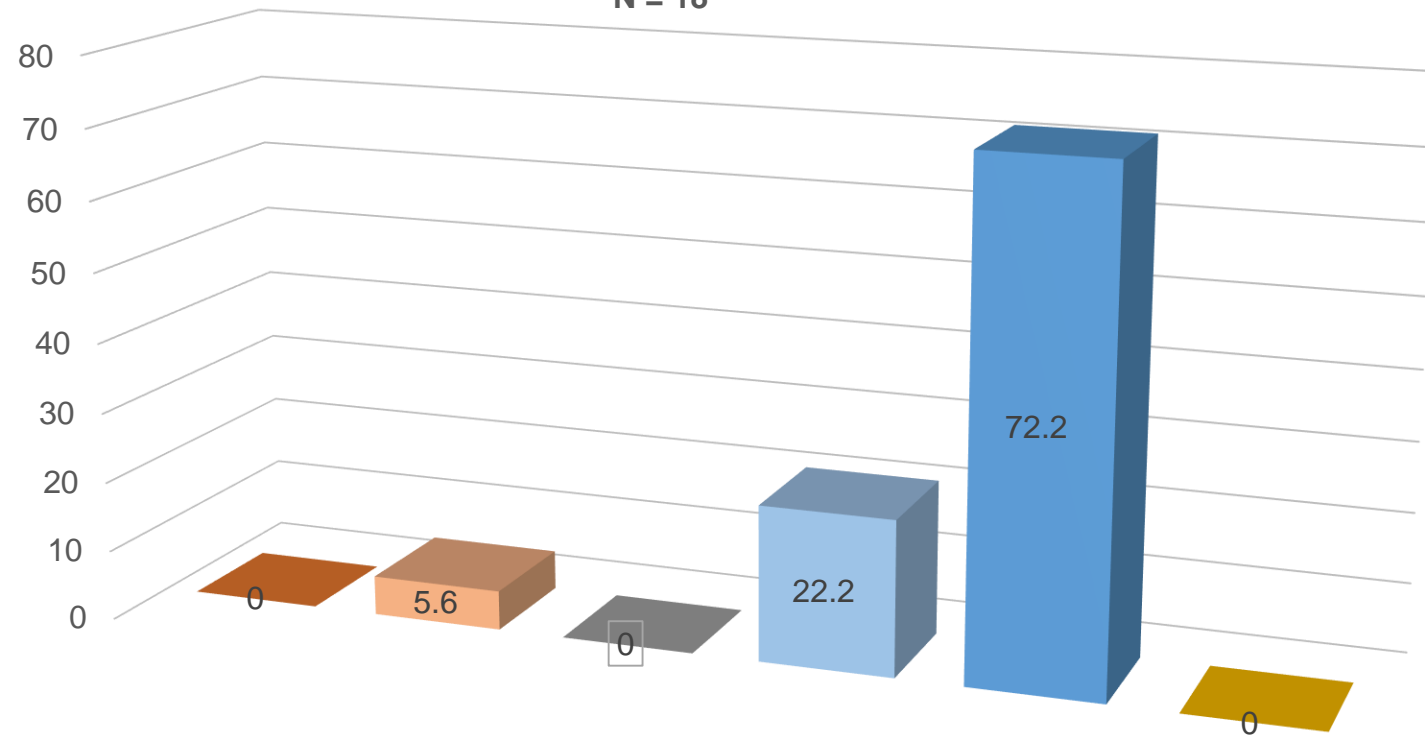
Parents
N = 18



The following questions are regarding the consent process* (1)

I felt comfortable asking questions before I agreed/declined to consent for my baby's participation (%)

Parents
N = 18



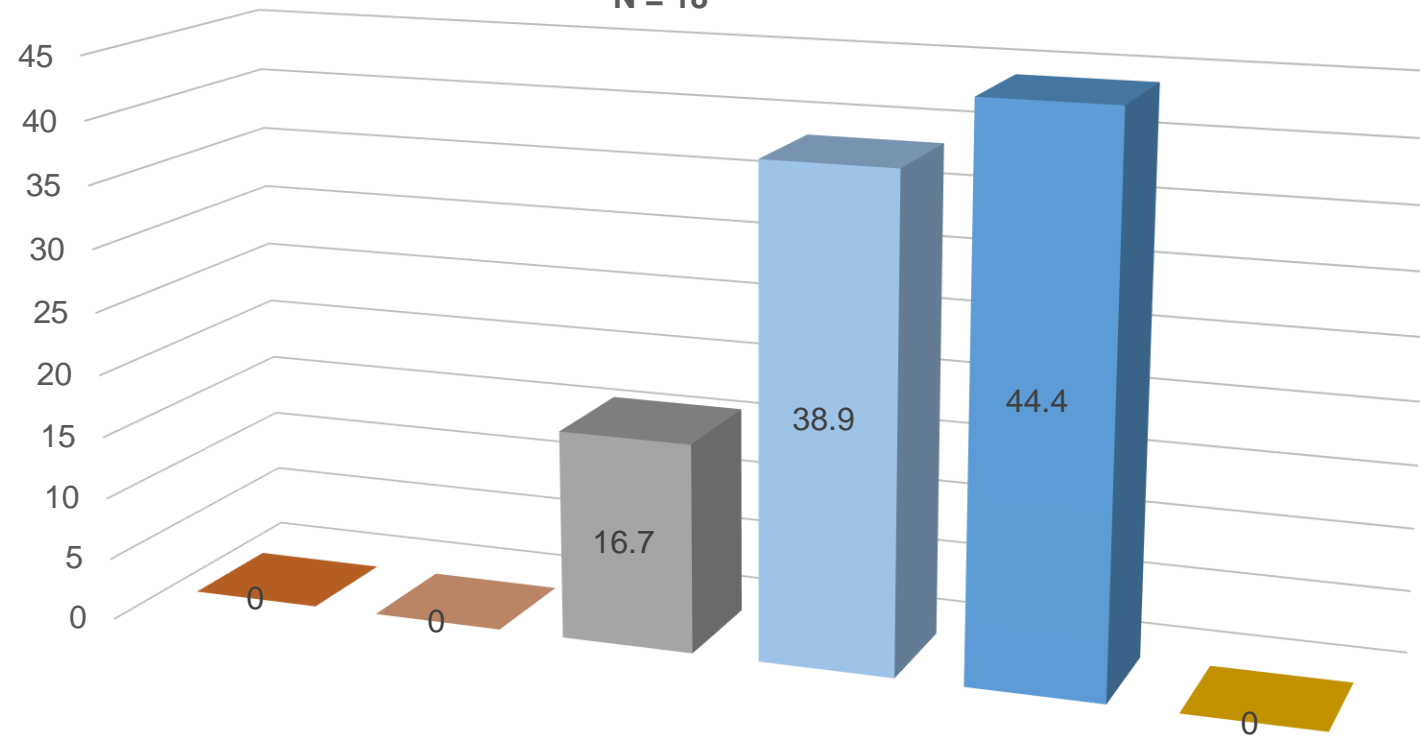
Strongly Disagree Disagree Neutral Agree Strongly Agree Unsure

* Special instructions: Please rate your level of agreement with the following statement on a scale of 1 (Strongly disagree) through 5 (Strongly agree).

The following questions are regarding the consent process* (2)

I had enough time to consider whether my baby should participate in the study (%)

Parents
N = 18

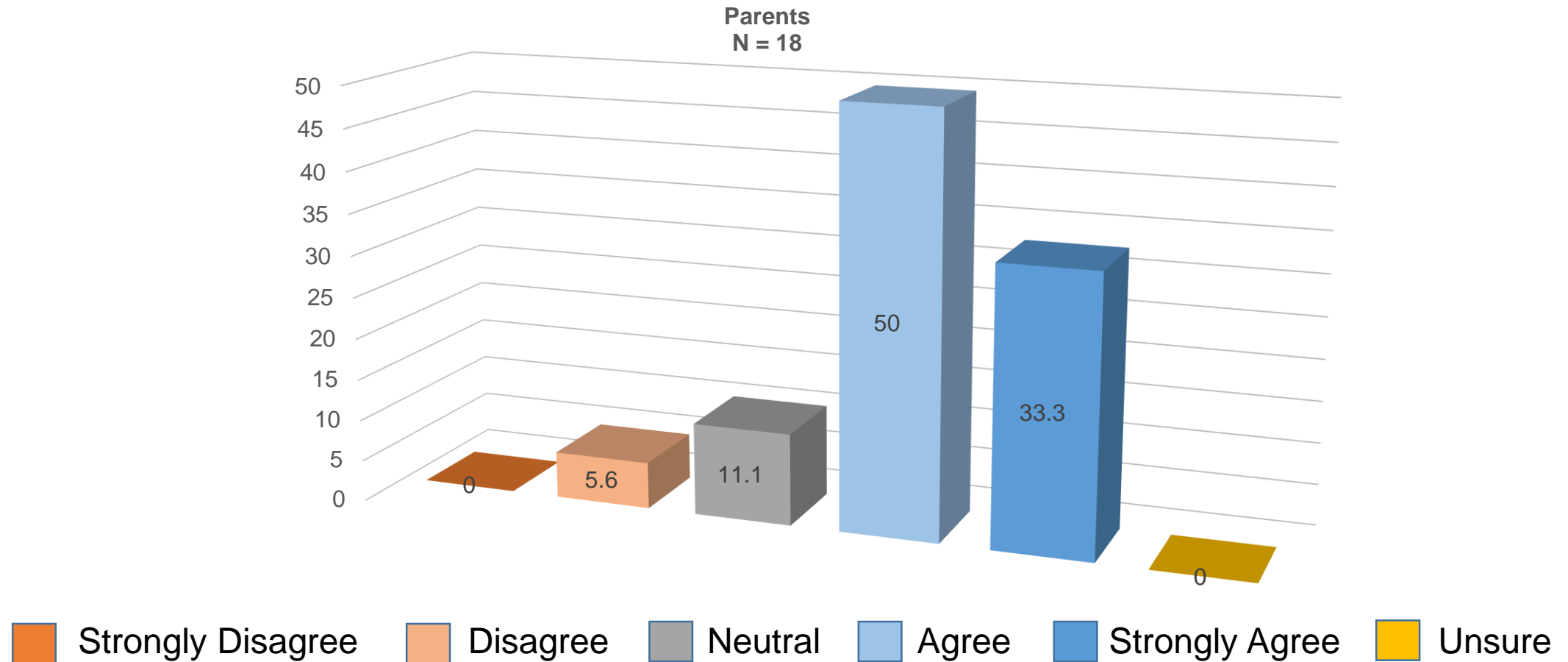


Strongly Disagree Disagree Neutral Agree Strongly Agree Unsure

* Special instructions: Please rate your level of agreement with the following statement on a scale of 1 (Strongly disagree) through 5 (Strongly agree).

The following questions are regarding the consent process* (3)

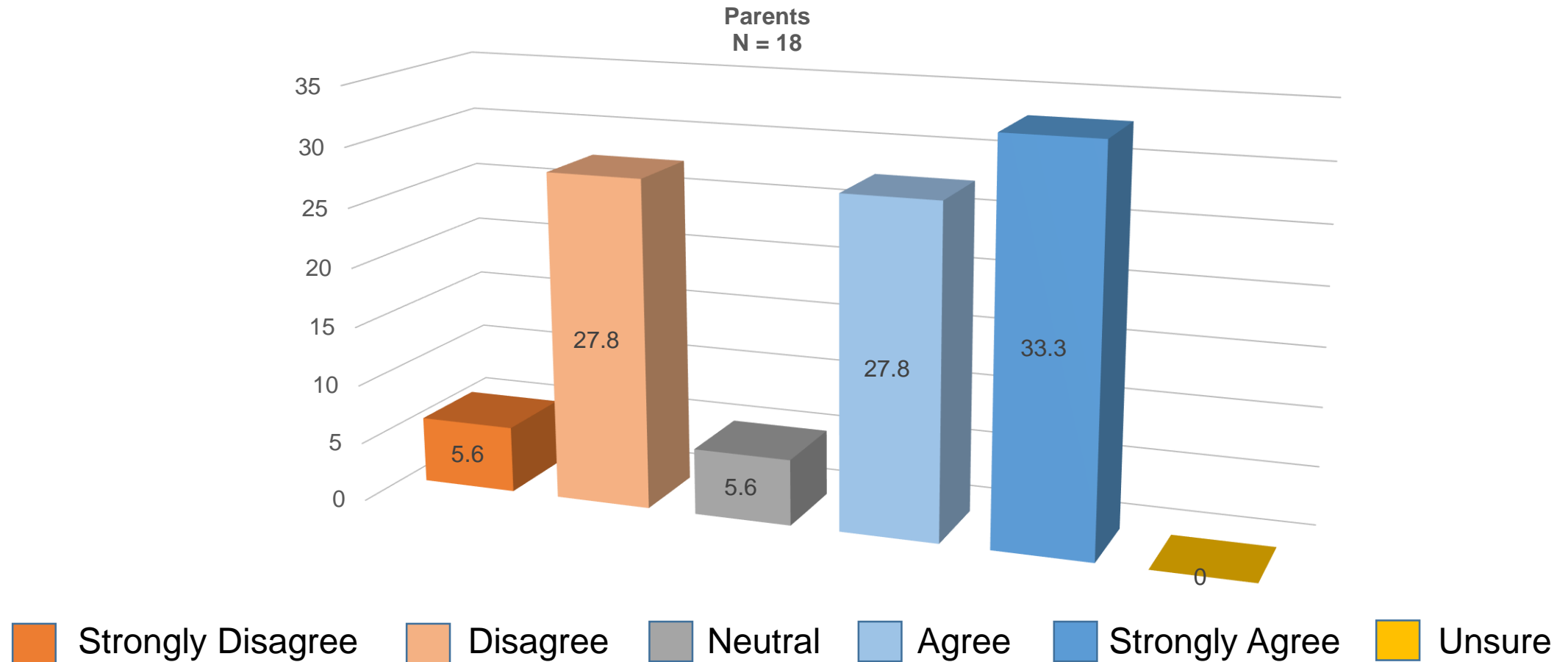
The resources provided to me about the study were adequate for me to agree/decline to consent for my baby's participation (%)



* Special instructions: Please rate your level of agreement with the following statement on a scale of 1 (Strongly disagree) through 5 (Strongly agree).

The following questions are regarding the consent process* (4)

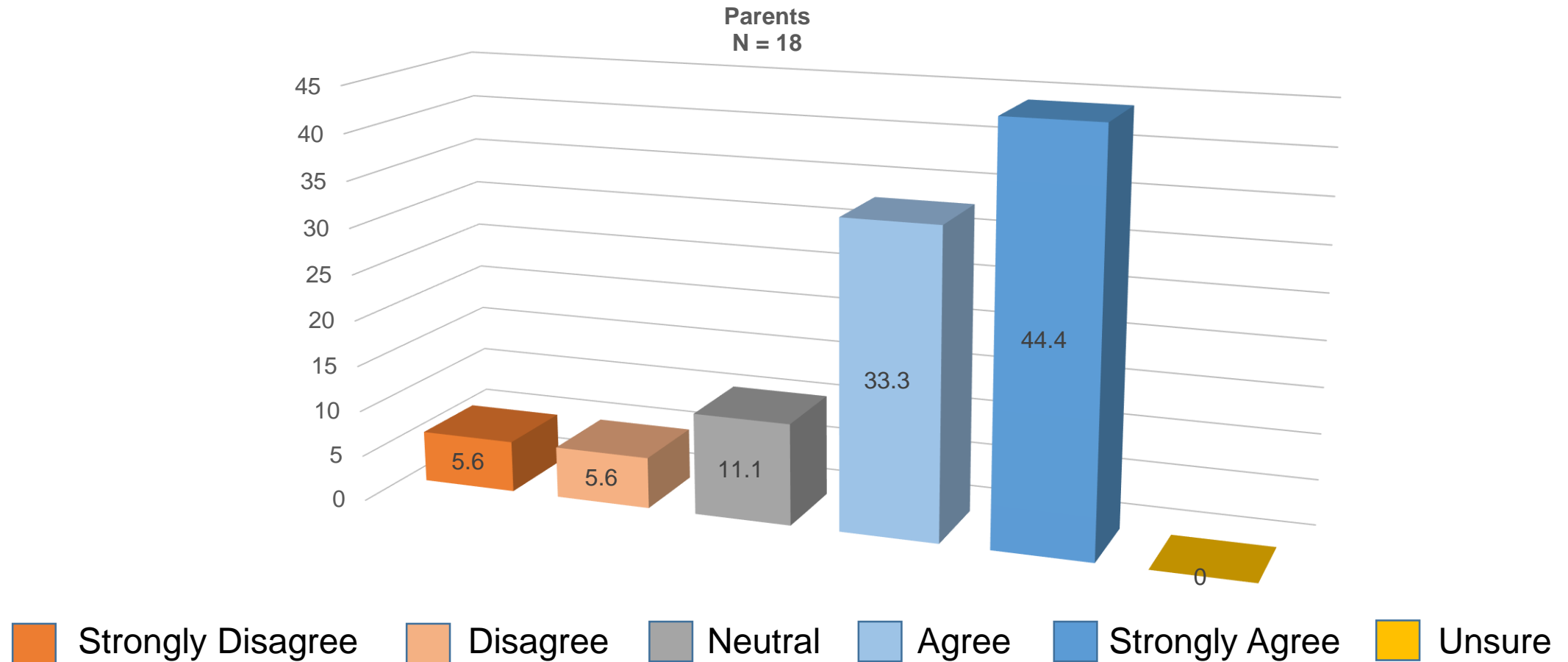
It was clear to me where I could get additional information about the study while my baby was participating in the study (%)



* Special instructions: Please rate your level of agreement with the following statement on a scale of 1 (Strongly disagree) through 5 (Strongly agree).

The following questions are regarding the consent process* (5)

I was comfortable asking questions while my baby was participating in the study (%)



* Special instructions: Please rate your level of agreement with the following statement on a scale of 1 (Strongly disagree) through 5 (Strongly agree).



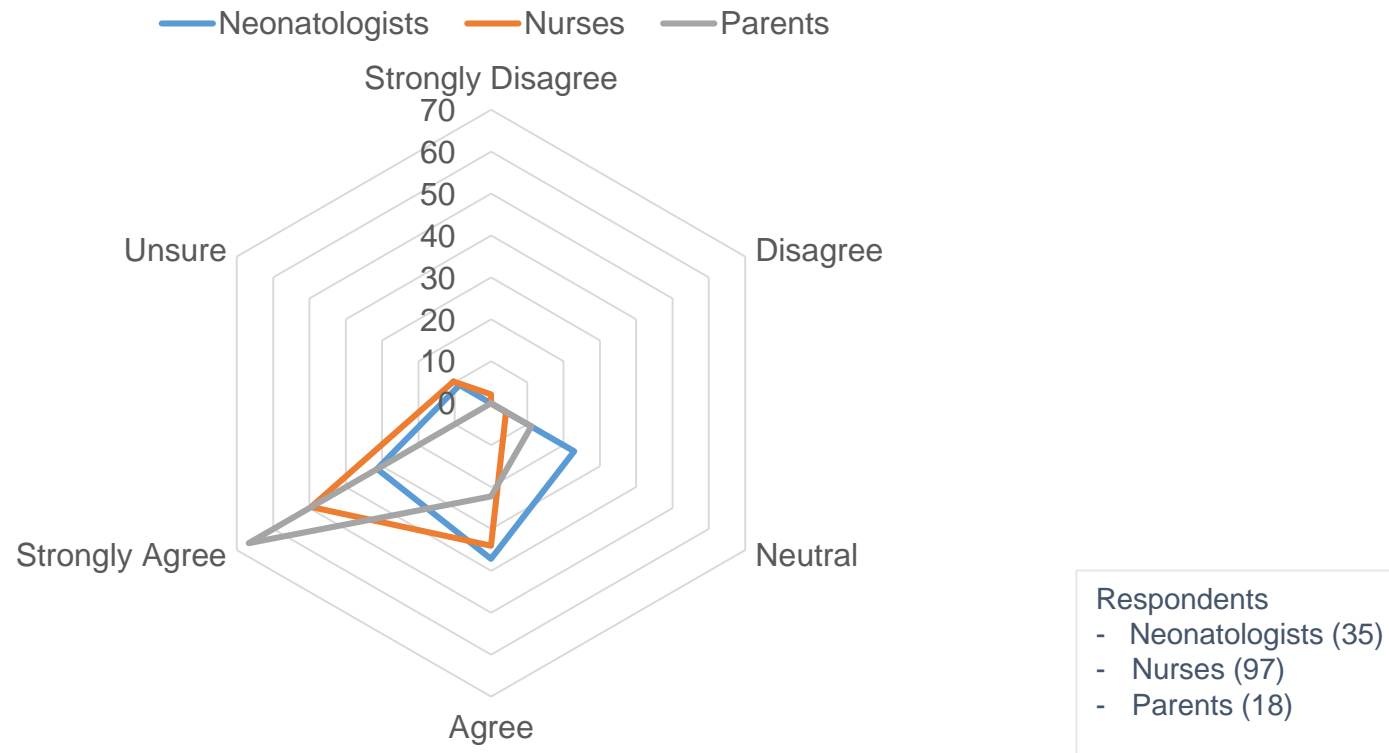
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Part VI: Research Results Disclosure



The following questions are regarding results disclosure.* (1)

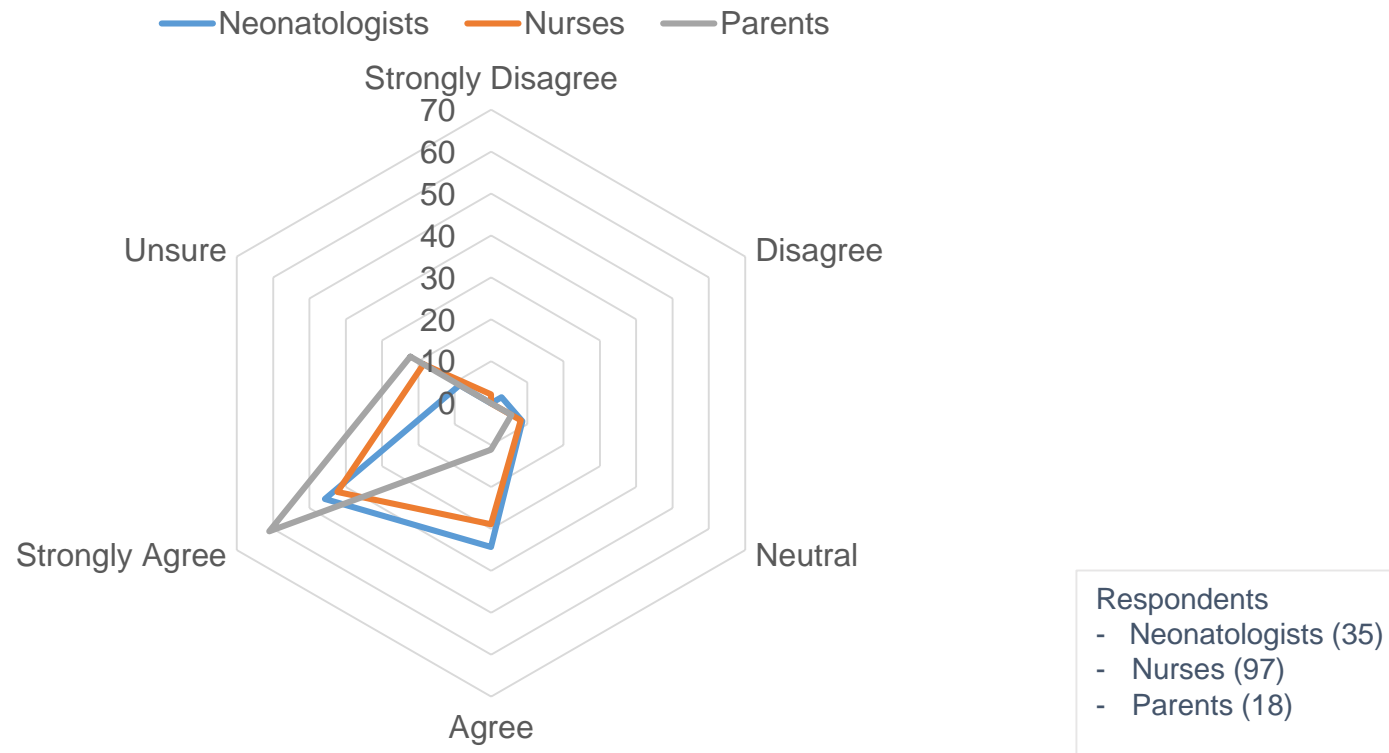
Families who consent to study participation for their babies should have study results made available to them upon study completion (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

The following questions are regarding results disclosure.* (2)

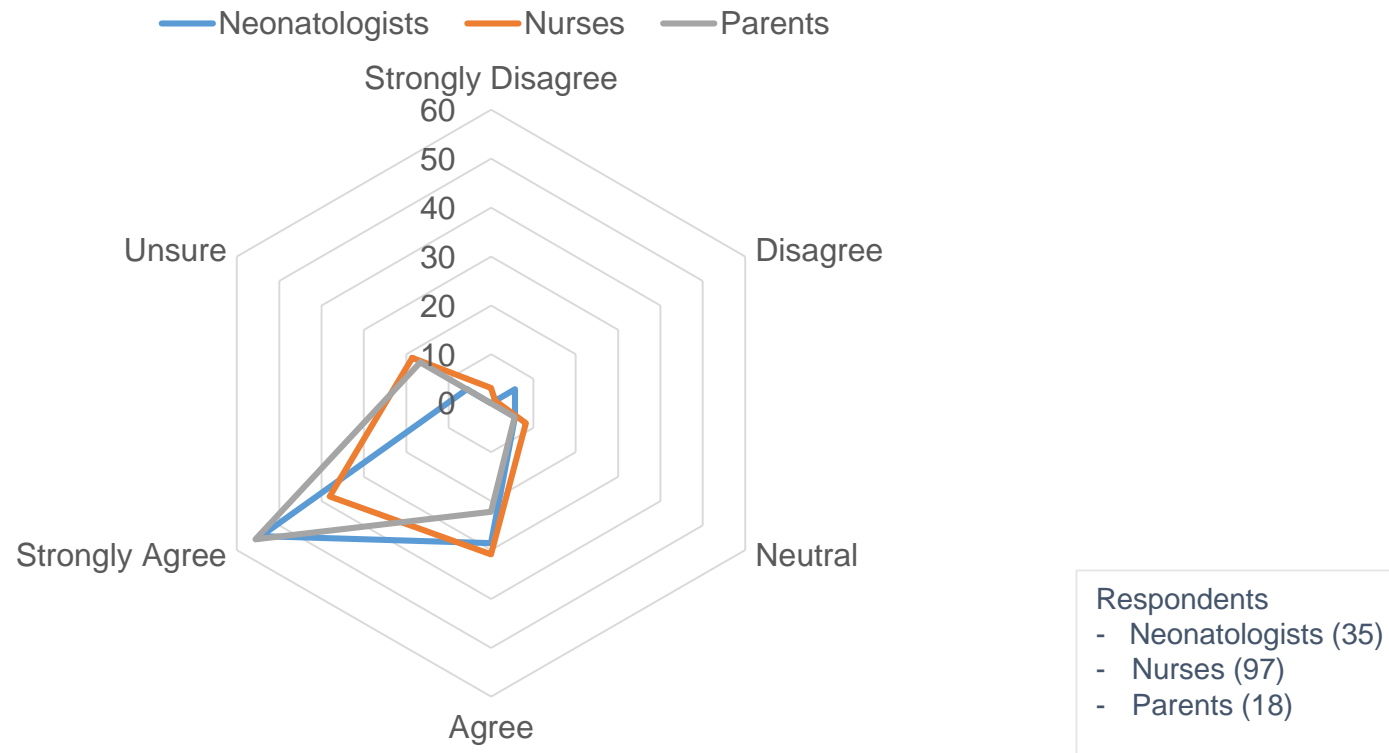
Results from pharmaceutical research (research conducted in the NICU by drug companies) are required to be made public upon study completion (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

The following questions are regarding results disclosure.* (3)

Results from studies (research conducted in the NICU not sponsored by drug companies) are required to be made public upon study completion (%)



* Special instructions: *Please rate your level of agreement with the following statements on a scale of 1 (Strongly disagree) through 5 (Strongly agree).*

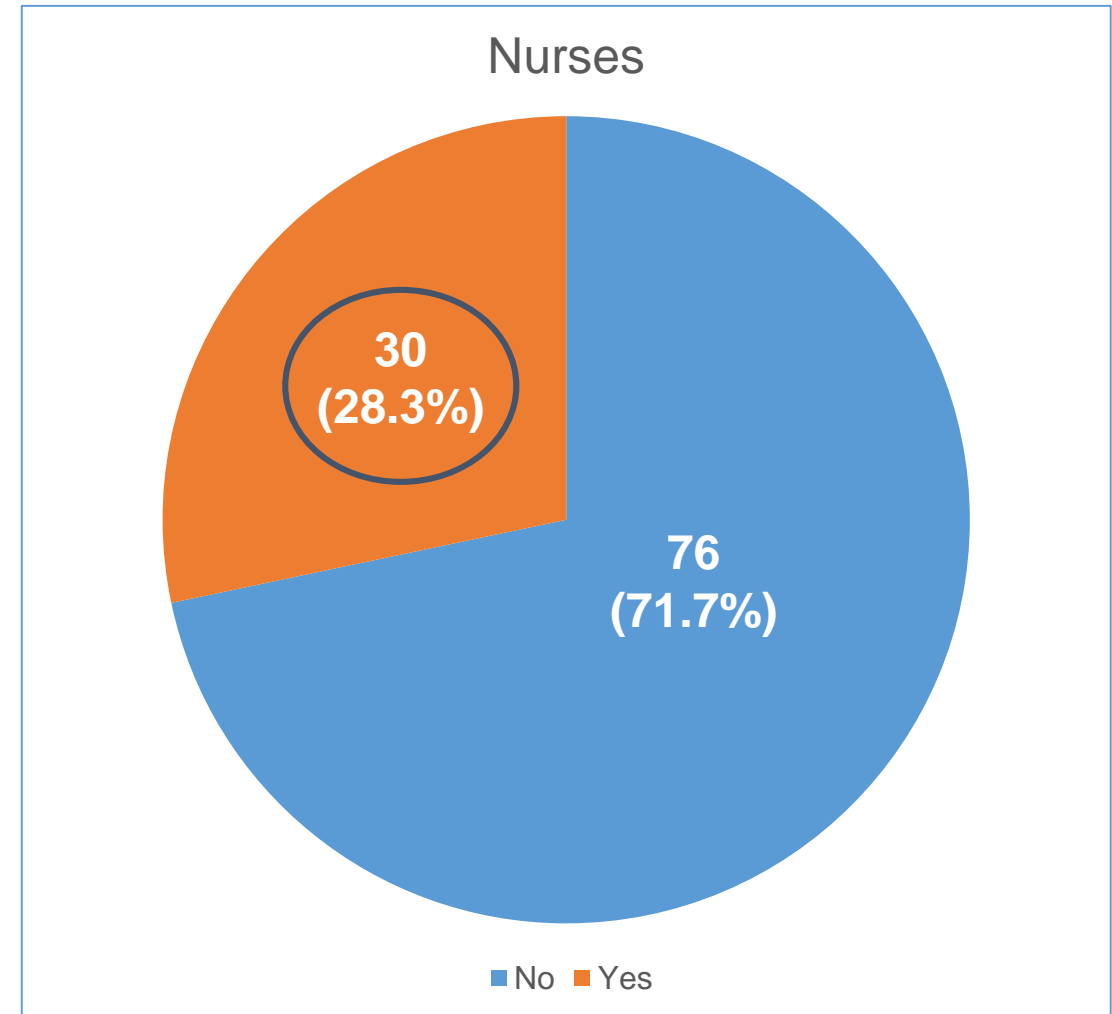
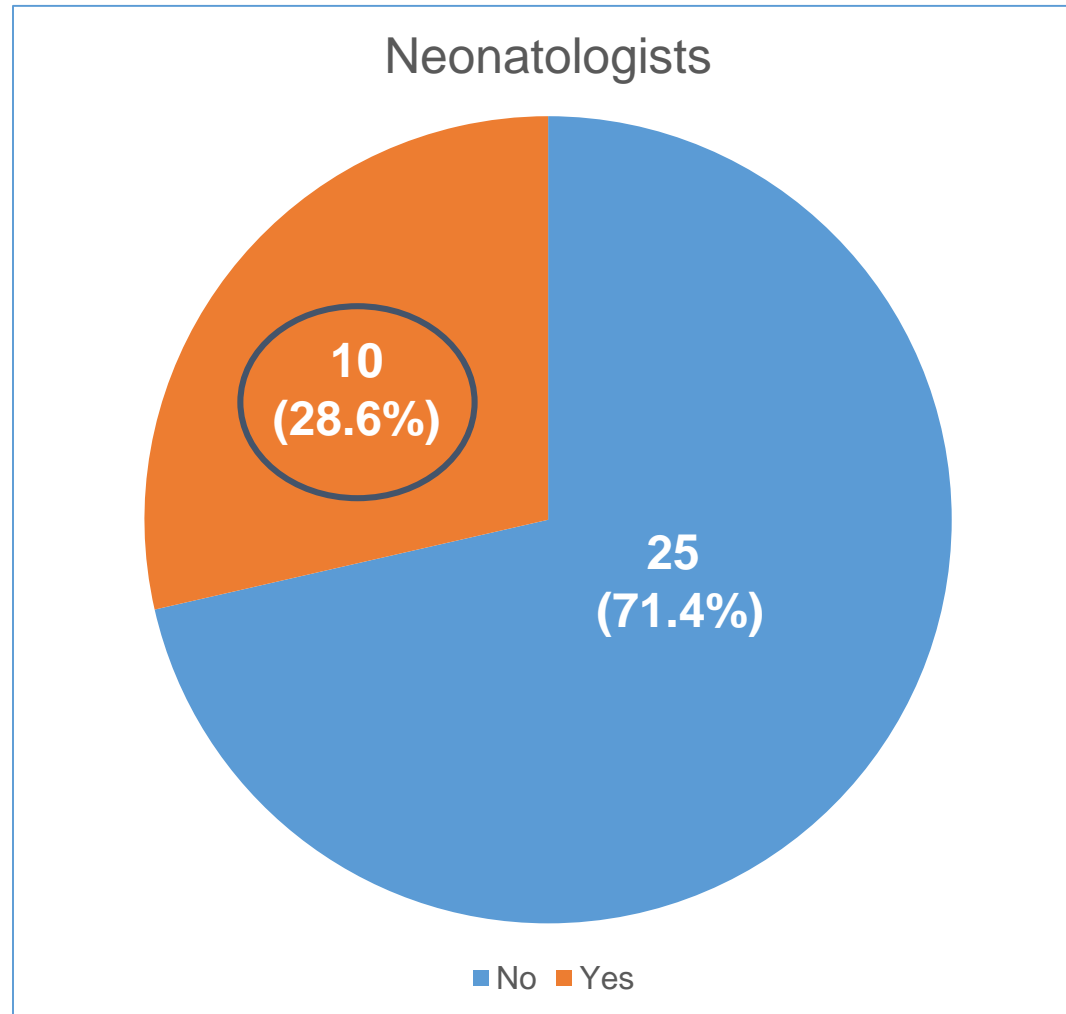


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Part VI: Research Results Disclosure (Neonatologist / Nurse-specific)



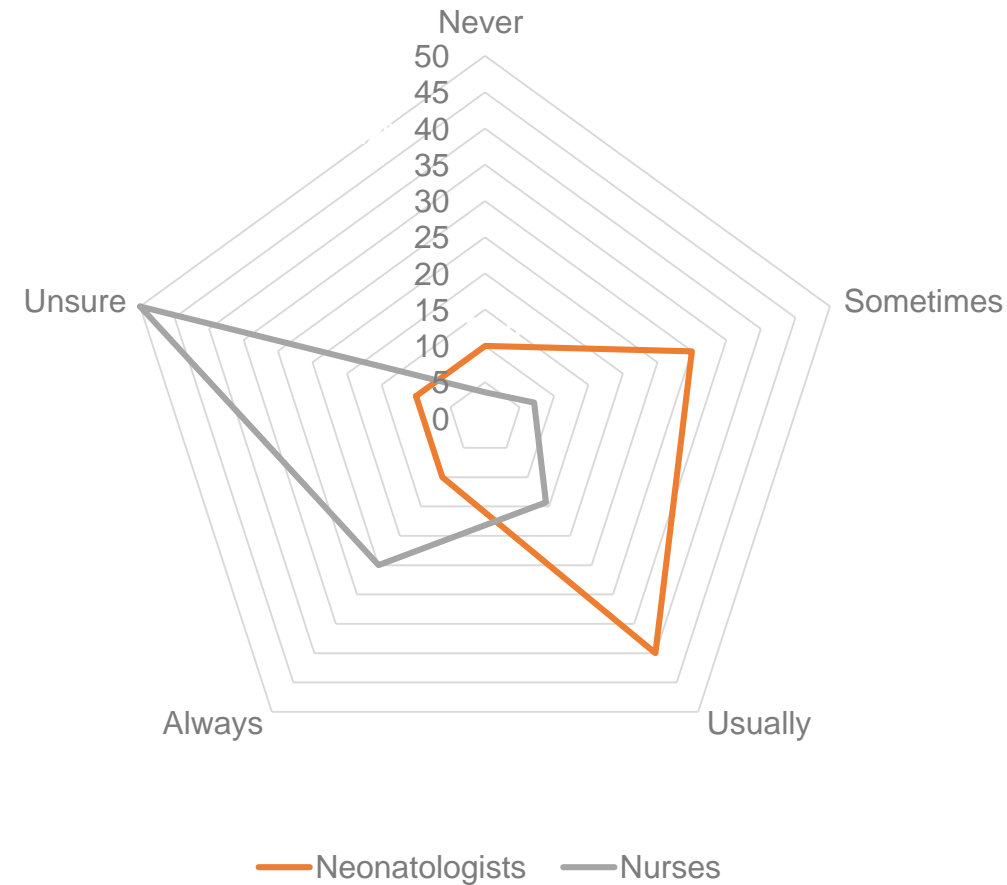
Does your NICU have a standard approach* in place to provide study results to the parents of the study participants?



* A standard approach was defined as “a written hospital guideline or guidance document or protocol”

Please rate your NICU/hospital on the standard approach to results disclosure on a Scale of “Never” to “Always” (1)

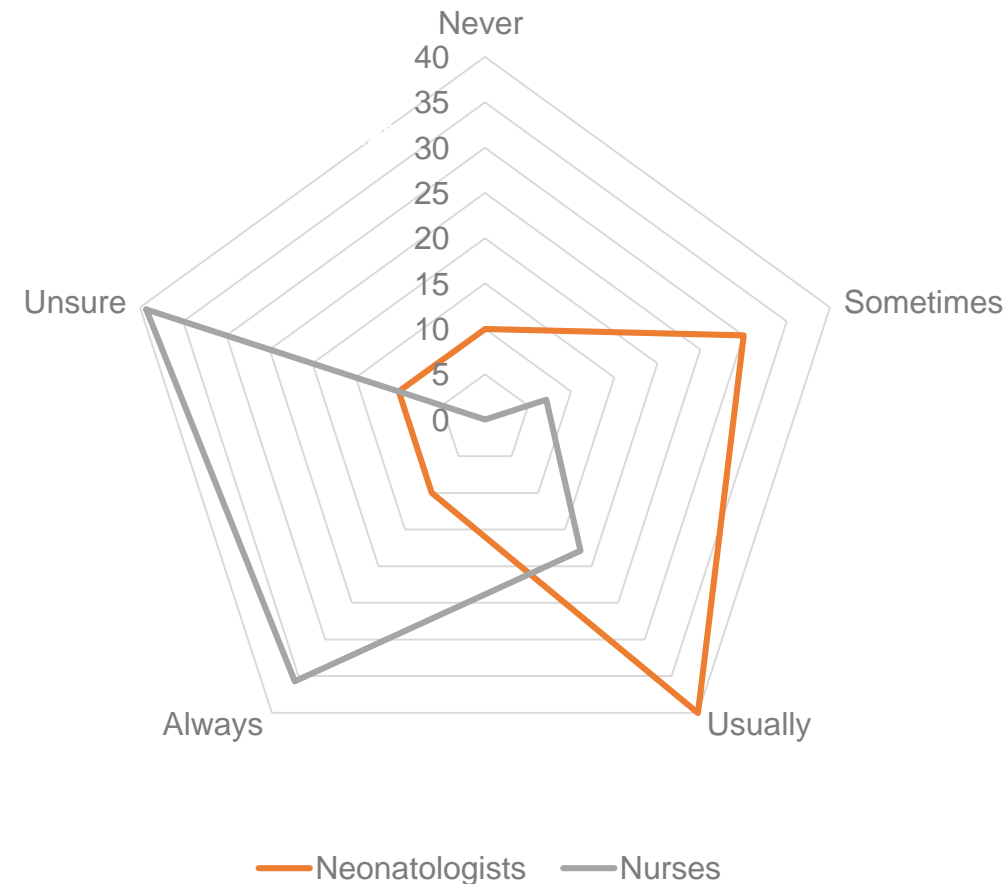
How often is the standard approach to results disclosure used by your NICU/hospital? (%)



Respondents
- Neonatologists (10)
- Nurses (28)

Please rate your NICU/hospital on the standard approach to results disclosure on a Scale of “Never” to “Always” (2)

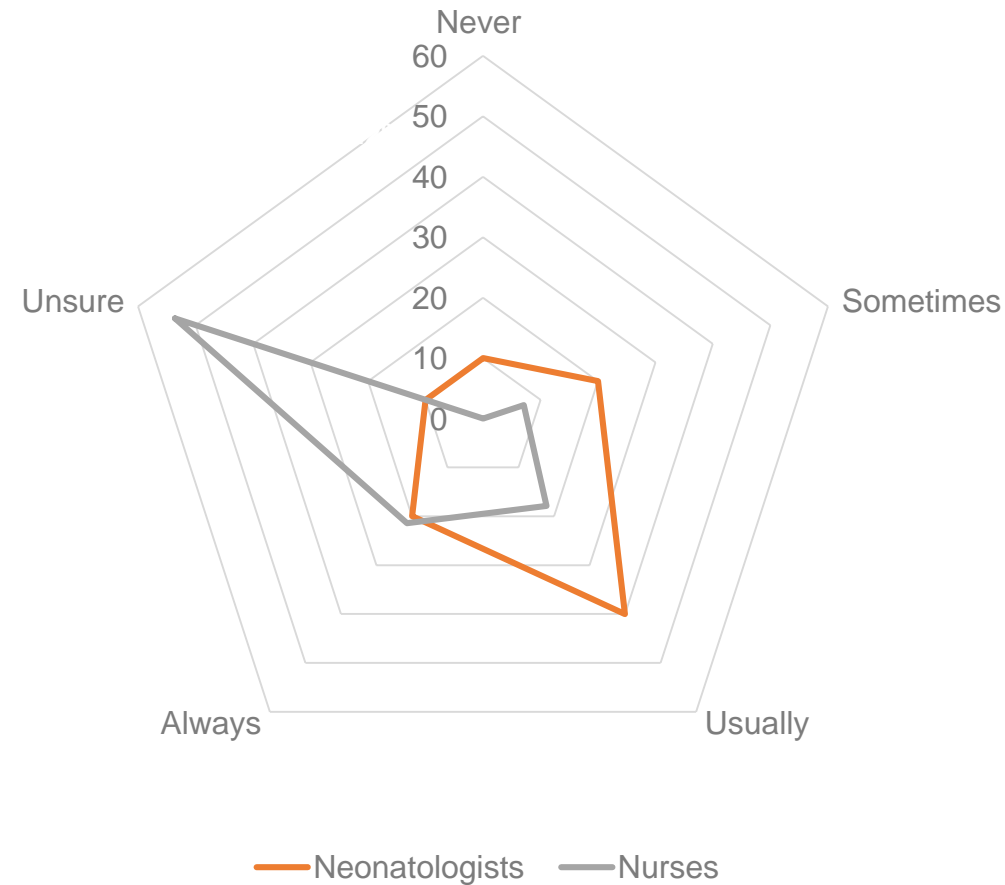
When parents are consented for their baby’s study participation, the NICU standard approach for results disclosure is included in the discussion (%)



Respondents
- Neonatologists (10)
- Nurses (28)

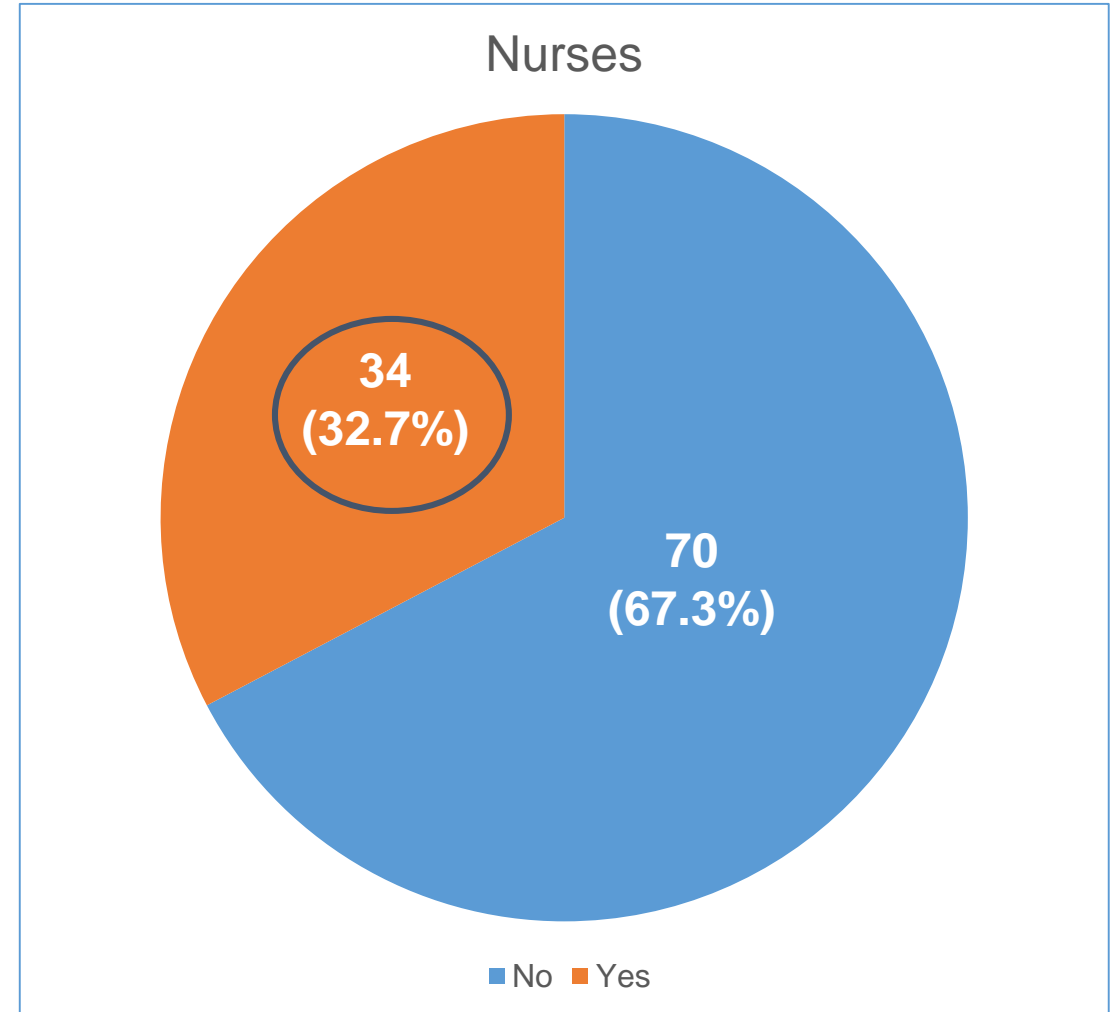
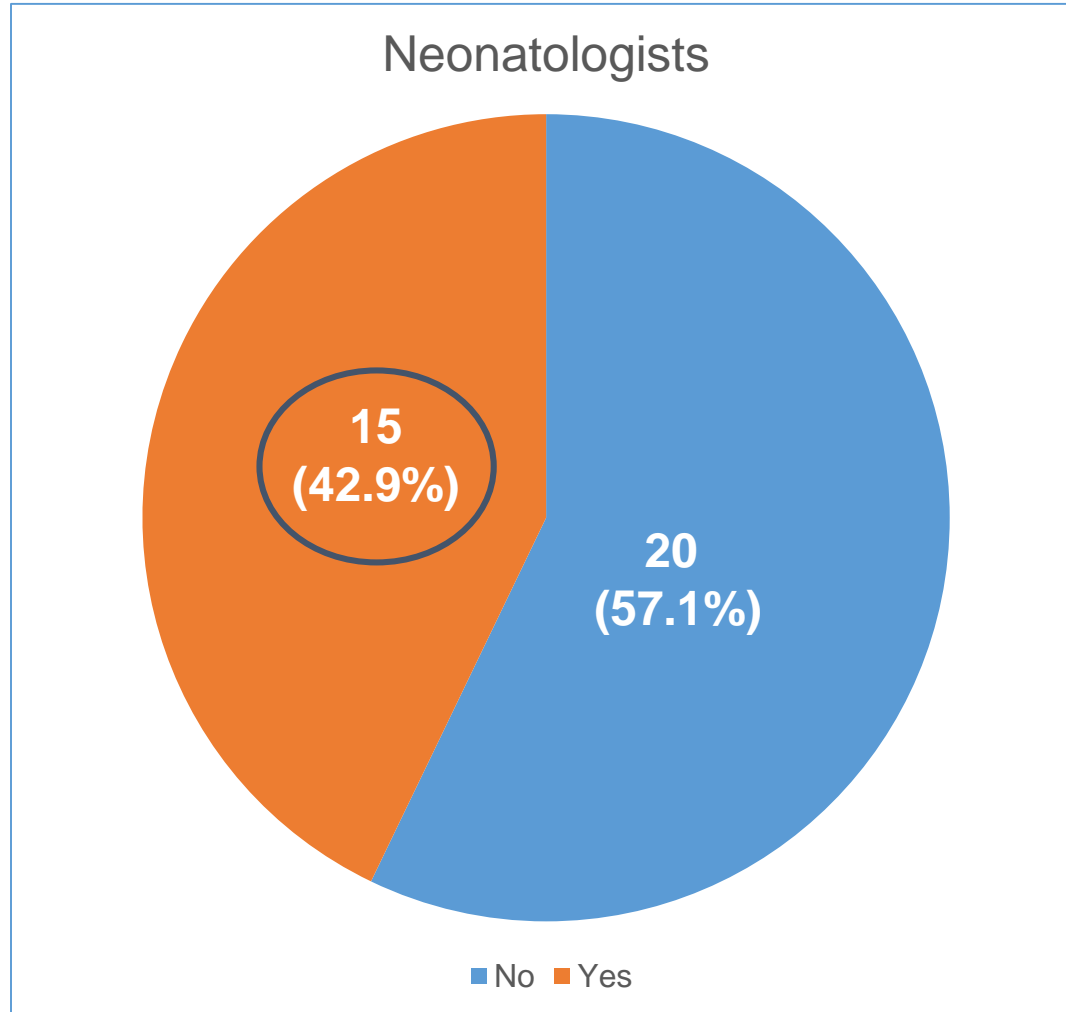
Please rate your NICU/hospital on the standard approach to results disclosure on a Scale of “Never” to “Always” (3)

Parents who have consented for their baby’s study participation are given an option whether they receive the aggregate results or not (%)



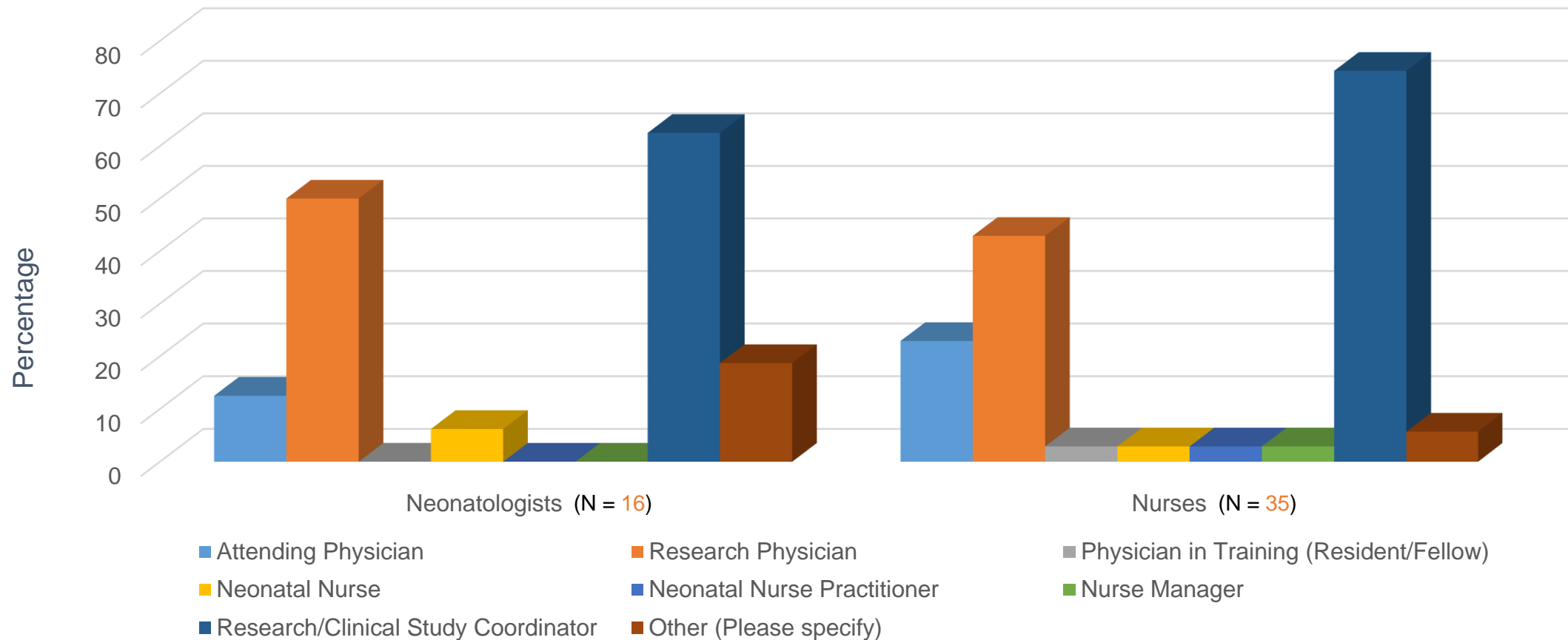
Respondents
- Neonatologists (10)
- Nurses (28)

Does your NICU/hospital have an individual* whose responsibility is to inform parents of the study participants how and when the results will be disseminated?



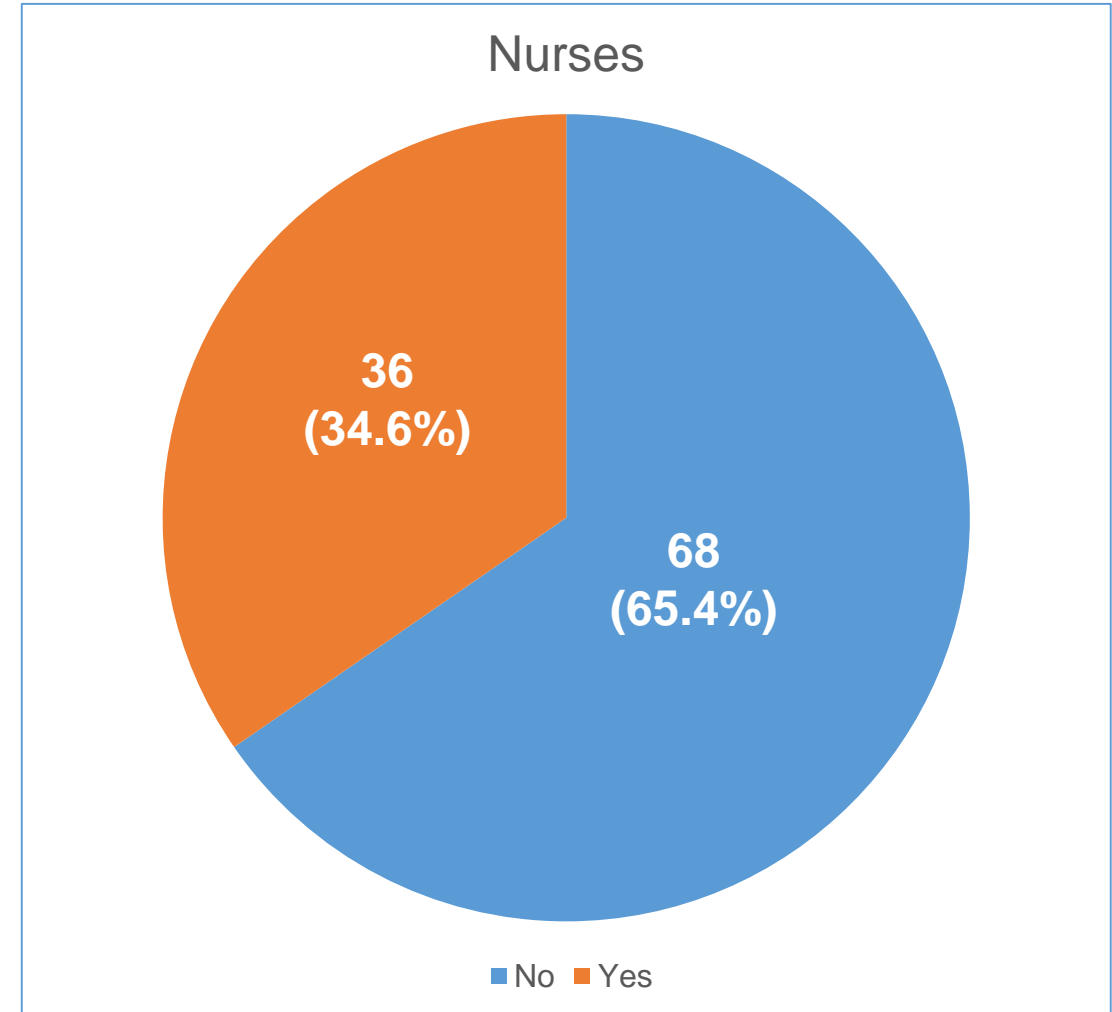
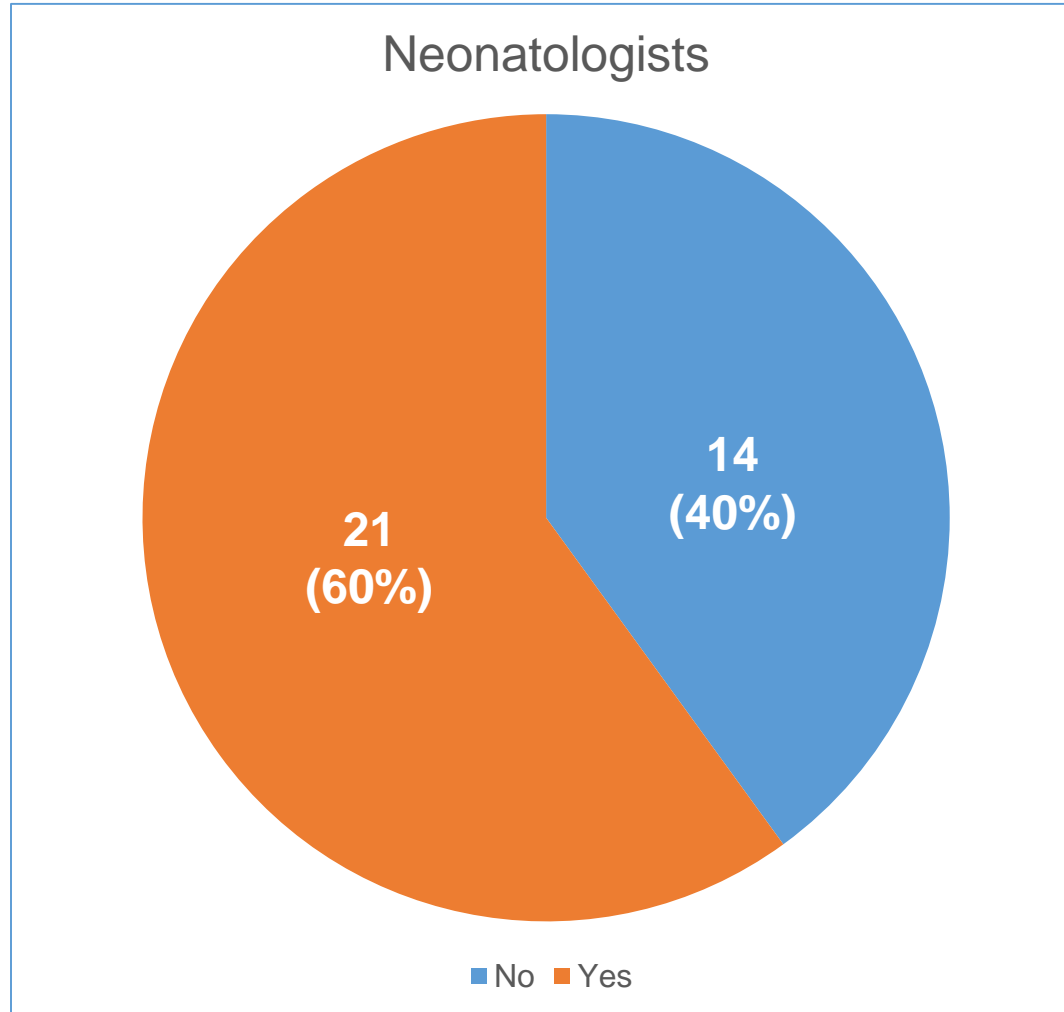
* Defined as *assigned personnel*.

If your NICU/hospital has an individual whose responsibility is to inform parents of the study participants how and when the results will be disseminated, please select all that apply.



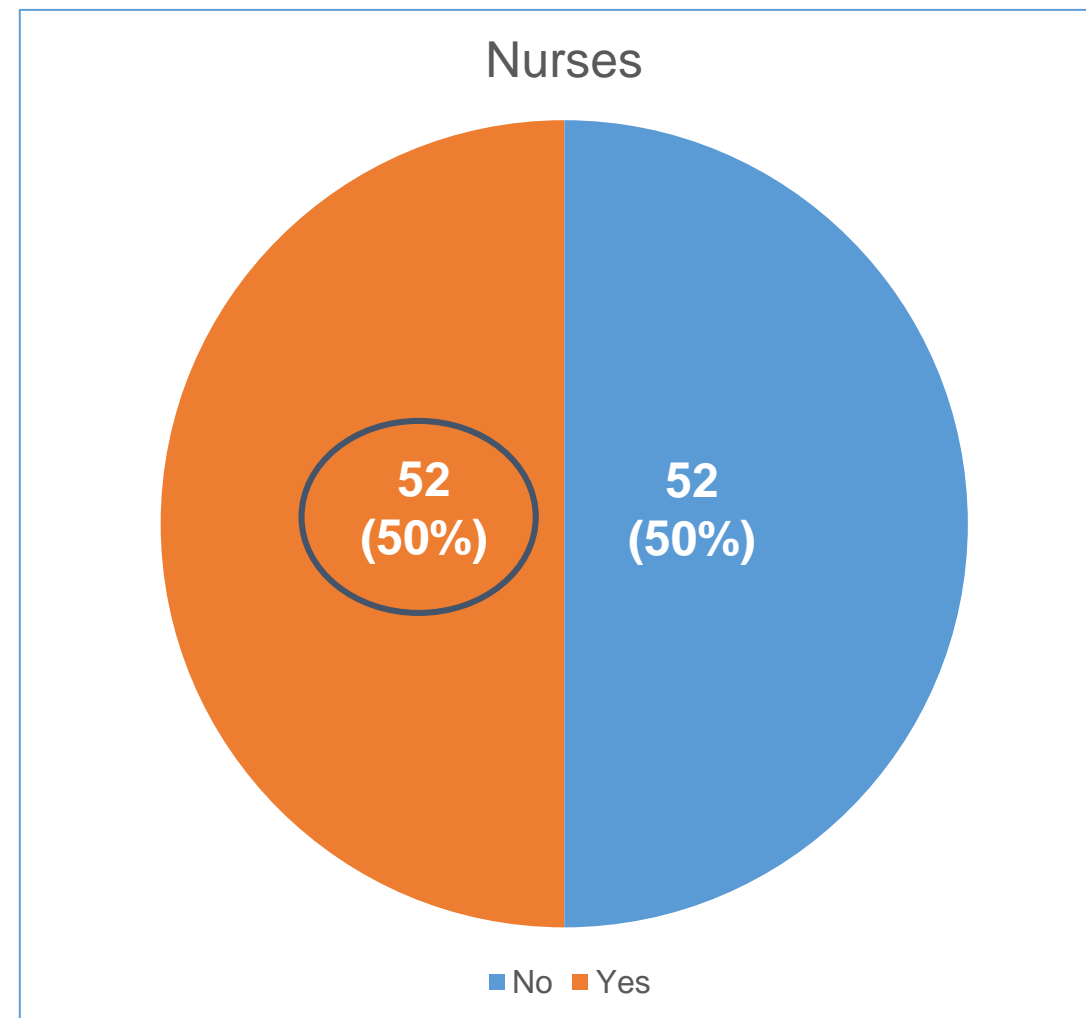
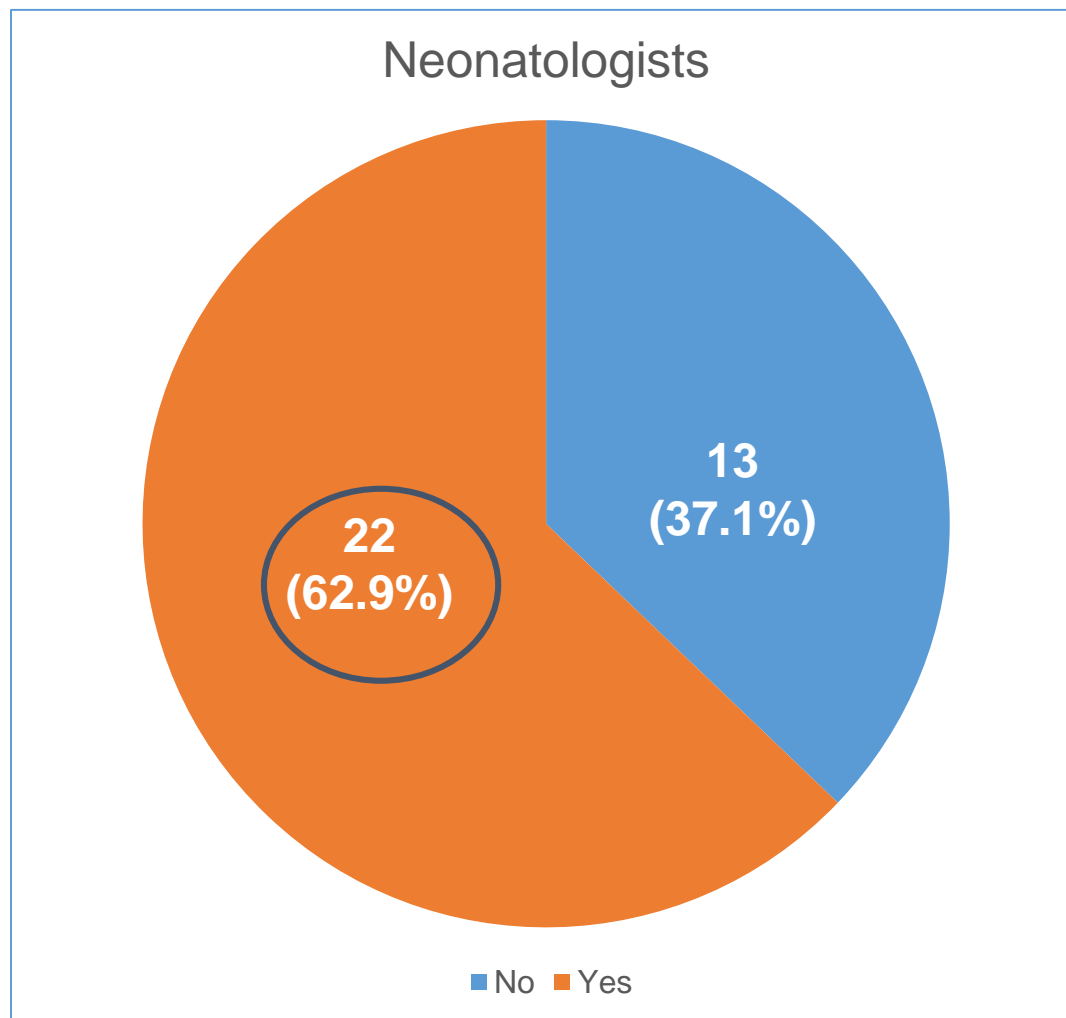
* Special Instructions: *Select all that Apply.*

Does your NICU/hospital have a standard approach (per-protocol) in place to keep contact information of the parents of the study participants up to date?



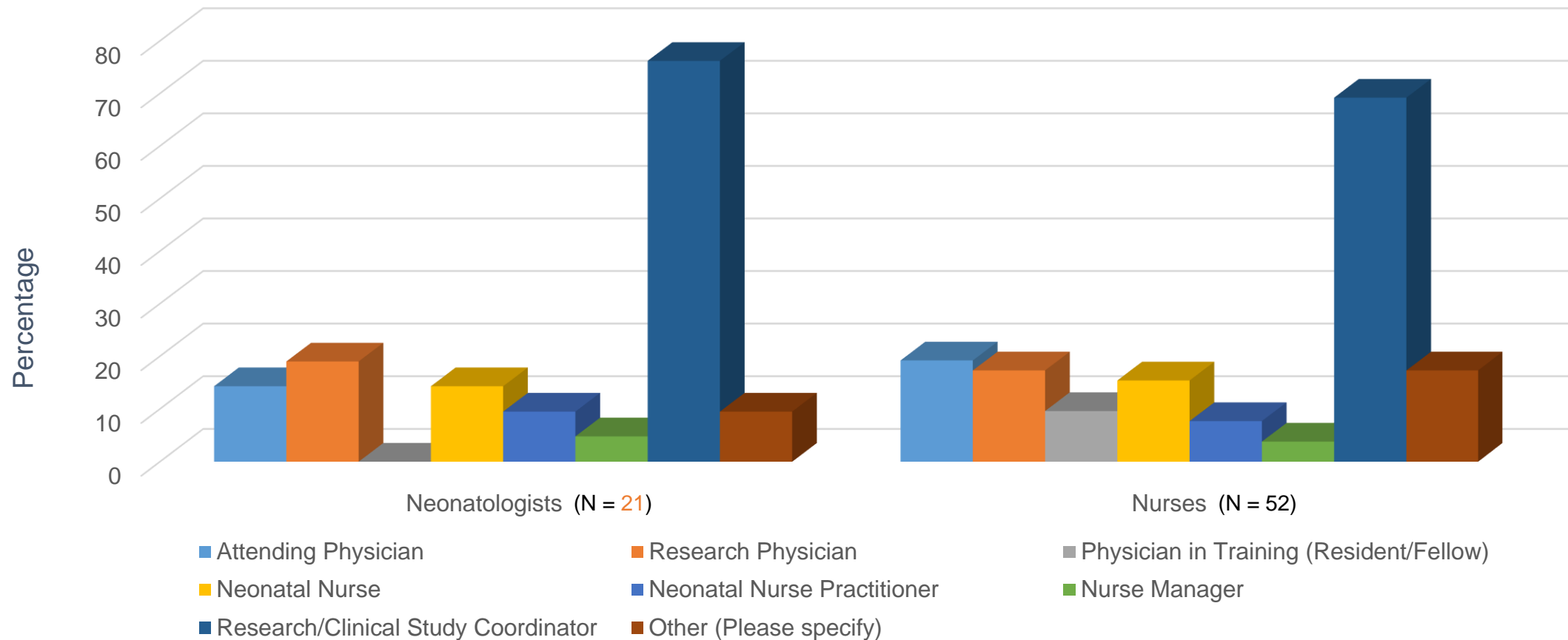
* Defined as *assigned personnel*.

Does your NICU/hospital have an individual (assigned personnel) who is responsible for maintaining up to date parental contact information?



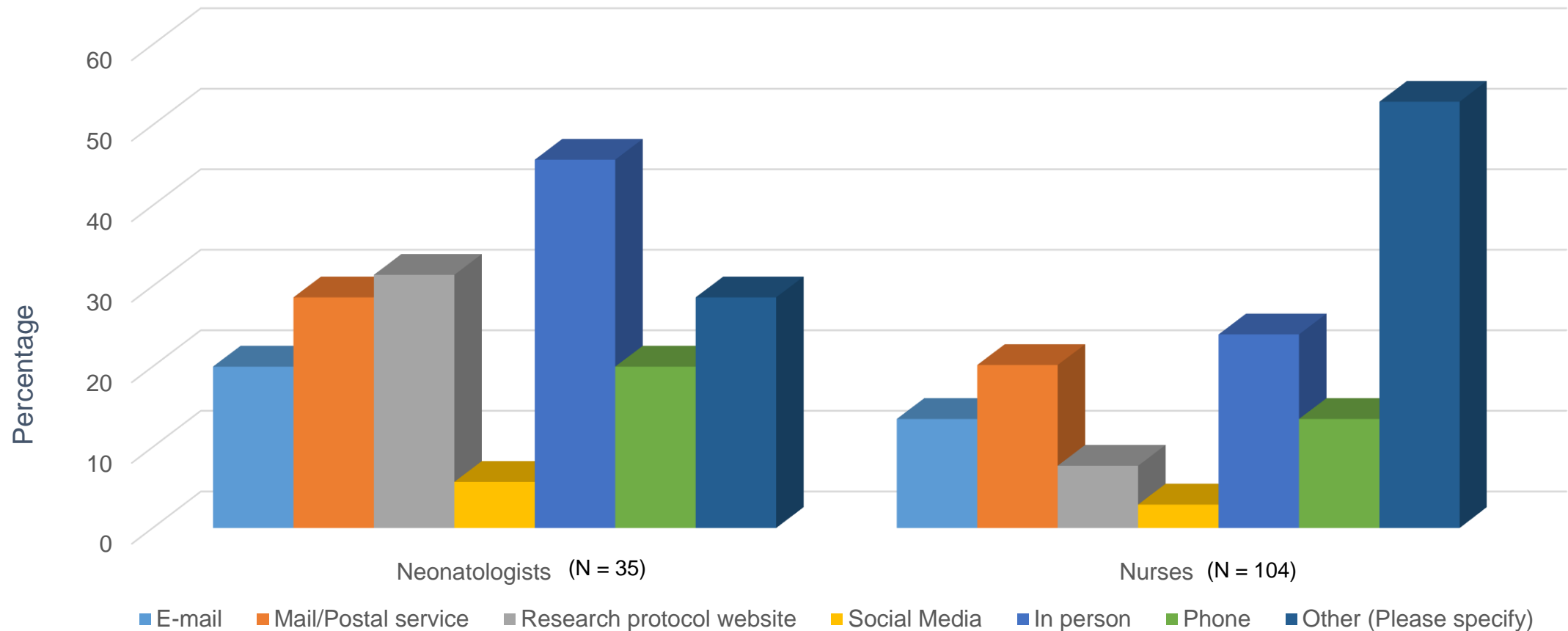
* Defined as *assigned personnel*.

If your NICU/hospital has an individual whose responsibility is to maintain up to date parental contact information, please select all that apply.



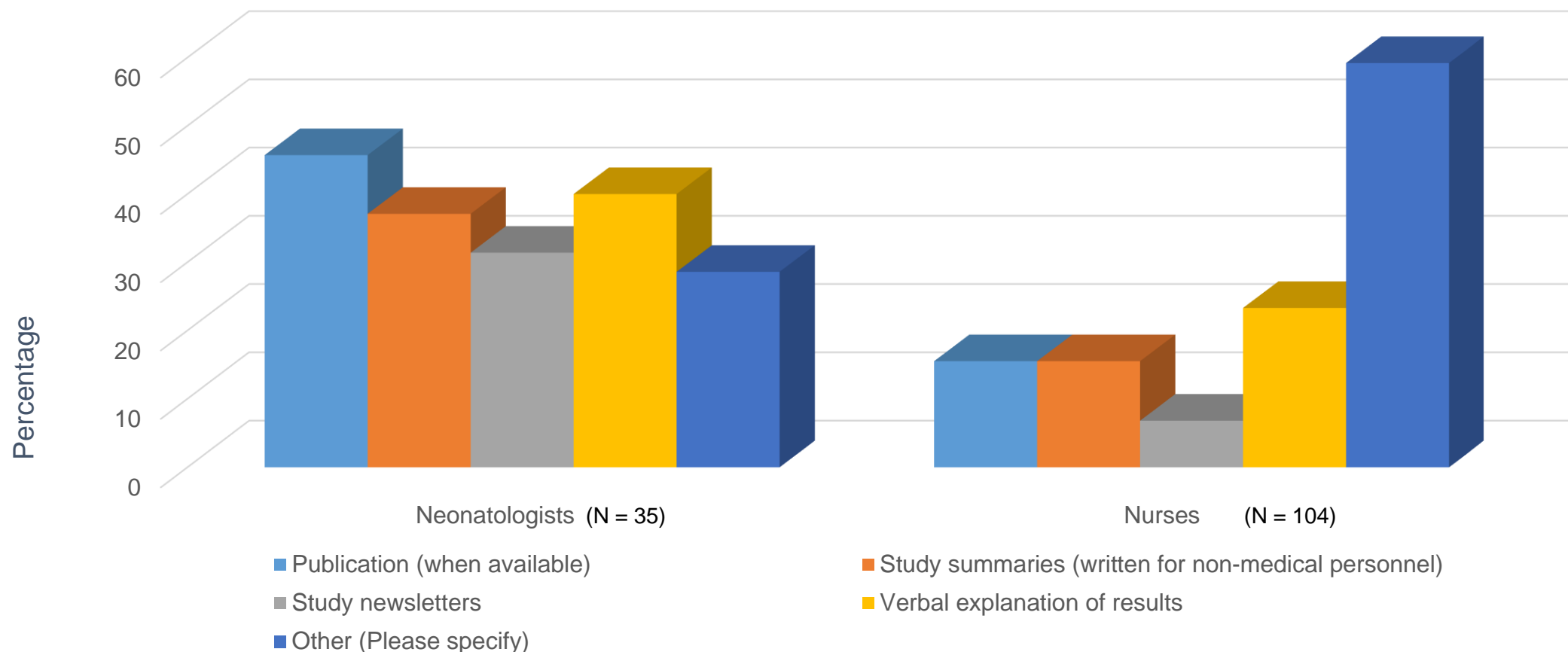
* Special Instructions: *Select all that Apply.*

What methods does your NICU/hospital use to disseminate study results to the parents of study participants?*



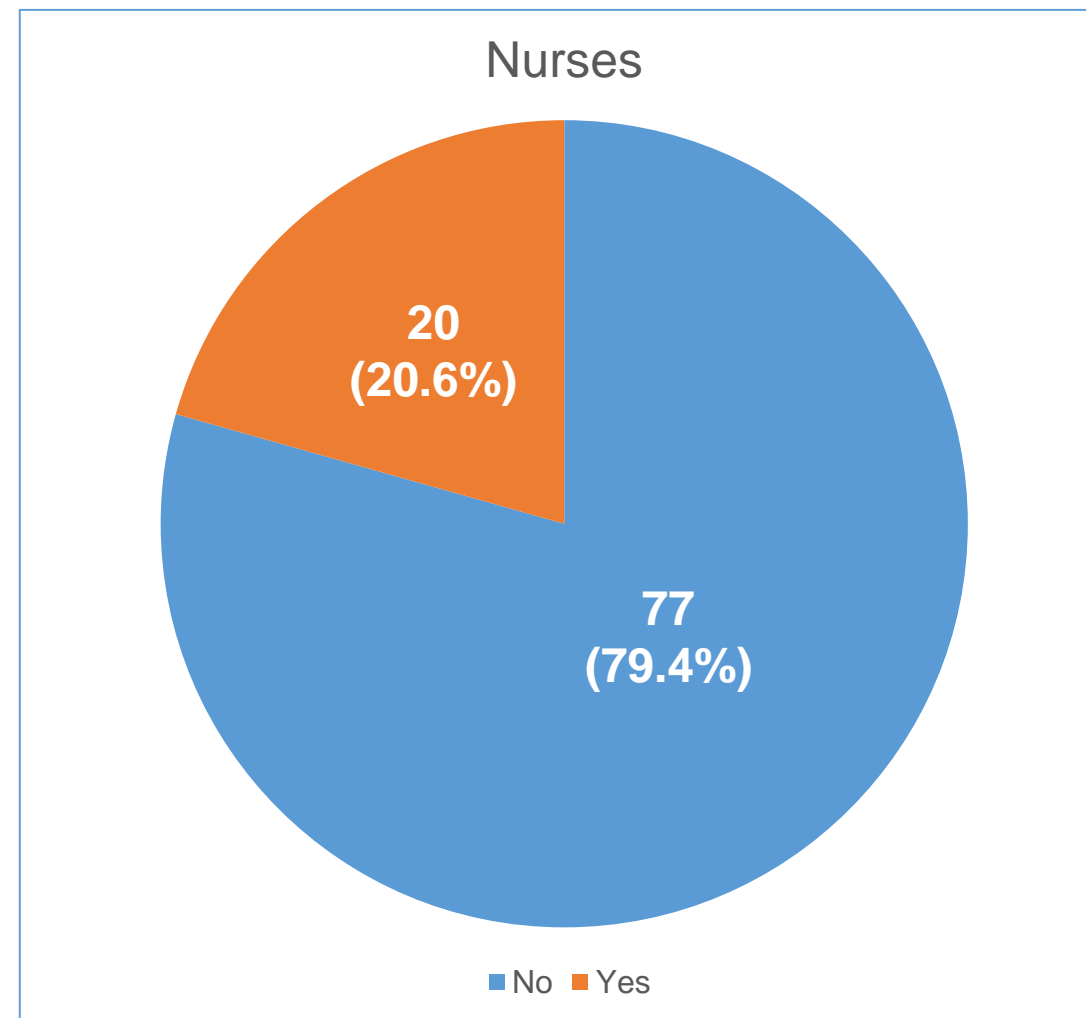
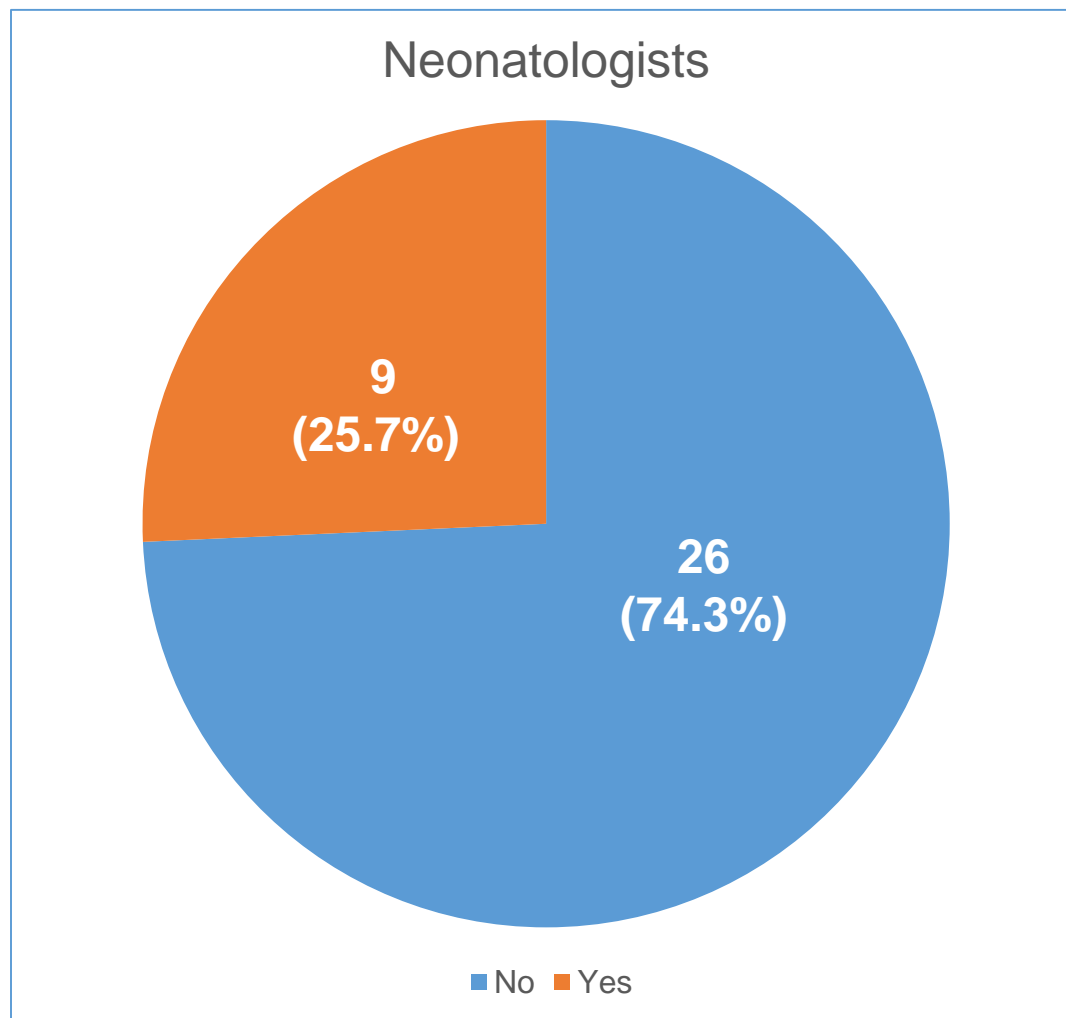
* Special Instructions: *Select all that Apply.*

What format does your NICU/hospital use to provide study results to the parents of study participants after the study is completed?*



* Special Instructions: *Select all that Apply.*

Does your NICU/hospital have a standard requirement (protocol) for post-study care for babies who have participated in active-controlled or placebo controlled studies?



* Defined as *assigned personnel*.



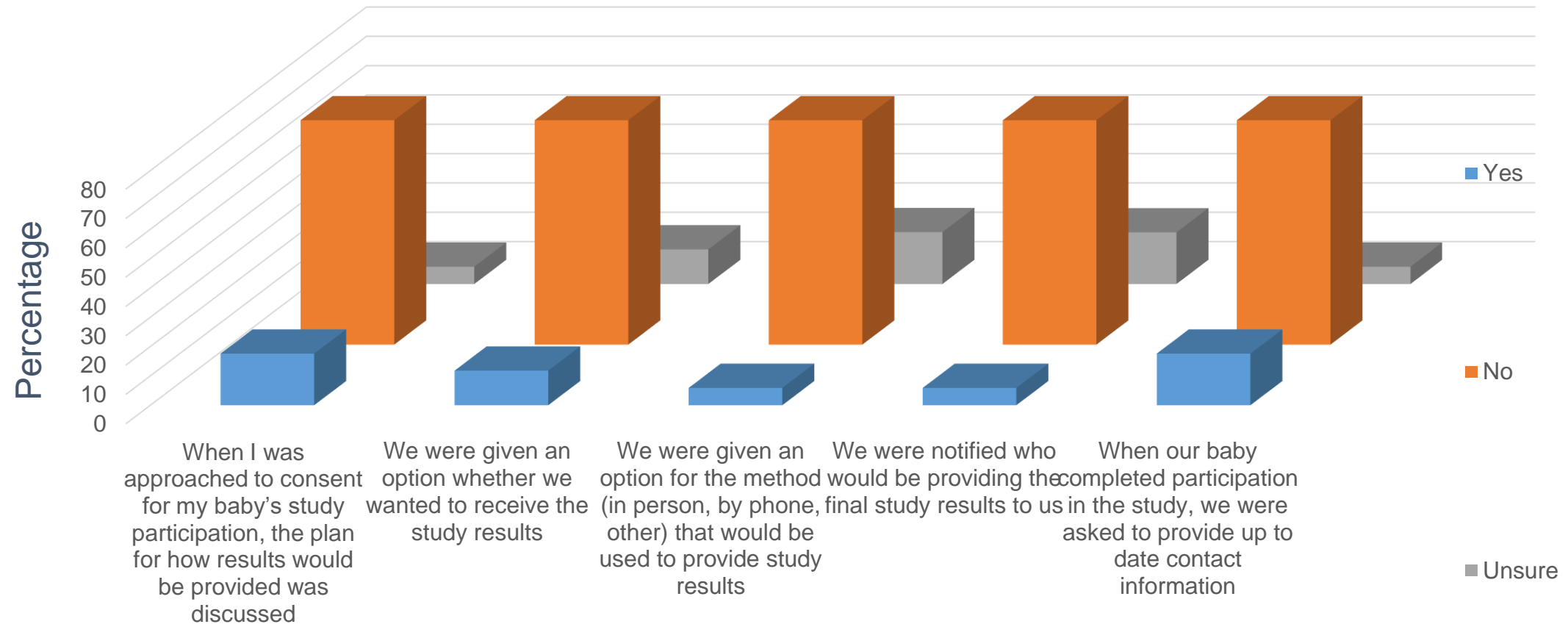
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Part VI: Research Results Disclosure (Parent-specific)

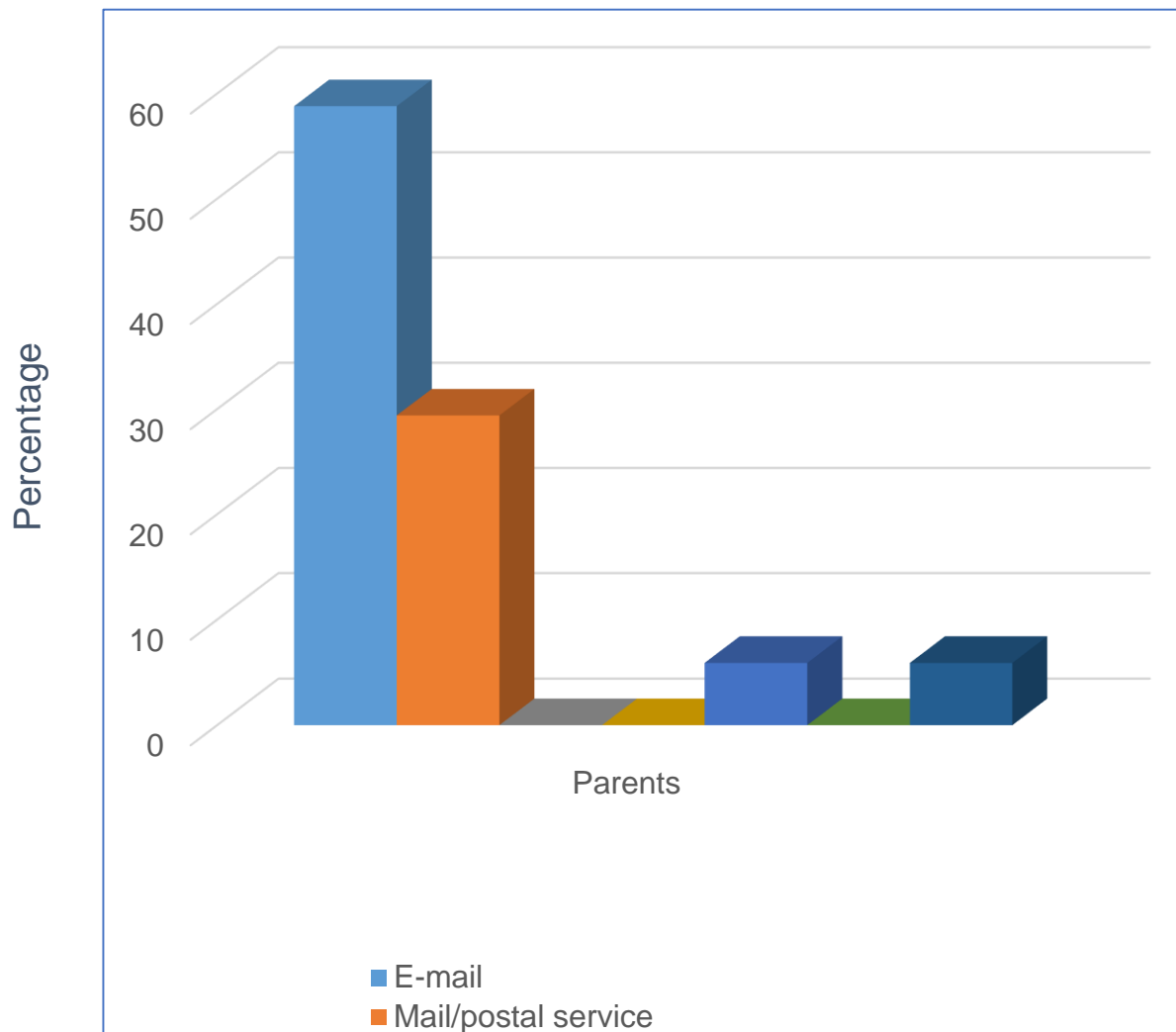


The following questions assess your experience receiving study results for the study your baby participated in

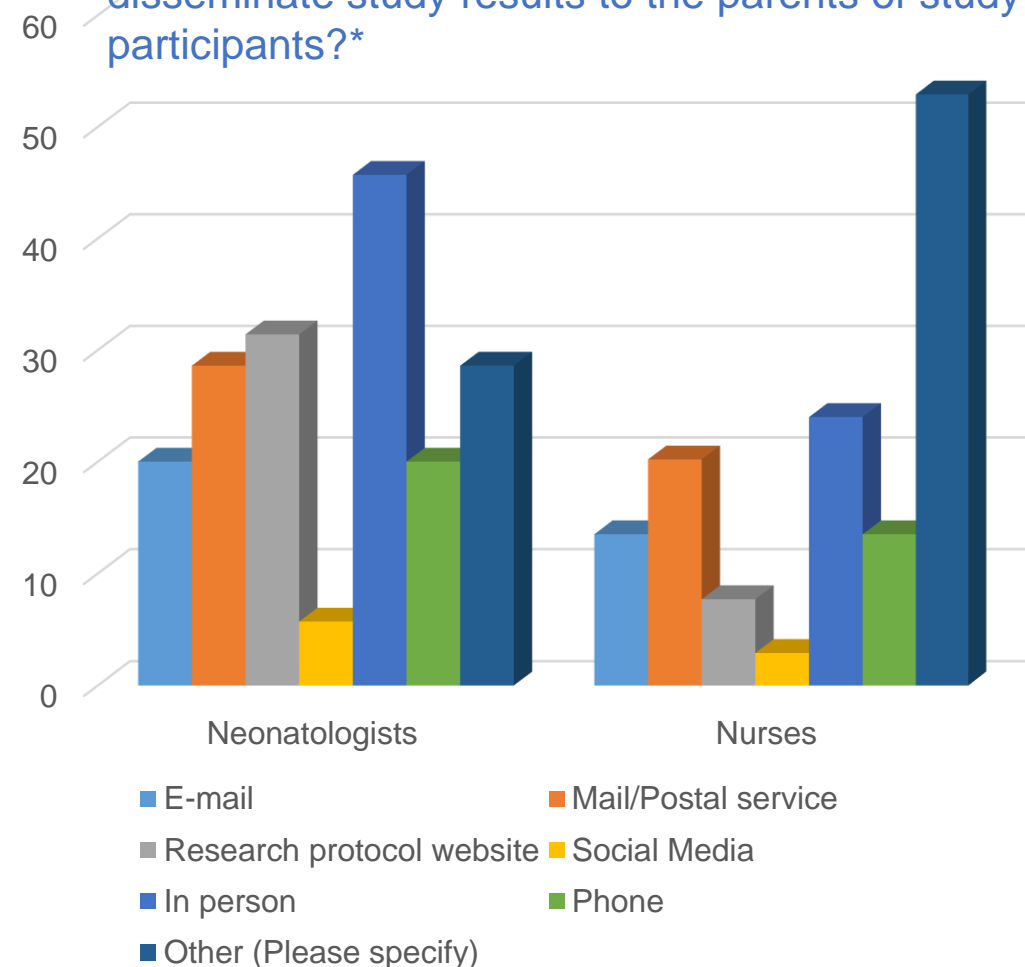
Parents
(N = 17)



What is your preferred method to receive the final study results for the study your baby participated in?*

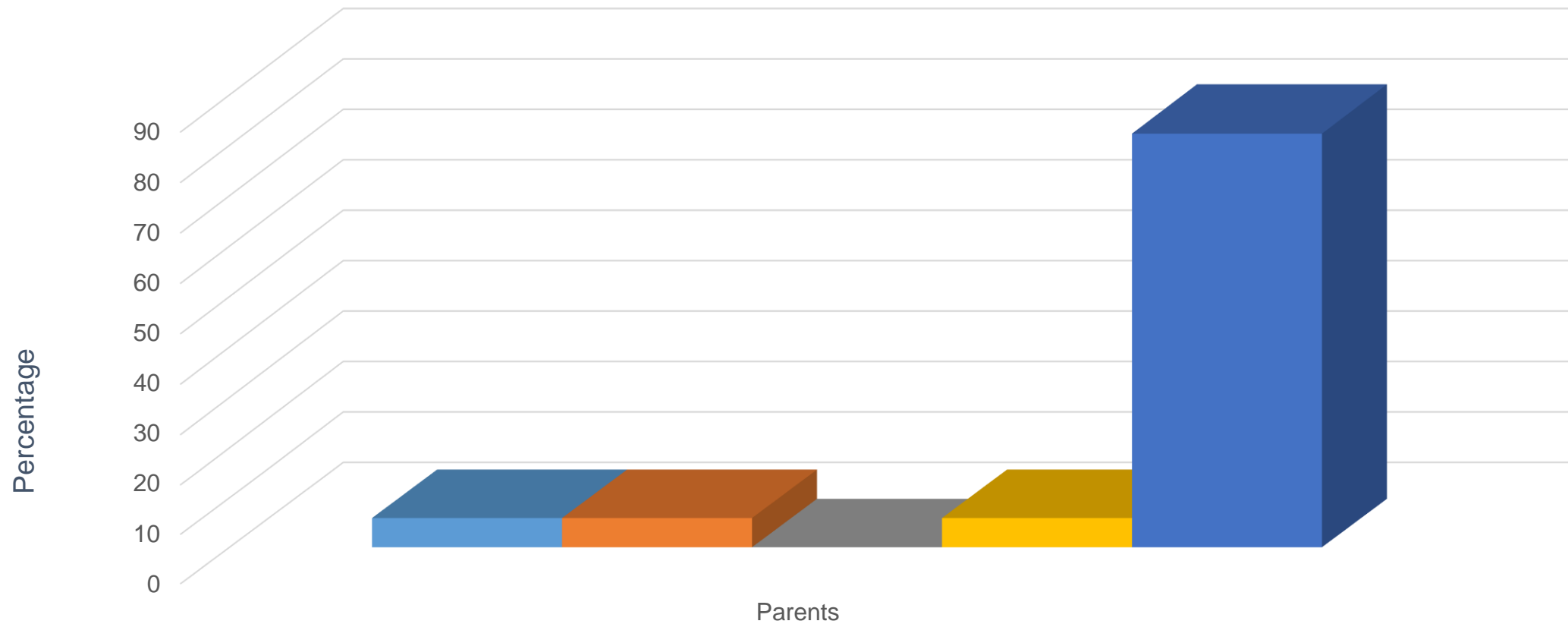


What methods does your NICU/hospital use to disseminate study results to the parents of study participants?*



* Special Instructions: *Select one.*

What format did your NICU/hospital use to provide final study results to you that your baby participated in?*



- Publication (when available)
- Study summaries (written for non-medical personnel)

* Special Instructions: *Select all that apply.*



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