Outcomes and follow-up programmes in extreme preterm children in Denmark in the EPICE/SHIPS cohort

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ABSTRACT

INTRODUCTION: This study presents outcomes and follow-up tools for children born very (28 + 0 – 31 + 6 weeks) and extremely (22 + 0 – 27 + 6 weeks) preterm in a Danish sub-cohort of the European project Effective Perinatal Intensive Care in Europe (EPICE) cohort.

METHODS: All live and stillbirths with a gestational age 22 + 0 – 31 + 6 weeks from eight hospitals in Eastern Denmark (Funen, Zealand, Lolland and Falster) in 2011-2012 were included in the cohort (n = 441). Questionnaires were sent to parents at two and five years (including subscales of the Ages and Stages Questionnaire (ASQ)). Full-scale IQ and motor function were assessed by professionals in extremely preterm children at five years of age using the Wechsler Preschool and Primary Scale of Intelligence and Movement Assessment Battery for Children.

RESULTS: The study included 141 extremely and 210 very preterm live-born children, and among these 87 and 199 survived to discharge, respectively. The full-scale IQ was not significantly lower in children with potential developmental difficulties according to the ASQ. Children with parental reporting of fine motor difficulties had a poorer overall motor function (mean difference 2.8 (95% confidence interval (CI): 1.2-4.5)) and fine motor function (mean difference 3.4 (95% CI: 1.7-5.1)) than children with no reported fine motor difficulties.

CONCLUSIONS: Few severe difficulties, e.g., cerebral palsy, were found. At five years, parental reporting on fine motor skills was associated with fine and overall motor skills as assessed by professionals.

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Owing to advances in perinatal care, survival of extremely (22 + 0 – 27 + 6 weeks) and very preterm (28 + 0 – 31 + 6 weeks) children has increased in recent decades [1]. Follow-up programmes and assessments for extremely and very preterm birth differ between regions in Denmark. Lately, a steering group in the Danish Paediatric Society presented suggestions for a new national guideline on follow-up for extremely preterm children. In continuation of this work, the aim of the present study was to investigate the outcomes and follow-up programmes for children born very and extremely preterm in a Danish sub-cohort of the European project Effective Perinatal Intensive Care in Europe (EPICE) cohort and the project Screening to Improve Health in Very Preterm Infants in Europe (SHIPS) [2]. In addition, this study investigated parental reporting and validated tests administered by professionals as follow-up tools for extremely and very preterm children and established how these correlated.

The EPICE cohort included 7,900 live-born children born from 22 + 0 to 31 + 6 weeks of gestation in 2011/2012 from 19 regions in 11 European countries including Eastern Denmark (Funen, Zealand, Lolland and Falster). The focus of the EPICE project was obstetric and neonatal care before and at the time of birth and during neonatal hospitalisation and during two years of follow-up [3]. The SHIPS project focused on follow-up programmes at five years of corrected age for the children also included in the EPICE cohort [3].

METHODS

Study population

All live and stillborn children with a gestational age from 22 + 0 to 31 + 6 weeks in Eastern Denmark (Funen, Zealand, Lolland and Falster) born from 1 May 2011 to 1 May 2012 were included in the Danish EPICE cohort. There are eight hospitals undertaking delivery and neonatal service in Eastern Denmark: Two level-3 Neonatal Intensive Care Units (NICU) (Rigshospitalet and Odense University Hospital) and six level-2 NICUs (Hvidovre, Glostrup/Herlev, Hillerød, Roskilde, Holbæk and Næstved). Perinatal data on maternal characteristics, pregnancy, birth and data from the neonatal period were obtained from medical records.

Two-year and five-year follow-up

All children in the EPICE cohort who survived to discharge were invited to participate in questionnaire-based follow-ups at two and five years of corrected age. The questionnaires included items on health, neurodevelopment, growth, health services and socio-demographic information. The five-year questionnaire included two subscales of the Ages and Stages Questionnaire (ASQ-3) designed for children up to six years, and the Strengths and Difficulties Questionnaire. The

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ABBREVIATIONS

ASQ = Ages and Stages Questionnaire
BPD = bronchopulmonary dysplasia
CI = confidence interval
EPICE = Effective Perinatal Intensive Care in Europe
IQR = interquartile range
ISCED = International Standard Classification of Education
IVH = intraventricular haemorrhage
M-ABC = Movement Assessment Battery for Children
MD = mean difference
PVL = periventricular leukomalacia
SHIPS = Screening to Improve Health in Very Preterm Infants in Europe
WPPSI = Wechsler Preschool and Primary Scale of Intelligence

ASQ addresses developmental problems. The subscales problem-solving and communication were scored according to the manual for ASQ 60 months [4]. The ASQ scores from the two subscales were converted into binary variables indicating "average development" or "potential developmental difficulties" (the cut-off values were 45 for problem-solving and communication).

The neurodevelopmental assessment

Extremely preterm children were invited to participate in neurodevelopmental assessments at five years of corrected age. Full-scale IQ was assessed by a psychologist using the Wechsler Preschool and Primary Scale of Intelligence (WPPSI) fourth edition [5]. Motor function was assessed by physiotherapists using the Movement Assessment Battery for Children (M-ABC), second edition [6]. The M-ABC overall score consists of three subscales: Manual dexterity, aiming/catching and balance. The subscale *manual dexterity* was used as a measure of fine motor skills. The raw scores from each subscale were converted into standard scores and percentiles and combined into a total standard score and total percentile rank using the reference table available in the manual. A score of less than or equal to the fifth percentile was used to classify a child as having a significant difficulty.

Variables

Information about the diagnoses intraventricular haemorrhage (IVH), periventricular leukomalacia (PVL), bronchopulmonary dysplasia (BPD), necrotising enterocolitis and retinopathy of prematurity was obtained from medical records. IVH was defined according to Papile grade 3-4 [7]. BPD was defined as need for oxygen supplement at 36 + 0 weeks of gestation. In the five-year questionnaire for parents, information about the diagnosis of CP was addressed by the following question *"Has your child been diagnosed with cerebral palsy by a doctor?"*. Gross motor function were addressed by the following questions *"Does your child have any difficulties walking?";* fine motor function by *"Does your child have any difficulties using his or her hands and fingers to handle small objects, such as buttoning buttons?"*. Gross and fine motor function was categorised as a binary factor (no difficulties/difficulties). Maternal educational level was classified according to the International Standard Classification of Education (ISCED) [8], as lower secondary (ISCED-level 1-2), upper secondary (ISCED-level 3-4) and tertiary (ISCED-level 5-8). Variables were categorised as presented in **Table 1** and **Table 2**.

Ethics and permission

Permissions to extract data from mothers and children's medical records and to invite families to participate in questionnaire-based follow-ups and neurodevelopmental assessments were obtained from the regional EPICE and SHIPS research coordinators and approved by the Danish Ethical Committee System and the Danish Data Protection Agency.

Statistics

Descriptive statistics were calculated. For variables with cell counts less than three, the exact number of individuals was not shown. p-values were computed to compare distributions of categorical variables based on χ^2-tests. For continuous variables, the Kolomogorow-Smirnov test was used to test for normality; and medians and interquartile range (IQR = 25- and 75 percentile quartile) were provided for non-normally distributed variables. An alpha level below 0.05 was considered statistically significant. Means and 95% confidence intervals (95% CI) were provided for M-ABC and WPPSI scores together with p-values from two-sided t-tests. Mean differences (MD) with 95% CIs were presented for overall motor function, fine motor function and full-scale IQ.

Trial registration: not relevant.

RESULTS

Danish EPICE cohort

The Danish EPICE cohort included 351 live-born and 90 stillborn children with gestational ages from 22 + 0 to 31 + 6 weeks. Among the live born children, 141 were extremely preterm and 210 were very preterm; of these, 87 and 199 survived to discharge, respectively. **Figure 1** presents the flow chart for the study population and the number of extremely and very preterm children at each follow-up. The response rate at two years was 66% (180/286 invited). The response rate at five years was 56.3% (152/270 invited and 16 children were lost to follow-up). A total of 47.1% (42/87) of the invited extremely preterm children participated in the neurodevelopmental assessment at five years.

TABLE 1 / Characteristics of live births and participants at the two-year and five-year follow-up and five-year neurodevelopmental assessment in the Danish EPICE/SHIPS cohort.

	Live births, n (%)			2-year follow-up, n (%)			5-year follow-up, n (%)			5-year neurodevelopmental assessment, n (%)		
	22-27 wks[a] BW: 798 (604-950) g[b] (N = 141)	28-31 wks[a] BW: 1,362 (1,165-1,605) g[b] (N = 210)	p-value	not followed BW: 1,235 (935-1,500) g[b] (N = 106)	followed BW: 1,199 (944-1,445) g[b] (N = 180)	p-value	not followed BW: 1,234 (925-1,445) g[b] (N = 134)	followed BW: 1,193 (945-1,471) g[b] (N = 152)	p-value	not tested BW: 851 (730-965) g[b] (N = 45)	tested BW: 903 (782-1,075) g[b] (N = 42)	p-value
Gestational age, wks[a]			-			0.7110			0.2753			0.3485
22-25	57 (40.4)	-		12 (11.3)	14 (7.8)		13 (9.7)	13 (8.6)		16 (35.6)	10 (23.8)	
26	32 (22.7)	-		6 (5.7)	14 (7.8)		7 (5.2)	13 (8.6)		8 (17.8)	12 (28.6)	
27	52 (36.9)	-		11 (10.4)	30 (16.7)		15 (11.2)	26 (17.1)		21 (46.7)	20 (47.6)	
28	-	43 (20.5)		16 (15.1)	25 (13.9)		21 (15.7)	20 (13.2)		-	-	
29	-	45 (21.4)		18 (17.0)	26 (14.4)		27 (20.2)	17 (11.2)		-	-	
30	-	51 (24.3)		17 (16.0)	31 (17.2)		20 (14.9)	28 (18.4)		-	-	
31	-	71 (33.8)		26 (24.5)	40 (22.2)		31 (23.1)	35 (23.0)		-	-	
Maternal age, wks			0.8830			0.2791			0.0293			0.0405
< 30	63 (44.7)	96 (45.7)		50 (47.2)	77 (42.8)		70 (52.2)	57 (37.5)		25 (55.6)	15 (35.7)	
30-34	40 (28.4)	65 (31.0)		36 (34.0)	54 (30.0)		39 (29.1)	51 (33.6)		14 (31.1)	12 (28.6)	
≥ 35	35 (24.8)	49 (23.3)		20 (18.9)	49 (27.2)		25 (18.7)	44 (29.0)		6 (13.3)	15 (35.7)	
Parity, n			0.5267			0.0570			0.1632			0.0866
0	87 (61.7)	120 (57.1)		55 (51.9)	118 (65.6)		75 (56.0)	98 (64.5)		34 (75.6)	24 (57.1)	
1	28 (19.9)	48 (22.9)		29 (27.4)	32 (17.8)		35 (26.1)	26 (17.1)		4 (8.9)	11 (26.2)	
≥ 2	21 (14.9)	39 (18.6)		22 (20.8)	29 (16.1)		23 (17.2)	28 (18.4)		7 (15.6)	7 (16.7)	
Sex			0.6135			0.0418			0.4310			0.9057
Girl	69 (48.9)	97 (46.2)		41 (38.7)	92 (51.1)		59 (44.0)	74 (48.7)		22 (48.9)	20 (47.6)	
Boy	72 (51.1)	113 (53.8)		65 (61.3)	88 (48.9)		75 (56.0)	78 (51.3)		23 (51.1)	22 (52.4)	
Type of pregnancy			0.0193			0.3750			0.2679			0.1711
Singleton	73 (51.8)	135 (64.3)		64 (60.4)	99 (55.0)		81 (60.5)	82 (53.9)		17 (37.8)	22 (52.4)	
Multiple	68 (48.2)	75 (35.7)		42 (39.6)	81 (45.0)		53 (39.6)	70 (46.1)		28 (62.2)	20 (47.6)	
Mode of delivery			0.0004			0.0085			0.0153			0.0756
Vaginal[c]	57 (40.4)	48 (22.9)		19 (17.9)	58 (32.2)		27 (20.1)	50 (32.9)		20 (44.4)	11 (26.2)	
Caesarean section	84 (59.6)	162 (77.1)		87 (82.1)	122 (67.8)		107 (79.9)	102 (67.1)		25 (55.6)	31 (73.8)	
Surfactant	86 (61.0)	74 (35.2)	< 0.0001	45 (42.5)	78 (43.6)	0.9061	59 (44.4)	64 (42.4)	0.7373	25 (56.8)	31 (73.8)	0.0984
Mechanical ventilation	81 (57.5)	37 (17.6)	< 0.0001	27.(25.5)	53 (29.6)	0.4525	39 (29.1)	41 (27.2)	0.7143	25 (55.6)	25 (59.5)	0.7083
Morbidity												
NEC	19 (13.5)	7 (3.3)	< 0.0001	8 (7.6)	7 (4.0)	0.1889	9 (6.8)	6 (4.0)	0.2989	4 (8.9)	5 (12.2)	0.6169
BPD	21 (26.3)	7 (3.7)	< 0.0001	10 (9.7)	17 (10.2)	0.9003	12 (9.6)	15 (10.3)	0.8388	12 (30.0)	9 (22.5)	0.4459
ROP	6 (4.3)	3 (1.4)	0.0557	5 (4.8)	4 (2.3)	0.2606	5 (3.9)	4 (2.7)	0.6054	3 (6.8)	3 (7.5)	0.9035
IVH	15 (10.6)	8 (3.8)	0.0040	4 (4.0)	5 (2.9)	0.2471	4 (3.1)	5 (3.4)	0.8710	< 3	< 3	-
PVL	< 3	< 3	-	4 (3.9)	0	-	< 3	< 3	-	0 (0.0)	< 3	-
In-hospital death	54 (38.3)	11 (5.2)	< 0.0001	-	-		-	-		-	-	-

BPD = bronchopulmonary dysplasia; BW = birth weight; EPICE = Effective Perinatal Intensive Care in Europe; IVH = intraventricular haemorrhage; IQR = interquartile range; NEC = necrotising enterocolitis; PVL = periventricular leukomalacia; ROP = retinopathy of prematurity; SHIPS = Screening to Improve Health in very Preterm Infants in Europe.
a) Completed wks. b) Median (IQR). c) Includes instrumental deliveries.

TABLE 2 / Outcomes at five-year follow-up.

	22-27 wks[a], n (%) (N = 52)	28-31 wks[a], n (%) (N = 100)	p-value
Parental rating of child health			0.2043
Excellent	23 (46.0)	49 (49.5)	
Good	22 (44.0)	47 (47.5)	
Fair/poor	5 (10.0)	3 (3.0)	
Parental rating of overall development			0.1399
Average/in advance	35 (74.4)	82 (82.0)	
Delayed	14 (28.6)	18 (18.0)	
Parental concerns			
Social interaction	6 (11.5)	8 (8.0)	0.4742
Learning	8 (15.4)	3 (3.0)	0.0052
Anxiety	4 (7.7)	10 (10.0)	0.6407
Appetite	9 (17.3)	13 (13.0)	0.4739
Sleep	5 (9.6)	5 (5.0)	0.2762
ASQ communication			0.8879
Average	33 (80.5)	75 (81.5)	
Potential difficulties	8 (19.5)	17 (18.5)	
ASQ problem solving			0.2796
Average	37 (74.0)	76 (81.7)	
Potential difficulties	13 (26.0)	17 (18.3)	
Fine motor difficulties	12 (23.1)	6 (6.1)	0.0022
Gross motor difficulties	< 3	5	-
Glasses/some vision difficulties	6 (11.5)	8 (8.1)	0.4864
Hearing difficulties	< 3	4	-
Diagnoses			
Cerebral palsy	< 3	4	-
Asthma	12 (25.0)	15 (15.3)	0.1564
Speech delay	4 (8.0)	12 (12.2)	0.4315
Developmental delay	7 (14.0)	6 (6.2)	0.2135
Visit(s) to specialists (last 12 months)			
Paediatrician	20 (38.5)	19 (20.2)	0.0170
Ear nose throat specialist	23 (44.2)	39 (41.5)	0.7483
Eye specialist	14 (26.9)	16 (17.0)	0.1562
Speech therapist	11 (21.2)	16 (17.0)	0.5380
Psychologist	8 (15.4)	5 (5.3)	0.0409
Physiotherapist	9 (17.3)	15 (16.1)	0.8547
Occupational therapist	8 (15.4)	10 (10.6)	0.4035

ASQ = Ages and Stages Questionnaire.
a) Completed wks.

Comparison of extremely preterm and very preterm live born children

The characteristics of the children in the Danish EPICE cohort are presented in Table 1. The median for birth weight was 798 (IQR: 604-950) g in the group of extremely preterm and 1,362 (IQR: 1,165-1,605) g in the group of very preterm infants. The proportion of multiples was highest among children born extremely preterm ($p = 0.019$). The proportion of neonatal morbidity including necrotising enterocolitis and bronchopulmonary dysplasia was highest in children born extremely preterm. In total, 38.3% extremely and 5.2% very preterm children died before discharge from hospital ($p < 0.001$).

Comparison of participants and non-participants at the two-year and five-year follow-up

Overall, the characteristics of participants and non-participants were similar. However, some significant differences were observed. The proportions of boys ($p = 0.042$), children born by Caesarean section ($p = 0.009$) and children with PVL (0/4 children with PVL) were lower in participants than in non-participants in the two-year follow-up (Table 1). At the five-year questionnaire-based follow-up, the proportions of children with younger mothers (< 30 years, $p = 0.029$) and children born by caesarean section ($p = 0.009$) were lower in participants than in non-participants. The maternal educational level was higher in participants (33.3% lower secondary, 19.1% upper secondary, 47.6% tertiary) than in non-participants (40.0% lower secondary, 26.7% upper secondary, 33.3% tertiary) at the five-year follow-up. However, the differences were not statistically significant. There was a significantly lower proportion of individuals with low maternal age (< 30 years) among participants than among non-participants.

Outcomes at the five-year questionnaire-based follow-up

In the five-year parent questionnaire, 94.6% of the parents rated their children's health as good or excellent, and 78.5% of the parents rated the children's overall development as average or in advance (Table 2). Less than three children did not attend kindergarten at five years; however, 31 (27.0%) children had special educational support such as higher teacher-to-child ratio in their kindergarten. Significantly more parents with extremely preterm children reported concerns regarding learning compared with parents with very preterm children. There were no other parental concerns that differed significantly between the two groups. No children had been diagnosed with ADHD, autism or epilepsy at the five-year follow-up. Four children in the very preterm group and less than three children in the extremely preterm group had been diagnosed with cerebral palsy. The proportions of children diagnosed with asthma and developmental delay were highest among extremely preterm children. However, these differences were not statistically significant. There was a larger proportion of parental reporting fine motor difficulties in extremely preterm children than in very preterm children ($p = 0.002$) (Table 2). Less than three children had gross motor difficulties among the extremely preterm and five had these difficulties among the very preterm children. Significantly more children in the extremely preterm group were followed by paediatricians ($p = 0.017$) and psychologists ($p = 0.041$).

Five-year neurodevelopmental assessment

The mean of the full-scale IQ based on WPPSI was 94.5 (95% CI: 89.1-99.8) for the 39 tested children (**Table 3**). The tested children whose mothers had a secondary education (e.g., compulsory school or high school) had a significantly lower full-scale IQ mean (MD = –15.0 (95% CI: –25.8–-4.2)) than children whose mothers had tertiary education (e.g., a bachelor's or master's degree). Children with an average development according to the ASQ subscales of problem-solving and communication had higher full-scale IQ scores than children with potential developmental difficulties ($MD_{problem\ solving}$ = 10.1 (95% CI: –2.1-22.4), $MD_{communication}$ = 7.6 (95% CI: –8.5-23.7)); however, these differences were not statistically significant.

Less than three children had gross motor difficulties and 12 (28.6%) children had fine motor difficulties according to parental reporting. Among the 12 children with parental reporting of fine motor difficulties, eight were classified as having fine motor impairment based on the M-ABC test. In the group of children with no parental reporting of fine motor difficulties, five (5/30) were classified as having fine motor impairment based on the M-ABC test. Extremely preterm children with parental reporting of fine motor difficulties had poorer overall motor function (MD = 2.8 (95% CI: 1.2-4.5)) and fine motor function (MD = 3.4 (95% CI: 1.7-5.1)) than extremely preterm children with no parental reporting of fine motor difficulties.

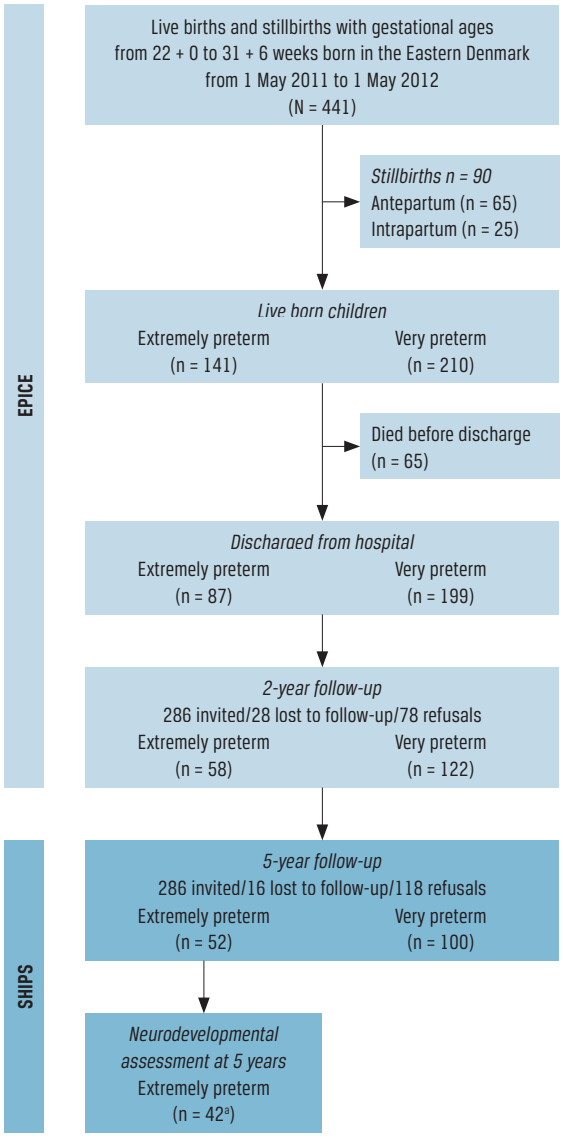

FIGURE 1 / Flow chart of the EPICE/SHIPS cohort.

EPICE = Effective Perinatal Intensive Care in Europe; M-ABC = Movement Assessment Battery for Children; SHIPS = Screening to Improve Health in very Preterm Infants in Europe; WPPSI = Wechsler Preschool and Primary Scale of Intelligence.
a) 42/42 completed M-ABC, 39/42 completed WPPSI.

DISCUSSION

In the Danish sub-cohort of the EPICE cohort, few children had severe functional limitations such as cerebral palsy and inability to walk. At five years, a larger proportion of extremely preterm children had fine motor skill difficulties. Most very and extremely preterm children attended kindergarten; however, a number of these children received special educational support. Parents of extremely preterm children were more likely to have concerns about the child's learning than parents of very preterm children.

Survival rate and morbidity data in the Danish sub-cohort born 2011-2012 were comparable to newly published data on children born preterm in 2018 from Dansk Kvalitetsdatabase for Nyfødte [9] and to data from the other European sub-cohorts of the EPICE cohort [2, 10, 11].

This study shows that parental reporting on fine motor function at five years correlates with fine motor function assessed by professionals at five years. Findings from this study indicate that parental questionnaires on fine motor function may be used as a tool to identify children with fine motor deficits as most of the children with parental reporting of fine motor difficulties had significant fine motor difficulty according to the M-ABC test. However, more children were identified as having significant fine motor difficulties using the M-ABC test than by parental reporting.

The working group preparing a national Danish guideline on follow-up of extremely and very preterm children could consider implementing the parental reporting tools used in the present study to compliment or possibly replace some of the professional tests in follow-up programmes of children born preterm. Future preterm cohorts could focus on enrolment of especially young mothers with lower levels of education who were less likely to participate in follow-ups.

TABLE 3 / Full-scale IQ and overall motor function at five years among extremely preterm children (22-27 weeks).

	Full-scale IQ: WPPSI-III			Overall motor function: M-ABC standard total score		
	n	mean (95% CI)	p-value	n	mean (95% CI)	p-value
Total	39	94.5 (89.1-99.8)		42	7.5 (6.7-8.4)	
Parental education			0.0077			0.3185
Lower/upper secondary	12	84.6 (72.6-96.6)		13	7.0 (5.3-8.7)	
Tertiary	26	99.6 (94.2-105.0)		27	7.9 (6.9-9.0)	
ASQ problem solving			0.1013			
Average	28	97.0 (90.5-103.6)				
Potential difficulties	10	86.9 (76.5-97.3)				
ASQ communication			0.3396			
Average	24	96.5 (88.7-104.3)				
Potential difficulties	7	88.9 (72.6-105.2)				
Parental reporting of fine motor function						0.0013
No difficulties				30	8.3 (7.5-9.2)	
Difficulties				12	5.5 (3.7-7.3)	

ASQ = Ages and Stages Questionnaire; CI = confidence interval; M-ABC = Movement Assessment Battery for Children; WPPSI = Wechsler Preschool and Primary Scale of Intelligence.

Limitations and strengths

In the present study, extremely preterm children were tested by professionals at five years with standardised tests. The WPPSI and the M-ABC test are reliable and valid [12, 13]. No term control group was included in the EPICE/SHIPS cohort, which limits the possibilities to compare the outcomes of very and extremely preterm children with those of children born at term. The response rate at the two-year follow-up was comparable to other European cohorts of very and extremely preterm children [11]. The response/participant rates fell in the 50.0-62.9% range in the follow-ups at five and two years. Therefore, the group of children who participated could potentially have been selected. Participants were more likely to have older mothers with a higher educational level. It seems likely that the parents to the children with the poorest health and developmental outcomes were less likely to participate in the questionnaire-based follow-ups. Thus, the rate of adverse health and developmental outcomes might be underestimated in this study. The small sample size increases the risk of not being able to detect true differences between groups (type-II errors). In addition, the χ^2-test may not be a valid test when expected cell counts are very low (< 5). Another strength of the EPICE/SHIPS cohort is that the participants and the information collected about the participants are comparable between different European regions as national transport and treatment guidelines regarding preterm children are fairly similar and the questionnaires were standardised between regions.

CONCLUSIONS

In the Danish sub-cohort of the European EPICE cohort, few children had severe difficulties such as cerebral palsy and lack of ability to walk at five years of corrected age. Parental questionnaire-based reporting of fine motor function difficulties was an indicator of significant fine motor difficulties found by professionals using the M-ABC test. National follow-up programmes could use standardised tests as used in the EPICE/SHIPS.

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