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QUALITY OF SURVIVAL IN SIOPE BRAIN TUMOUR CLINICAL TRIALS FOR CHILDREN AGED LESS THAN 5 YEARS: DEVELOPMENT OF A CLINICAL TRIAL PROTOCOL

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INTRODUCTION

- There is international recognition of the need to assess Quality of Survival (QoS) in children treated for brain tumours.
- The QoS working group of the European Society of Paediatric Oncology (SIOPE) Brain Tumour group developed the **core 'plus' model** of QoS assessment in clinical trials for children aged 5–18 years (Limond et al., 2015).
- As a next step the QoS group of SIOPE brain tumour group has established a consensus for QoS assessment for children aged <5 years.

QoS ASSESSMENT IN CHILDREN AGED <5 YEARS

- Similar to older children, areas of assessment discussed include **core medical domains** (e.g. vision, hearing, mobility, endocrine), **emotion, behaviour, adaptive behaviour, and cognitive functioning**.
- For **children aged 0-3 years** it was agreed that significant difficulties are encountered in obtaining reliable and valid data from direct assessments. Therefore **indirect assessment** (i.e. parent-report questionnaires, medical and endocrine data) are recommended as the primary outcome measures, and makes up the core battery.
- For **children aged 4 years**, as with the 5-18 year consensus, a **core 'plus' approach** is suggested in which core assessments (direct and indirect tests) are recommended for all clinical trials.
- The **core component** is a brief screening assessment (direct and indirect tests) that, in most countries, is a sub-component of routine clinical provision and therefore achievable even where specific resources for QoS assessment are unavailable.
- The **'plus' component** enables the addition of assessments which can be selected by individual countries and/or tumour-, age-, and location-specific groups in order to enhance the overview of specific medical (e.g. detailed H-P hormone function for suprasellar tumors), cognitive and other relevant domains.
- Due to the risk of incomplete data collection due to young age and limited participation, a **specific test order** is recommended for the core/plus model of cognitive functioning to maximise data sets for cross-centre and cross-country comparison.
- Issues highlighted for this younger age group include reliability and validity of infant and young child measures, predictive value of early measures, and compatibility of measures across countries and age groups.

INDIRECT MEASURES OF COGNITIVE, PSYCHOSOCIAL AND MEDICAL FUNCTIONING CORE COMPONENT (age 0-4 years)

Demographic and Medical Information (from 0 years)	
Medical, Educational and Employment and Social Questionnaire (MEES, adapted)	
Adaptive functioning (from 0 years)	
Vineland III parent report questionnaire	
Quality of Life (from 1 month)	
PedsQL core and multidimensional fatigue	
Mental Health, Social Interactions and Behaviour (from 2 years)	
The Strengths and Difficulties Questionnaire	
Executive Functioning (from 2 years)	
The Behaviour Rating Inventory of Executive Function - Preschool	
Endocrine measures	
Birth Weight (kg)	
Gestation (weeks)	
Parental heights (cm)	
Standing height (cm or SDS) or lying height (0-2 years)	
Sitting height (cm)	
Weight (kg)	
Tanner pubertal staging and age at menarche in girls	
FT4 and thyroid stimulating hormone	
Follicle Stimulating hormone	
Start and end dates of any hormone replacement therapy	

DIRECT MEASURES OF COGNITIVE FUNCTIONING (Age>3 years, except development domain) CORE 'PLUS' MODEL AND HIERARCHICAL TEST ORDER

Domain			
Order	Core Measures	Supplementary/ 'Plus' Measures Order	Examples of specific measures available in Europe
Development			
		Developmental quotient	Bayley-III; Griffiths, Brunet-Lezine R
Language			
1.	Receptive		Wechsler Receptive Vocabulary
2.	Expressive		Wechsler Picture Naming
Perceptual/Fluid Reasoning			
3.	Matrices		Wechsler Matrix Reasoning or Raven's CPM
		9. Visual motor reasoning	Wechsler Block Design
Processing Speed			
4.	Processing Speed		Wechsler – Bug Search or Symbol Search
6.	Processing Speed		Wechsler - Animal Coding or Coding
Short Term / Working Memory			
5.	Number Recall		K-ABC – Digit Span Forwards
		10. Locations recall	Wechsler – Picture memory
Fine Motor Skills			
		7. Pegboard	Purdue Pegboard; WRAVMA Pegboard
Visual Motor Skills			
		8. Visual motor integration	Beery VMI or WRAVMA Drawing Test or NEPSY Design Copy
Semantic Memory/Knowledge			
		11. Verbal semantic memory	Wechsler - Information Kaufman ABC - Riddles Wechsler - Vocabulary
Long-term Memory			
		12. Verbal episodic memory	NEPSY-II Narrative Memory Kaufmann ABC - Atlantis

CONCLUSIONS

- The QoS group has developed the core 'plus' model to assess Quality of Survival in children under five
- The QoS group has agreed a hierarchy of neuropsychological assessments to maximise data collection to enable statistical analyses of these data in a larger number of patients than has previously been possible.