SAGE Research Methods Cases

Medicine & Health

Submission for Consideration

Case Title

Conducting a Feasibility Study in a Global Health Setting for constructing a Caregiver-reported Measurement Tool: an example in Infant and Young Child Development (IYCD)

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Contributor Biographies

Gillian Lancaster is Professor of Medical Statistics, Director of Keele Clinical Trials Unit and Head of the Biostatistics Group within the School of Primary, Community and Social Care at Keele University. Her research scopes many medical and social applications, with a specific interest in global health and methodology for developing Patient Reported Outcome Measures and assessment tools primarily for use on children and young people (e.g. Alder Hey Triage Pain score, EARLI, MDAT, ADNAT, CLCF). She is currently Editor in Chief of the BMC journal Pilot and Feasibility Studies and co-author of the CONSORT extension to pilot and feasibility trials. She is also a member of a global health working group convened by the World Health Organisation (WHO) to develop indicators for Infant and Young Child Development (WHO IYCD), and the Global Scales of Early Development (GSED) funded by the Gates Foundation. She is a strong advocate of statistics education and was Director of the Lancaster Postgraduate Statistics Centre for 9 years.

Patricia Kariger PhD, is a developmental psychologist specializing in assessing child development in US, Africa, South and Southeast Asia, and Latin America. She has extensive experience working on nutrition, health and early education evaluations. Dr. Kariger is part of the IYCD team and a World Health Organization (WHO) team developing a population-level tool (Global Scales of Early Development) for children under three years of age. She currently is a Senior Research Associate in the School of Public Health, University of California, Berkeley.

Gareth McCray completed his PhD at Lancaster University in late 2014. He is currently working in the School of Primary, Community and Social Care at Keele University. His current research includes modelling child development trajectories in developing countries, test linking IRT, and the diagnosis of Neurodevelopmental delay in 0-3 year-olds. He has expertise in psychometrics, simulation methods and expert judgement collection and analysis. He has worked extensively on the construction of the IYCD (Infant and Young Child Development) indicators for the WHO and the GSED. He has also worked as a consultant for Oxford University Press, and The British Council language testing divisions.

Magdalena Janus has a PhD in behavioural sciences from Cambridge University, UK and is a Professor at McMaster University, Hamilton, Canada, where she holds the Ontario Chair in Early Child Development (ECD). She is a co-author of the Early Development Instrument (EDI), a measure of children's readiness to learn at school entry. Dr. Janus and her team led the implementation of the EDI in Canada, which now surpassed 1 million children and is a widely-used source of population-level data on early child development.  The EDI has been adapted for use in a number of countries. Dr. Janus regularly works with organizations such as the World Bank, WHO, UNICEF, and UNESCO on the measurement and indicators of early child development. She has been a core member of the IYCD team since its inception, and is currently a member of the Global Scales of Early Development (GSED) funded by the Gates Foundation.

Melissa Gladstone is a Senior Lecturer in Neurodevelopmental Paediatrics and International Child Health at the University of Liverpool. Her main research interest is in the assessment of neurodevelopmental and neurobehavioural outcomes in children in low income settings globally. She has undertaken and is presently undertaking large field studies in a number of African settings looking at the effect of health and social factors on early child development (malaria in pregnancy, nutrition, prematurity, HIV exposure) but is also interested to pursue the linkages between assessment of children’s development and behaviour with interventions which can be provided in low income settings. She created a neurodevelopmental assessment tool, the MDAT, which is being utilised in over 10 countries in Africa for research and programmatic work – much of this linking early interventions in nutrition, WASH and early stimulation programmes with later outcomes in children. She has recently been working with the WHO on creation of the Infant and Young Child Developmental (IYCD) indicators and the Global Scales of Early Development (GSED). Her future plans include incorporating ways of better measuring childhood disability in the early years in multiple settings globally.

Vanessa Cavallera, M.D is a child neurologist and psychiatrist with a Master’s in Public Health. She conducted clinical work at Besta Neurological Institute in Italy, and evaluations of early childhood development programmes for different NGOs. She currently consults for the Mental Health and Substance Abuse at the World Health Organization in Geneva where she works on indicators to measure early child development and approaches for scaling up programmes.

Tarun Dua is a Coordinator in the World’s Health Organization Headquarters in the Department of Mental Health and Substance Abuse and the focal point for neurological disorders in the organization. Currently, she leads the WHO project on population-based assessment of early child development. She is a member of the WHO Secretariat for the newest (2016) Lancet Series on early child development; and for establishing research priorities for early child development.

Claudia Regina Lindgren Alves, PhD, is a pediatrician and Associate Professor in the Pediatric Department of the Federal University of Minas Gerais (UFMG). She has been working with primary health care system for more than 20 years and more recently on the cultural adaptation and validation of tools to assess child development in this setting. She coordinated the Primary Health Care Nucleus (NAPS) programme (2009-2018), was a member of the WHO IYCD research team (2016), and coordinated a project “Fostering the development of preemies through stronger child-family wellbeing”, funded by Grand Challenges Canada - Saving Brains (2014-2016). She currently coordinates a validation study of the “Survey of the Wellbeing of Young Children” (SWYC) in Brazil for screening developmental and behavioral disorders, and is a project member evaluating an educational intervention funded by the Brazilian Ministry of Health (2018-2019). She is senior advisor of the Postgraduate Program in Health Sciences and has been the Head of the Department of Pediatrics (2014-2016).

Muneera A. Rasheed is a faculty member in the Department of Paediatrics and Child Health, Aga Khan University, Karachi, Pakistan. A paediatric psychologist by profession, her interest is studying how psychology and implementation sciences can complement healthcare for improved health outcomes and quality of life of children and families using the services. Her recent work includes improving employee engagement for enhanced patient experience of care within paediatric services. She also has significant experience with early responsive care for young children and families in community-based services. Future endeavours are looking at application of knowledge gleaned from her community based studies to the children either admitted or accessing outpatient services. Currently, she is an investigator on multiple ECD implementation grants.

Limbika Senganimalunje, MA, is a consultant Psychologist at Chancellor College, University of Malawi. Limbika does research in Clinical Psychology, Psychometrics and Developmental Psychology. She has a vast eperience in training and supervising assessors administering different neurodevelopmental and behavioral standardized tests to HIV exposed and non-exposed children across Malawi and Zimbabwe. In addition, she also has experience with attachment tools in infancy.

Published Articles relevant to the case study

1. Lancaster G.A., McCray G., Kariger P., Dua T., Titman A., Chandna J., McCoy D., Abubakar A., Hamadani J., Fink G., Tofail F., Gladstone M., Janus M. (2018) Creation of the WHO Indicators of Infant and Young Child Development (IYCD): meta-data synthesis across ten countries. *BMJ Global Health* 3:e000747.
2. Lancaster G.A., Thabane L. A guide to the reporting of non-randomised pilot and feasibility studies. *Pilot and Feasibility Studies* 5:114*.*
3. Eldridge S., Chan C., Campbell M., Bond C., Hopewell S., Thabane L., Lancaster G.A. (2016) CONSORT Statement: extension to randomised pilot and feasibility trials. *BMJ* 355:i5239. (dual publication with Pilot and Feasibility Studies journal).
4. [Lancaster, G.](http://www.research.lancs.ac.uk/portal/en/people/gillian-lancaster%28ad4fed9a-4ce7-4749-92b5-f2a12424f81d%29.html)A (2015) [Pilot and feasibility studies come of age!](http://www.research.lancs.ac.uk/portal/en/publications/pilot-and-feasibility-studies-come-of-age%28da54edd0-674b-4862-97fe-aa0d5dbc8277%29.html) *Pilot and Feasibility Studies* 1, 1.

Abstract

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The early childhood years provide an important window of opportunity to build a strong foundation for future development. The newborn’s skills and abilities increase rapidly in a secure, stimulating environment, with supportive interactions and adequate nutrition. These environmental conditions however are not in place for millions of young children living in underprivileged conditions in poorer countries, putting them at risk for suboptimal development. The urgent need for early child development (ECD) support has been widely acknowledged, but one impediment to global progress is the lack of a population-based measurement framework for children under 3 years of age that can provide reliable estimates of developmental status.

This case study describes the feasibility phase of a programme of work to create the World Health Organisation (WHO) Infant and Young Child Development (IYCD) assessment tool for use in surveillance monitoring and as an outcome measure in intervention studies.

Learning Outcomes

By the end of this case, students should be able to:

* Explain the importance of conducting a feasibility study in preparation for a main study
* State feasibility objectives appropriate for developing and testing measurement tools in global health settings
* Design a feasibility study to be carried out in low and/or middle income countries concerned with measuring early child development
* Anticipate potential problems that may arise and how these might be addressed
* Appreciate the importance of working in collaboration with country experts in the field

Case Study [2,000 to 5,000 words.]

**Project Overview and Context**

There are several reasons why global indicators for population-level measurement of early child development (ECD) are important: they provide epidemiological information on the burden of sub-optimal development in early childhood in countries; they aid in national decision-making regarding priorities for funding; they direct interventional efforts to improve ECD and monitor progress and performance; and they serve as benchmarks for international and national efforts to improve ECD. Even though advances have been made in measurement of children’s development at preschool and school entry ages (3 to 6 years), the population level assessment of very early child development (0-3 years) and their environments has been hampered by several challenges, including lack of consensus about what is to be measured, how it will be measured, and by whom.

In the global health setting programmatic interventions require robust outcome measures that are easy to use and have been shown to be valid and reliable. However the number of potential measurement tools available for assessing child development is limited, especially in the early years. Tools generally comprise of a set of items divided into several domains that test gross and fine motor skills, language and cognition, and socio-emotional skills. The items can be directly assessed by a trained assessor observing the child passing or failing the items, or by caregiver-report by asking the caregiver (usually the mother) to state whether the child can or cannot perform the particular task - which is the most cost-effective method.

The *preliminary work* in our programme, completed prior to the feasibility study undertaken and described here, included a conceptual and empirical process to identify items from 7 instruments used to gather data on the development of children under three years in 10 low- and middle-income countries (LMIC), amounting to a meta data synthesis of 21,083 children. This preliminary work has been described elsewhere (Lancaster et al., 2018) and produced version 1.0 of our prototype IYCD tool, with items spanning the domains of: fine and gross motor development, expressive and receptive language, and socio-emotional development. At this age cognitive items were dispersed among the other domains as they are closely interlinked and did not form a separate domain.

**Research Design**

The feasibility study was carried out in preparation for a larger cross-sectional study, which would validate the IYCD tool, in 3 countries (Brazil, Pakistan and Malawi). The feasibility study was conducted to set up, prepare and test procedures prior to field testing the tool. We followed the CONSORT extension to pilot trials guideline and related editorials for reporting non-randomised studies when planning the study (Lancaster, 2015; Eldridge, Chan et al., 2016; Eldridge, Lancaster et al. 2016; Lancaster and Thabane, 2019).

Our feasibility objectives were to:

1) prepare v1.0 of the tool in a format ready for administration, together with Standard Operating Procedures (SOPs) and training instructions for data collection, and draft forms for collecting additional, relevant contextual data; then train country team assessors in the use of the materials

2) translate and back translate all items in the tool in all three settings

3) confirm cultural acceptability of all items through focus groups and interviews with both lay persons and professionals within each country

4) test recruitment and data collection in the field in a small sample of children and caregivers from each site, and examine the performance of items previously assessed by direct observation, and now reframed to be assessed via caregiver report, in the 3 countries (a less expensive implementation).

The feasibility study utilised a mixed methods approach by collecting both qualitative and quantitative data. Procedures for data collection included creation of paper versions of the forms, the set-up of tablets for remote data capture, and devising recruitment procedures for identifying suitable child/caregiver participants in each country.

**Study settings and ethics approval**

The study was limited to three countries for carrying out the feasibility, training and implementation work. Country team leads from three institutions were identified as partners to test implementation of the procedures: i) CLA at the Federal University of Minas Gerais, Brazil; ii) MR at Aga Khan University, Pakistan; iii) LS at the University of Malawi, Malawi. In each stage of the study, the three country teams were fully engaged and contributed to the process of designing the tool and field test methodology.

The feasibility (and field test) protocol was approved, by the WHO Ethical Review Committee (ERC 0002747), the Ethics committee of the Federal University of Minas Gerais (1.487.028), the Aga Khan University Ethics committee (4139-Ped-ERC-16), the College of Medicine Research Ethics Committee, University of Malawi (P.03/16/1916), and the McMaster Hamilton Ethics Review Board (1613).

**Methods**

1. **Data collection tools, SOPs and training**

The list of IYCD items finalized during the preliminary work was set out in a formatted Word document with helpful prompts for some items to aid understanding, and a training manual with instructions on how to carry out the assessments was created. One member of the WHO team drafted each piece of material and then it was circulated to other team members to add information and/or amend in an iterative process.

A comprehensive set of 11 Standard Operating Procedures (SOPs) was written for the administration of the tool and delivery of all processes during this phase of work by the WHO team. The SOPs were based on existing documents (e.g., for anthropometry), or on the investigators’ experience, and in consultation with country team leads.

**Data collection of contextual information including demographic, household, and child health characteristics**

In global health studies it is important to place developmental assessment in the context of where the child lives and their home environment. Therefore additional data were collected on i) children’s demographic characteristics, such as age, sex and health status, and ii) the quality of the child’s family environment. A number of existing measures for assessing this information were piloted for their potential use in the future larger scale study. The specific measures proposed were child anthropometric measures (WHO Multicentre Growth Reference Study Group, 2006), socio-economic status (Demographic and Health Surveys Wealth Index) (Rutsein and Johnson, 2004; Rutstein and Staveteig**,** 2014), and the MICS (Multiple Indicator Cluster Survey) Family Care Indicators (Kariger, Frongillo et al., 2012) for measuring support for learning and around the home. Appropriate data collection forms were created for the sites, including a front sheet comprising information on age, date of birth, whether the child was well, exclusion criteria checks, and anthropometric data.

**Training of assessors**

Flexibility was given to country leads to organize training of their teams based on the experience of the assessors recruited. The learning objectives of the training included how to:

* teach effective rapport building techniques for use with caregivers and children
* collect caregiver-reported data using the prototype tool guide
* collect data through direct administration by a trained assessor, to compare whether items previously assessed by a trained assessor could be accurately reported by the caregiver when presented as a caregiver-reported item
* ensure accurate completion of all data collection forms
* apply and use the standard operating procedures guidelines.

In Brazil not much training was needed because the assessors all had previous experience in measurement work. CLA, the country team lead, was a pediatrician and academic, who had been working in primary health care for more than 20 years and in the cultural adaptation and validation of tools to assess child development in this setting. Additionally, two research assistants were recruited - a physical therapist, and an occupational therapist.

The country lead in Pakistan (MR) was a Senior Instructor at Aga Khan University in Karachi. She had extensive experience with adaptation of measures for child development and of training community based field assessors from South Asia, Eastern Europe, Africa and South America. She was helped by a psychology graduate and an experienced operational manager of ECD studies. Two additional assessors were recruited for data collection: a graduate with experience in field base data collection, and a masters in sociology graduate. The training was conducted over 4 days with a mixture of lectures, group discussions and role plays. Additionally, direct supervision during a field visit (with two families) was organized for one morning.

In Malawi the country lead was LS, a psychologist at the University of Malawi. She had experience over 3 years of using and training on the Mullen Developmental Scales. The two assessors who were trained included one nurse, who had been working and training on the Malawi Developmental Assessment Tool (MDAT) for the last 10 years and one research field worker, a graduate who had trained on Care for Child Development and the MDAT in the past two years. The training was conducted over 1 day at Malawi Liverpool Wellcome Trust and was followed by a few days practice in the field.

1. **Translation and back translations**

The translation and back translation process for the prototype tool was standardized across the three study sites. The tool was translated into Brazilian Portuguese, Sindhi and Chichewa by two different local translators (unaffiliated with the research project). A consensus meeting was then held at each site to agree on the wording in the local language. The country leads identified the best people to be present during the meeting, including at least 2 or 3 who had adequate expert knowledge to ensure that the translations captured nuances related to child development. The version that was agreed upon was then forwarded to two different local translators (unaffiliated to the research project) for back translation into English. A second consensus meeting was held to agree on the back translation. The version that was agreed upon was sent to the WHO team who reviewed it. Items that appeared to differ in wording or meaning from the original English version were flagged and underwent additional translation and back translation for definition of the final wording of the items.

1. **Qualitative focus groups and interviews to assess cross-cultural acceptability of items**

Version 1.0 of the topic guide was used for focus groups and interviews with additional simple questions asked about the understanding and cross-cultural relevance of each item. The qualitative component included focus group discussions (FGDs), and semi-structured in-depth interviews (IDIs), at which each item was discussed and checked, to inform the cultural adaptation and appropriate translation of the tool. The sampling scheme for participants of the FGDs included caregivers of young children 0-3 years (n=38), and professionals with (n=42) and without (n=38) knowledge of early childhood development distributed among 7, 6 and 7 FGDs, respectively, held among the three countries (with at least 2 FGDs per country conducted in a rural and urban/peri-urban area). Similarly a total of around 15 IDIs were planned with people from each lay and professional groups. The sampling was purposive and therefore participant figures were approximate when planning the scheme.

In Brazil professionals and lay people were recruited while the team was working in the primary health care units in Belo Horizonte and in Diamantina. In Pakistan participants for the focus group discussion were recruited through convenience sampling by the local country team. In Malawi lay people and caregiver participants were recruited through local health care workers in under-5 clinics in Chilomoni and Bangwe. The Malawi research team also conducted study sensitization meetings with management teams, clinicians, nurses and local health care workers prior to study initialization, reassuring the health care workers that if they did not take part this would not affect their employment in any way. Some professionals were contacted through one of the leads in Paediatrics or Community Health so that no one specific person was coerced into being involved in the study.

In all countries a form containing the list of items in the prototype was given out to all members of the focus group beforehand (if they had good literacy) or read out during the focus group for those with lower literacy levels. Semi structured interviews were conducted with individuals separate from those in the focus groups. During both the FGDs and interviews, all items were read aloud by the facilitator and notes were taken item-by-item.

**4) Testing data collection in the field**

We aimed to administer the tool to a convenience sample of 32 child/caregiver dyads, sampling 2 males and 2 females from each of 8 age categories (0-2, 3-5, 6-8, 9-11, 12-18, 19-24, 25-36, 37-42 months) in Brazil, Malawi and Pakistan; a total sample size of 96.

In Brazil participants were recruited when they attended a health care centre receiving any type of assistance (e.g. medical consultation, immunizations etc.). If the caregiver and child were available they were interviewed and assessed at time of recruitment. If not, another time was scheduled with them at the centre or at home, whichever the caregiver preferred. In addition in the urban setting mothers working at the hospital in roles not directly related to children (e.g. cleaners, cooks, office workers etc) were recruited at the Sofia Feldman day care centre and interviewed during working hours with permission from the director. In the rural setting community health agents provided a list of all eligible children living in their area, who were invited to come to clinic to be interviewed and/or assessed, or the team visited the home to approach the family.

In Pakistan the country team recruited in districts where they had been working for the last 9 years in partnership with the District Health department. A relationship of trust existed in the community, and the Lady Health Workers (LHWs) had been part of numerous child health and development studies. The District Health Officer was informed of the study and his approval was taken prior to the study. Participants were selected through random sampling from a list of registered children in the area with the respective LHWs, and then research assistants approached the families, and an appointment was scheduled for the administration of the measures.

In Malawi participants were identified and recruited through under-5 clinics in Bangwe and Chilomoni. The team then asked those who were selected and interested to come back for recruitment and assessment in a week’s time. The assessment took place in a separate private room in the Bangwe and Chilomoni health centres.

The performance of each item with respect to caregiver report vs direct observation, was examined using quantitative methods. A statistical report showing plotted empirical responses (probabilities of passing the item) for each item by age, for both caregiver reported and directly assessed items, was used to facilitate discussion of items. Frequency counts and summary statistics were provided to determine how well each set of results related to the other, and whether a caregiver report could be substituted for direct observation of the item with or without modification. This process identified any confusing wording, potential inconsistencies in data collection and problematic items.

All data were reviewed for each item by a panel of experts (including the research team) at a face-to-face meeting to identify whether items should either: i) stay the same, ii) be reworded, or iii) be removed from the tool before going forward to the larger study. The following criteria were considered:

* comments from focus groups and interviews regarding the cultural acceptability and understanding of the item
* issues with translation and back translation of items
* empirical item response curves plotted against age
* age range of children undertaking and passing the item.

**Testing feasibility of tablet-based data collection**

In the latter part of the feasibility study we decided to determine whether data collection could be carried out on tablets. IT specialists at Liverpool School of Tropical Medicine were engaged to set up and implement a system for piloting this approach. This development ran concurrently to the feasibility study.

Section summary

* *It is important to sit down and plan what the feasibility objectives are right at the start of the study*
* *Methods should describe how each objective is to be addressed, and may be adapted or changed during the study to ensure they will work well in the larger future study*
* *A feasibility study allows any uncertainties in study design to be trialed and tested in preparation for conducting the main study*

**Research Practicalities**

Several practical considerations emerged from our feasibility work when testing out the items as outlined below:

* **Language/translation:** For gross motor items in particular, it became apparent that language needed to be specific to the context – sometimes this might mean changing a word used, or that a similar word to the English did not exist in another language.
* **Standardisation of training:** For some items it was suggested to add clear and specific probes and/or guidelines for administration (with examples) and for scoring whether an item was a pass or fail (Yes or No).
* **Cultural considerations:** In the feedback, for certain items, caregivers either did not have opportunity to observe their child performing certain tasks (e.g. playing with blocks in Malawi), or children did not typically have access to pens/pencils at an early age (e.g. in Pakistan until 1 year); or one or two item tasks were found to be too specific to girls rather than boys (e.g. Does your child ever try to imitate you, when you are cooking or cleaning? Does your child try to sweep or pretend to sweep, or pretend to cook or wash clothes, etc.?). Items in the fine motor domain in particular were modified according to the cultural availability of certain named objects, and gender-oriented tasks were altered or examples of other tasks added to the probes.
* **Administration:** For some items it was suggested to add pictures or demonstrations to explain the items; or to score multiple similar items in a single administration (e.g. identifying 2, 5, 10 objects); or to change the format of the data collection form to facilitate the scoring. Pictures and sounds were recorded from then on and implemented into the paper and tablet versions of the tool, with caregivers’ consent.
* **Reliability of items:** Items relating mainly to the socio-emotional domain caused some concerns with respect to caregivers finding it hard to decide on a definitive Yes/No response. It was decided to add a third category response for these items so caregivers could choose ‘Always/Almost always’, ‘Sometimes’ or ‘Never/Almost never’ as to whether their child showed certain behaviours.

Section summary

* *Close scrutiny of translation and back-translations of a tool may highlight language anomalies which need to be dealt with before use in the field*
* *Standardisation of methods of training for implementing the tool helps maintain consistency of use across country sites*
* *It is important to tease out cultural aspects which may affect item responses before, during and after field testing*
* *Pictures and sounds may aid understanding of certain items*

**Practical Lessons Learned**

We were an experienced team of researchers who all had practical expertise in ECD, pilot and feasibility studies and/or tool development, which helped in troubleshooting any problems. A few lessons learned are as follows:

* Try and select country team leads to work with that are already known to members of the team. It is easier to work with people that you know and/or have worked well with before.
* We recommend that a brief introductory session on ECD is held at the beginning of assessor training, as it can help country teams to build the basic knowledge required to complete their tasks well. Such training should include things like age-based milestones, and types of activities children are likely to be able to do at different ages.
* Training should include practicing in the field, and allow opportunity to practice across the age range of children. Data collection should take place as much as possible straight after the training has taken place.
* Translation and back translation of items across countries takes up quite a bit of time and requires input from the country teams, as the meaning may become distorted away from colloquial language if professional translators are employed.Reaching consensus on a correct translation needs to include all partners to ensure commensurate meaning of items – we held many joint meetings by skype with the country teams. We used excel spreadsheets to list all the item translations and then a summary sheet to collate the feedback on each item from each country team lead.
* Videos and pictures are helpful for caregivers to visualize the skill that is being considered, and understand the concept behind the question. During the latter part of data collection we realised that this would be helpful and began to take pictures and record sounds to be used as prompts for some of the items, with caregiver consent, ready to be added to the next version of the prototype tool, which in our case would be tablet based, for the larger study.
* The use of a tablet is recommended as a standard data collection procedure, but it is advised to also always have a paper version at the ready for training purposes and in case IT problems occur out in the field.
* Make sure you have good file naming conventions for forms and materials development up front, with version numbers and dates to facilitate the amendment of documents trail e.g. “DCF1a Translation 1\_[Country] [dd.mm.yy]” Keep all generated materials in a central file repository for the research team to easily access – we used Dropbox.

Section summary

* *Working with country teams as academic partners makes the project enjoyable and rewarding*
* *Enough time should be factored into the study for training, translation and practicing with families on the ground, and for development of tablet data entry Apps*
* *Having an organized approach to file management and storage will be very helpful once amendments to documents start to be made by multiple team members.*

**Conclusion**

The most important outcomes of the feasibility study were that following the setup, and refining and testing of the procedures we were confident that the larger field test study could go ahead as planned. The translation of the IYCD tool into 3 languages, which based on the small amount of data collected and analysed, contained items that empirically appeared to work well across ages, domains, and settings.

An additional advantage, was that this feasibility study enabled us to have a full set of SOPs and additional contextual data collection tools ready and piloted across the three countries. These could now be used in the larger field study to validate the IYCD tool.

We established processes for translation and back translation of the tool, as well we managed to prepare a tablet implementation with pictures and sounds which made things faster and easier for data collection going forward.

Section summary

* *There is a need for easy to use measurement tools to assess early child development in very young children aged 0-3 years*
* *We created the first prototype version of a caregiver-reported tool to measure Infant and Young Child Development (IYCD) and tested the feasibility of implementing it in 3 countries*
* *We established and tested a set of processes and procedures that worked well and would be adopted in the larger scale validation study.*

Classroom Discussion Questions

1. Discuss the pros and cons of conducting a feasibility study in preparation for a larger scale definitive study. Should the specified aims and objectives differ between the two types of studies?
2. Do you think the recruitment strategies used within each country were appropriate in the IYCD feasibility study - why, or why not?
3. Could the methods employed in the IYCD feasibility study be applied in other types of outcome development studies conducted: i) in children and ii) in adults? Please give reasons for your answer.
4. What do you think are the essential phases of development in creating health outcome measures in a dedicated programme of research based on what you have read here?

Multiple Choice Quiz Questions

1. Our aim in carrying out a feasibility study was to:

A. Prepare for a larger cross-sectional validity study (CORRECT)

B. Prepare for a meta-data synthesis of child data collected from multiple studies

C Prepare for conducting a randomized controlled trial

 2. We recruited a small sample of caregivers/children because:

A Our funding would not allow us to recruit anymore participants

B. We did not manage to collect large enough numbers to carry out the main study

C. We wanted to test out the processes and procedures that would be used in the main study before proceeding with the larger scale study (CORRECT)

3. The feasibility study showed that:

A. The IYCD tool was not good enough for measuring early child development

B. It is important to work with country teams to understand cultural differences when translating and implementing a newly developed tool (CORRECT)

C. The country assessors wrote the SOPs in a shared iterative process of amendment which worked well.

**Declaration of Conflicting Interests**

*The Authors declare that there are no conflicts of interest.*

Acknowledgements

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Further Reading

**Cooper H., Lancaster G.A., Gichuru P., Peak M**. (2018). A mixed methods study to evaluate the feasibility of using the Adolescent Diabetes Needs Assessment Tool App in paediatric diabetes care in preparation for a longitudinal cohort study. *Pilot and Feasibility Studies* 4:13.

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Web Resources

[Insert links to up to six relevant web resources here]

**IYCD tool website:** <https://ezcollab.who.int/iycd>

**PAFS (Pilot and Feasibility Studies) working group.** Pilot and feasibility studies: giving your research the best chance of success. <https://pilotandfeasibilitystudies.qmul.ac.uk/>

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**The Lancet series on Advancing Early Childhood Development: from Science to Scale.** <https://www.thelancet.com/series/ECD2016>

**WHO Multicentre Growth Reference Study Group**. WHO Child Growth Standards: Length/height-for-age, weight-for-age, weight-for-length, weight-for-height and body mass index-for-age: Methods and development. Geneva: World Health Organization, 2006.

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