Mali - Project Jigifa Endline Survey 2016

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Identification

SURVEY ID NUMBER
MLI_2016_PJ-EL_v01_M

TITLE
Project Jigifa Endline Survey 2016

SUBTITLE
Impact Evaluation of an Integrated Nutrition, Malaria Prevention and Parenting Intervention to Improve Nutrition and Early Child Development in Pre-School Children (0-6 Years): A Randomized Controlled Trial

TRANSLATED TITLE
Evaluation d'Impact d'une Intervention Intégrée de Nutrition, Prévention de Paludisme et Éducation Parentale visant à Améliorer l'État Nutritionnel et Développement des Enfants Préscolaires (0-6 ans) : un Essai Contrôlé Randomisé

COUNTRY/ECONOMY

Name	Country code
Mali	MLI

STUDY TYPE
Other Household Health Survey [hh/hea]

SERIES INFORMATION
This impact evaluation consists of baseline and endline surveys. The baseline data is not publicly available. The endline survey was conducted after 3 years of implementation and is documented here.citReq

ABSTRACT
The objective of the endline surveys in 2016 were to gather household, biomedical, and cognition data in order to evaluate the long-term impact of home supplementation with micronutrient powders (MNP), when combined with seasonal malaria chemoprevention (SMC) and early stimulation, delivered through community preschools and parenting sessions, on the health and cognitive development of children during the first five years of life.

The trial consisted of 3 arms. First, 60 villages with established Early Childhood Development centres (ECD) were randomised to 1 of 2 arms:

1) Children living in villages in the ECD control arm received SMC as part of national health programming and a national parenting intervention delivered by ECD center staff trained and supported by Save the Children, with ALL resident children eligible to participate in the interventions irrespective of enrolment in ECD program (ECD Control group).

2) Children living in villages in the intervention arm also received the SMC and parenting interventions described above, but additionally were eligible to receive home supplementation with micronutrient powders (MNP intervention arm).

3) Second, a third non-randomised arm was recruited comprised of children living in 30 randomly selected villages where there were no ECD centers in place and thus both the parenting interventions and MNPs were absent. These children received SMC only, as part of national health programming (non-ECD comparison arm).

Trial arm and Interventions received:

T1. MNP intervention arm: 30 villages with ECD centre (randomised); MNP-Yes, Parenting-Yes, SMC-Yes
C1. ECD control arm: 30 villages with ECD centre (randomised); MNP-No, Parenting-Yes, SMC-Yes
C2. Non-ECD comparison arm: 30 villages without ECD centre (not randomised); MNP-No, Parenting-No, SMC-Yes

Three cross-sectional endline surveys took place during the period May-August 2016, three years after the original MNP intervention began, and consisted of the following questionnaires and assessments in two age groups of children, 3 year olds and 5 year olds:

i) A household questionnaire was used to collect data from the primary adult caregiver of the child on home environment, exposure to the interventions, and reported practice outcomes of relevance to the parenting intervention.

ii) Biomedical outcomes were measured in children through laboratory and clinical assessment.

iii) A battery of tests were used to assess cognitive performance and school readiness in childen, using a different age-specific test battery for each age group adapted for local language and culture.

Note: Household and cognitive performance data were gathered from participants in all three arms. Biomedical data were only collected from children in the two randomised arms, to evaluate impact of MNP supplementation on anaemia (primary biomedical outcome) in children who received MNPs and those who did not, using a robust study design.

KIND OF DATA
Sample survey data [ssd]

UNIT OF ANALYSIS
Individuals and communities

Version

VERSION DESCRIPTION
v02: Edited, anonymised datasets for public distribution

VERSION NOTES
The datasets comprise data collected through three distinct surveys which have been merged for analysis. All datasets have been anonymised after merging, through the removal of personal identifying information including names, dates of birth and geolocation data. Data from individual children can be linked using a unique numeric identifier.

Scope

NOTES
The scope of the endline surveys includes:

Household: Household characteristics collected using caregiver questionnaires conducted with the primary caregiver of the child, including parental age, parental education, language(s) spoken in the home, socio-economic status, and home environment for literacy and maths.

Child: Child-level characteristics on child's exposure to the intervention(s) and parenting practices captured retrospectively via adult caregiver report during the household survey: type of adult-child interactions, child discipline, ECD enrolment and attendance, dietary diversity, nutrition practices, use of malaria prevention (seasonal malaria chemoprevention and insecticide-treated mosquito nets), recent health status and activity levels of child. With an optional module for acceptability and use of MNPs.

Health and nutrition characteristics of children: Haemoglobin concentration; anaemia (the primary outcome), defined as haemoglobin concentration of less than 110g/L; serum ferritin; and malaria infection status. Anthropometric data, including the following derived parameters: height-for-age, weight-for-age and weight-for-height Z score (HAZ, WAZ, and WHZ) with reference to WHO standard population. BMI-for-age was also calculated.

Child development characteristics: Cognitive-linguistic literacy and numeracy-related foundation knowledge and skills, expressive vocabulary, attention, executive functioning, short-term memory, fine and gross motor skills, socio-emotional maturity and other aspects of school-readiness.

KEYWORDS

Keyword
Randomized Controlled Trial, Health, Nutrition, Home Supplementation, Seasonal Malaria Chemoprevention, Early Stimulation, Early Childhood Development, Mali

Coverage

GEOGRAPHIC COVERAGE
Districts (cercles) of Sikasso and Yorosso, Region of Sikasso

GEOGRAPHIC UNIT
Districts (cercles)

UNIVERSE
Random sample of target population for the intervention in the 90 communities that consented to participate in the trial, namely pre-school children 0-6 years.

Producers and sponsors

PRIMARY INVESTIGATORS

Name	Affiliation
Natalie Roschnik	Save the Children, UK
Sian Clarke	London School of Hygiene & Tropical Medicine, UK

PRODUCERS

Name	Affiliation	Role
Niélé Hawa Diarra, Philippe Thera, Yahia Dicko, Kalifa Sidibé, Modibo Bamadio	Save the Children International, Sahel Office, Mali	Questionnaire design, design of the cognitive battery, and data collection
Professor Sian Clarke, Dr. Hans Verhoef, Sham Lal, Louise Abela, Karla Smuts	London School of Hygiene & Tropical Medicine, United Kingdom	Trial design, sampling methodology, questionnaire design, design of the cognitive battery, data collection, data processing and data analysis
Rebecca Jones	University College London, London, United Kingdom	Sampling methodology, sample selection, statistics and data analysis
Professor Moussa Sacko, Renion Saye	Institut National de Recherche en Santé Publique (INRSP), Mali	Biomedical data collection, laboratory analysis and data processing
Dr. Yvonne Griffiths	School of Education, University of Leeds, United Kingdom	Design of the cognitive battery, data processing and analysis
Lauren Pisani	Save the Children, United States of America	Design of the cognitive battery, data processing and analysis
Professor Michael Boivin	Michigan State University, United States of America	Design of the cognitive battery, and analysis
Maria Sangaré	Direction Nationale de l'Education Préscolaire et Spéciale, Mali	Design of the cognitive battery
Aissata Traoré	Direction Nationale de l'Education Préscolaire (DNEP), Mali	Design of the cognitive battery
Dr. Hamidou Niangaly	Malaria Research and Training Center, Université de Bamako, Mali	Cost data collection and analysis
Dr. Josselin Thuilliez	Centre d'Economie de Sorbonne, Paris, France	Cost data collection and analysis
Pierre Kamano	The World Bank, Bamako, Mali	Study Task Team Leader who provided national level oversight for the study and links to national priorities

FUNDING AGENCY/SPONSOR

Name	Abbreviation	Role

Strategic Impact Evaluation Fund	SIEF	Funded endline surveys, cost data collection and impact evaluation
Save the Children		Funded implementation of the programme and additional survey related costs

OTHER IDENTIFICATIONS/ACKNOWLEDGMENTS

Name	Affiliation	Role
Klaus Kraemer	Sight and Life	Contributing to the design of the MNP nutrition intervention
Roland Kupka	UNICEF	Contributing to the design of the MNP nutrition intervention
Judy McClean	University of British Columbia, Canada	Contributing to the design of the MNP nutrition intervention
Kathy Ho and Fatou Diarrassouba	University of British Columbia, Canada	Conducting qualitative research to inform the design and improvement of the MNP intervention
Fatoumata Dougnon, Mamadou Traoré and Seybou Guindo	Direction Nationale de la Santé (DNS), Division Nutrition	Advised on the development of the intervention and the evaluation surveys
Mouctar Coulibaly	Institut Polytechnique Rural de Formation et de Recherche Appliquee (IPR/IFRA)	Advised on the development of the intervention and the evaluation surveys
Bonaventure Maiga	Ministère de l'éducation	Advised on the development of the intervention and the evaluation surveys
Bore Saran Diakité	Programme National de Lutte contre le Paludisme (PNLP)	Advised on the development of the intervention and the evaluation surveys

Sampling

SAMPLING PROCEDURE

The target population for the interventions comprised all children aged 3 months to 6 years, who were resident in the 90 study communities participating in the trial; the primary sampling unit is the individual child.

Sample Frame:

To identify the number of target beneficiaries, a complete census of all children of eligible age was carried out in the 90 study villages in August 2013. The census listing from 2013 thus defined the population of children who are eligible to have received the interventions every year for the three years between 2013-2016; and was used as the sampling frame of children in whom the impact after three years of implementation of the interventions was evaluated. The intention was to evaluate study outcomes in the same child one year after the start of the MNP intervention (May 2014) and again after three years of the intervention (2016).

A random sample of children was drawn from all children listed in the census for each community participating in the trial, according to the following age criteria:

Date of Birth, or Age in August 2013 (Age group in 2016 surveys)
(i) Born between 1 Jan 2013 – 30 June 2013, or aged <1 year in 2013 census if DOB not known (3 years)
(ii) Born between 1 May 2010 – 30 April 2011, or aged 2 years in census if DOB not known (5 years)

Thus, all children previously randomly selected and enrolled in the evaluation cohort in 2014 were, if still resident in the village and present on the day of the survey, re-surveyed in May 2016.

Sample Size:

Power analysis was undertaken for a comparison of two arms, taking account of clustering by community. Survey data on biomedical and cognitive outcomes collected in 2014 were used to inform sample size assumptions, including prevalence of

primary outcomes, intraclass correlation (ICC) and number of children recruited per cluster. Prevalence of anaemia amongst 3-year old children in 2014 was found to be 61.6% and 64.0% in the intervention and control arms respectively (p=0.618) and 53.8% and 51.9% respectively amongst 5-year old children (p=0.582). The observed ICC for anaemia endpoint at baseline was 0.08 in 3-year old children and 0.06 in 5-year old children. Observed ICC for cognitive outcomes measured in 2014 was 0.09, ranging from 0.05 to 0.16 for individual tasks within the cognitive battery.

Sample Size Estimation for Health Outcomes:

Approximately 20-25 children per cluster were recruited into each age cohort in 2013. Power calculations for anaemia (primary endpoint) were undertaken for three alternative scenarios at endline: (i) to allow for the possibility of up to 20% loss to follow up between 2014 and 2016, power calculations were performed for a sample size at endline of 16 children per cluster; (ii) a smaller cluster size of 14 children sampled per village, under a scenario of 30% loss to follow-up; and (iii) unequal clusters, to allow for the possibility that variation in losses to follow-up between villages could result in an unequal number of children sampled in each village. In this case, cluster size is the mean number of children sampled per cluster.

Thus, assuming a conservative prevalence of anaemia of 50% in the control group and ICC of 0.08, a sample size of 30 communities per arm with 14-20 children sampled per community, will under all of these scenarios provide 80% power to detect a reduction in anemia of at least 28% at 5% level of significance.

Sample Size Estimation for Cognitive Outcomes:

Power calculations for cognitive outcomes explored: (i) a smaller cluster size of 14 children sampled per village, for example resulting from a higher than expected loss to follow-up of 30%; (ii) statistical analysis of differences between arms which does not adjust for baseline - a scenario which allows for the possibility to increase the sample size to compensate for losses to follow-up by increased recruitment of new children for whom no baseline data would be available; and (iii) effect of unequal clusters. Thus, for cognitive-linguistic skills, a sample size of 30 communities per arm with 14-20 children in each age cohort sampled per community will provide 80% power to detect an effect size between 0.27-0.29 at 5% level of significance, assuming an (ICC) of 0.10 and individual, household and community-level factors account for at least 25% of variation in cognitive foundation skills. Whilst for a similar sample size of 30 communities per arm with 14-20 children sampled per community and ICC of 0.10, a statistical analysis which does not adjust for baseline will provide 80% power to detect an effect size between 0.28-0.30 at 5% level of significance.

The sample at endline in May 2016 thus comprised a total of up to 600 children aged 3y and 600 children aged 5y at endline in each arm:
T1 Intervention group (with ECD): 30 communities, with approx. 40 randomly selected children in each community (20 aged 3y; 20 aged 5y).
C1 ECD control group (with ECD): 30 communities, with approx. 40 randomly selected children in each community (20 aged 3y; 20 aged 5y).
C2 Comparison group (without ECD): 30 communities, with approx. 40 randomly selected children in each community (20 aged 3y; 20 aged 5y).

Strategy for Absent Respondents/Not Found/Refusals:

Every effort was made to trace children previously recruited into the evaluation cohort. Since some losses-to-follow-up (for example to due to child deaths, outward migration) were expected between 2014 and 2016, the primary strategy was to oversample in 2014. However, for villages where loss-to-follow-up was higher than expected and it was not possible to trace sufficient number of children remaining from the original sample to meet the required sample size per cluster, additional children were recruited into the evaluation survey in 2016. New recruits were selected at random from the children listed as resident in the village at the time of the original census in 2013. All new recruits had thus been resident in the village and exposed to the interventions throughout the three preceding years.

RESPONSE RATE

All analyses will be according to intention-to-treat, and all children will be included in the analysis irrespective of whether they actually received the intervention or not. This approach provides a realistic estimate of the intervention effect in randomized trials, as variation in the level of take up is taken into account in the analysis. As ITT recognizes that take up may be less than 100%, the power calculations and MDE do not need to be adjusted for take-up rates.

Data Collection

DATES OF DATA COLLECTION

Start	End	Cycle
2016-05	2016-08	Endline

DATA COLLECTION MODE
Face-to-face [f2f]

SUPERVISION
Following training, enumerators were organised in teams of 6-8 that included a field supervisor from the main research team.

DATA COLLECTION NOTES
We did not use placebo micronutrient powders, but steps were taken to blind evaluators to the intervention status of communities. Measurement of study outcomes were undertaken using standardized tests by independent field teams unaware of which communities have received the intervention. Biomedical assessments, such as slide microscopy, were likewise performed by technicians blinded to the intervention status of communities, and all outcome data analyzed in London by research staff blinded to intervention status of communities.

Cognitive performance outcomes in children were assessed individually by trained assessors using a standard set of instructions; with assessments conducted in the child's mother tongue. Survey staff undertook 5-8 days of training (parent questionnaire and cognitive assessment in children), including by a period of observed pilot data collection in the field. During the surveys, each team was accompanied and supervised in the field by a member of the IE research staff, throughout the data collection period for cognitive assessments.

Data (parental questionnaire and cognitive assessment in children) were collected electronically, with inbuilt consistency checks and prompts to guide accuracy of the data collection. Biomedical data were quality controlled through double entry data validation; blood slide readings were performed twice by two independent laboratory technicians, and discrepant readings were resolved by a third independent microscopist, blinded to the results of any prior readings.

Data limitations: Finger-prick blood samples were collected from children (since this is more acceptable to local populations than venous blood collection) which limited the volume of blood sampled, and there was insufficient volume to complete all the laboratory tests. Assessment of malaria infection status, haemoglobin concentration and serum ferritin were prioritised. Measurement of inflammatory markers was not performed, limiting the ability of the study to determine the prevalence of iron-deficiency.

The biomedical assessments were originally planned to coincide with the end of the dry season and start of the rains, and the beginning of the next malaria transmission season – and thus measure the maximum impact on anaemia that would be expected to be achieved by the interventions. However due to delays in funding, these assessments took place further into rainy season than initially expected (July-August 2016). The increase in malaria transmission following the onset of the rains may therefore have impacted on the ability of surveys to capture the full impact of the combined interventions on anaemia.

DATA COLLECTORS

Name
Save the Children, Mali
Institut National de Recherche en Santé Publique, Mali

Questionnaires

QUESTIONNAIRES
1. Household questionnaire (Form_Parent_MaliSIEF_2016_french.pdf ; Form_Parent_MaliSIEF_2016_english.pdf)

The questionnaires for the parent interview were structured questionnaires. A questionnaire was administered to the child's primary caregiver (parent/guardian, or if unavailable other adult in family) in May-June 2016, which collected information on the home environment for each child selected for inclusion in the evaluation surveys. Household characteristics included parental age, parental education, language(s) spoken in the home, socio-economic status, and home environment for literacy and maths. The questionnaire also recorded parental report of the child's exposure to the intervention(s) and parenting practices: type of adult-child interactions, child discipline, ECD enrolment and attendance, dietary diversity, nutrition practices, use of malaria prevention (seasonal malaria chemoprevention and insecticide-treated mosquito nets), recent health status and activity levels of child. With an optional module for acceptability and use of MNPs. Questionnaires

were published in French and Bambara, and administered in the local language (predominantly Bambara, Shenara or Mamara). An English translation is also available. The questionnaire was based on a similar questionnaire previously administered in the same villages in 2014, with some very slight modification.

2. Cognitive batteries (FINAL_3 years_cognitive_SIEF 2016_french_bambara_7 June_final for training.pdf; FINAL_5 years_cognitive_SIEF 2016_French_Bambara_8 June.pdf)

Cognitive performance was assessed using an age-specific battery of cognitive tests in June-July 2016 in both intervention and control communities, to capture cognitive performance and school-readiness at the time of children transitioning into and out of ECD centers (to primary school); at ages 3 and 5 respectively. A battery of tests was developed for each age to assess cognitive-linguistic literacy and numeracy-related foundation knowledge and skills in children aged 3 and 5 years; adapted from existing tests which have previously been used in pre-school children elsewhere. All instruments were adapted for local language and culture, and pre-tested in Mali to confirm their developmental appropriateness for the age group to be tested. The same tests were used in 2014 and 2016.

In the 5-year-old battery, assessments focussed on cognitive-linguistic skills known to predict the ease with which children acquire literacy and numeracy skills at school, including tests of cognitive skills known to be precursors of early literacy skills in alphabetic writing systems, such as the rapid automatised naming (RAN) task and expressive vocabulary; the head-shoulders-knees-toes (HSKT) task to assess executive function, and the digit span test, as a measure of verbal short-term memory. Other core dimensions of school readiness were assessed using a subset of tasks from an early version of the International Development and Early Learning Assessment (IDELA) tool developed by Save the Children to examine differences in early literacy and numeracy skills (concepts about print, oral comprehension, letter and number recognition, basic number concepts); fine and gross motor skills; and socio-emotional development. Task items were selected with an eye to feasibility, cultural and program relevance, and adapted and tested in a variety of settings to ensure appropriateness for a developing country context. See FINAL_5 years_cognitive_SIEF 2016_French_Bambara_8 June.pdf for details

In the 3-year-old battery, assessments focussed on developmental milestones, including gross and fine motor skills, cognitive and spoken language development using a small subset of the tasks used with the 5 year olds. See FINAL_3 years_cognitive_SIEF 2016_french_bambara_7 June_final for training.pdf for details.

Children were assessed individually by trained assessors using a standard set of instructions which were in French and Bambara. All investigators were instructed to carry out the assessments in the child's mother tongue. At the end of the assessment for each child, field workers recorded any important observations or field notes for subsequent data cleaning. For example, if the child was unwell, struggled to understand instructions and/or maintain attention when completing the tasks during the assessment session.

3. Biomedical assessment (Form_Biomed_MaliSIEF_Sikasso_2016.pdf)

Clinical observations were recorded on a structured questionnaire used during the cross-sectional biomedical surveys carried out in July-August 2016; and fingerprick blood samples collected to measure malaria infection and anaemia. Survey forms were published in French.

Haemoglobin (Hb) concentration was measured using a portable Hemocue photometer; quality control was carried out daily using a standard microcuvette or control blood sample of known Hb concentration. Malaria infection status was determined by light microscopy, performed twice by two independent laboratory technicians. Slides were declared negative after examination of 100 high-power fields. Weights were measured using an electronic scale; and height measured using a stadiometer. Height-for-Age, Weight-for-Age and Weight-for-Height Z scores (HAZ, WAZ and WHZ) were computed with reference to WHO standard population using Anthro (version 3.2.2, 2011).

Data Processing

DATA EDITING

Data editing took place at a number of stages throughout the process. Data (parental questionnaire and cognitive assessment in children) were collected electronically using Open Data Kit (ODK) installed on smartphones, with inbuilt consistency checks and prompts to guide the accuracy of the data collection. Biomedical data and laboratory results were recorded on paper forms and quality controlled through double entry data validation. After merging, the data were subject to additional structure checking and completeness, as well as inconsistencies between variables. The data were not edited for missing values.

Data Appraisal

DATA APPRAISAL
If there is differential loss in follow-up between groups, this can introduce a risk of participation bias. To check this, the characteristics of children examined in 2014 were compared between two groups of children, (i) those successfully traced and re-examined in 2016, and (ii) those lost-to-follow-up. The characteristics of the two groups were found to be comparable.

Access policy

CONTACTS

Name	Affiliation	Email
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Lauren Pisani	Save the Children	lpisani@savechildren.org
Renion Saye	Institut National de Recherche en Santé Publique, Mali	srenion@yahoo.fr

ACCESS CONDITIONS
Public Access

CITATION REQUIREMENTS
Natalie Roschnik, Save the Children UK; Siân E Clarke, London School of Hygiene & Tropical Medicine; Niélé Hawa Diarra, Philippe Thera, Yahia Dicko, Kalifa Sidibé, Modibo Bamadio, Save the Children International; Moussa Sacko, Renion Saye, Institut National de Recherche en Santé Publique, Mali; Lauren Pisani, Save the Children USA; Yvonne Griffiths, University of Leeds, UK; Michael Boivin, Michigan State University, USA and Josselin Thuilliez, Centre d'Economie de Sorbonne, France. Mali - Project Jigifa Endline Survey 2016, Impact Evaluation of an Integrated Nutrition, Malaria Prevention and Parenting Intervention to Improve Nutrition and Early Child Development in Pre-School Children (0-6 Years): A Randomized Controlled Trial. Ref: MLI_2016_PJ-EL_v01_M. Dataset downloaded from [insert World Bank microdata URL] on [insert date].

ACCESS AUTHORITY

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LOCATION OF DATA COLLECTION
World Bank Microdata Library

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Metadata production

DDI DOCUMENT ID
DDI_MLI_2016_PJ-EL-v01_M_WB

PRODUCERS

Name	Abbreviation	Affiliation	Role
Development Economics Data Group	DECDG	The World Bank Group	Documentation of the study

DATE OF METADATA PRODUCTION
2023-08-07

DDI DOCUMENT VERSION
Version 01 (August 2023)

Data Dictionary

Data file	Cases	Variables
dataset_biomedanthroparent_malisief_2016_puf_labeled.dta Includes anonymized data from biomedical survey in children, merged with data from household survey with adult caregiver. (for 2 randomized arms: MNP+ECD and ECD control).	2134	89
dataset_cogsraparent_age3_malisief_2016_puf_july23_labeled.dta Includes anonymized data from cognitive assessment in children aged 3 years in 2016, merged with data from household surveys with adult caregiver. (for all 3 arms: MNP+ECD; ECD control; and non-ECD comparison)	1469	284
dataset_cogsraparent_age5_malisief_2016_puf_july23_labeled.dta Includes anonymized data from cognitive and school-readiness assessment in children aged 5 years in 2016, merged with data from household surveys with adult caregiver. (for all 3 arms: MNP+ECD; ECD control; and non-ECD comparison)	1563	445
dataset_cogsraparentbiomed_age3_malisief_2016_puf_july23_labeled.dta Includes anonymized data from cognitive assessment in children aged 3 years in 2016, merged with data from the biomedical survey in children and data from household surveys with adult caregiver. (for 2 randomized arms only: MNP+ECD and ECD control)	1055	319
dataset_cogsraparentbiomed_age5_malisief_2016_puf_july23_labeled.dta Includes anonymized data from cognitive and school-readiness assessment in children aged 5 years in 2016, merged with data from the biomedical survey in children and data from household surveys with adult caregiver. (for 2 randomized arms only: MNP+ECD and ECD control)	1106	480