Integrated eDiagnosis Approach (IeDA) for the management of illness in under-five children at the primary health care level in Burkina Faso:

Findings from a stepped-wedge cluster randomised trial

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Abstract

Background

The experience with using Information and Communication Technologies to improve adherence to the Integrated Management of Childhood illness (IMCI) guidelines is limited. From 2014, Terre des hommes, in partnership with the Burkinabe Ministry of Health (MoH), implemented the Integrated eDiagnosis Approach (IeDA) package of interventions in primary health facilities of two regions of Burkina Faso. An evaluation was performed by an independent team from the London School of Hygiene and Tropical Medicine (LSHTM), and Centre Muraz. The aim of the trial was to determine whether the IeDA intervention increased adherence to the IMCI guidelines during under-five child consultations.

Methods

The evaluation was conducted in eight health districts of the regions Boucle du Mouhoun and Nord and used a stepped-wedge cluster randomised design, with districts ("clusters") receiving the intervention at different time points in a randomised order. Data collection was conducted from September 2014 to November 2017. Ten primary health facilities per district were randomly selected, and were visited, at each step. After obtaining informed consent from the HCW and the child's caretaker, one independent trained nurse observed and recorded the HCW's practices during the consultation, the classification and prescription given to the child. Validation data were collected by another independent trained nurse, who conducted a repeat consultation with the child, using the electronic Clinical Decision Support System (eCDSS). These validation data were intended to provide a "gold standard" classification for each child. In addition, a shortened version of the WHO Service Availability and Readiness Assessment (SARA) questionnaire was completed at each visit.

All analyses included consultations for children aged between two months and five years old only and excluded follow-up visits. We focussed on the IMCI algorithms for danger signs, cough/difficult breathing, diarrhoea, fever and nutritional status, excluding algorithms related to HIV, ear

problems and anaemia (with the exception of clinical assessment for the latter). The primary outcomes included: overall adherence to IMCI clinical assessment tasks; overall correct classification ignoring the severity of the classifications; overall correct prescription according to HCWs' classifications.

Results

While the IMCI paper-form was used for 69% and 68% of the consultations at baseline and in the control arm

respectively, the eCDSS was used in nearly all consultations in the intervention arm (97%). Overall, the average percentage of tasks completed by the HCWs across the IMCI algorithms was 48% at baseline, 54% in the control districts and 79% in the intervention districts with strong evidence for a difference between trial arms (cluster-level mean difference = 29.9%; P-value = 0.002). The proportion of children for whom the validation nurses and the HCWs recorded the same classifications (ignoring the severity of the classifications) was 75%

at baseline, 73% in the control districts and 79% in the intervention districts with strong evidence for a difference between trial arms (cluster-level mean difference = 10.1%; P-value = 0.004). The proportion of children who received at least all the recommended prescriptions in accordance with the HCWs' classifications was 76% at baseline, 78% in the control districts and 77% in the intervention districts with no evidence for a difference between trial arms (cluster-level mean difference = -1.1%; P-value = 0.788). Nevertheless, substantial improvements were observed with respect to classification of and prescriptions for dysentery and malnutrition. The data were also consistent with an improvement in danger sign identification, correct referrals/hospitalisations and management of severe malaria or severe febrile illness, although these are based on small numbers of children, limiting our ability to draw firm conclusions.

Discussion

The IeDA intervention improved substantially HCWs' adherence to IMCI's clinical assessment tasks, including the assessment of danger signs, which led to some overall increase in the proportion of children being correctly classified but to little or no improvement in overall proportion of children receiving correct prescriptions. Achieving correct classification depends, at least in part, on the clinical skills of the HCWs, which may be more difficult to improve than task adherence itself. This may have limited somewhat the effect of the intervention on correct classification.

Two limitations of our evaluation approach should be acknowledged. First, it is possible that the clinical status of some children (e.g. respiratory rate) may have changed in the interval between the initial consultation and the repeat consultation simply because of the time delay between the two. In addition, some clinical signs may be more subjective than other (e.g. stridor) and therefore we should not expect full agreement between HCWs and validation nurses. Thus, our "gold standard" is certainly less

than perfect, and this would tend to reduce the apparent magnitude of any improvement in classifications. Second, it is likely that the behaviour of HCWs was impacted by the fact that they were observed. The high proportion of HCWs observed using IMCI paper-forms in the control arm suggest that they were motivated to perform better than usual. In the intervention arm, the behaviour of HCWs may also have been affected by the presence of observers. Therefore, our findings may over-estimate how well HCWs perform, but it is difficult to assert whether or in which direction this may have affected the comparison of intervention and control arms.

Bigger improvements tended to be observed for less common conditions for which HCWs in the control arm performed relatively poorly. For the most common, conditions (e.g. malaria and pneumonia), HCWs in the control arm, who may have been influenced by a Hawthorne effect, performed relatively well, limiting the scope to detect an overall impact.

The IeDA intervention had a positive impact on some aspects of HCWs' practices. However, these are complex behaviours that have many potential influences. Lower availability of some essential medicines in the intervention arm, pressure from children's caretakers, the presence of multiple conditions, professional norms, experiences and beliefs, or incomplete coverage of some components of the intervention (training and supervision) are some of the possible contextual and intrinsic factors that may also have limited the effect of the intervention.

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Executive summary

Background

Recent advances in Information and Communication Technologies (ICT) could potentially transform health care services in low- and middle-income countries. However, the experience with using such technology to improve adherence to the Integrated Management of Childhood illness (IMCI) guidelines is limited.

From 2014, Terre des hommes, in partnership with the Burkinabe Ministry of Health (MoH), implemented the Integrated eDIagnosis Approach (IeDA) package of interventions in primary health facilities of two regions of Burkina Faso with the objective of improving health care workers' (HCW) adherence to the IMCI guidelines.

An evaluation was performed by an independent team from the London School of Hygiene and Tropical Medicine (LSHTM), United Kingdom, and Centre Muraz, Burkina Faso. The aim of the trial was to determine whether the IeDA package of interventions increased adherence to the IMCI guidelines during under-five child consultations in primary health care centres.

Methods

The evaluation was conducted in eight health districts of the regions Boucle du Mouhoun and Nord and used a stepped-wedge cluster randomised design, with districts ("clusters") receiving the intervention at different time points in a randomised order. Full implementation of the intervention was defined as having occurred when the electronic Clinical Decision Support System (eCDSS) was provided to all facilities of the district and when all HCWs who were to be involved in conducting child consultations had been trained in its use and IMCI guidelines.

Nine steps were initially planned: a first step in the eight districts prior to the intervention (baseline), and one additional step per additional district receiving the intervention with data collection at each step in all districts. However, due to logistic issues, the roll-out of the intervention in the first district was delayed (completed at step 3 instead of step 2) and, due to a lack of funding available to the implementing agencies, the intervention was implemented in only four districts from steps 3 to 6. The baseline phase, therefore, included the first two steps. Eight rounds of data collection in all districts were nevertheless conducted up to step 8,

but step 9 was not conducted.

Data collection was conducted from September 2014 to November 2017 by two teams of two trained independent nurses. Ten primary health facilities per district were randomly selected. Only primary health facilities with staff trained in IMCI were considered for selection, and all hospitals were excluded. At each step, all selected primary health care facilities in all eight districts, were visited once for data collection. Each visit lasted 1 to 2 days and data were collected for all under-five child consultations occurring during the visit.

After obtaining informed consent from the HCW and the child's caretaker, one independent trained nurse observed and recorded the HCW's practices during the consultation, and recorded the illness classification and prescription given to the child. Observations were passive, and the observer never intervened during the consultation. Validation data were collected by another independent trained nurse, who conducted a repeat consultation with the child, using the eCDSS. These validation data were intended to provide a "gold standard" classification for each child.

In addition, a shortened version of the WHO Service Availability and Readiness Assessment (SARA) questionnaire was completed at each visit to document the availability of essential medicines and equipment required to conduct a consultation in accordance with the IMCI guidelines.

All analyses included consultations for children aged two months to five years old only as very few consultations with children younger than 2 months were observed. In addition, all analyses excluded follow-up visits.

We focussed on the IMCI algorithms for danger signs, cough/difficult breathing, diarrhoea, fever and nutritional status, excluding algorithms related to HIV and ear problems due to their very low prevalence recorded during the trial period. With respect to anaemia, adherence to clinical assessment was evaluated only, excluding classifications, prescriptions and referrals/hospitalisations due to the difficulty of assessing anaemia reliably when laboratory testing was locally unavailable.

Primary outcomes included:

▶ Overall adherence to IMCI clinical assessment tasks;
▶ Overall correct classification ignoring the severity of the classifications;
▶ Overall correct prescription according to HCWs' classifications.

Secondary outcomes included:

▶ Adherence to danger signs' assessment tasks;
▶ Correct identification of at least one danger sign;
▶ Overall correct classification accounting for the severity of the classifications;
▶ Overall correct prescription according to validation nurses' classifications;
▶ Overall correct referral or hospitalisation according to HCWs' classifications or danger signs' identification;
▶ Overall correct referral or hospitalisation according to validation nurses' classifications or danger signs' identification;
▶ Overall correct treatment counselling.

Results

While the IMCI paper-form was used for 69% (471/686) and 68% (916/1,343) of the consultations at baseline and in the control arm respectively, it was used in only 3% (20/694) of consultations in the intervention arm while the eCDSS was used in nearly all consultations (97%, 674/694). The occasional use of the eCDSS at baseline (1%, 8/686) or in the control arm (9%, 120/1,343) reflects instances of early roll-out of the eCDSS prior to training.

Adherence to IMCI's clinical assessment

Overall, the average percentage of tasks completed by the HCWs across the six IMCI algorithms (danger signs, cough/difficult breathing, diarrhoea, fever, anaemia and nutritional status) was 48% at baseline, 54% in the control districts and 79% in the intervention districts with strong evidence for a difference between trial arms (cluster-level mean difference = 29.9%; P-value = 0.002). For all IMCI algorithms of interest, HCWs in the intervention arm completed more of the recommended tasks resulting in higher adherence indices compared to HCWs in the control arm. In particular, HCWs in the intervention arm completed more of the recommended tasks for assessing danger signs compared

to the control arm: 95% versus 34% respectively (cluster-level mean difference = 71.2%; P-value = 0.002).

Correct identification of danger signs

The proportion of children correctly identified, by the HCWs, with at least one danger sign was 67% (16/24) at baseline and 56% (14/25) in the control districts. It appeared to be somewhat higher (75%, 12/16) in the intervention arm but this could be a chance finding given the small number of children with danger signs (cluster-level mean difference = 19.0%; P-value = 0.322).

Correct classifications

Overall, the proportion of children for whom the validation nurses and the HCWs recorded the same classifications (ignoring the severity of the classifications) was 75% (457/609) at baseline, 73% (767/1,049) in the control districts and 79% (450/572) in the intervention districts with strong evidence for a difference between trial arms (cluster-level mean difference = 10.1%; P-value = 0.004). Accounting for the severity of the classifications slightly lowered the proportions of correct classifications

at baseline (71%, 430/609), and in the control (70%, 732/1,049) and intervention (75% 427/572) arms (cluster-level mean difference = 9.1%; P-value = 0.038).

By IMCI algorithm and ignoring the severity of the classifications, HCWs in the intervention arm correctly classified children having diarrhoea, dysentery and malnutrition more often than those in the control arm: 77% (147/192) versus 66% (228/346), 83% (10/12) versus 44% (12/27), and 75% (89/118) versus 55% (91/165) respectively. Although based on a small number of children, HCWs in intervention districts also appeared to correctly classify children with severe malaria or severe febrile illness more often than those in control districts: 82% (14/17) versus 63% (15/24) respectively. HCWs in the intervention arm were also less likely to wrongly diagnose pneumonia as being present when it was not: 7% (38/521) versus 19% (209/1,113). For other conditions, false positive diagnoses were rare (<5%) in both arms.

Correct prescriptions

The proportion of children who received at least all the recommended prescriptions in accordance with the HCWs' classifications was 76% (465/614) at baseline, 78% (836/1,074) in the control districts and 77% (437/567) in the intervention districts with no evidence for a difference between trial arms (cluster-level mean difference = -1.1%; P-value = 0.788). However, correct prescriptions for dysentery were much more common in the intervention arm (69%, 9/13) than in the control arm (11%, 5/45). Correct prescriptions for malnutrition (all classifications together) and severe malaria or severe febrile illness were also more common in the intervention arm, though still infrequent: 17% (19/112 versus 7% (9/124) for malnutrition and 33% (8/24) versus 8% (2/26) for severe malaria or severe febrile illness.

According to the validation nurses' classifications, the overall proportions of children who received at least all the recommended prescriptions were 65% (398/610) at baseline, 66% (693/1,049) in the control districts and 69% (392/572) in the intervention districts with no evidence for a difference between trial arms (cluster-level mean difference = 6.7%; P-value = 0.226). By IMCI algorithm, similar patterns were observed as for correct prescriptions according to the HCWs' classifications, with the exception of correct prescriptions for diarrhoea (all classifications together) higher in the intervention arm compared to the control arm: 77% (147/192) versus 65% (226/346) in the control arm.

Over-prescriptions

According to HCWs' classifications, the proportion of children who were not in need of an antibiotic but who were actually prescribed one (injectable ampicillin or gentamycin, cotrimoxazole, amoxicillin, ciprofloxacin or metronidazole) was 12% (81/682) at baseline, 15% (200/1,341) in the control arm and 9% (63/694) in the intervention arm. According to validation nurses' classifications, these proportions were 20% (137/676) at baseline, 27% (347/1,300) in the control arm and 12% (83/682) in the intervention arm. This suggests a reduction in over-prescription of antibiotics of about 6% to 15% points in the intervention arm compared to the control arm, almost all of which is explained by a reduction in over-prescription of cotrimoxazole and to some extent amoxicillin.

With respect to antimalarials, the proportion of children who were over-prescribed either injectable artesunate, artemether or quinine or ACT was low and similar at baseline and between trial arms, suggesting no reduction in over-prescription: around 2% to 4% according to HCWs' classifications and validation nurses' classifications.

Correct referrals or hospitalisations

The proportion of children in need of referral or hospitalisation according to the HCWs' assessment who were actually referred or hospitalised by the HCWs was 60% (21/35) at baseline, 52% (22/42) in the control districts and 61% (25/41) in the intervention districts but with no evidence for a difference between trial arms (cluster-level mean difference = 8.6%; P-value = 0.509). According to the validation nurses' assessment, these proportions

were 55% (16/29) at baseline, 53% (17/32) in the control districts and 68% (15/22) in the intervention districts, again with no evidence for a difference between trial arms (cluster-level mean difference = 15.1%; P-value = 0.398). Interpretation of these findings is hampered by the small number of children requiring referral/hospitalisation.

By classification warranting referral or hospitalisation, there were generally too few children to perform meaningful comparisons. The one possible exception to this is severe malaria/severe febrile illness for which HCWs in the intervention clusters appeared to perform better than in the control clusters: 96% (23/24) versus 73% (19/26) according to HCWs' assessment and 77% (13/17) versus 58% (14/24) according to validation nurses' assessment.

Correct treatment counselling

The proportion of children's caretakers to whom the HCWs mentioned both the number of doses a day and the number of days for all the relevant oral medicines prescribed for treating the child at home was 77% (473/612) at baseline, 92% (1,046/1,143) in the control districts and 88% (506/576) in the intervention districts with no evidence for a difference between trial arms (cluster-level mean difference = -4.1%; P-value = 0.355).

Availability of essential medicines and equipment

Availability of essential equipment at the health facilities was high: 87% at baseline, 87% in the control arm and 91% in the intervention arm. However, the proportion of facilities with all equipment available, although better in the intervention arm, was

still very low: 20% (33/166) versus 10% (29/290) in the intervention and control arms respectively.

The average proportion of essential oral medicines that were observed to be available at the health facilities was 98% at baseline, 94%

in the control arm and 89% in the intervention arm. Although there was a relatively good availability of each medicine in both arms (about 70% or more), deworming treatments, amoxicillin, ORS and zinc as well as multivitamins were less frequently

available in the intervention arm compared to the control arm. The proportion of facilities with all oral medicines available was only 29% (47/165) in the intervention arm compared to 53% (149/284) in the control arm.

Discussion

The IeDA intervention improved substantially HCW's adherence to IMCI's clinical assessment tasks, including the assessment of danger signs, which led to some overall increase in the proportion of children being correctly classified but to little or no improvement in overall proportion of children receiving correct prescriptions. Achieving correct classification depends, at least in part, on the clinical skills of the HCWs, which may be more difficult to improve than task adherence itself. This may have limited somewhat the effect of the intervention on correct classification. Nevertheless, substantial improvements were observed with respect to classification of and prescriptions for dysentery and malnutrition. The data were also consistent with an improvement in danger sign identification, correct referrals/hospitalisations and management of severe malaria or severe febrile illness (classification, prescriptions and referral/hospitalisation), although these are based on small numbers of children, limiting our ability to draw firm conclusions. Lastly, the intervention appeared to have reduced over-prescription of antibiotics, most or all of which is explained by a reduction in over-prescription of cotrimoxazole and to a lesser extent of amoxicilline

Two limitations of our evaluation approach should be acknowledged. First, the "gold standard" classifications were provided by a repeat consultation after the initial

consultation and it is possible that the clinical status of some children (e.g. respiratory rate, temperature, current convulsions) may have changed in the interval between the initial consultation and the repeat consultation simply because of the time delay between the two. In addition, some clinical signs may be more subjective than other (e.g. stridor, chest indrawing) and therefore we should not expect full agreement between HCWs and validation nurses. Thus, our "gold standard" is certainly less than perfect and some consultations in which the HCWs correctly classified the child based on their status at the initial consultation may have been recorded as having resulted in an incorrect classification. This would tend to reduce the apparent magnitude of any improvement in classifications.

Second, it is likely that the behaviour of HCWs was impacted by the fact that they were observed. The high proportion of HCWs observed using paper-based IMCI forms in the control arm (68% overall) compared to routine practice suggest that HCWs in this arm were motivated to perform better than usual. However, the frequent use of IMCI paper-based forms in the control arm did not seem to have resulted in better HCWs' performance. In the intervention arm, the behaviour of HCWs may also have been affected by the presence of observers. Therefore, our findings may over-estimate how well HCWs perform in the absence of an

observer but it is difficult to assert whether or in which direction this may have affected the comparison of intervention and control arms.

Bigger improvements tended to be observed for less common conditions for which HCWs in the control arm performed relatively poorly. For the most common, conditions (e.g. malaria and pneumonia), HCWs in the control arm, who may have been influenced by a Hawthorne effect, performed relatively well, limiting the scope to detect an overall impact.

The IeDA intervention had a positive impact on some aspects of HCWs' practices. However, these are complex behaviours that have many potential influences. Lower availability of some essential medicines in the intervention arm, pressure from children's caretakers, the presence of multiple conditions, professional norms, experiences and beliefs, or incomplete coverage of some components of the intervention (training and supervision) are some of the possible contextual and intrinsic factors that may also have limited the effect of the intervention.

1. Background

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The Integrated Management of Childhood Illness (IMCI) strategy, developed in the mid-1990s by the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF), encompasses three components: Improvement in the case management skills of health care worker (HCW); Strengthening health system support (e.g. supervision, essential medicines and commodities supply); and improvement in family and community behaviours (e.g. appropriate care seeking, home-based treatment, child feeding behaviours) (WHO, 1999). At the first level of care, where access to laboratory and medical equipment is limited, the IMCI provides algorithms to Health Care Workers (HCW) to assess, classify and treat children with a focus on the leading causes of childhood mortality, i.e. pneumonia, diarrhoea, malaria, measles, and malnutrition (Gove, 1997).

In Bangladesh, Brazil, Peru, Tanzania, and Uganda, a multi-country evaluation of the effectiveness of IMCI found that where training was properly implemented with sufficient coverage, ill children were assessed more thoroughly and were more

likely to receive correct treatment compared to settings where HCWs had not been trained to IMCI. Caretakers were also more likely to receive appropriate counselling about how to administer treatment at home and when to return to the facility (Amaral et al., 2004, Gouws et al., 2004, Schellenberg et al., 2004a Bryce et al., 2005a, Arifeen et al., 2009).

In Tanzania, where facility utilisation was relatively high, there was some evidence for a reduction in under-five mortality in IMCI districts compared to control districts (Schellenberg et al., 2004b), but in Bangladesh where facility utilisation was low, no evidence for an effect on child mortality was found within the timeframe of the evaluations (Arifeen et al., 2009).

Currently, more than 75 countries are implementing the IMCI strategy on a large scale. However, poor adherence of HCW to guidelines has often been reported (Horwood et al., 2009, Baiden et al., 2011, Rowe et al., 2012, Kruger et al., 2017), likely due to health system limitations, such as a lack of training, coordination and supervision, or low availability of essential medicines and equipments (Bryce et al., 2005b, Pariyo et al., 2005, Huicho et al., 2005, Mushi et al., 2011).

In Burkina Faso, where the IMCI strategy was introduced in 2003, an evaluation conducted in two regions of the country in 2011, reported a low coverage of training (only 24% of HCWs trained in IMCI) and poor performance in terms of adherence to clinical assessment, correct classifications, prescriptions and referrals (Kouanda et al., 2012). On average only six out of ten tasks that should be performed were performed. Only 28% of children were checked for three danger signs, and 40% of children judged to require referral by an IMCI expert were referred by the HCW. While 91% of children with uncomplicated malaria received an ACT, only 34% of children with

pneumonia were correctly prescribed antibiotics and only 30% of children with diarrhoea were correctly prescribed ORS (Kouanda et al., 2012).

Recent advances in Information and Communication Technologies (ICT) could potentially transform health care services in low- and middle-income countries. However, several reviews reveal the lack of evidence for a scalable and sustainable impact on health indicators (Gurman et al., 2012, Kallander et al., 2013, Aranda-Jan et al., 2014, Hall et al., 2014, Chib et al., 2015). In particular, the experience with using such technology to improve adherence to the IMCI guidelines is limited (DeRenzi et al., 2008, Rhode, 2012, Mitchell, Mitchell et al., 2012, Mitchell et al., 2013, Ginsburg et al., 2016).

From 2014, Terre des hommes, in partnership with the Burkinabe Ministry of Health (MoH), implemented the Integrated eDIagnosis Approach (IeDA) in primary health facilities of two regions of Burkina Faso with the objective of improving HCW's adherence to the Integrated Management of Childhood illness (IMCI) guidelines.

From 2014 to 2017, an evaluation was performed using a stepped wedge cluster randomised design by an independent team from the London School of Hygiene and Tropical Medicine (LSHTM), United Kingdom, and Centre Muraz, Burkina Faso. The aim of the trial was to determine whether the IeDA package of interventions increases adherence to the IMCI guidelines and hence improves classification, prescription, referral and counselling during under-five child consultations in primary health care centres.

2. Methodology

2.1. Setting

Burkina Faso is a landlocked country in West Africa with a population in 2015 estimated at 18,106,000 inhabitants (https://esa.un.org/unpd/wpp). About three-quarters of the population live in rural areas, largely dependent on subsistence agriculture, and about half of the population live below the poverty line (INSD, 2012). Since 1990, the under-five mortality rate has declined from an estimated 202 deaths per 1000 live births to 89 deaths per 1000 live births in 2015 (You et al., 2015).

The government is the main health service provider, managing 83% of facilities within the country in 2014 (Ministère de la Santé, 2014). The country is divided into 13 regions and 63 health districts each with one

district or regional hospital. In 2014, the public health system included 4 Centres Hospitaliers Universitaires (CHU), 9 Centres Hospitaliers Regionaux (CHR), 51 Centres Medicaux avec Antenne Chriurgicale (CMA), 65 Centres Medicaux sans antenne chirurgicale (CM) and 1,824 primary health facilities, corresponding to about 1 hospital per 300,000 inhabitants and 1 primary facility per 10,000 inhabitants.

In rural areas, primary health facilities, usually run by one or more nurses with the support of health assistants ("agent itinerant de santé"), are the most common point of care and provide a basic package of outpatient services. During the trial, in April 2016, free care for under-five children was introduced in all public facilities (SIG, 2016, Ridde et al., 2018).

The trial took place in the Boucle du Mouhoun and Nord regions. Of the 11 districts in these two regions, three districts were selected by the implementing agencies to pilot the first versions of the eCDSSand were therefore excluded from the evaluation, which was restricted to the eight remaining districts (figure 1).

2.2. The IeDA intervention

The IeDA package of interventions comprised five components:

An electronic Clinical Decision Support System (eCDSS) available on tablets and provided to primary health facilities. The eCDSS guides HCWs through the IMCI protocol during under-five consultations, from the clinical assessment of the

Figure 1: Eight health districts included in the trial

Blue and rec circles indicate control and intervention districts respectively

child, through the classification, prescription, referral and counselling (Deflaux, 2010, Yameogo et al., 2011, Deflaux et al., 2014).

A 6-day training course on IMCI guidelines, including 2 days on the use of the eCDSS, provided to HCWs.

A quality assurance coaching system involving team meetings two to four times a year through which districts and their primary health facilities were encouraged to find appropriate solutions to improve the functioning of health facilities and the quality of health care.

A supervision system including a monthly supervisory visit to primary health care facilities and support to the health district authorities in their annual supervision scheme.

A health information system based on under-five child consultation data collected through the eCDSS.

The initial package above evolved during the trial. Several versions of the eCDSS (versions 2.0 to 2.5) were deployed following feedback from users and stakeholders. In 2017, during the last year of the trial, online learning modules with short demonstration videos were available via the eCDSS to support continuous training. In addition, during the two last steps, descriptive dashboards on under-five consultations from data collected through the eCDSS were fed back through the tablet to the health district authorities and primary health care facilities' staff.

2.3. Evaluation design

Because some aspects of the intervention could only be delivered at the district level, and because the implementing agencies needed to roll out the intervention in a phased manner for practical reasons, the evaluation used a stepped-wedge cluster randomised design, with health districts ("clusters") receiving the intervention at different time points in a randomised order.

The original intention was that the IeDA intervention would eventually be delivered to all primary health facilities located in all eight districts with the intervention being introduced in one additional district every four months (figure 2a). Restricted randomisation was used to determine which district (i.e. cluster) should receive the intervention during each time period (step). In addition, during the period preceding the intervention (i.e. in year 1 step 1), a first round of data collection would be conducted in the eight districts to provide baseline (pre-intervention) measurements.

For the purposes of data collection, 10 primary health care facilities per district were randomly selected. Only primary health care facilities with staff trained in IMCI were considered for selection, and all hospitals were excluded. Since the intervention effect might vary by health staff workload, sampling of facilities was stratified on the 2013 annual under-five consultations caseload, as provided by the MoH. In each district, five facilities were randomly selected from among those with fewer than an average of seven consultations per working day and five facilities were randomly selected from among those with an average of seven consultations or more per working day.

Details of the randomisation procedure used to allocate districts to receive the intervention and details of the sampling approach to select primary health care facilities within each district have been published elsewhere (Blanchet et al., 2016).

The allocation of the intervention to each district was gradually communicated by the research team to the implementing agencies, so that the latter only knew which two districts were due to receive the intervention next. In addition, the list of facilities selected for the evaluation was not communicated to the implementing agencies to reduce the likelihood that they targeted these facilities for more intensive support.

District		Step								
		1	2	3	4	5	6	7	8	9
Gourcy										
Dedougou										
Boromo										
Nouna										
Ouahigouya										
Titao										
Solenzo										
Toma										

Figure 2a: Initial stepped-wedge design

District	IeDA full implementation (REC implemented & IMCI/REC training) completion dates	Step & Data collection dates								Total by district
		1	2	3	4	5	6	7	8	
		22 Sep 14 - 29 Jan 15	26 Feb 15 - 29 Apr 15	07 Jul 15 - 30 Nov 15	20 Dec 15 - 08 Apr 16	14 Jun 16 - 16 Oct 16	16 Jan 17 - 13 Apr 17	14 Apr 17 - 10 Aug 17	11 Sep 17 - 11 Nov 17	
Gourcy	Dec 17	N = 75	N = 26	N = 37	N = 52	N = 32	N = 1	N = 40	Dates: 25 Sep - 10 Oct 2017 N = 55 REC implemented: 56% (31) REC used: 55% (30)	N = 318
Dedougou	-	N = 95	N = 41	N = 60	N = 52	N = 65	N = 52	N = 73	N = 73	N = 473
Boromo	-	N = 86	N = 36	N = 59	N = 17	N = 59	N = 47	N = 35	N = 44	N = 383
Nouna	-	N = 49	N = 23	N = 51	N = 27	N = 67	N = 41	N = 31	N = 57	N = 346
Ouahigouya	28 Aug 16	N = 78	N = 26	N = 57	N = 17	Dates: 29 Jul - 12 Aug 2016 N = 46 REC implemented: 100% REC used: 94% (43)	N = 23	N = 21	N = 19	N = 287
Titao	Apr 16	N = 47	N = 22	N = 57	N = 30	N = 46	N = 40	N = 2	N = 55	N = 299
Solenzo	Dec 15	N = 23	N = 17	Dates: 18-30 Nov 2015 N = 47 REC implemented: 100% REC used: 100%	N = 42	N = 82	N = 50	N = 37	N = 61	N = 359
Toma	Jul 15	N = 17	Dates: 20-29 Apr 2015 N = 25 REC implemented: 84% (21) REC used: 32% (8)	N = 38	N = 20	N = 52	N = 37	N = 27	N = 43	N = 259
Total by step		N = 470	N = 216	N = 406	N = 257	N = 449	N = 291	N = 228	N = 407	N = 2,724

Districts shaded in green had full implementation of the IeDA intervention
REC cells indiquates early implementation of the intervention, resulting in some "contamination" of these control districts (dates correspond to data collection in these districts)
The numbers in each cell (N) indicate the number of children aged 2-59 months observed at each step in each district

Figure 2b: Actual roll-out of the IeDA intervention across the stepped wedge trial

2.4. Actual roll-out of the IeDA intervention across the stepped-wedge trial

Figure 2b shows the actual roll-out of the IeDA intervention across the stepped wedge trial. Cells shaded in green represent districts where there was full implementation of the IeDA intervention. Full implementation was defined as having occurred when the eCDSS was provided to all facilities of the district and when all HCWs who were to be involved in conducting child consultations had been trained in its use and IMCI guidelines. The completion dates of full implementation by district are provided in figure 2b.

During the first step, the intervention was, as planned, not implemented in any of the eight districts.

Due to logistics issues, the full implementation of the intervention in the first district (Toma) was delayed by four months (one step). Therefore, steps 1 and 2 together constitute the baseline period, i.e. prior to intervention.

During each of the next four steps, from step 3 to step 6, an additional district received the intervention. Thus, by step 6, the intervention had been fully implemented in four districts (Toma, Solenzo, Titao and Ouahigouya districts). However, due to a lack of funding available to the implementing agencies, the roll-out of the intervention to the remaining districts did not occur and the number of intervention districts remained capped at four until step 8 when some partial implementation occurred in Gourcy district. Given constraints of time and funding, no additional step (step 9) was conducted.

In some control districts, data were collected after the implementation of the intervention started but before the full implementation was completed, resulting in some "contamination" of these control districts (indicated in red in figure 2b). Primary analyses treated "contaminated" districts as control districts based on the intention-to-treat (ITT) principle, while secondary analyses excluded these districts from the analyses (see analysis section).

2.5. Data collection

Data collection was conducted from September 2014 to November 2017. At each step, all eight districts, and all 10 selected primary health care facilities per district, were visited once for data collection. Within each step, the district that started the intervention during that step was visited last, to maximise the chances that HCWs had learnt how to use the technology correctly and to avoid any "teething problems". Each visit was notified by the evaluation team in charge of data collection to the head of the facility the afternoon of the day before the visit. Each visit lasted 1 to 2 days and data were collected for all under-five child consultations occurring during the visit. If the health centre had multiple child consultations happening simultaneously, data were collected for the first child who was called for consultation. For each consultation, after obtaining informed consent from the HCW and the child's caretaker, observation and validation (repeat consultation) data were collected by a team of two independent trained nurses using observation forms programmed into tablets and the eCDSS respectively. Each child was given a unique identifier to link the two datasets.

One independent trained nurse observed and recorded the HCW's practices during the consultation, and recorded the illness classification and prescription given to the child. Observations were passive, and the observer never intervened during the consultation. Whether the HCW used the eCDSS, an IMCI paper-form or neither to conduct the consultation was also recorded. Three observation forms were designed, one per age group as defined by the IMCI guidelines (i.e. 0-6 days, 7 days-1.9 months, 2-59 months), and each form was structured and pre-tested to follow the different IMCI algorithms for each age group, to assess, classify and treat the child. For instance, the form used to observe consultations of children aged 2 months or above

included 9 sections, corresponding respectively to the assessment of danger signs, cough/difficult breathing, diarrhoea, fever, ear problems, anaemia, nutritional status, HIV, immunisation and vitamin A uptake.

Validation data were collected by another independent trained nurse, who conducted a repeat consultation with the child, using the eCDSS (version 1.4 from steps 1 to 5, version 2.5 from steps 6 to 8). These validation data were intended to provide a "gold standard" classification for each child (i.e. as recommended according to IMCI guidelines). Limitations of this approach are discussed later. When there were discrepancies between the HCW and the validation nurse, the final management of the child was agreed between the two of them, but the initial records were used for the purpose of evaluation.

In addition, a shorter version of the WHO Service Availability and Readiness Assessment (SARA) questionnaire (WHO, 2013) was completed at each visit to document the availability of essential medicines and equipment required to conduct a consultation in accordance with the IMCI guidelines.

Two evaluation teams, deployed across the eight districts, were recruited for data collection, each team comprising two nurses, one observing the initial consultation and one conducting the repeat consultation. The four nurses had previously been trained in the IMCI guidelines by the MoH and had at least 5 years of experience working in a health centre. The two validation nurses were also IMCI trainers. In addition, all underwent 2 weeks of training, provided by the investigators, on the study methods prior to the trial, and benefited from two refresher trainings, provided by TDH, on IMCI and the eCDSS during the trial.

2.6. Outcomes

Primary outcomes included:

- Overall adherence to IMCI clinical assessment tasks;
- Overall correct classification ignoring the severity of the classifications;
- Overall correct prescription according to HCWs' classifications.

Secondary outcomes included:

- Adherence to danger signs' assessment tasks;
- Correct identification of at least one danger sign;
- Overall correct classification accounting for the severity of the classifications;
- Overall correct prescription according to validation nurses' classifications;
- Overall correct referral or hospitalisation according to HCWs' classifications or danger signs' identification;
- Overall correct referral or hospitalisation according to validation nurses' classifications or danger signs' identification;
- Overall correct treatment counselling.

Other reported outcomes, but for which no statistical tests were performed to test evidence for a difference between trial arms (in order to reduce the problem of multiple testing), included: Adherence to clinical assessment related to each IMCI algorithm of interest; Correct identification of all danger signs; Sensitivity and specificity of the HCWs to correctly classify or not classify children in a given classification; Correct prescription specific to each HCWs' and validation nurses' classification; Over-prescription of antibiotics and antimalarials; Correct referral or hospitalisation specific to each HCWs' and validation nurses' classification; Correct specific treatment counselling; Mean duration

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of consultations; Overall availability of essential oral medicines and equipment.

All analyses excluded the components of IMCI related to HIV and ear problems. The prevalence of HIV in these two regions was very low during the study period (0.9% of children recorded with either confirmed or suspected HIV infection, across all steps, according to the validation nurses) as was the prevalence of ear problems (2.7% of children recorded with either mastoiditis or acute ear infection, across all steps, according to the validation nurses) and neither are not among the leading causes of under-five mortality in Burkina Faso (Liu et al., 2016). We also did not consider the component related to checking vitamin A supplementation and vaccination status as vitamin A uptake and vaccination coverage are high in Burkina Faso. We therefore focussed on the algorithms for danger signs, cough/difficult breathing, diarrhoea, fever and nutritional status.

With respect to the algorithm related to anaemia, we only evaluated adherence to clinical assessment. Upon the advice of the trial's

scientific advisory committee, classifications, prescriptions and referrals/hospitalisations related to anaemia (severe anaemia and anaemia) were excluded from our analysis due to the difficulty of assessing anaemia reliably when laboratory testing was locally unavailable.

Overall adherence to IMCI's clinical assessment tasks is one of the three primary outcomes and was defined as the average proportion of required tasks (either questions to address to the child's caretaker or clinical examinations to perform) that were observed to be completed across the IMCI's algorithms for danger signs, cough/difficult breathing, diarrhoea, fever, anaemia, and nutritional status. For each child, the proportion of completed tasks was computed and the arithmetic mean of all individual proportions across all consultations was then computed to give the overall adherence index.

According to the IMCI guidelines, while some tasks are required for all children, many of them are "conditional" tasks (table 6). For example, one would only ask about duration of a cough if one had already

asked about a cough and received a positive response. Conditional tasks were included in the calculation of the adherence index only if the condition was met.

The IMCI guidelines emphasise four danger signs: unable to drink or breastfeed, vomits everything, convulsions (either history of convulsions or current convulsions), lethargy or unconsciousness. The HCW should identify the first two danger signs and history of convulsions by questioning the child's caretaker and identified current convulsions and lethargy/unconsciousness by observing the child. Adherence to the assessment of danger signs only considered the following tasks: questioning the caregiver whether the child was unable to drink or breastfeed, was vomiting everything or had a history of convulsions as there are no obvious clinical examinations that could be observed by the independent nurse who observed consultations to record whether or not the HCW assessed if a child had current convulsions or was lethargic or unconscious.

Adherence to clinical assessment tasks related to each IMCI algorithm was defined as above but restricted to each IMCI algorithm of interest (danger signs, cough/difficult breathing, diarrhoea, fever, anaemia, and nutritional status).

Due to programming issues in the observation form, such as errors in skip programming, some data were missing for some tasks at some steps. "*Ask about difficult breathing*" was missing for 13.0% and 3.6% in of the observations in intervention and control arms respectively. "*If cough/difficult breathing, ask for duration of cough/difficult breathing*" was missing for 40.9% of observations at baseline, and 4.7% and 19.1% in intervention and control arms respectively. "*If diarrhoea, pinch the skin of the abdomen*" was missing

for 36.8% of observations at baseline, 3.9% and 18.1% in intervention and control arms respectively. "*Ask about history of fever*" was missing for 5.9% and 1.8% of observations in intervention and control arms respectively. "*If fever or history of fever, ask for duration of fever*" was missing for 1.9% and 5.1% of observations in intervention and control arms respectively. Therefore, for these tasks, the proportion of children for who the task was performed was computed based on a smaller total number of children (denominator) as shown in table 7.

Correct identification of at least one danger sign was defined as the proportion of children recorded, by the validation nurse, as having at least one danger sign who were also identified, by the HCW, with at least one danger sign.

Note that all four danger signs were considered here, i.e. unable to drink or breastfeed, vomiting everything, convulsions (history of convulsions or current convulsions), lethargy

or unconsciousness. Although the independent nurse who observed consultations could not observe whether the HCW assessed current convulsions or lethargy/unconsciousness, s/he recorded whether the child convulsed during the consultation or was lethargic/unconscious, making the information available for the analysis.

Correct identification of all danger signs was defined as the proportion of children recorded, by the validation nurse, with x given danger signs who were also identified, by the HCW, with the same x given danger signs.

Overall correct classification was defined as the proportion of children recorded, by the validation nurse, with x given classifications who were also classified, by the HCW, with the same x given classifications.

Classifications considered to compute this outcome included: severe pneumonia, pneumonia for the IMCI's algorithm related to cough/difficult breathing (cough/cold is

not a life threatening condition and only one child was recorded as coughing for more than 14 days, warranting referral, by the validation nurse, therefore this classification was excluded); diarrhoea with severe, moderate or no dehydration, severe persistent diarrhoea, persistent diarrhoea, dysentery for the IMCI's algorithm related to diarrhoea; severe malaria, malaria for the IMCI's algorithm related to fever (classifications related to measles were never recorded by the validation nurse and therefore were excluded); and severe acute malnutrition (SAM), moderate acute malnutrition (MAM) for the IMCI's algorithm related to nutritional status. For the latter, children who were recorded by the HCW as already being under follow-up for SAM (n = 38) or MAM (n = 24) were analysed with respect to correct classifications other than SAM or MAM.

Upon the advice of the trial's scientific advisory committee, overall correct classification was

computed both ignoring the severity of the classifications, e.g. combining severe or not severe pneumonia, and accounting for the severity of the classifications.

Sensitivity of the HCW's classification was defined as the proportion of children recorded by the validation nurse with a given classification who were also classified, by the HCW, with the same classification. It reflects the ability of the HCW to correctly classify children in a given classification ("true positive rate").

Specificity of the HCW's classification was defined as the proportion of children not recorded by the validation nurse with a given classification who were also not classified, by the HCW, with the same classification. It reflects the ability of the HCW to correctly not classify children in a given classification ("true negative rate").

As above for correct classification, sensitivity and specificity was computed both ignoring the severity of the classifications, e.g. combining severe or not severe pneumonia, and accounting for the severity of the classifications.

Overall correct prescription was defined as the proportion of children with x given classifications who were prescribed at least all the recommended medicines (i.e. over-prescription was not penalised and data on dosage were not collected).

Prescriptions that were recommended in the IMCI guidelines in Burkina Faso during the trial period are listed for each relevant classification in the table 1. It should be noted that in 2015, recommended prescriptions in the national IMCI guidelines changed for some conditions:

Pneumonia: From 2012 to 2014: 1st line: Cotrimoxazole, 2nd line: Amoxicillin; From 2015: Amoxicillin

Severe malaria or severe febrile illness: From 2012 to 2014: Quinine IM/IV & Ampicillin IM/IV & Gentamycin IM/IV (pre-transfer); From 2015: 1st line: Artesunate or Artemether IM/IV & Ampicillin IM/IV & Gentamycin IM/IV (pre-transfer); 2nd line: Quinine IM/IV & Ampicillin IM/IV & GentamycinIM/IV (pre-transfer)

Severe anaemia: From 2012 to 2014: Quinine IM/IV (pre-transfer); From 2015: 1st line: Artesunate or Artemether IM/IV (pre-transfer); 2nd line: Quinine IM/IV (pre-transfer)

Anaemia: From 2012 to 2014: ACT & Iron/Folic acide & (Mebendazole or Albendazole if age>11 months & no dose in the past 6 months); From 2015: Iron/Folic acide & (Mebendazole or Albendazole if age>11 months & no dose in the past 6 months)

We therefore defined prescriptions for these conditions in such a way that allow both recommended prescriptions to be correct.

Classifications considered to compute this outcome included the same classifications as above to ensure consistency with the computation of the overall correct classification.

Overall correct prescription was computed both according to the HCWs' classifications and the validation nurses' classifications.

Correct prescription specific to each classification was defined as above but restricted to each classification given by the HCWs or the validation nurses.

Over-prescription of antibiotics and antimalarials was defined as the proportion of children who were not in need of an antibiotic and an antimalarial according to their classification but who were

actually prescribed it. Per medicine of relevance, over-prescription was defined as:

◗ injectable Ampicillin: prescribed in the absence of severe pneumonia, severe malaria and SAM with complications
◗ injectable Gentamycin: prescribed in the absence of severe pneumonia and severe malaria
◗ Cotrimoxazole: prescribed in the absence of pneumonia
◗ Amoxicillin: prescribed in the absence of pneumonia, SAM without complications
◗ Ciprofloxacin: prescribed in the absence of dysentery
◗ Metronidaazole: prescribed in the absence of dysentery
◗ injectable Artesunate or artemether: prescribed in the absence of severe malaria and severe anaemia
◗ injectable Quinine: prescribed in the absence of severe malaria and severe anaemia
◗ Artemisinin-based combination therapy (ACT): prescribed in the absence of malaria and anaemia

Over-prescription was computed for each antibiotic and antimalarial, for all antibiotics and all antimalarials, and both according to the HCWs' classifications and the validation nurses' classifications.

Overall correct referral or hospitalisation was defined as the proportion of children in need of referral or hospitalisation who were actually referred or hospitalised. Due to the poor road network and usually very long distance to the closest district hospital in Burkina Faso, hospitalisation at the primary health care facility is common and was considered as a practice in line with the IMCI guidelines in place of referral to a higher level facility.

Children were considered in need of referral or hospitalisation if they were identified with at least one danger sign (out of 4 danger signs emphasised in the IMCI guidelines) or classified with one of the following severe classifications: severe pneumonia or very severe disease, diarrhoea with severe dehydration and another severe classification, diarrhoea with some dehydration and another severe classification, severe persistent diarrhoea, severe malaria or severe febrile illness, severe acute malnutrition with complications (any danger sign or other severe classification).

Overall correct referral or hospitalisation was computed both according to the HCWs' danger sign identification/classification and the validation nurses' danger sign identification/classification.

Correct referral/hospitalisation specific to each classification was defined as above but restricted to each classification given by the HCWs or the validation nurses.

Overall correct treatment counselling was defined as the proportion of child's caretakers to whom the HCW mentioned both the number of doses a day and the number of days of treatment among all children who were prescribed, by the HCW, an oral medicine for treating the child at home.

Correct specific treatment counselling was defined as above but restricted to each treatment prescribed by the HCWs.

Mean duration of the consultation was defined as the mean difference in minutes between the time at the start of the consultation and the time at the end of the consultation.

The duration recorded was negative for 18 consultations (0.7%) or exceeded one hour for 85 consultations (3.1%). These impossible/implausible durations may be due to fieldworkers opening the form multiple times after the consultation for editing purpose for instance. These durations (less than 5% of all consultations) were excluded from the analysis of duration on the grounds of their implausibility.

Overall availability of essential medicines and equipment were defined as the average proportion of essential oral medicines and equipment that were observed to be available at the health facility. At each health facility visit, the proportions of available essential oral medicines and equipment were computed, and the arithmetic means of all individual proportions across all visits were then computed to give the overall availability indexes.

Availability of all essential oral medicine and equipment as well as each of item were also computed. Information on the availability of essential injectable medicines were not collected.

2.7. Analyses

Analyses were performed using STATA version 14.

All analyses included consultations for children aged two months to five years old only as there was only a small number of newborns (0-6 days and 7 days-1.9 months) who visited the facilities during the trial period. In addition, all analyses excluded follow-up visits.

We only considered districts as intervention districts once the intervention had been fully implemented. Thus, for instance, Toma district was only considered

as an intervention district from step 3 onwards (rather than from step 2 onwards as originally planned) as the intervention had not been fully implemented as reported by the implementing agencies.

Primary analyses included "contaminated" control districts as control districts based on the intention-to-treat (ITT) principle and given the likely ineffectiveness of new technology without training. Secondary analyses, excluding these districts for the period when they were contaminated, were also performed.

Point estimates and confidence intervals for all outcomes were computed on individual-level data accounting for the clustering of observations within districts and primary health facilities using the svy family of commands in STATA.

Statistical tests to investigate evidence of a difference between trial arms were only performed on the primary and secondary outcomes listed above to reduce the problem of multiple testing. Statistical tests were computed on cluster/district-level aggregated data - as recommended by Moulton and Hayes (2009) with fewer than about 15 clusters per arm - and accounting for the stepped wedge design of the trial using the swpermute command in STATA. We however excluded data for Gourcy district in step 6 and Titao district in step 7 because the theft of a laptop and a problem with data transfer to the cloud) resulted in only 1 and 2 consultations being available for these steps in these districts respectively (figure 1b). Student's t test was used to compare the mean cluster/district-level estimates in the intervention arm and in the control arm. One exception was however made for the comparison between trial arms of the identification of at least one danger sign and overall

correct referral/hospitalisation for which Fisher's exact tests were performed on individual level data and ignoring clustering, given the very small number of children with danger signs or severe classifications warranting referral/hospitalisation.

In addition to comparison between trial arms, and in order to assess whether the use of IMCI paper-based form in the control arm had an effect on HCWs performance, we also compared, in the control arm, primary and secondary outcomes in HCWs who were observed to use a paper-based IMCI form and those who did not.

Lastly, the level of agreement between HCWs and validation nurses was assessed for some measurements: Weight, height, MUAC, temperature, respiratory count and RDT result. For quantitative measures, we calculated the mean, the standard deviation (SD) and the square root of the mean square errors (RMSE) of the difference between validation nurses and HCWs' measurement, and we produced Bland Altman plots. For qualitative

measures, we calculated the Cohen's Kappa coefficient.

The SD is a measure that is used to quantify the amount of variation or dispersion of a set of values around the mean. A low standard deviation indicates that the data points tend to be close to the mean of the set, while a high standard deviation indicates that the data points are spread out over a wider range of values. If all values of a data set are the same, the standard deviation is zero.

While the mean is a useful information, it can mask important differences that cancel out. The RMSE is also a measure of the differences between two sets of values but that does not mask important differences. It aggregates the magnitudes of the differences (or errors) into a single measure by taking the square root of the mean of the squared errors. RMSE is always non-negative, and a value of 0 (almost never achieved in practice) would indicate a perfect agreement between the two sets of values.

A Bland Altman plot displays the difference between the two values against their average. It gives the 95% limits of agreement together with the proportion of the sets of values

outside these limits. Bland-Altman plots allow identification of any systematic difference between the measurements or possible outliers.

Cohen's kappa coefficient (κ) is a statistic which measures inter-rater agreement, for qualitative (categorical) items, beyond that expected by chance. If the raters are in complete agreement then k=1. If there is no agreement among the raters other than what would be expected by chance, then k=0.

2.8. Ethics

Ethical approval was granted by the National Health Ethics Committee of the Ministry of Health of Burkina Faso (Reference 2014-4-026), and the London School of Hygiene and Tropical Medicine (Reference 7261). Written informed consent was obtained from the HCW and child's caretaker prior to the observation of the consultation and was obtained from the child's caretaker prior to the repeat consultation. The trial is registered at ClinicalTrials.gov (Reference NCT02341469).

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3. Results

The number of consultations for which data were collected by district and by step is indicated in each cell of figure 1b. In total, after excluding 189 follow-up visits, data were recorded for 2,724 new consultations of children aged two months to five years old: 686 consultations at baseline (white cells in steps 1 and 2), 1,343 consultations in control districts (white cells from step 3 to step 8) and 695 consultations in intervention districts (green cells).

3.1. Region, district, children's gender, age and classification distribution

While about 70% and 30% of consultations in both trial arms occurred in the Boucle du Mouhoun and Nord regions respectively, there were important imbalances in terms of district between trial arms (table 2). In the intervention arm, about a third of consultations occurred in Solenzo (39%) and Toma (31%), 20% in Titao district and 9% in Ouahigouya district. Boromo, Dedougou, Nouna and Gourcy districts never benefited from the intervention. In the control arm, around 20% f consultations occurred in either Boromo, Dedougou, Nouna or Gourcy. Only 9%, 7% and 4% of consultations occurred in Ouahigouya, Titao and Solenzo districts respectively.

Overall, about 55% of children who consulted were boys and about 45% were girls (table 3). Nearly two thirds (60%) of children were aged less than 24 months (table 4). Gender and age distributions were similar at baseline and by trial arm.

The most frequent classification given to children, by both the HCWs and the validation nurses, was malaria (between 50% to 69% of children across baseline and trial arms) (table 5a). Across baseline and trial arms, between 12% and 26% of children were classified with cough/cold, between 17% and 27% of children

were classified with diarrhoea with no dehydration, between 16% and 34% were classified with pneumonia, and between 6% and 16% were classified with MAM. Severe classifications were rarely given (5% or less), as well as dysentery (3% or less).

According to both HCWs and the validation nurses, and excluding cough/cold (as in the analysis), around half of children had one classification, around a third had two classifications, between 5% and 12% had three classifications (table 5b). Only a few children had more than 3 classifications. Between 11% and 21% of children had no IMCI classification. Including cough/cold reduced the proportion of children without IMCI classification (between 6% and 14%) (table 5b).

3.2. Use of IMCI paper-form and eCDSS

While the IMCI paper-form was used for 69% (471/686) and 68% (916/1,343) of the consultations at baseline and in the control arm respectively, it was used in only 3% (20/694) of consultations in the intervention arm while the eCDSS was used in nearly all consultations (97%, 674/694) (table 6). The occasional use of the eCDSS, only or in combination with IMCI paper-form, at baseline (1%, 8/686) or in the control arm (9%, 120/1,343) reflects instances of early roll-out of the eCDSS prior to training (incomplete implementation resulting in contamination).

Across all steps, when HCWs opened the eCDSS, only a few were observed to not use it until the end of the consultation (2%, 13/803) and to experience difficulties in using it (3%, 20/803).

The mean duration of consultations was 18.6 minutes at baseline, 13.5 minutes in the control districts and 15.3 minutes in the intervention districts (table 7a). In the control

arm, whether the HCWs used an IMCI paper-form, the eCDSS (due to early roll-out of the intervention in control districts) or neither of those, the mean duration of consultation was very similar and about 13 minutes. In the intervention arm, very small numbers of HCWs used an IMCI paper-form or neither of the two tools (paper-form or eCDSS). When using the eCDSS, the mean duration of consultations was 15.1 minutes, similar to the control arm. Looking at the consultation duration when HCWs used the eCDSS and by number of steps since the IeDA implementation in the intervention arm, the mean duration of consultations appeared fairly similar regardless of the number of steps, around its average of 15 minutes (table 7b).

A triage area was observed for 17% (26/157), 16% (45/284) and 45% (71/160) of health facility visits at baseline, and in the control and intervention arms respectively. Consequently, some child's measurements were observed to be performed in the triage area more often in the intervention arm compared to the control arm: 32% (186/582) versus 19% (205/1,070) of measurements of the child's temperature, 36% (198/546) versus 18% (170/937) of RDTs, 55% (376/689) versus 29% (355/1,209) of measurements of the child's height, 53% (361/681) versus 31% (413/1,318) of measurements of the child's weight and 45% (276/610) versus 21% (246/1,155) of measurements of the child's MUAC. Therefore, the mean duration of the consultation itself is not fully comparable between trial arms. The higher proportion of consultations involving a triage area in the intervention arm might under-estimate consultation's duration in the intervention arm relative to the control arm.

3.3. Primary and secondary outcomes

Findings with respect to the primary and secondary outcomes are summarised in table 8. Supplementary material (appendix 1) provides plots of cluster-level estimates of primary and secondary outcomes by step and trial arm with the exception of identification of danger signs and correct referral/hospitalisation due to too small numbers of records. Subsequent tables (tables 9 to 15) present findings specific to each IMCI algorithm with respect to clinical assessments (table 9), danger signs' identification (table 10), classifications (tables 11a and 11b), correct prescriptions (tables 12a and 12b), over-prescriptions (tables 13a and 13b), referrals/hospitalisations (tables 14a and 14b) and counselling (table 15). Appendix 2 shows tabulations of the HCWs' classifications against the validation nurses' classifications. Appendix 3 shows findings with respect to the primary and secondary outcomes when excluding "contaminated" control districts from the analysis (secondary analysis). Excluding "contaminated" control districts removed a total of 173 consultations from the analysis and made little or no difference to the results.

3.3.1. Adherence to IMCI's clinical assessment

Overall, the average percentage of completed tasks by the HCWs across the six IMCI algorithms of danger signs (3 tasks), cough/difficult breathing (2 to 6 tasks), diarrhoea (1 to 5 tasks), fever (2 to 14 tasks), anaemia (1 task) and nutritional status (4 to 5 tasks) was 48% at baseline, 54% in the control districts and 79% in the intervention districts with strong evidence for a difference between trial arms (cluster-level mean difference = 29.9%; P-value = 0.002) (table 8). Step-specific

mean differences, however, did not suggest an increase in adherence to IMCI's clinical assessment with time (7.8%, 34.9%, 26.1%, 32.9%, 39.6% and 26.0% in steps 3, 4, 5, 6, 7 and 8 respectively), with HCWs in the first step of implementation performing as well as HCWs during last steps of implementation. To note, in step 3, only one district belonged to the intervention arm, and therefore the small difference (7.8%) is based on a small number of observations (N = 38).

On average, for each condition-specific IMCI algorithm of interest, HCWs in the intervention arm completed more of the recommended tasks resulting in higher adherence indices compared to HCWs in the control arm: 95% versus 34% respectively for assessing danger signs (cluster-level mean difference = 71.2%; P-value = 0.002), 68% versus 50% respectively for assessing cough/difficult breathing, 94% versus 82% respectively for assessing diarrhoea, 72% versus 53% for assessing fever, 92% versus 52% for assessing anaemia, and 93% versus 77% for assessing nutritional status (table 9). Restricting the adherence index to children with the condition increased the difference between arms for the algorithms of cough or difficult breathing and diarrhoea, suggesting that HCWs in the intervention arm not only checked more frequently the presence of each condition but followed more of the recommended subsequent tasks than HCWs in the control arm (table 9).

3.3.2. Correct identification of danger signs

Overall, the proportion of children correctly identified, by the HCWs, with at least one danger sign was 67% (16/24) at baseline and 56% (14/25) in the control districts. It appeared to be somewhat higher (75%, 12/16) in the intervention arm but this could be a chance finding given the small number of children with danger signs (cluster-level mean difference = 19.0%; P-value = 0.322) (tables 8 and 10). In particular only 4 children were identified as unable to drink or breastfeed throughout the study.

3.3.3. Correct classifications

Overall, the proportion of children for whom the validation nurses and the HCWs recorded the same classifications (ignoring the severity of the classifications) was 75% (457/609) at baseline, 73% (767/1,049) in the control districts and 79% (450/572) in the intervention districts with strong evidence for a difference between trial arms (cluster-level mean difference = 10.1%; P-value = 0.004) (table 8). Accounting for the severity of the classifications slightly lowered the proportions of correct classifications at baseline (71%, 430/609), and in the control (70%, 732/1,049) and intervention (75%, 427/572) arms as well as the difference between arms and the strength of evidence for a difference (cluster-level mean difference = 9.1%; P-value = 0.038) (table 8).

Across classifications, sensitivity and specificity were broadly similar at baseline and in the control arm (tables 11a and 11b). By IMCI algorithm and ignoring the severity of the classifications, the ability of the HCWs to correctly classify children (sensitivity) with diarrhoea, dysentery and malnutrition was higher in the

intervention arm compared to the control arm: 77% (147/192) versus 66% (228/346), 83% (10/12) versus 44% (12/27), and 75% (89/118) versus 55% (91/165) respectively (table 11a). Sensitivity of the HCWs with respect to pneumonia (ignoring severity) was only slightly higher in the intervention arm compared to the control arm: 79% (136/173) versus 73% (167/228) respectively. Sensitivity of the HCWs with respect to malaria (ignoring severity) was similar in both arms. Although based on a small number of children, HCWs in intervention districts appeared to correctly classify children with severe malaria or severe febrile illness more often than those in control districts: 82% (14/17) versus 63% (15/24) respectively.

The ability of the HCWs to correctly not classify children (specificity) with a given classification (ignoring severity,) was generally high in both arms (95% or more for most conditions), or in other words, false positive classifications were rare (<5%) for most conditions (table 11b). One exception to this was pneumonia (ignoring severity), with specificity of 93% (483/521) in the intervention arm compared to 81% (904/1,113) in the control arm, suggesting that the intervention reduced over-diagnosis of pneumonia.

It should, however, be noted that comparisons between baseline and the control arm and between trial arms of the sensitivity and specificity of HCWs' classifications are limited by the small numbers of children in some classifications, in particular dysentery or severe classifications.

3.3.4. Correct prescriptions

Correct prescriptions according to the HCWs' classifications

Overall, the proportion of children who received at least all the recommended prescriptions in accordance with the HCWs' classifications was 76% (465/614) at baseline, 78% (836/1,074) in the control districts and 77% (437/567) in the intervention districts with no evidence for a difference between trial arms (cluster-level mean difference = -1.1%; P-value = 0.788) (table 8).

However ,correct prescriptions for dysentery were much more common in the intervention arm (69%, 9/13) than in the control arm (11%, 5/45) (table 12a). Correct prescriptions for malnutrition (all classifications together) were also more common, though still infrequent, in the intervention arm (17%, 19/112) compared to the control arm (7%, 9/124). Correct prescriptions for pneumonia (all classifications together) were similar between arms (93%, 162/174 versus 94%, 352/376 in intervention and control arms respectively) as well as correct prescriptions for diarrhoea (all classifications together) (88%, 137/155 versus 83%, 236/283 in intervention and control arms respectively) and malaria (all classifications together) (94%, 349/371 versus 96%, 698/730 in intervention and control arms respectively). With respect to the latter, correct prescriptions for severe malaria or severe febrile illness were however more common, though based on a small number of children, in the intervention arm (33%, 8/24) compared to the control arm (8%, 2/26).

Appendix 4a shows, by HCWs' classification, recommended medicines that were not prescribed to children leaving the health centre with an incorrect prescription. For

instance, among children classified by the HCWs with severe pneumonia and who were not prescribed recommended medicines in the intervention arm, 75% (3/4) did not receive an injection of ampicillin and none received an injection of gentamycin.

Appendix 4b shows, by HCWs' classification, other medicines that were prescribed to children leaving the health centre with an incorrect prescription. For instance, among children classified by the HCWs with severe pneumonia and who were not prescribed recommended medicines in the intervention arm, 50% (2/4) and 25% (1/4) received an injection of quinine and artesunate respectively.

Correct prescriptions according to the validation nurses' classifications

Overall, the proportion of children who received at least all the recommended prescriptions in accordance with the validation nurses' classifications was 65% (398/610) at baseline, 66% (693/1,049) in the control districts and 69% (392/572) in the intervention districts with no evidence for a difference between trial arms (cluster-level mean difference = 6.7%; P-value = 0.226) (table 8).

However, correct prescriptions for dysentery were much higher in the intervention arm (75%, 9/12) compared to the control arm (11%, 3/27); correct prescriptions for malnutrition (all classifications together) were also higher in the intervention arm (15%, 18/118) compared to the control arm (6%, 10/166); as were correct prescriptions for diarrhoea (all classifications together) (77%, 147/192 in the intervention arm versus 65%, 226/346 in control arm) (table

12b). Correct prescriptions for pneumonia (all classifications together) were similar between arms (79%, 137/173 versus 75%, 172/228 in intervention and control arms respectively); as were correct prescriptions for malaria (all classifications together) (92%, 354/383 in the intervention arm versus 91%, 691/758 in the control arm). As above, correct prescriptions for severe malaria or severe febrile illness were however more common in the intervention arm (29%, 5/17) compared to the control arm (0%, 0/24).

3.3.5. Over-prescriptions

Over-prescriptions according to the HCWs' classifications

Overall, the proportion of children who were not in need of an antibiotic according to HCWs' classifications but who were actually prescribed one (injectable ampicillin or gentamycin, cotrimoxazole, amoxicillin, ciprofloxacin or metronidazole) was 12% (81/682) at baseline, 15% (200/1,341) in the control arm and 9% (63/694) in the intervention arm (table 13a). This suggests a reduction in over-prescription of antibiotics of about 6% points in the intervention arm compared to the control arm, almost all of which is explained by a reduction in over-prescription of cotrimoxazole.

With respect to antimalarials, the proportion of children who were over-prescribed either injectable artesunate, artemether or quinine or ACT was 2% (12/685) at baseline, 2% (24/1,343) in the control arm and 3% (19/694) in the intervention arm (table 13a), suggesting very little over-prescription of antimalarials in the first place and no reduction in over-prescription in the intervention arm compared to the control arm.

Over-prescriptions according to the validation nurses' classifications

According to validation nurses' classifications, the proportion of children who were over-prescribed an antibiotic was 20% (137/676) at baseline, 27% (347/1,300) in the control arm and 12% (83/682) in the intervention arm, suggesting a reduction in over-prescription in the intervention arm of about 15% percentage points compared to the control arm (table 13b). Over-prescription was particularly reduced for cotrimoxazole (10% points reduction) and to some extent for amoxicillin (4% points reduction).

The proportion of children who were over-prescribed an antimalarial was 4% (27/686) at baseline, 3% (38/1,343) in the control arm and 3% (21/695) in the intervention arm, suggesting, as above, very little over-prescription of antimalarials in the first place and no reduction in over-prescription in the intervention arm compared to the control arm (table 13b).

3.3.6. Correct referrals or hospitalisations

Overall, the proportion of children in need of referral or hospitalisation according to the HCWs' assessment who were actually referred or hospitalised by the HCWs was 60% (21/35) at baseline, 52% (22/42) in the control districts and 61% (25/41) in the intervention districts but with no evidence for a difference between trial arms (cluster-level mean difference = 8.6%; P-value = 0.509) (table 8). According to the validation nurses' assessment, these proportions 55% (16/29) at baseline, 53% (17/32) in the control districts and 68% (15/22) in the intervention districts, again with no evidence for a difference between trial arms (cluster-level mean difference = 15.1%; P-value = 0.398) (table 8).

Interpretation of these findings is hampered by the small numbers of children requiring referral/ hospitalisation.

By classification warranting referral or hospitalisation (tables 14a and 14b), there are generally too few children to perform meaningful comparisons. The one possible exception to this is severe malaria/severe febrile illness for which HCWs in the intervention clusters appeared to perform better than in the control clusters: 96% (23/24) versus 73% (19/26) according to HCWs' assessment and 77% (13/17) versus 58% (14/24) according to validation nurses' assessment.

3.3.7. Correct treatment counselling

Overall, the proportion of children's caretakers to whom the HCWs mentioned both the number of doses a day and the number of days for all the relevant oral medicines prescribed for treating the child at home was 77% (473/612) at baseline, 92% (1,046/1,143) in the control districts and 88% (506/576) in the intervention districts with no evidence for a difference between trial arms (cluster-level mean difference = -4.1%; P-value = 0.355) (table 8).

Both the number of doses per day and the number of days across all treatments were mentioned by the HCWs to a high proportion of children's caretakers at baseline and in both trial arms (table 15).

3.4. Availability of essential medicines and equipment

The average proportion of essential equipment that were observed to be available at the health facilities was high: 87% at baseline, 87% in the control arm and 91% in the intervention arm (table 16). By item of equipment, better availability was observed in the intervention arm compared to the control arm for electricity (67%, 112/254 versus 33%, 56/198 of facilities without any power cut in the past 7 days) and equipment to administer ORS (85%, 143/168 versus 33%, 95/289). However, the proportion of facilities with all equipment available, although better in the intervention arm, was still very low: 20% (33/166) versus 10% (29/290) in the intervention and control arm respectively. The availability of essential equipment per district and trial arms is given in Appendix 5a.

The average proportion of essential oral medicines that were observed to be available at the health facilities was 98% at baseline, 94% in the control arm and 89% in the intervention arm (table 16). Although there was a relatively good availability of each medicine in both arms (about 70% or more), deworming treatments (albendazole and mebendazole), amoxicillin, ORS and zinc as well as multivitamins were less frequently available in the intervention arm compared to the control arm. The proportion of facilities with all oral medicines available was only 29% (47/165) in the intervention arm compared to 53% (149/284) in the control arm. The availability of essential medicines per district and trial arms is given in Appendix 5b. While amoxicillin and multivitamins were particularly less available in Titao intervention district, ORS and zinc were particularly less available in Ouahigouya intervention district.

94/2683 = 3.50% outside the limits of agreement
Mean difference 0.049
95% limits of agreement (-1.273, 1.371)
Averages lie between 2.300 and 21.000

Figure 3a: Differences in child's weight

74/2485 = 2.98% outside the limits of agreement
Mean difference 0.157
95% limits of agreement (-5.161, 5.476)
Averages lie between 51.000 and 117.000

Figure 3b: Differences in child's height

168/2231 = 7.53% outside the limits of agreement
Mean difference -0.492
95% limits of agreement (-9.783, 8.800)
Averages lie between 90.000 and 180.000

Figure 3c: Differences in child's MUAC

Note that deworming treatments were not accounted for in the analysis of prescription (due to lack of information about uptake in the past 6 months), so that their lower availability did not impact on our findings related to correct prescription.

3.5. Comparison of HCWs' performance with and without use of IMCI paper-forms in the control arm

Surprisingly, HCWs who were observed to not use a paper-based IMCI form in the control arm seem to have better assessed danger signs than those who were observed to use a form: on average 45% versus 22% of the recommended tasks were completed to assess danger signs respectively (table 17). To some extent, this could have led in a better identification of at least one danger sign by HCWs who did not use a form compared to those who use one (67%, 4/6 versus 50%, 9/18), but these proportions are based on very small numbers and prevent firm conclusion. All other indicators appeared, however, similar between the two groups.

3.6 Child measurements' agreement between HCWs and validation nurses

The RMSE for the differences in child's weight, height and temperature measurements between HCWs and validation nurses indicate differences of a small magnitude (< 1 kg, < 3 cm or < 1°C) at baseline and in the trial arms (table 18a). Higher RMSE, although still of relatively small size, were observed between HCWs and validation nurses's

116/2518 = 4.61% outside the limits of agreement
Mean difference -0.064
95% limits of agreement (-1.100, 0.971)
Averages lie between 34.400 and 43.700

Figure 3d: Differences in child's temperature

47/680 = 6.91% outside the limits of agreement
Mean difference 0.103
95% limits of agreement (-17.855, 18.060)
Averages lie between 26.000 and 83.500

Figure 3e: Differences in child's respiratory count

measurements of MUAC (around 5 mm) and respiratory count (around 9 counts). All differences were fairly balance between trial arms. Bland altam plots allowed to identify outliers which are either gross errors in measurements or data entry errors

Figures 3a – 3e: Bland Altman plots for the differences in child's measurements between HCWs and validation nurses

With respect to RDT results, about 97% of RDT results were in agreement between HCWs and

validation nurses at baseline and in the trial arms (table 18b). The Kappa coefficients indicate that 90% or more RDT results were in agreement beyond that expected by chance. Tables displaying RDT results by HCWs and validation nurses are given in Appendix 6.

4. Discussion

We found strong evidence that the intervention substantially increased adherence to the IMCI assessment tasks (a 30% point increase on average across the intervention districts compared to the control districts, P-value = 0.002), including the assessment of danger signs. This is in line with findings from our realistic evaluation which showed good acceptability and a positive opinion of HCWs, in particular with respect to the usefulness of the eCDSS in guiding through the clinical assessment:

"When using the REC, we have to follow each step, which means we are to screen all potential problems of the child, even the ones not mentioned by the carer. The REC pushes us to ask the right questions" (Healthcare worker) (Blanchet et al., 2018).

This led to some improvement in the overall proportion of children correctly classified, but this improvement was smaller than the improvement in task adherence (around a 10% point increase on average across the intervention districts compared to the control districts, P-value < 0.038). Achieving correct classification depends, at least in part, on the clinical skills of the HCWs, which may be more difficult to improve than task adherence itself. This may have limited somewhat the effect of the intervention on correct classification. Furthermore, one limitation of our evaluation approach should be acknowledged. The "gold standard" classifications were provided by a repeat consultation after the initial consultations and it is possible that the clinical status of some children may have changed in the interval between the initial consultation and the repeat consultation simply because of the time delay between the two. For instance, this might be the case for respiratory rate, temperature or current convulsions. In addition, some clinical signs may be more subjective than other (e.g. stridor, chest indrawing) and therefore we should not expect full agreement between HCWs and validation nurses. Thus, our "gold standard" is certainly less than perfect and some consultations in which the HCWs correctly classified the child based on their status at the initial consultation may have been recorded as having resulted in an incorrect classification. This would tend to reduce the apparent magnitude of any improvement in classifications.

Nevertheless, improvement in classifications was particularly marked for dysentery and malnutrition. To some degree, we also observed an improvement in danger sign identification and classifications related to diarrhoea (mainly diarrhoea with no dehydration) and severe malaria or severe febrile illness, although the small numbers of children with danger signs or severe malaria limit our ability to draw firm conclusions (the observed difference could be a chance finding).

We did not detect an improvement in the overall proportion of children who received the correct prescription according to the HCWs' classifications, though there may have been a small improvement in correct prescriptions according to the validation nurses' classifications (a 7% point increase on average across the intervention districts compared to the control districts) but with no statistical evidence for this (P-value = 0.226). Nevertheless, there were improvements in correct prescriptions for dysentery, malnutrition and severe malaria or severe febrile illness, although the proportions of correct prescriptions for the two latter remained quite low (around 15% for malnutrition and around 30% for severe malaria or severe febrile illness). It is also noteworthy that the intervention appeared to have reduced over-prescription of antibiotics by about 6% to 15% points (depending on on HCWs or validation nurses' classifications), most all of which is explained by a reduction in over-prescription of cotrimoxazole and to a lesser extent of amoxicilline. There may also have been an improvement in correct referral/hospitalisation (between 9% and 15% point increase on average across the intervention districts compared to the control districts depending on HCWs or validation nurses' classifications, P-values = 0.509 and 0.398 respectively) but the small numbers of such children preclude firm conclusions.

Improvements in individual classifications and prescriptions tended to be greater for relatively rare or less common conditions (while dysentery, severe malaria and SAM were diagnosed for less than 5% of children, MAM and diarrhoea with no dehydration, although more frequent, were diagnosed for around 15% and 25% of children) which explains, at least in part, why there were little or modest overall improvements in correct classifications and prescriptions. In addition, HCWs in the control arm performed relatively well in classifying and in prescribing the correct medicines for other, more common, conditions (e.g. malaria or

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pneumonia), thus limiting the scope for an overall impact. This is, perhaps, not surprising when considering that maintaining management skills is likely to be harder for rare conditions for which HCWs have less opportunity to practice.

Our findings are broadly consistent with the limited evidence available on the effectiveness of eCDSS for improving adherence to IMCI. In Ghana and South Africa, small scale studies reported good acceptability of electronic IMCI (Ginsburg et al., 2016) and better knowledge of IMCI and adherence to guidelines during training when using such strategy (Rhode, 2012). In four districts in Tanzania, providers and caretakers expressed positive opinions of electronic IMCI (Mitchell et al., 2012), and completeness of clinical assessment improved compared to paper-based IMCI (DeRenzi et al., 2008, Mitchell et al., 2013). Correct classifications for pneumonia, dehydration (i.e diarrhoea for less than 14 days), persistent diarrhoea (i.e diarrhoea for more than 14 days), malaria were high in both arms but the electronic protocol led to more accurate classifications across the four areas: 82.7% of encounters had correct classification in all areas under pIMCI compared to 90.9% under eIMCI (p < 0.001) (Mitchell et al., 2013). HCW's performance in terms of prescription was however not assessed.

HCW practices are complex behaviours that have many potential contextual and intrinsic influences. The relatively lower availability of some essential medicines, such as amoxicillin, ORS and zinc in the intervention arm compared to the control arm is an obvious first contextual factor that may have limited the scope of improvement in correct prescriptions for pneumonia, SAM without complications, diarrhoea and dysentery. The distribution of essential medicines by district and by trial arm suggest that the observed lower availability in the intervention districts was not related to pre-existing issues in the supply chain management. One possible explanation is that the better adherence to guidelines may have resulted in issues in the supply chain management in some intervention districts. However, it should be noted that availability is sometimes based on a small number of observations, particularly in the intervention districts.

Nevertheless, availability is a necessary but not sufficient condition to ensure that recommended medicines are correctly prescribed. Multiple conditions may also have influenced the medicines prescribed. Across baseline and trial arms, about a third to a half of children were diagnosed with two or more classifications. HCWs may not have always prescribed all recommended medicines considering that those already prescribed were covering all conditions. For instance, among children classified by the HCWs with pneumonia and who were not prescribed amoxicillin or cotrimoxazole in the intervention arm, 38% (3/8) received an injection of ampicillin and/or gentamycin, and 63% (5/8) received a prescription of erythromycin (appendix 4b). Or,

among children classified by HCWs with SAM without complications and who did not receive amoxicillin or RUTF, 6% (1/18) received an injection of ampicillin and gentamycin and 28% (5/18) received a prescription cotrimoxazole (appendix 4b).

Our realistic evaluation also noted that, although HCWs recognised that the use of the eCDSS leads to more rational prescriptions, they reported that pressure from children's caretakers, implicit or explicit, was a challenge (Blanchet et al., 2018):

"The person expects to be prescribed drugs like in the old times. This was routine practice during consultations. People are used to drugs. For people who are illiterate, you explain but they will go to another facility to ask for drugs. It is about trust between us and the patient." (Healthcare worker).

Thus, following the recommendations and not over-prescribing medicines requires HCWs to resist pressure from caretakers.

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In Tanzania, a large know-do gap was observed, and a lack of knowledge was not the only constraint identified for improved performance. HCW's weak belief in the importance of following guidelines and confidence in their own experience, lack of intrinsic motivation, and physical or cognitive "overload" were also reported, with poor remuneration contributing to several of these factors (Lange et al., 2014).

Lastly, incomplete coverage of some components of the intervention may have limited its effect on performance overall. Our realistic evaluation reported that, in 2017, in the four districts where IeDA was implemented, 36% of HCWs had not benefited from the IMCI/eCDSS training (Blanchet et al., 2018). While this proportion was lower in nurses (10% to 12%) it was not negligible in HCW assistants (20%) and higher in midwifes (40%) and auxiliary midwifes (89%) who were sometimes observed conducting consultations when nurses were absent. In the four intervention districts, around a third of HCWs (36%) had been changed during the past 12 months, and this high staff turnover likely explains, at least in part, the incomplete coverage of IMCI/eCDSS training. Even though peer support had developed between HCWs working at the same health centre, the relatively high proportion of HCWs not trained in IMCI/eCDSS may have limited the effect of the intervention. Staff turn over may also explain why the mean duration of the consultation when using the eCDSS in the intervention arm appeared similar, at around 15 minutes, regardless of the number of steps since the implementation of IeDA. Lastly, staff turnover may have also resulted, to some extent, in an increase of more skilled HCWs in the control arm, which may also have limited the apparent effect of the intervention.

With respect to supervision, the health district management teams (HDMT) reported that their limited

budget and access to vehicles at the district level challenged these activities. They also reported that HDMT supervisors did not have enough time to dedicate to these visits (Blanchet et al., 2018). Such findings are similar to those reported in Benin during the implementation of an intervention designed to strengthen supervision and improve adherence to IMCI (Rowe et al., 2010). To sustain supervision during the IeDA intervention, the HDMT reported having assigned other staff to these activities, for instance HCWs from health centres, All HCWs recognised the importance of supervisory visits and coaching meetings following the initial training in order to be able to ask questions, be reassured that they were doing the right thing and understand trouble shooting methods to solve software or tablet issues (Blanchet et al., 2018). It has previously been noted that training alone does not secure adherence to IMCI and there is evidence that supervision and audit with feedback can be effective (Rowe et al., 2005, Rowe et al., 2009, Magge et al., 2014). None of these studies, however, reported on the effect of supervisory visits conducted by HCW's peers rather than by a member of the district supervisory team, such a physician (Rowe et al., 2009) or a "clinical mentor" (Magge et al., 2014).

Before concluding, a general limitation of our evaluation approach should be acknowledged. It is likely that the behaviour of HCWs was impacted by the fact that they were observed (Leonard et al., 2006). Although Leonard et al. (2006) found that this Hawthorne effect declined over time, the high proportion of HCWs observed using paper-based IMCI forms in the control arm across all steps (68% overall) compared to routine practice suggest that HCWs in this arm were motivated to perform better than usual. In 2012, an evaluation of the coverage of the IMCI strategy in Burkina Faso reported that only 8% of under-five child consultation were managed

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using the IMCI strategy and that for only 13% of them a paper-based IMCI form was completed (Ministère de la santé, 2013). However, the frequent use of IMCI paper-based forms in the control arm did not seem to result in better HCW performance. Surprisingly, HCWs in the control arm who did not use a form seem to have better assessed danger signs than those who did use a form (45% versus 22%) and all other outcomes appeared similar between the two groups. In the intervention arm, the behaviour of HCWs may also have been affected by the presence of observers. Therefore, our findings may over-estimate how well HCWs perform in the absence of an observer but it is difficult to assert whether or in which direction this may have affected the comparison of intervention and control arms. Data from observations of 81,856 consultations in 18 countries (Service Provision Assessment

Surveys and the baseline surveys of Results Based Financing impact evaluations from 2007 to 2016) showed that adherence to IMCI clinical assessment tasks is low, from 27% (Nepal) to 53% (Namibia) of recommended tasks completed (Kruk et al., 2018). In Burkina Faso, 49% of the recommended tasks were observed to be completed.

In addition, data from clinical vignettes from the Service Delivery Indicators surveys in Kenya (2012), Nigeria (2013), Tanzania (2014), Togo (2013), and Uganda (2013) and from the Service Provision Assessment survey in Ethiopia (2014) revealed wide variations in diagnostic accuracy: from 0% (Togo) to 43% (Tanzania) for malaria with anaemia, from 24% (Nigeria) to 78% (Kenya) for diarrhoea, and from 36% (Togo) to 83% (Kenya) pneumonia (Kruk et al., 2018).

To conclude, the IeDA intervention improved substantially HCW's adherence to IMCI clinical assessment, including the assessment of danger signs, which led to some improvements in overall correct classifications but little or no improvement in overall correct prescriptions. Substantial improvements were however observed in correct classifications and prescriptions of dysentery and malnutrition. To some degree, we also observed an improvement in danger sign identification, correct referrals/hospitalisations and management of severe malaria or severe febrile illness (classification, prescriptions and referral/hospitalisation), although these observations are based on small numbers of children, limiting

our ability to draw firm conclusions. Bigger improvements tended to be observed for less common conditions for which HCWs in the control arm performed relatively poorly. For the most common, conditions (e.g. malaria and pneumonia), HCWs in the control arm, who may have been influenced by a Hawthorne effect, performed relatively well, limiting the scope to detect an overall impact. The IeDA intervention nevertheless had a positive impact on some aspects of HCW's practices. A further advantage of the intervention is that it enabled rapid sharing of changes in recommended treatments that occurred during the period of the trial. However, HCW practices are complex behaviours that have many potential influences. Lower availability of some essential medicines in the intervention arm, pressure from children's caretakers, the presence of multiple conditions, professional norms, experiences and beliefs, or incomplete coverage of some components of the intervention (training and supervision) are some of the possible contextual and intrinsic factors that may also have limited the effect of the intervention.

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Appendix

Appendix 1: Cluster-level estimates of primary and secondary outcomes by step and trial arm
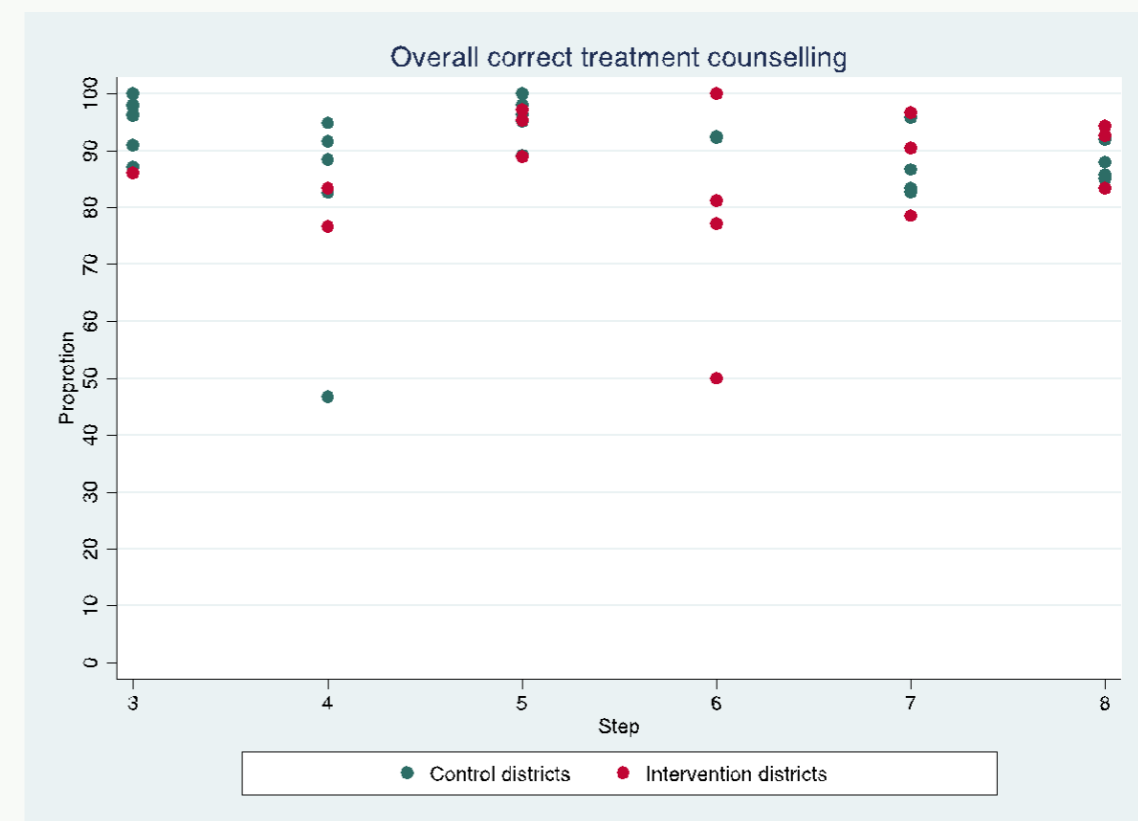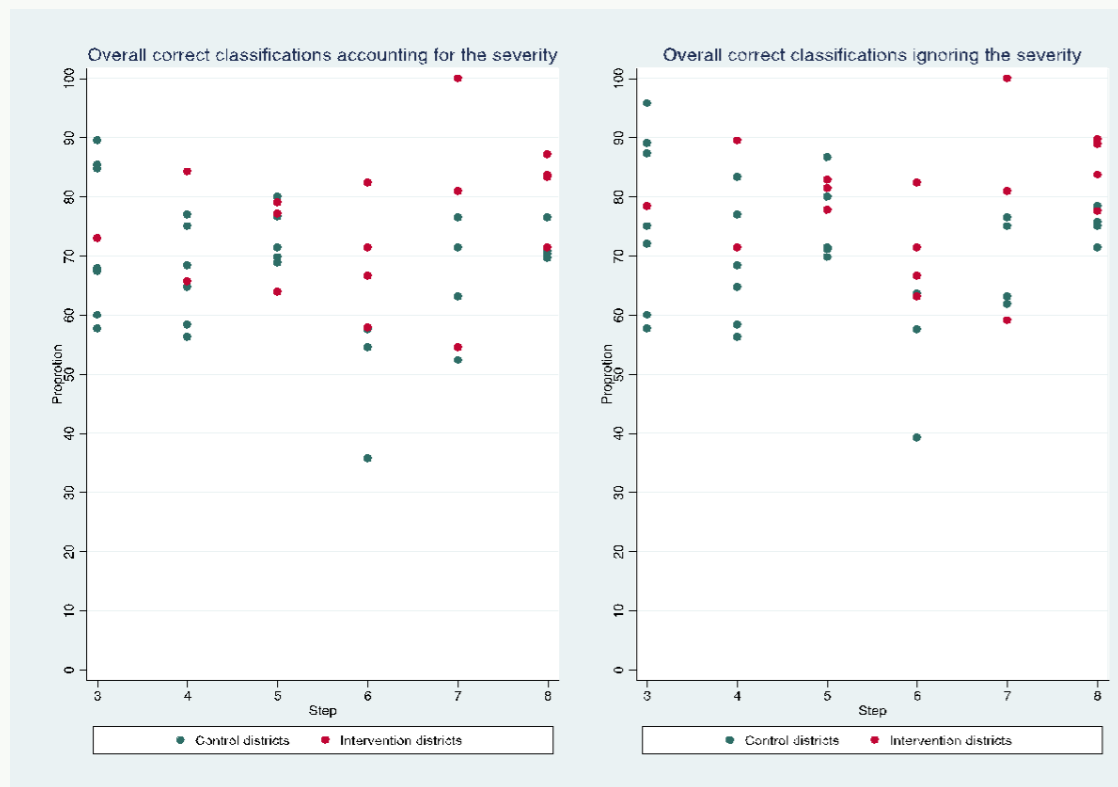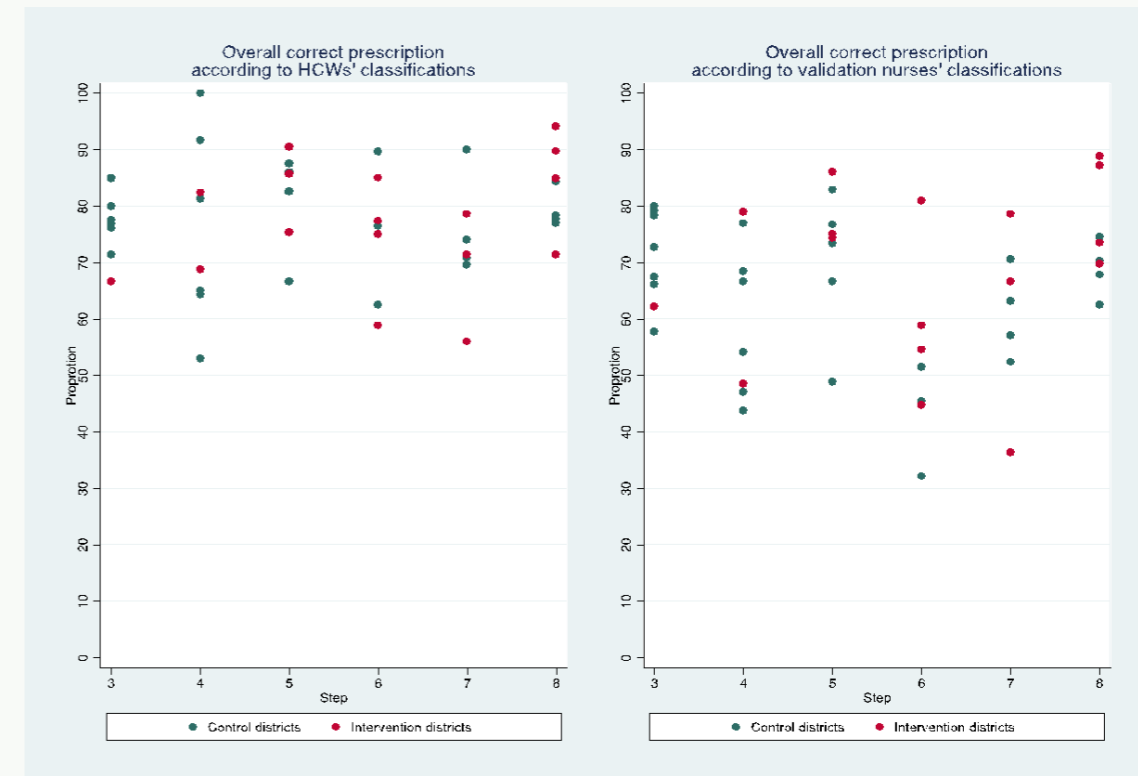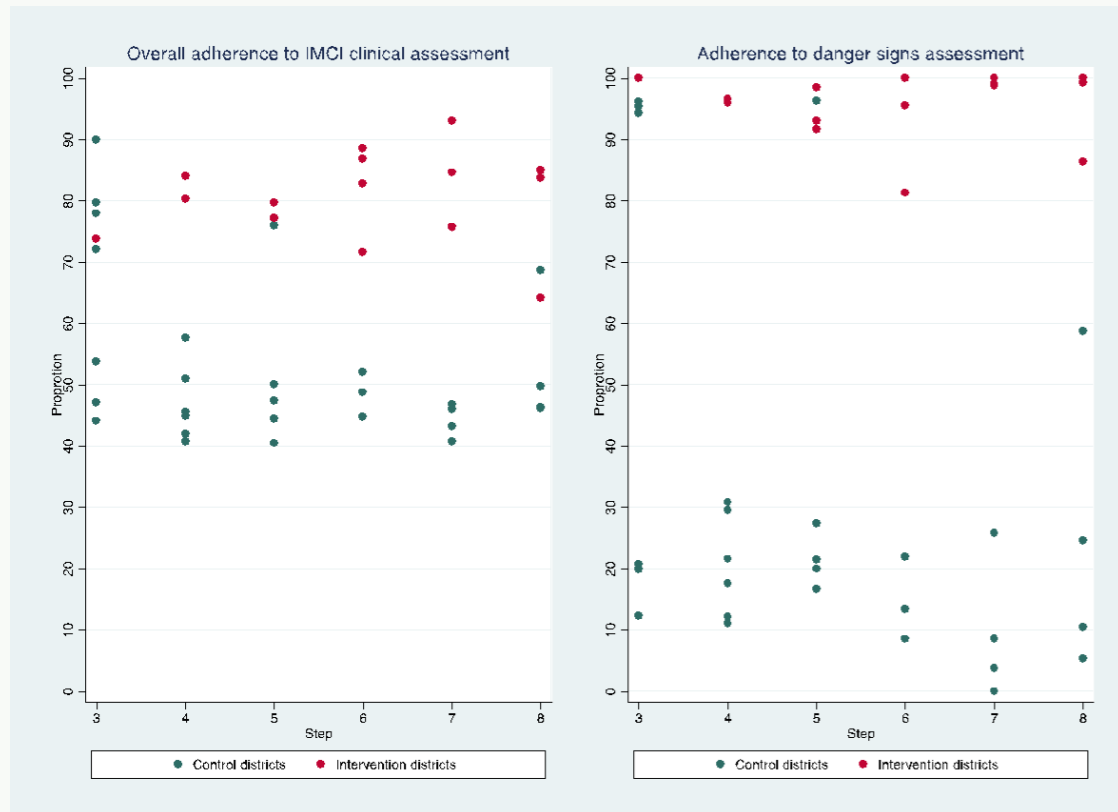
Appendix 2: Tabulations of the HCWs' classifications against the validation nurses' classifications

Cough/difficult breathing

Baseline Severe pneumonia or severe disease		HCW's classifications				
		Pneumonia	Cough/cold	No cough or difficult breathing	Total	
Validation nurse's classifications	Severe pneumonia or severe disease	14.3% (2)	57.1% (8)	0	28.6% (4)	100% (14)
	Pneumonia	0.5% (1)	75.7% (140)	11.9% (22)	11.9% (22)	100% (185)
	Cough/cold	0	47.8% (66)	29.7% (41)	22.5% (31)	100% (138)
	No cough or difficult breathing	0	2.5% (8)	4.1% (13)	93.4% (296)	100% (317)
	Total	0.5% (3)	33.9% (222)	11.6% (76)	54.0% (353)	100% (654)

Control arm Severe pneumonia or severe disease		HCW's classifications				
		Pneumonia	Cough/cold	No cough or difficult breathing	Total	
Validation nurse's classifications	Severe pneumonia or severe disease	20.0% (2)	50.0% (5)	20.0% (2)	10.0% (1)	100% (10)
	Pneumonia	1.8% (4)	71.6% (156)	15.1% (33)	11.5% (25)	100% (218)
	Cough/cold	0.9% (3)	50.0% (161)	33.9% (109)	15.2% (49)	100% (322)
	No cough or difficult breathing	0	5.7% (45)	3.8% (30)	90.5% (716)	100% (791)
	Total	0.7% (9)	27.4% (367)	13.0% (174)	59.0% (791)	100% (1,341)

Intervention arm Severe pneumonia or severe disease		HCW's classifications				
		Pneumonia	Cough/cold	No cough or difficult breathing	Total	
Validation nurse's classifications	Severe pneumonia or severe disease	25.0% (1)	25.0% (1)	50.0% (2)	0	100% (4)
	Pneumonia	3.0% (5)	76.3% (129)	14.8% (25)	5.9% (10)	100% (169)
	Cough/cold	0.6% (1)	17.3% (31)	69.3% (124)	12.9% (23)	100% (179)
	No cough or difficult breathing	0.6% (2)	1.2% (4)	2.3% (8)	95.9% (328)	100% (342)
	Total	1.3% (9)	23.8% (165)	22.9% (159)	52.0% (361)	100% (694)

Diarrhoea

Baseline Severe dehydration		HCW's classifications						
		Dehydration	No dehydration	Severe persistent diarrhoea	Persistent diarrhoea	No diarrhoea	Total	
Validation nurse's classifications	Severe dehydration	60.0% (3)	20.0% (1)	0	0	0	20.0% (1)	100% (5)
	Dehydration	0	80.0% (4)	0	0	0	20.0% (1)	100% (5)
	No dehydration	0	0.6% (1)	58.3% (102)	0.6% (1)	0.6% (1)	40.0% (70)	100% (175)
	Severe persistent diarrhoea	0	0	0	0	0	0	0
	Persistent diarrhoea	0	0	0	0	0	0	0
	No diarrhoea	0	0	3.0% (15)	0	0	97.0% (480)	100% (495)
	Total	0.4% (3)	0.9% (6)	17.2% (117)	0.2% (1)	0.2% (1)	81.2% (552)	100% (680)

Control arm Severe dehydration		HCW's classifications						
		Dehydration	No dehydration	Severe persistent diarrhoea	Persistent diarrhoea	No diarrhoea	Total	
Validation nurse's classifications	Severe dehydration	0	100% (1)	0	0	0	0	100% (1)
	Dehydration	0	50.0% (1)	50.0% (1)	0	0	0	100% (2)
	No dehydration	0	0.9% (3)	64.7% (222)	0	0	34.4% (118)	100% (343)
	Severe persistent diarrhoea	0	0	0	0	0	0	0
	Persistent diarrhoea	0	0	0	0	0	0	0
	No diarrhoea	0.1% (1)	0.2% (2)	5.2% (52)	0	0	94.5% (942)	100% (997)
	Total	0.1% (1)	0.5% (7)	20.5% (275)	0	0	78.9% (1,060)	100% (1,343)

Intervention arm		HCW's classifications						
Severe dehydration		Dehydration	No dehydration	Severe persistent diarrhoea	Persistent diarrhoea	No diarrhoea	Total	
Validation nurse's classifications	Severe dehydration	0	0	0	0	0	0	0
	Dehydration	0	66.7% (2)	0	0	0	33.3% (1)	100% (3)
	No dehydration	0	2.1% (4)	74.6% (141)	0	0	23.3% (44)	100% (189)
	Severe persistent diarrhoea	0	0	0	0	0	0	0
	Persistent diarrhoea	0	0	0	0	0	0	0
	No diarrhoea	0	0.2% (1)	1.2% (6)	0	0.2% (1)	98.4% (495)	100% (503)
	Total	0	1.0% (7)	21.2% (147)	0	0.1% (1)	77.7% (540)	100% (695)

Dysentery

Baseline		HCW's classifications		
Dysentery		No dysentery	Total	
Validation nurse's classifications	Dysentery	41.7% (5)	58.3% (7)	100% (12)
	No dysentery	2.6% (17)	97.5% (650)	100% (667)
	Total	3.2% (22)	96.8 (657)	100% (679)

Control arm		HCW's classifications		
Dysentery		No dysentery	Total	
Validation nurse's classifications	Dysentery	44.4% (12)	55.6% (15)	100% (27)
	No dysentery	2.5% (33)	97.5% (1,283)	100% (1,316)
	Total	3.4% (45)	96.7% (1,298)	100% (1,343)

Intervention arm		HCW's classifications		
Dysentery		No dysentery	Total	
Validation nurse's classifications	Dysentery	83.3% (10)	16.7% (2)	100% (12)
	No dysentery	0.4% (3)	99.6% (680)	100% (683)
	Total	1.9% (13)	98.1% (682)	100% (695)

Fever or history of fever

Baseline		HCW's classifications			
Severe malaria		Malaria	No fever or other aetiology	Total	
Validation nurse's classifications	Severe malaria	60.9% (14)	34.8% (8)	4.4% (1)	100% (23)
	Malaria	1.1% (5)	93.9% (446)	5.1% (24)	100% (475)
	No fever or other aetiology	1.6% (3)	6.0% (11)	92.4% (171)	100% (185)
	Total	3.2% (22)	68.1% (465)	28.7% (196)	100% (683)

Control arm		HCW's classifications			
Severe malaria		Malaria	No fever or other aetiology	Total	
Validation nurse's classifications	Severe malaria	62.5% (15)	29.2% (7)	8.3% (2)	100% (24)
	Malaria	1.2% (9)	92.0% (675)	6.8% (50)	100% (734)
	No fever or other aetiology	0.3% (2)	3.8% (22)	95.9% (561)	100% (585)
	Total	1.9% (26)	52.4% (704)	45.6% (613)	100% (1,343)

Intervention arm		HCW's classifications			
Severe malaria		Malaria	No fever or other aetiology	Total	
Validation nurse's classifications	Severe malaria	82.4% (14)	11.8% (2)	5.9% (1)	100% (17)
	Malaria	1.9% (7)	91.0% (333)	7.1% (26)	100% (366)
	No fever or other aetiology	1.0% (3)	3.9% (12)	95.2% (297)	100% (312)
	Total	3.5% (24)	49.9% (347)	46.6% (324)	100% (695)

Anaemia

Baseline		HCW's classifications			
Severe anaemia		Anaemia	No anaemia	Total	
Validation nurse's classifications	Severe anaemia	33.3% (1)	0	66.7% (2)	100% (3)
	Anaemia	0	21.4% (18)	78.6% (66)	100% (84)
	No anaemia	0	1.2% (7)	98.8% (583)	100% (590)
	Total	0.2% (1)	3.7% (25)	96.2% (651)	100% (677)

Control arm		HCW's classifications			
Severe anaemia		Anaemia	No anaemia	Total	
Validation nurse's classifications	Severe anaemia	50.0% (1)	50.0% (1)	0	100% (2)
	Anaemia	1.1% (1)	15.7% (14)	83.2% (74)	100% (89)
	No anaemia	0.2% (2)	0.6% (8)	99.2% (1,232)	100% (1,242)
	Total	0.3% (4)	1.7% (23)	98.0% (1,306)	100% (1,333)

Intervention arm		HCW's classifications			
Severe anaemia		Anaemia	No anaemia	Total	
Validation nurse's classifications	Severe anaemia	100% (1)	0	0	100% (1)
	Anaemia	3.2% (1)	16.1% (5)	80.7% (25)	100% (31)
	No anaemia	0.2% (1)	0.8% (5)	99.1% (649)	100% (655)
	Total	0.4% (3)	1.5% (10)	98.1% (674)	100% (687)

Nutritional status

Baseline		HCW's classifications			
Severe acute malnutrition		Moderate acute malnutrition	No malnutrition	Total	
Validation nurse's classifications	Severe acute malnutrition	81.8% (18)	0	18.2% (4)	100% (22)
	Moderate acute malnutrition	16.1% (9)	46.4% (26)	37.5% (21)	100% (56)
	No malnutrition	0.6% (3)	6.7% (34)	92.7% (470)	100% (507)
	Total	5.1% (30)	10.3% (60)	92.7% (495)	100% (585)

Control arm		HCW's classifications			
Severe acute malnutrition		Moderate acute malnutrition	No malnutrition	Total	
Validation nurse's classifications	Severe acute malnutrition	57.8% (26)	11.1% (5)	31.1% (14)	100% (45)
	Moderate acute malnutrition	8.3% (10)	41.7% (50)	50.0% (60)	100% (120)
	No malnutrition	0.2% (2)	2.9% (28)	96.9% (950)	100% (980)
	Total	3.3% (38)	7.3% (83)	89.4% (1,024)	100% (1,145)

Intervention arm		HCW's classifications			
Severe acute malnutrition		Moderate acute malnutrition	No malnutrition	Total	
Validation nurse's classifications	Severe acute malnutrition	91.3% (21)	0	8.7% (2)	100% (23)
	Moderate acute malnutrition	9.5% (9)	62.1% (59)	28.4% (27)	100% (95)
	No malnutrition	0	3.6% (18)	96.4% (476)	100% (494)
	Total	4.9% (30)	12.6% (77)	82.5% (505)	100% (612)

Appendix 3: Primary and secondary outcomes (secondary analysis, i.e. excluding "contaminated" control districts)

Adherence to IMCI's clinical assessment	Baseline			Control arm			Intervention arm			Cluster-level mean difference between arms	P-value*
	N	%	95%CI	N	%	95%CI	N	%	95%CI		
Overall adherence (13 to 33 tasks)	661	**48.0**	44.3	51.8	1,195	**51.8**	47.2	56.5	695	**79.3**	72.7	85.9	**32.4**	0.002
Adherence to danger signs' assessment (3 tasks)	661	**18.4**	11.6	25.1	1,195	**28.1**	21.0	35.2	695	**95.2**	90.0	99.9	**76.9**	0.002

* t test on cluster level summaries & accounting for the stepped wedge design

Identification of at least one danger sign (out of 4): Proportion of children correctly identified with at least one danger sign	Baseline			Control arm			Intervention arm			Individual-level difference between arms	P-value**
	N†	%	95%CI	N†	%	95%CI	N†	%	95%CI		
	24	**66.7**	47.2	81.7	24	**54.2**	31.9	74.8	16	**75.0**	50.5	89.8	**20.8**	0.318

†Number of children identified, by the validation nurse, with a given danger sign; ** Fisher's exact test on individual level data & ignoring clustering

Overall correct classification: Proportion of children correctly classified with x given classifications	Baseline			Control arm			Intervention arm			Cluster-level mean difference between arms	P-value*
	N†	%	95%CI	N†	%	95%CI	N†	%	95%CI		
Accounting for the severity of classifications	589	**71.1**	64.2	77.2	920	**68.6**	64.2	72.7	572	**74.7**	66.9	81.1	**9.7**	0.023
Ignoring the severity of the classifications	589	**75.4**	68.1	81.5	920	**72.0**	66.8	76.6	572	**78.7**	72.9	83.5	**10.6**	0.002

† Number of children classified, by the validation nurse, with x given classification; * t test on cluster level summaries & accounting for the stepped wedge design

Overall correct prescription: Proportion of children who were prescribed the correct treatments	Baseline			Control arm			Intervention arm			Cluster-level mean difference between arms	P-value*
	N†	%	95%CI	N†	%	95%CI	N†	%	95%CI		
According to the HCWs' classifications	597	**76.2**	68.4	82.6	950	**77.6**	71.6	82.6	567	**77.1**	71.6	81.8	**-1.2**	0.753
According to the validation nurses' classifications	590	**66.3**	61.1	71.1	920	**65.0**	59.6	70.0	572	**68.5**	58.8	76.9	**6.9**	0.195

†Number of children classified, by the HCW or by the validation nurse, with a given classification; * t test on cluster level summaries & accounting for the stepped wedge design

Overall correct referral/hospitalisation: Proportion of children in need of referral/hospitalisation who were actually referred or hospitalised	Baseline			Control arm			Intervention arm			Individual-level difference between arms	P-value**
	N†	%	95%CI	N†	%	95%CI	N†	%	95%CI		
According to the HCWs' classifications	34	**61.8**	47.8	74.0	34	**58.8**	27.9	84.1	41	**61.0**	21.5	89.9	**2.2**	0.999
According to the validation nurses' classifications	28	**57.1**	35.7	76.2	31	**51.6**	38.1	64.9	22	**68.2**	47.8	83.4	**16.6**	0.268

†Number of children identified, by the HCW or the validation nurse, with at least one danger sign or a classification requiring referral/hospitalisation; ** Fisher's exact test on individual level data & ignoring clustering

Overall correct treatment counselling: Proportion of child's caretakers who received information on the prescription for treating the child at home	Baseline			Control arm			Intervention arm			Cluster-level mean difference between arms	P-value*
	N†	%	95%CI	N†	%	95%CI	N†	%	95%CI		
	589	**78.6**	69.7	85.4	1,013	**91.5**	88.7	93.6	576	**87.9**	77.9	93.7	**-4.7**	0.289

† Number of children who were prescribed, by the HCW, a given treatment (regardless of the classification); * t test on cluster level summaries & accounting for the stepped wedge design

Appendix 4a: Recommended medicines not prescribed in children with an incorrect prescription

Classification according to HCWs	Recommended medicine not prescribed	Control arm		Intervention arm	
		N†	%	N†	%
Severe pneumonia or very severe disease	Ampicilline injectable	5	60.0	4	75.0
	Gentamycine injectable	5	100.0	4	100.0
Pneumonia	Cotrimoxazole or Amoxicilline	19	100.0	8	100.0
Severe dehydration with other severe classification	Ringer lactate IV or ORS	1	100.0	-	-
Severe dehydration without other severe classification		-	-	-	-
Dehydration with other severe classification	Ringer lactate IV or ORS	1	100.0	0	-
Dehydration without other severe classification	ORS	1	100.0	0	-
	Zinc	1	100.0	0	-
Diarrhoea with no dehydration	Zinc	44	100.0	17	100.0
Severe persistent diarrhoea		-	-	-	-
Persistent diarrhoea	Multivitamins	-	-	1	100.0
	Zinc	-	-	1	0.0
Dysentery	Ciprofloxacine	40	100.0	4	100.0
	Zinc	40	35.0	4	0.0
Severe malaria or severe febrile illness	Artesunate injectable or quinine injectable	24	25.0	16	6.3
	Ampicilline injectable	24	62.5	16	62.5
	Gentamycine injectable	24	100.0	16	93.8
Malaria	ACT	8	100.0	6	100.0
Severe anaemia	Artesunate injectable or quinine injectable	2	100.0	1	100.0
Anaemia	Iron	5	100.0	4	100.0
Severe acute malnutrition with complications	Ampicilline injectable	3	100.0	-	-
Severe acute malnutrition without complications	Amoxicilline	29	72.4	18	55.6
	RUTF	29	86.2	18	61.1
Moderate acute malnutrition	Iron	83	78.3	75	33.3
	RUTF	83	100.0	75	100.0

† Number of children classified, by the HCW, with a given classification and who were not prescribed the recommended medicines

Appendix 4b: Other medicines prescribed in children with an incorrect prescription

Classification according to HCWs	Other medicine prescribed	Control arm		Intervention arm	
		N†	%	N†	%
Severe pneumonia or very severe disease	Amoxicilline	5	20.0	4	0.0
	Artesunate injectable	5	20.0	4	25.0
	Glucose solution	5	20.0	4	0.0
	Metronidazole	5	20.0	4	0.0
	ORS	5	20.0	4	0.0
	Paracetamol/Ibuprofen/ASL	5	60.0	4	75.0
	Quinine injectable	5	0.0	4	50.0
	Wrapping in damp cloth	5	20.0	4	0.0
	Zinc	5	20.0	4	0.0
Pneumonia	ACT	19	26.3	8	37.5
	Ampicilline injectable	19	5.3	8	37.5
	Carbocysteine/ Douba syrup	19	10.5	8	0.0
	Artesunate injectable	19	5.3	8	12.5
	Chlorpheniramine	19	10.5	8	0.0
	Erythromycine	19	63.2	8	62.5
	Gentamycine injectable	19	0.0	8	25.0
	Glucose solution	19	0.0	8	12.5
	Metoclopramide	19	5.3	8	0.0
	ORS	19	0.0	8	12.5
	Paracetamol/Ibuprofen/ASL	19	73.7	8	62.5
	Penicilline V	19	10.5	8	0.0
	Quinine injectable	19	0.0	8	12.5
	RUTF	19	0.0	8	12.5
	Vitamin A	19	0.0	8	12.5
	Wrapping in damp cloth	19	21.1	8	12.5
	Zinc	19	0.0	8	12.5
Severe dehydration with other severe classification	Amoxicilline	1	100.0	-	-
	Albendazole	1	100.0	-	-
	RUTF	1	100.0	-	-
Severe dehydration without other severe classification		-	-	-	-
Dehydration with other severe classification		1	none	0	-
Dehydration without other severe classification	Amoxicilline	1	100.0	0	-
	ACT	1	100.0	0	-
Diarrhoea with no dehydration	ACT	44	47.7	17	29.4
	Amoxicilline	44	29.6	17	23.5
	Ampicilline injectable	44	6.8	17	29.4
	Artesunate injectable	44	4.6	17	5.9
	Erythromycine	44	0.0	17	5.9
	Carbocysteine/ Douba syrup	44	2.3	17	0.0
	Chlorpheniramine	44	0.0	17	5.9
	Cotrimoxazole	44	22.7	17	0.0
	Diazepam injectable/intra-rectal	44	2.3	17	0.0
	Gentamycine injectable	44	2.3	17	0.0

	Glucose solution	44	2.3	17	5.9
	Mebendazole	44	11.4	17	5.9
	Metoclopramide	44	2.3	17	5.9
	Nystatine suspension	44	9.1	17	0.0
	Metronidazole	44	18.2	17	0.0
	ORS	44	6.8	17	5.9
	Paracetamol/Ibuprofen/ASL	44	68.2	17	82.4
	Quinine injectable	44	0.0	17	35.3
	RUTF	44	0.0	17	5.9
	Vitamin A	44	2.3	17	17.7
	Wrapping in damp cloth	44	13.6	17	11.8
Severe persistent diarrhoea		-	-	-	-
Persistent diarrhoea	ACT	-	-	1	100.0
	Ciprofloxacine	-	-	1	100.0
	Metronidazole	-	-	1	100.0
	ORS	-	-	1	100.0
Dysentery	ACT	40	40.0	4	0.0
	Amoxicilline	40	17.5	4	0.0
	Ampicilline injectable	40	2.5	4	0.0
	Artesunate injectable	40	2.5	4	0.0
	Carbocysteine/ Douba syrup	40	5.0	4	0.0
	Cotrimoxazole	40	40.0	4	25.0
	Diazepam injectable/intra-rectal	40	2.5	4	0.0
	Mebendazole	40	2.5	4	0.0
	Metoclopramide	40	5.0	4	0.0
	Metronidazole	40	57.5	4	100.0
	Nystatine suspension	40	10.0	4	25.0
	ORS	40	65.0	4	100.0
	Paracetamol/Ibuprofen/ASL	40	60.0	4	0.0
	RUTF	40	2.5	4	0.0
	Vitamin A	40	2.5	4	0.0
	Wrapping in damp cloth	40	15.0	4	0.0
Severe malaria or severe febrile illness	Amoxicilline	24	4.2	16	0.0
	Ciprofloxacine	24	4.2	16	0.0
	Diazepam injectable/intra-rectal	24	16.7	16	6.3
	Glucose solution	24	29.2	16	12.5
	Iron	24	8.3	16	0.0
	Mebendazole	24	8.3	16	0.0
	Metoclopramide	24	16.7	16	6.3
	Metronidazole	24	8.3	16	0.0
	ORS	24	12.5	16	0.0
	Paracetamol/Ibuprofen/ASL	24	66.7	16	87.5
	RUTF	24	4.2	16	0.0
	Vitamin A	24	4.2	16	0.0
	Wrapping in damp cloth	24	33.3	16	25.0
	Zinc	24	16.7	16	0.0
Malaria	Amoxicilline	8	25.0	6	16.7

	Ampicilline injectable	8	12.5	6	33.3
	Artesunate injectable	8	25.0	6	16.7
	Chlorpheniramine	8	12.5	6	0.0
	Ciprofloxacine	8	0.0	6	16.7
	Cotrimoxazole	8	25.0	6	0.0
	Gentamycine injectable	8	12.5	6	16.7
	Metronidazole	8	0.0	6	16.7
	Multivitamins	8	12.5	6	0.0
	Nystatine suspension	8	12.5	6	0.0
	ORS	8	25.0	6	16.7
	Paracetamol/Ibuprofen/ASL	8	50.0	6	16.7
	Quinine injectable	8	0.0	6	16.7
	RUTF	8	0.0	6	16.7
	Wrapping in damp cloth	8	25.0	6	0.0
	Zinc	8	25.0	6	33.3
Severe anaemia	ACT	2	50.0	1	0.0
	Amoxicilline	2	50.0	1	0.0
	Honey & Lemon	2	0.0	1	100.0
	Paracetamol/Ibuprofen/ASL	2	50.0	1	100.0
	Wrapping in damp cloth	2	50.0	1	100.0
Anaemia	ACT	5	0.0	4	25.0
	Albendazole	5	0.0	4	25.0
	Ampicilline injectable	5	20.0	4	50.0
	Amoxicilline	5	20.0	4	25.0
	Artesunate injectable	5	0.0	4	25.0
	Gentamycine injectable	5	0.0	4	25.0
	Glucose solution	5	40.0	4	0.0
	Nystatine suspension	5	20.0	4	0.0
	ORS	5	0.0	4	50.0
	Paracetamol/Ibuprofen/ASL	5	60.0	4	75.0
	Quinine injectable	5	0.0	4	25.0
	Vitamin A	5	40.0	4	0.0
	Zinc	5	0.0	4	50.0
Severe acute malnutrition with complications	Albendazole	3	33.3	-	-
	Amoxicilline	3	33.3	-	-
	Artesunate injectable	3	33.3	-	-
	Ciprofloxacine	3	33.3	-	-
	Metronidazole	3	33.3	-	-
	RUTF	3	33.3	-	-
	Zinc	3	33.3	-	-
Severe acute malnutrition without complications	ACT	29	65.5	18	72.2
	Ampicilline injectable	29	0.0	18	5.6
	Artesunate injectable	29	0.0	18	5.6
	Carbocysteine/ Douba syrup	29	3.5	18	0.0
	Chlorpheniramine	29	3.5	18	0.0
	Ciprofloxacine	29	0.0	18	5.6
	Cotrimoxazole	29	27.6	18	27.8

	Erythromycine	29	**6.9**	18	**11.1**
	Gentamycine injectable	29	**0.0**	18	**5.6**
	Iron	29	**3.5**	18	**22.2**
	Mebendazole	29	**17.2**	18	**33.3**
	Metronidazole	29	**10.3**	18	**11.1**
	Multivitamins	29	**3.5**	18	**0.0**
	Nystatine suspension	29	**24.1**	18	**0.0**
	ORS	29	**31.0**	18	**16.7**
	Paracetamol/Ibuprofen/ASL	29	**65.5**	18	**38.9**
	Vitamin A	29	**20.7**	18	**16.7**
	Wrapping in damp cloth	29	**17.2**	18	**11.1**
	Zinc	29	**31.0**	18	**22.2**
Moderate acute malnutrition	ACT	83	**53.0**	75	**50.7**
	Albendazole	83	**0.0**	75	**10.7**
	Ampicilline injectable	83	**1.2**	75	**1.3**
	Amoxicilline	83	**22.9**	75	**36.0**
	Artesunate injectable	83	**0.0**	75	**1.3**
	Carbocysteine/ Douba syrup	83	**8.4**	75	**4.0**
	Chlorpheniramine	83	**3.6**	75	**2.7**
	Ciprofloxacine	83	**0.0**	75	**2.7**
	Cloxacilline	83	**0.0**	75	**1.3**
	Cotrimoxazole	83	**21.7**	75	**8.0**
	Erythromycine	83	**4.8**	75	**5.3**
	Eucalyptus infusion	83	**0.0**	75	**6.7**
	Glucose solution	83	**1.2**	75	**0.0**
	Honey & Lemon	83	**2.4**	75	**6.7**
	Mebendazole	83	**22.9**	75	**22.7**
	Metoclopramide	83	**0.0**	75	**4.0**
	Metronidazole	83	**2.4**	75	**1.3**
	Multivitamins	83	**1.2**	75	**5.3**
	Nystatine suspension	83	**8.4**	75	**2.7**
	ORS	83	**27.7**	75	**24.0**
	Paracetamol/Ibuprofen/ASL	83	**71.1**	75	**45.3**
	Penicilline V	83	**1.2**	75	**0.0**
	Quinine injectable	83	**1.2**	75	**0.0**
	Vitamin A	83	**20.5**	75	**30.7**
	Wrapping in damp cloth	83	**18.1**	75	**6.7**
	Zinc	83	**28.9**	75	**24.0**

† Number of children classified, by the HCW, with a given classification and who were not prescribed the recommended medicines

Appendix 5a: Availability of essential equipment by district and trial arm

	Baseline		Control arm		Intervention arm	
District	N	%	N	%	N	%
Availability of all essential equipment						
Boromo	20	**0.0**	53	**20.8**	-	-
Dedougou	20	**0.0**	57	**17.5**	-	-
Nouna	20	**15.0**	50	**12.0**	-	-
Solenzo	19	**21.1**	10	**20.0**	43	**76.7**
Toma	20	**15.0**	-	-	57	**0.0**
Gourcy	20	**0.0**	70	**0.0**	-	-
Ouahigouya	19	**0.0**	30	**0.0**	29	**0.0**
Titao	20	**5.0**	20	**0.0**	37	**0.0**
Availability index of essential equipment						
Boromo	20	**81.7**	54	**91.0**	-	-
Dedougou	20	**86.6**	57	**90.5**	-	-
Nouna	20	**87.3**	50	**89.4**	-	-
Solenzo	19	**92.2**	10	**90.0**	45	**97.3**
Toma	20	**88.8**	-	-	57	**87.7**
Gourcy	20	**85.4**	71	**82.6**	-	-
Ouahigouya	19	**86.2**	30	**82.1**	29	**85.4**
Titao	20	**86.9**	20	**83.8**	37	**90.8**

Appendix 5b: Availability of essential medicines by district and trial arm

	Baseline		Control arm		Intervention arm	
District	N	%	N	%	N	%
Availability of all essential medicines						
Boromo	20	**70.0**	52	**67.3**	-	-
Dedougou	20	**95.0**	56	**75.0**	-	-
Nouna	20	**85.0**	48	**50.0**	-	-
Solenzo	19	**84.2**	10	**70.0**	44	**27.3**
Toma	20	**80.0**	-	-	55	**49.1**
Gourcy	20	**75.0**	70	**27.1**	-	-
Ouahigouya	19	**79.0**	30	**40.0**	29	**3.5**
Titao	20	**75.0**	18	**55.6**	37	**18.9**
Availability index of essential oral medicines						
Boromo	20	**95.0**	54	**97.0**	-	-
Dedougou	20	**99.6**	57	**97.2**	-	-
Nouna	20	**98.4**	49	**94.6**	-	-
Solenzo	19	**98.8**	10	**96.2**	45	**87.9**
Toma	20	**97.3**	-	-	55	**93.8**
Gourcy	20	**96.5**	71	**89.6**	-	-
Ouahigouya	19	**98.4**	30	**93.8**	29	**83.8**
Titao	20	**96.5**	20	**96.5**	37	**86.0**
Availability of amoxicilline						
Boromo	20	**95.0**	54	**98.2**	-	-

Dedougou	20	100.0	57	98.3	-	-
Nouna	20	100.0	49	83.7	-	-
Solenzo	19	100.0	10	100.0	45	77.8
Toma	20	95.0	-	-	55	74.6
Gourcy	20	90.0	71	80.3	-	-
Ouahigouya	19	100.0	30	80.0	29	86.2
Titao	20	100.0	20	100.0	37	56.8
Availability of multivitamins						
Boromo	20	80.0	53	88.7	-	-
Dedougou	20	100.0	57	84.2	-	-
Nouna	20	100.0	49	87.8	-	-
Solenzo	19	100.0	10	80.0	45	51.1
Toma	20	100.0	-	-	55	80.0
Gourcy	20	95.0	71	57.8	-	-
Ouahigouya	19	100.0	30	66.7	29	75.9
Titao	20	90.0	20	65.0	37	64.9
Availability of ORS						
Boromo	20	90.0	54	98.2	-	-
Dedougou	20	95.0	57	100.0	-	-
Nouna	20	95.0	49	95.9	-	-
Solenzo	19	100.0	10	100.0	45	88.9
Toma	20	85.0	-	-	55	98.2
Gourcy	20	90.0	71	76.1	-	-
Ouahigouya	19	100.0	30	100.0	29	62.1
Titao	20	100.0	20	100.0	37	81.1
Availability of zinc						
Boromo	20	90.0	53	98.1	-	-
Dedougou	20	100.0	57	100.0	-	-
Nouna	20	95.0	47	97.9	-	-
Solenzo	19	100.0	10	100.0	44	95.5
Toma	20	85.0	-	-	55	98.2
Gourcy	20	95.0	71	74.7	-	-
Ouahigouya	19	100.0	30	100.0	29	62.1
Titao	20	100.0	20	100.0	37	81.1

Appendix 6: 2x2 tables for HCWs and validation nurses RDT results

Baseline		HCWs					Total	
		RDT negative		RDT positive				
		n	%	n	%	n	%	
Validation nurses	RDT negative	73	91.3	7	8.8	80	100.0	
	RDT positive	6	1.7	342	98.3	348	100.0	

Control arm		HCWs					Total	
		RDT negative		RDT positive				
		n	%	n	%	n	%	
Validation nurses	RDT negative	278	96.5	10	3.5	288	100.0	
	RDT positive	18	2.9	607	97.1	625	100.0	

intervention arm		HCWs					Total	
		RDT negative		RDT positive				
		n	%	n	%	n	%	
Validation nurses	RDT negative	178	95.7	8	4.3	186	100.0	
	RDT positive	12	3.5	332	96.5	344	100.0	

Annex: Tables

Table 1: Definition of correct prescriptions

Classification	Correct prescription
Severe pneumonia or very severe disease	Ampicilline IM/IV & Gentamicine IM/IV (pre-transfer)
Pneumonia	Cotrimoxazole or Amoxicilline
Severe dehydration with other severe classification	Ringer lactate IV or ORS NG or ORS per os (pre-transfer)
Severe dehydration without other severe classification	Plan C: Ringer lactate IV or ORS NG or ORS per os
Dehydration with other severe classification	Ringer lactate IV or ORS NG or ORS per os (pre-transfer)
Dehydration without other severe classification	Plan B: ORS per os & zinc
Diarrhoea with no dehydration	Plan A: (ORS per os or increase liquids) & zinc
Severe persistent diarrhoea	Ringer lactate IV or ORS NG or ORS per os (pre-transfer)
Persistent diarrhoea	Multivitamins & zinc
Dysentery	(Ciprofloxacine or (Ciprofloxacine & Metronidazole)) & zinc
Severe malaria or severe febrile illness	(Artesunate IM/IV or Artemether IM/IV or Quinine IM/IV) & (Ampicilline IM/IV & Gentamicine IM/IV) (pre-transfer)
Malaria	ACT (Artesunate+Amodiaquine or Artemether/Lumefantrine)
Severe acute malnutrition with complications (any danger sign or other severe classification)	Ampicilline IM/IV (pre-transfer)
Severe acute malnutrition without complications	Amoxicilline & (Mebendazole or Albendazole if age>11 months & no dose in the past 6 months) & RUTF
Moderate acute malnutrition	(Vitamin A if age > 5 & no dose in the past 6 months) & Iron/Folic acid & (Mebendazole or Albendazole if age>11 months & no dose in the past 6 months) & RUTF

Vitamin A, Albendazole or Mebendazole not accounted for in the analysis due to lack of information about uptake in the past 6 months

Table 2: Region & district at baseline and by trial arm

	Baseline		Control		Intervention	
	n	%	n	%	n	%
Boromo	122	**17.8**	261	**19.4**	0	**0.0**
Dedougou	136	**19.8**	337	**25.1**	0	**0.0**
Nouna	72	**10.5**	274	**20.4**	0	**0.0**
Solenzo	40	**5.8**	47	**3.5**	272	**39.1**
Toma	42	**6.1**	0	**0.0**	217	**31.2**
Boucle du Mouhoun region	412	**60.1**	919	**68.4**	489	**70.4**
Gourcy	101	**14.7**	217	**16.2**	0	**0.0**
Ouahigouya	104	**15.2**	120	**8.9**	63	**9.1**
Titao	69	**10.1**	87	**6.5**	143	**20.6**
Nord region	274	**39.9**	424	**31.6**	206	**29.6**
Total	686	**100.0**	1,343	**100.0**	695	**100.0**

Table 3: Child's gender at baseline and by trial arm

	Baseline		Control		Intervention	
	n	%	n	%	n	%
Females	311	**45.3**	596	**44.4**	319	**45.9**
Males	375	**54.7**	747	**55.6**	376	**54.1**
Total	686	**100.0**	1,343	**100.0**	695	**100.0**

Table 4: Child's age group at baseline and by trial arm

	Baseline		Control		Intervention	
	n	%	n	%	n	%
2 - 11 months	218	**31.8**	389	**29.0**	220	**31.7**
12 - 23 months	196	**28.6**	415	**30.9**	193	**27.8**
24 - 35 months	126	**18.4**	241	**17.9**	131	**18.9**
36 - 47 months	78	**11.4**	164	**12.2**	86	**12.4**
48 - 60 months	68	**9.9**	134	**10.0**	65	**9.4**
Total	686	**100.0**	1,343	**100.0**	695	**100.0**

Table 5a: Child's classification at baseline and by trial arm

| Classification | Baseline (N = 686) | | | | Control arm (N = 1,343) | | | | Intervention arm (N = 695) | | | |
| | HCWs | | Validation nurses | | HCWs | | Validation nurses | | HCWs | | Validation nurses | |
	N	%	N	%	N	%	N	%	N	%	N	%
Cough/cold	654	11.6	686	20.3	1,341	13.0	1,343	24.0	694	22.9	695	25.9
Severe pneumonia or very severe disease	654	0.5	686	2.2	1,341	0.7	1,343	0.7	694	1.3	695	0.6
Pneumonia	654	33.9	686	27.3	1,341	27.4	1,343	16.2	694	23.8	695	24.3
Pneumonia ignoring severity	654	34.4	686	29.5	1,341	28.0	1,343	17.0	694	25.1	695	24.9
Severe dehydration	680	0.4	686	0.7	1,343	0.1	1,343	0.1	695	0.0	695	0.0
Dehydration	680	0.9	686	0.7	1,343	0.5	1,343	0.2	695	1.0	695	0.4
Diarrhoea with no dehydration	680	17.2	686	25.7	1,343	20.5	1,343	25.5	695	21.2	695	27.2
Severe persistent diarrhoea	680	0.2	686	0.0	1,343	0.0	1,343	0.0	695	0.0	695	0.0
Persistent diarrhoea	680	0.2	686	0.0	1,343	0.0	1,343	0.0	695	0.1	695	0.0
Diarrhoea ignoring severity	680	18.8	686	27.1	1,343	21.1	1,343	25.8	695	22.3	695	27.6
Dysentery	679	3.2	686	1.8	1,343	3.4	1,343	2.0	695	1.9	695	1.7
Severe malaria or severe febrile illness	683	3.2	686	3.4	1,343	1.9	1,343	1.8	695	3.5	695	2.5
Malaria	683	68.1	686	69.4	1,343	52.4	1,343	54.7	695	49.9	695	52.7
Malaria ignoring severity	683	71.3	686	72.7	1,343	54.4	1,343	56.4	695	53.4	695	55.1
Severe anaemia	677	0.2	686	0.4	1,336	0.3	1,340	0.2	687	0.4	695	0.1
Anaemia	677	3.7	686	12.5	1,336	1.7	1,340	6.6	687	1.5	695	4.5
Anaemia ignoring severity	677	3.8	686	13.0	1,336	2.0	1,340	6.8	687	1.9	695	4.6
Severe acute malnutrition	675	4.6	613	4.6	1,328	3.0	1,192	4.9	690	4.4	624	4.0
Moderate acute malnutrition	675	9.5	613	10.8	1,328	6.3	1,192	11.4	690	11.9	624	16.2
Malnutrition ignoring severity	675	14.1	613	15.3	1,328	9.3	1,192	16.3	690	16.2	624	20.2

Table 5b: Child's number of classifications at baseline and by trial arm

| Number of classifications | Baseline (N = 686) | | Control arm (N = 1,343) | | Intervention arm (N = 695) | |
| | HCWs | Validation nurses | HCWs | Validation nurses | HCWs | Validation nurses |
	%	%	%	%	%	%
Excluding cough/cold						
0	10.5	10.5	19.7	21.3	18.3	17.3
1	49.7	41.3	49.4	45.5	50.5	44.6
2	28.1	32.7	24.9	24.7	24.6	28.4
3	9.5	11.8	4.9	6.9	5.6	8.5
4	2.0	3.2	0.9	1.5	1.0	1.2
5	0.2	0.6	0.1	0.2	0.0	0.1
Including cough/cold						
0	6.6	5.5	14.3	12.7	11.4	8.8
1	49.4	36.9	49.9	44.6	46.2	42.3
2	30.5	37.9	27.6	29.4	32.2	34.1
3	10.5	14.1	7.0	10.7	8.2	12.1
4	2.8	4.8	1.1	2.2	1.9	2.5
5	0.3	0.7	0.1	0.4	0.1	0.3

Table 6: Use of IMCI paper-form and eCDSS

| | Baseline | | Control | | Intervention | |
	n	%	n	%	n	%
Neither	207	**30.2**	307	**22.9**	15	**2.2**
IMCI paper-form	471	**68.7**	916	**68.2**	5	**0.7**
eCDSS	0	-	118	**8.8**	659	**95.0**
Both	8	**1.2**	2	**0.2**	15	**2.2**
Total	686	**100.0**	1,343	**100.0**	694	**100.0**

Table 7a: Duration of consultations (minutes)

| | Baseline | | | Control | | | Intervention | | |
	n	mean (SD)	median (IQR)	n	mean (SD)	median (IQR)	n	mean (SD)	median (IQR)
Neither	200	**17.7 (8.6)**	**15 (10)**	305	**12.6 (5.7)**	**11 (7)**	13	**22.8 (15.3)**	**16 (21)**
IMCI paper-form	437	**19.3 (9.0)**	**17 (11)**	878	**13.9 (7.9)**	**12 (8)**	5	**11.0 (1.9)**	**11 (1)**
eCDSS	0	-	-	115	**13.3 (5.8)**	**13 (9)**	642	**15.1 (8.3)**	**14 (8)**
Both	7	**14.7 (7.0)**	**15 (10)**	2	**18.5 (14.8)**	**18.5 (21)**	15	**18.5 (7.4)**	**15 (10)**
Overall	644	**18.6 (8.9)**	**17 (11)**	1,300	**13.5 (7.3)**	**12 (7)**	676	**15.3 (8.5)**	**14 (8)**

Table 7b: Time trend in consultation's duration when using the eCDSS in the intervention arm

Number of steps	n	mean (SD)	median (IQR)
1	135	**15.6 (9.0)**	15 (11)
2	158	**15.3 (8.7)**	13 (9)
3	108	**16.3 (9.7)**	14 (9)
4	111	**14.6 (7.7)**	13 (7)
5	87	**13.4 (5.4)**	13 (7)
6	43	**14.9 (6.0)**	14 (5)

Table 8: Primary and secondary outcomes

Adherence to IMCI's clinical assessment	Baseline			Control arm			Intervention arm			Cluster-level mean difference between arms	P-value*
	N	%	95%CI	N	%	95%CI	N	%	95%CI		
Overall adherence (13 to 33 tasks)	686	**48.0**	44.3	51.6	1,343	**54.3**	50.6	58.0	695	**79.3**	72.7	85.9	**29.9**	0.002
Adherence to danger signs' assessment (3 tasks)	686	**18.4**	12.0	24.9	1,343	**34.2**	25.5	42.9	695	**95.2**	90.0	99.9	**71.2**	0.002

* t test on cluster level summaries & accounting for the stepped wedge design

Identification of at least one danger sign (out of 4): Proportion of children correctly identified with at least one danger sign	Baseline			Control arm			Intervention arm			Individual-level difference between arms	P-value**
	N†	%	95%CI	N†	%	95%CI	N†	%	95%CI		
	24	**66.7**	47.2	81.7	25	**56.0**	30.8	78.4	16	**75.0**	50.5	89.8	**19.0**	0.322

†Number of children identified, by the validation nurse, with a given danger sign; ** Fisher's exact test on individual level data & ignoring clustering

Overall correct classification: Proportion of children correctly classified with x given classifications	Baseline			Control arm			Intervention arm			Cluster-level mean difference between arms	P-value*
	N†	%	95%CI	N†	%	95%CI	N†	%	95%CI		
Accounting for the severity of classifications	609	**70.6**	63.7	76.7	1,049	**69.8**	66.0	73.4	572	**74.7**	66.9	81.1	**9.1**	0.038
Ignoring the severity of the classifications	609	**75.0**	68.0	81.0	1,049	**73.1**	68.8	77.0	572	**78.7**	72.9	83.5	**10.1**	0.004

† Number of children classified, by the validation nurse, with x given classification; * t test on cluster level summaries & accounting for the stepped wedge design

Overall correct prescription: Proportion of children who were prescribed the correct treatments	Baseline			Control arm			Intervention arm			Cluster-level mean difference between arms	P-value*
	N†	%	95%CI	N†	%	95%CI	N†	%	95%CI		
According to the HCWs' classifications	614	**75.7**	68.0	82.1	1,074	**77.8**	72.5	82.4	567	**77.1**	71.6	81.8	**-1.1**	0.788
According to the validation nurses' classifications	610	**65.3**	59.8	70.4	1,049	**66.1**	60.7	71.0	572	**68.5**	58.8	76.9	**6.7**	0.226

†Number of children classified, by the HCW or by the validation nurse, with a given classification; * t test on cluster level summaries & accounting for the stepped wedge design

Overall correct referral/hospitalisation: Proportion of children in need of referral/hospitalisation who were actually referred or hospitalised	Baseline			Control arm			Intervention arm			Individual-level difference between arms	P-value**
	N†	%	95%CI	N†	%	95%CI	N†	%	95%CI		
According to the HCWs' classifications	35	**60.0**	47.7	71.1	42	**52.4**	23.7	79.6	41	**61.0**	21.5	89.9	**8.6**	0.509
According to the validation nurses' classifications	29	**55.2**	36.0	72.9	32	**53.1**	36.5	69.1	22	**68.2**	47.8	83.4	**15.1**	0.398

†Number of children identified, by the HCW or the validation nurse, with at least one danger sign or a classification requiring referral/hospitalisation; ** Fisher's exact test on individual level data & ignoring clustering

Overall correct treatment counselling: Proportion of child's caretakers who received information on the prescription for treating the child at home	Baseline			Control arm			Intervention arm			Cluster-level mean difference between arms	P-value*
	N†	%	95%CI	N†	%	95%CI	N†	%	95%CI		
	612	**77.3**	67.5	84.8	1,143	**91.5**	88.8	93.6	576	**87.9**	77.9	93.7	**-4.1**	0.355

† Number of children who were prescribed, by the HCW, a given treatment (regardless of the classification); * t test on cluster level summaries & accounting for the stepped wedge design

Table 9: Adherence to IMCI's clinical assessment

IMCI algorithm	Task: Questions to address to the mother or examinations to perform	Baseline N	%	95%CI		Control arm N	%	95%CI		Intervention arm N	%	95%CI		P-value*
Danger signs	Ask if the child is able to drink/breastfeed	686	15.9	9.2	26.1	1,343	28.7	20.4	38.8	695	94.5	75.1	99.0	
	Ask if the child vomits everything	686	15.7	8.6	27.0	1,342	40.8	33.0	49.0	695	95.8	81.2	99.2	
	Ask about recent convulsions †	686	23.6	15.0	35.1	1,342	33.1	23.3	44.6	695	95.3	90.3	97.7	
	Observe if the child convulses	not observable												
	Observe if the child is lethargic/ unconscious	not observable												
	Adherence index (3 tasks)	686	18.4	12.0	24.9	1,343	34.2	25.5	42.9	695	95.2	90.0	99.9	0.002
Cough/ difficult breathing	Ask about cough †	686	94.8	90.4	97.2	1,342	94.3	87.2	97.6	695	99.4	97.4	99.9	
	Ask about difficult breathing †	686	2.8	1.6	4.8	1,295	7.9	3.1	18.6	605	11.4	4.0	28.5	
	If cough/difficult breathing: Ask for duration of cough/ difficult breathing	188	93.1	85.4	96.9	450	82.2	74.4	88.1	324	96.9	87.5	99.3	
	If cough/difficult breathing: Count number of breaths per minute	317	54.9	40.6	68.4	554	44.8	34.0	56.1	340	88.5	79.2	94.0	
	If cough/difficult breathing: Look for chest indrawing	318	47.8	37.5	58.2	554	41.2	28.9	54.7	340	82.4	75.0	87.9	
	If cough/difficult breathing: Listen for stridor or "wheeze" breathing	318	27.0	17.9	38.7	554	17.2	10.8	26.1	339	51.6	18.8	83.1	
	Adherence index (2 to 6 tasks)	686	48.3	44.4	52.2	1,342	50.0	45.8	54.3	695	67.8	55.0	80.7	
	Adherence index restricted to children with cough/difficult breathing (4 tasks)	318	51.3	46.0	56.7	556	47.8	42.7	52.8	340	72.5	61.3	83.7	
Diarrhoea	Ask about diarrhoea †	686	94.8	87.4	97.9	1,343	92.3	85.1	96.2	695	98.7	94.8	99.7	
	If diarrhoea: Ask for duration of diarrhoea	152	92.1	86.2	95.6	340	87.1	80.0	91.9	178	96.6	90.5	98.9	
	If diarrhoea: Ask for blood in the stool †	151	53.0	45.3	60.5	346	58.4	45.3	70.4	178	89.9	81.3	94.8	
	If diarrhoea: Observe if the child is lethargic/ unconscious	not observable												
	If diarrhoea: Observe if the child is restless or irritated	not observable												
	If diarrhoea: Look for sunken eyes	not observable												
	If diarrhoea: Offer water to the child	151	9.9	3.1	27.5	347	6.6	3.6	11.8	178	41.6	21.7	64.6	
	If diarrhoea: Pinch the skin of the abdomen	98	46.9	35.0	59.3	285	47.0	26.1	69.0	172	76.7	65.7	85.0	
	Adherence index (1 to 5 tasks)	686	86.2	81.3	91.2	1,343	82.1	74.9	89.2	695	93.8	91.6	96.1	
	Adherence index restricted to children with diarrhoea (4 tasks)	155	62.3	58.2	66.4	348	60.3	53.8	66.9	179	81.0	76.4	85.6	

Category	Task	Baseline N	%	95%CI		Control N	%	95%CI		Intervention N	%	95%CI		P-value
Fever or history of fever	Ask about current fever †	686	88.2	72.7	95.4	1,343	96.9	92.1	98.8	694	100.0	-	-	
	Ask about history of fever †	686	23.5	14.0	36.6	1,319	75.1	51.2	89.7	654	72.9	42.8	90.6	
	If fever or history: Ask for duration of fever	543	91.7	87.0	94.8	1,027	88.4	84.5	91.4	575	96.7	95.0	97.8	
	If fever or history & fever > 7 days: Ask if the child had fever every day	8	25.0	2.8	79.5	10	40.0	13.6	73.9	4	75.0	17.4	97.7	
	If fever or history: Ask if child's urine were dark or not abundant	544	10.9	6.8	16.9	1,081	19.8	13.9	27.5	581	81.2	67.8	89.9	
	If fever or history: Ask about abnormal bleeding	544	6.3	3.0	12.4	1,081	14.7	7.5	26.8	581	75.7	59.0	87.1	
	If fever or history: Ask about history of measles in the past 3 months	544	10.9	6.4	17.8	1,081	17.7	13.2	23.2	581	65.8	29.7	89.7	
	If fever or history: Take the temperature	544	99.8	98.4	99.9	1,082	99.1	98.5	99.4	586	99.7	98.9	99.9	
	If fever or history: Perform a RDT	544	74.3	53.8	87.7	1,082	86.7	79.5	91.6	584	93.7	88.6	96.6	
	If fever or history: Look for neck stiffness	544	16.2	7.6	31.3	1,081	23.0	15.2	33.3	582	47.6	37.8	57.6	
	If fever or history: Take the pulse	544	2.4	0.5	9.9	1,075	8.2	2.7	22.3	582	1.6	0.4	5.6	
	If fever or history: Look for cold hands or feet	544	1.3	0.4	4.5	1,078	1.2	0.5	2.7	578	33.7	11.0	67.7	
	If fever or history: Look for jaundice or redness in the eyes	544	82.5	70.8	90.2	1,081	83.0	73.3	89.6	584	94.0	86.9	97.4	
	If fever or history: Look for general rash (undress the child)	544	14.9	7.4	27.6	1,082	14.1	9.3	20.6	583	34.3	21.0	50.6	
	If fever or history: Look for running nose	not observable												
	Adherence index (2 to 14 tasks)	686	40.3	38.1	42.5	1,343	52.5	47.8	57.2	694	71.5	65.6	77.4	
	Adherence index restricted to children with fever (12 tasks)	544	40.9	38.4	43.4	1,082	48.8	45.4	52.2	586	69.2	62.0	76.5	
Anaemia	Look for palmar pallor	686	59.9	44.2	73.8	1,341	51.5	42.6	60.4	692	92.2	78.4	97.5	

Category	Task	Baseline N	%	95%CI		Control N	%	95%CI		Intervention N	%	95%CI		P-value
Nutritional status	Look for severe and visible weight loss	not observable												
	Measure height	686	88.3	61.8	97.3	1,343	90.4	79.1	95.9	695	99.6	98.9	99.8	
	Weigh the child	686	98.5	94.3	99.6	1,343	98.4	93.7	99.6	695	99.1	97.5	99.7	
	Measure upper arm circumference	686	84.3	70.4	92.3	1,342	86.1	82.2	89.2	692	88.4	83.5	92.1	
	Look for feet oedema	686	23.5	14.3	36.1	1,342	35.1	22.8	49.8	692	86.6	55.0	97.1	
	If age > 5 months & MUAC < 115 mm & no danger sign or severe classification: Offer RUTF to the child	17	0.0	-	-	34	8.8	1.9	32.8	16	43.8	20.3	70.4	
	Adherence index (4 to 5 tasks)	686	73.2	64.5	81.9	1,343	77.1	71.6	82.5	695	93.2	87.3	99.1	
Overall adherence index (13 to 33 tasks)		686	48.0	44.3	51.6	1,343	54.3	50.6	58.0	695	79.3	72.7	85.9	0.002

† or reported by the caretaker spontaneously when the consultation started or when asked the reason for consulting

* Student's t test on cluster level summaries & accounting for the stepped wedge design

Table 10: Danger sign identification: Proportion of children correctly identified with a given danger sign

Danger sign	Baseline N†	%	95%CI		Control arm N†	%	95%CI		Intervention arm N†	%	95%CI		P-value*
Unable to drink or breastfeed	1	**0.0**	-	-	1	**0.0**	-	-	2	**0.0**	-	-	
Vomit everything	14	**28.6**	15.2	47.1	13	**38.5**	11.5	75.1	8	**62.5**	-	-	
Convulsions	4	**100.0**	-	-	11	**63.6**	20.4	92.3	4	**75.0**	17.4	97.7	
Lethargy/unconsciousness	9	**33.3**	10.4	68.3	2	**100.0**	-	-	2	**100.0**	-	-	
All danger signs (out of the 4 above)	24	**41.7**	28.0	56.8	25	**40.0**	23.8	58.7	16	**56.3**	37.1	73.7	
At least one danger sign (out of the 4 above)	24	**66.7**	47.2	81.7	25	**56.0**	30.8	78.4	16	**75.0**	50.5	89.8	0.322

† Number of children identified, by the validation nurse, with a given danger sign

* Fisher's exact test on individual level data & ignoring clustering

Table 11a: Sensitivity of the HCW's classification: Proportion of children correctly classified in a given classification

Classification	Baseline				Control arm				Intervention arm			
	N†	%	95%CI		N†	%	95%CI		N†	%	95%CI	
Severe pneumonia or very severe disease	14	**14.3**	2.5	51.7	10	**20.0**	1.3	82.6	4	**25.0**	-	-
Pneumonia	185	**75.7**	66.6	82.9	218	**71.6**	65.6	76.9	169	**76.3**	46.8	92.2
Pneumonia ignoring severity	199	**75.9**	67.0	83.0	228	**73.3**	65.8	79.5	173	**78.6**	50.5	93.0
Severe dehydration	5	**60.0**	20.1	90.0	1	**0.0**	-	-	0	**-**	-	-
Dehydration	5	**80.0**	17.1	98.7	2	**50.0**	0.6	99.4	3	**66.7**	1.1	99.7
Diarrhoea with no dehydration	175	**58.3**	44.5	70.9	343	**64.7**	51.9	75.7	189	**74.6**	62.9	83.6
Severe persistent diarrhoea	0	**-**	-	-	0	**-**	-	-	0	**-**	-	-
Persistent diarrhoea	0	**-**	-	-	0	**-**	-	-	0	**-**	-	-
Diarrhoea ignoring severity	185	**61.1**	48.1	72.7	346	**65.9**	52.6	77.1	192	**76.6**	64.8	85.3
Dysentery	12	**41.7**	22.9	63.2	27	**44.4**	29.3	60.6	12	**83.3**	17.8	99.1
Severe malaria or severe febrile illness	23	**60.9**	37.7	80.0	24	**62.5**	36.1	83.1	17	**82.4**	53.2	95.0
Malaria	475	**93.9**	90.9	96.0	734	**92.0**	87.6	94.9	366	**91.0**	87.7	93.4
Malaria ignoring severity	498	**95.0**	91.9	96.9	758	**93.1**	90.0	95.3	383	**93.0**	87.5	96.1
Severe acute malnutrition	22	**81.8**	50.0	95.3	45	**57.8**	37.6	75.6	23	**91.3**	67.6	98.1
Moderate acute malnutrition	56	**46.4**	29.9	63.8	120	**41.7**	31.6	52.5	95	**62.1**	52.2	71.1
Malnutrition ignoring severity	78	**68.0**	52.8	80.0	165	**55.2**	45.5	64.4	118	**75.4**	63.1	84.6

† Number of children classified, by the validation nurse, with a given classification

Table 11b: Specificity of the HCW's classification: Proportion of children correctly not classified in a given classification

Classification	Baseline				Control arm				Intervention arm			
	N†	%	95%CI		N†	%	95%CI		N†	%	95%CI	
Severe pneumonia or very severe disease	640	**99.8**	98.6	99.9	1,331	**99.5**	98.4	99.8	690	**98.8**	96.3	99.6
Pneumonia	469	**82.5**	72.0	89.6	1,123	**81.2**	72.5	87.6	525	**93.1**	78.4	98.1
Pneumonia ignoring severity	455	**83.7**	73.4	90.6	1,113	**81.2**	72.9	87.4	521	**92.7**	76.4	98.0
Severe dehydration	675	**100.0**	-	-	1,342	**99.9**	99.4	99.9	695	**100.0**	-	-
Dehydration	681	**99.7**	98.3	99.9	1,341	**99.6**	98.5	99.9	692	**99.3**	98.6	99.6
Diarrhoea with no dehydration	505	**97.0**	94.9	98.3	1,000	**94.7**	89.0	97.5	506	**98.8**	97.4	99.5
Severe persistent diarrhoea	680	**99.9**	98.1	99.9	1,343	**100.0**	-	-	695	**100.0**	-	-
Persistent diarrhoea	680	**99.9**	98.1	99.9	1,343	**100.0**	-	-	695	**99.9**	99.1	99.9
Diarrhoea ignoring severity	495	**97.0**	94.8	98.2	997	**94.5**	88.8	97.4	503	**98.4**	95.6	99.4
Dysentery	667	**97.5**	93.0	99.0	1,316	**97.5**	95.0	98.8	683	**99.6**	98.9	99.8
Severe malaria or severe febrile illness	660	**98.8**	97.7	99.4	1,319	**99.2**	96.1	99.8	678	**98.5**	96.1	99.5
Malaria	208	**90.9**	83.4	95.2	609	**95.2**	90.7	97.6	329	**95.7**	91.9	97.8
Malaria ignoring severity	185	**92.4**	85.6	96.2	585	**95.9**	92.3	97.9	312	**95.2**	91.8	97.2
Severe acute malnutrition	563	**97.9**	95.4	99.0	1,100	**98.9**	98.4	99.3	589	**98.5**	96.7	99.3
Moderate acute malnutrition	529	**93.6**	89.7	96.0	1,025	**96.8**	94.0	98.3	517	**96.5**	94.3	97.9
Malnutrition ignoring severity	507	**92.7**	89.2	95.2	980	**96.9**	94.0	98.5	494	**96.4**	94.1	97.8

† Number of children not classified, by the validation nurse, with a given classification

Table 12a: Correct prescription according to the HCWs' classifications: Proportion of children who were prescribed the correct treatments

Classification	Baseline N†	%	95%CI		Control arm N†	%	95%CI		Intervention arm N†	%	95%CI		P-value*
Severe pneumonia or very severe disease	3	33.3	2.2	91.7	9	44.4	9.7	85.7	9	55.6	25.5	82.0	
Pneumonia	222	93.2	89.7	95.6	367	94.8	86.7	98.1	165	95.2	92.8	96.8	
All classifications related to pneumonia	225	92.4	88.1	95.3	376	93.6	86.2	97.2	174	93.1	88.8	95.8	
Severe dehydration with another severe classification	3	33.3	2.2	91.7	1	0.0	-	-	0	-	-	-	
Severe dehydration without another severe classification	0	-	-	-	0	-	-	-	0	-	-	-	
Dehydration with other severe classification	3	66.7	8.3	97.8	2	50.0	0.6	99.4	2	100.0	-	-	
Dehydration without other severe classification	3	100.0	-	-	5	80.0	7.1	99.5	5	100.0	-	-	
Diarrhoea with no dehydration	117	70.1	52.7	83.1	275	84.0	79.4	87.7	147	88.4	73.3	95.5	
Severe persistent diarrhoea	1	100.0	-	-	0	-	-	-	0	-	-	-	
Persistent diarrhoea	1	0.0	-	-	0	-	-	-	1	0.0	-	-	
All classifications related to diarrhoea	128	69.5	53.3	82.0	283	83.4	79.3	86.8	155	88.4	72.8	95.6	
Dysentery	22	0.0	-	-	45	11.1	2.3	39.4	13	69.2	34.7	90.5	
Severe malaria or severe febrile illness	22	9.1	1.6	38.6	26	7.7	1.3	34.6	24	33.3	7.9	74.5	
Malaria	465	98.9	97.4	99.6	704	98.9	97.3	99.5	347	98.3	96.1	99.2	
All classifications related to malaria	487	94.9	91.9	96.8	730	95.6	93.1	97.2	371	94.1	84.9	97.8	
Severe acute malnutrition with complications (any danger sign or other severe classification)	3	0.0	-	-	5	40.0	7.2	85.1	0	-	-	-	
Severe acute malnutrition without complications	25	32.0	17.3	51.5	35	17.1	5.0	45.0	30	40.0	30.7	50.1	
Moderate acute malnutrition	64	12.5	7.0	21.2	84	1.2	0.1	11.1	82	8.5	5.1	14.0	
All classifications related to malnutrition	95	16.8	10.3	26.3	124	7.3	4.2	12.3	112	17.0	10.1	27.0	
All classifications	614	75.7	68.0	82.1	1,074	77.8	72.5	82.4	567	77.1	71.6	81.8	0.788

† Number of children classified, by the HCW, with a given classification

* Student's t test on cluster level summaries & accounting for the stepped wedge design

Table 12b: Correct prescription according to the validation nurses' classifications: Proportion of children who were prescribed the correct treatments

Classification	Baseline N†	%	95%CI		Control arm N†	%	95%CI		Intervention arm N†	%	95%CI		P-value*
Severe pneumonia or very severe disease	15	6.7	0.7	43.6	10	0.0	-	-	4	0.0	-	-	
Pneumonia	187	81.8	74.1	87.6	218	78.9	70.8	85.2	169	81.1	61.5	92.0	
All classifications related to pneumonia	202	76.2	69.1	82.2	228	75.4	65.3	83.4	173	79.2	55.2	92.1	
Severe dehydration with another severe classification	5	20.0	2.7	69.1	1	0.0	-	-	0	-	-	-	
Severe dehydration without another severe classification	0	-	-	-	0	-	-	-	0	-	-	-	
Dehydration with other severe classification	1	100.0	-	-	2	50.0	-	-	0	-	-	-	
Dehydration without other severe classification	4	50.0	4.3	95.7	0	-	-	-	3	66.7	-	-	
Diarrhoea with no dehydration	176	50.0	40.5	59.5	343	65.6	57.5	72.9	189	76.7	52.9	90.6	
Severe persistent diarrhoea	0	-	-	-	0	-	-	-	0	-	-	-	
Persistent diarrhoea	0	-	-	-	0	-	-	-	0	-	-	-	
All classifications related to diarrhoea	186	49.5	39.8	59.2	346	65.3	57.5	72.4	192	76.6	52.1	90.8	
Dysentery	12	8.3	0.7	54.0	27	11.1	2.1	42.4	12	75.0	29.2	95.6	
Severe malaria or severe febrile illness	23	8.7	1.4	38.7	24	0.0	-	-	17	29.4	4.5	78.7	
Malaria	476	94.5	91.7	96.4	734	94.1	90.3	96.5	366	95.4	92.1	97.3	
All classifications related to malaria	499	90.6	87.1	93.2	758	91.2	87.0	94.1	383	92.4	82.4	97.0	
Severe acute malnutrition with complications (any danger sign or other severe classification)	3	0.0	-	-	3	33.3	0.1	99.9	0	-	-	-	
Severe acute malnutrition without complications	19	15.8	5.5	37.8	42	14.3	4.1	39.6	23	43.5	33.0	54.6	
Moderate acute malnutrition	57	8.8	4.6	16.2	121	2.5	0.5	11.2	95	8.4	5.4	12.9	
All classifications related to malnutrition	79	10.1	5.3	18.6	166	6.0	3.9	9.2	118	15.3	11.1	20.6	
All classifications †	610	65.3	59.8	70.4	1,049	66.1	60.7	71.0	572	68.5	58.8	76.9	0.226

† Number of children classified, by the validation nurse, with a given classification

* Student's t test on cluster level summaries & accounting for the stepped wedge design

Table 13a: Over-prescription according to HCWs' classifications: Proportion of children who were not in need of a given medicine but who were actually prescribed it

Medicines	Baseline				Control arm				Intervention arm			
	N	%	95%CI		N	%	95%CI		N	%	95%CI	
Ampicilline injectable	686	0.0	-	-	1,343	0.1	-	-	694	0.3	0.0	1.8
Gentamycine injectable	686	0.0	-	-	1,343	0.0	-	-	695	0.1	-	-
Cotrimoxazole	685	6.1	4.0	9.3	1,343	6.8	4.7	9.8	695	2.0	0.8	4.9
Amoxicilline	683	4.5	2.6	7.8	1,341	6.8	4.2	10.7	694	5.9	4.5	7.7
Ciprofloxacine	686	0.3	-	-	1,343	0.0	-	-	695	0.3	-	-
Metronidazole	686	0.9	0.2	3.8	1,343	2.0	1.4	2.8	695	0.6	0.1	2.2
All antibiotics	682	**11.9**	8.9	15.7	1,341	**14.9**	10.4	20.9	694	**9.1**	5.9	13.6
Artesunate or Artemether injectable	686	0.4	0.1	1.5	1,343	0.1	-	-	695	0.1	-	-
Quinine injectable	686	0.0	-	-	1,343	0.0	-	-	695	0.0	-	-
ACT	685	1.3	0.5	3.8	1,343	1.7	0.7	4.0	694	2.6	1.0	6.8
All antimalarials	685	**1.8**	0.8	3.8	1,343	**1.8**	0.8	4.0	694	**2.7**	1.0	7.2

ACT: Artesunate + Amodiaquine or Artemether/ Lumefantrine

Table 13b: Over-prescription according to validation nurses' classifications: Proportion of children who were not in need of a given medicine but who were actually prescribed it

Medicines	Baseline				Control arm				Intervention arm			
	N	%	95%CI		N	%	95%CI		N	%	95%CI	
Ampicilline injectable	686	0.6	0.2	1.4	1,339	0.3	0.1	1.5	693	1.0	0.3	2.9
Gentamycine injectable	686	0.0	-	-	1,343	0.3	0.1	1.6	695	0.9	0.3	2.2
Cotrimoxazole	686	12.1	7.5	19.0	1,343	12.1	7.8	18.5	695	2.3	1.0	5.0
Amoxicilline	675	5.6	3.4	9.1	1,299	11.3	6.1	20.0	682	7.5	4.0	13.6
Ciprofloxacine	686	0.2	-	1.5	1,343	0.2	-	0.7	695	0.3	0.1	0.6
Metronidazole	686	1.9	0.7	4.8	1,343	3.0	2.0	4.4	695	1.0	0.3	2.9
All antibiotics	676	**20.3**	13.6	29.1	1,300	**26.7**	19.3	35.7	682	**12.2**	6.0	23.0
Artesunate or Artemether injectable	686	0.7	0.3	2.0	1,343	0.6	0.1	4.1	695	0.7	0.3	1.7
Quinine injectable	686	0.4	0.1	1.5	1,343	0.2	-	1.4	695	0.7	0.3	1.7
ACT	686	2.8	2.0	3.8	1,343	2.1	0.8	5.6	695	1.6	0.5	4.5
All antimalarials	686	**3.9**	2.6	6.0	1,343	**2.8**	1.2	6.3	695	**3.0**	1.2	7.4

ACT: Artesunate + Amodiaquine or Artemether/ Lumefantrine

Table 14a: Correct referral or hospitalisation according to the HCWs' classifications or danger signs' identification: Proportion of children in need of referral/hospitalisation who were actually referred or hospitalised

Danger sign or severe classification	Baseline				Control arm				Intervention arm				P-value*
	N†	%	95%CI		N†	%	95%CI		N†	%	95%CI		
At least one danger sign (out of 4)	26	57.7	47.3	67.4	30	50.0	16.8	83.2	31	58.1	11.8	93.5	
Severe pneumonia or very severe disease	3	66.7	8.3	97.8	9	44.4	20.9	70.7	9	88.9	78.1	94.7	
Severe dehydration with another severe classification	3	100.0	-	-	1	100.0	-	-	0	-	-	-	
Dehydration with other severe classification	3	66.7	8.3	97.8	2	50.0	0.6	99.4	2	0.0	-	-	
Severe persistent diarrhoea	1	0.0	-	-	0	-	-	-	0	-	-	-	
All severe classifications related to diarrhoea	7	71.4	38.5	90.9	3	66.7	4.3	98.9	2	0.0	-	-	
Severe malaria or severe febrile illness	22	86.4	52.4	97.3	26	73.1	43.8	90.4	24	95.8	55.6	99.8	
Severe acute malnutrition with complications (any danger sign or other severe classification)	3	100.0	-	-	5	40.0	0.8	98.3	0	-	-	-	
Any of the above	35	**60.0**	47.7	71.1	42	**52.4**	23.7	79.6	41	**61.0**	21.5	89.9	0.680

† Number of children identified, by the HCW, with at least one danger sign or a classification requiring referral or hospitalisation

* Student's t test on cluster level summaries & accounting for the stepped wedge design

Table 14b: Correct referral or hospitalisation according to the validation nurses' classifications or danger signs' identification: Proportion of children in need of referral/hospitalisation who were actually referred or hospitalised

Danger sign or severe classification	Baseline				Control arm				Intervention arm				P-value*
	N†	%	95%CI		N†	%	95%CI		N†	%	95%CI		
At least one danger sign (out of 4)	24	58.3	30.3	81.9	25	60.0	40.1	77.1	16	68.8	54.9	79.9	
Severe pneumonia or very severe disease	15	53.3	26.8	78.1	10	40.0	15.6	70.7	4	25.0	-	-	
Severe dehydration with other severe classification	5	80.0	30.9	97.3	1	0.0	-	-	0	-	-	-	
Dehydration with other severe classification	1	100.0	-	-	2	100.0	-	-	0	-	-	-	
Severe persistent diarrhoea	0	-	-	-	0	-	-	-	0	-	-	-	
All severe classifications related to diarrhoea	6	83.3	34.3	98.0	3	66.7	0.3	99.9	0	-	-	-	
Severe malaria or severe febrile illness	23	56.5	31.4	78.7	24	58.3	36.4	77.4	17	76.5	54.5	89.8	
Severe acute malnutrition with complications (any danger sign or other severe classification)	3	66.7	25.1	92.3	3	0.0	-	-	0	-	-	-	
Any of the above	29	**55.2**	36.0	72.9	32	**53.1**	36.5	69.1	22	**68.2**	47.8	83.4	0.460

† Number of children identified, by the validation nurse, with at least one danger sign or a classification requiring referral or hospitalisation

* Student's t test on cluster level summaries & accounting for the stepped wedge design

Table 15: Correct treatment counselling: Proportion of child's caretakers who received information on the prescription for treating the child at home

Treatment	Explain the number of doses per day						Explain the number of days					
	Baseline		Control		Interv.		Baseline		Control		Interv.	
	N[†]	%	N[†]	%	N[†]	%	N[†]	%	N[†]	%	N[†]	%
Amoxicilline	116	95.7	293	95.6	202	93.6	116	80.2	293	95.2	202	92.1
Cotrimoxazole	174	93.7	246	97.2	26	96.2	174	84.5	246	95.1	26	100.0
Oral antibiotics for pneumonia[1]	290	94.5	538	96.3	228	93.9	290	82.8	538	95.2	228	93.0
Artesunate + Amodiaquine	379	97.4	262	98.9	29	96.6	379	94.5	262	97.3	29	93.1
Artemether/ Lumefantrine	91	98.9	459	97.4	332	98.5	91	94.5	459	97.4	332	97.6
ACT[2]	470	97.7	721	97.9	360	98.3	470	94.5	721	97.4	360	97.2
ORS	99	88.9	264	94.7	148	87.8	99	48.5	264	88.3	148	89.2
Zinc	99	93.9	268	96.6	153	88.2	99	85.9	268	94.8	153	90.9
Ciprofloxacine	2	100.0	5	80.0	11	100.0	2	100.0	5	80.0	11	100.0
Metronidazole	17	82.4	54	94.4	16	100.0	17	58.8	54	87.0	16	93.8
Oral anti-infectious for dysentery[3]	19	84.2	54	92.6	18	100.0	19	63.2	54	85.2	18	94.4
Albendazole	11	90.9	17	94.1	22	86.4	11	63.6	17	94.1	22	86.4
Mebendazole	62	96.8	94	97.9	47	93.6	62	85.5	94	94.7	47	91.5
Deworming treatments[4]	73	95.9	111	97.3	68	91.2	73	82.2	111	94.6	68	89.7
Iron/ folic acid	42	90.5	40	95.0	72	87.5	42	47.6	40	95.0	72	88.9
Plumpy nut or equivalent	28	50.0	16	93.8	27	63.0	28	39.3	16	75.0	27	70.4
All treatments (95%CI)	612	92.2 (86.9, 95.4)	1,143	95.5 (94.2, 96.4)	576	90.3 (82.9, 94.7)	612	78.1 (68.8, 85.2)	1,143	93.2 (90.5, 95.1)	576	91.0 (83.0, 95.4)

† Number of children who were prescribed, by the HCW, a given treatment (regardless of the classification)

1 Amoxicilline, Cotrimoxazole, Ciprofloxacine; 2 Artesunate + Amodiaquine, Artemether/ Lumefantrine; 3 Ciprofloxacine, Metronidazole; 4 Albendazole, Mebendazole

Treatment	Explain the number of doses per day & the number of days						P-value*
	Baseline		Control		Interv.		
	N[†]	%	N[†]	%	N[†]	%	
Amoxicilline	116	78.5	293	93.9	202	91.1	
Cotrimoxazole	174	83.9	246	93.9	26	96.2	
Oral antibiotics for pneumonia[1]	290	81.7	538	93.9	228	91.7	
Artesunate + Amodiaquine	379	93.4	262	97.0	29	93.1	
Artemether/ Lumefantrine	91	94.5	459	96.1	332	97.0	
ACT[2]	470	93.6	721	96.4	360	96.7	
ORS	99	46.5	264	86.7	148	84.5	
Zinc	99	83.8	268	94.0	153	87.6	
Ciprofloxacine	2	100.0	5	80.0	11	100.0	
Metronidazole	17	52.9	54	85.2	16	93.8	
Oral anti-infectious for dysentery[3]	19	57.9	54	83.3	18	94.4	
Albendazole	11	63.6	17	94.1	22	86.4	
Mebendazole	62	83.9	94	94.7	47	91.5	
Deworming treatments[4]	73	80.8	111	94.6	68	89.7	
Iron/ folic acid	42	47.6	40	92.5	72	83.3	
Plumpy nut or equivalent	28	32.1	16	75.0	27	63.0	
All treatments (95%CI)	612	77.3 (67.5, 84.8)	1,143	91.5 (88.8, 93.6)	576	87.9 (77.9, 93.7)	0.355

† Number of children who were prescribed, by the HCW, a given treatment (regardless of the classification)

1 Amoxicilline, Cotrimoxazole, Ciprofloxacine; 2 Artesunate + Amodiaquine, Artemether/ Lumefantrine; 3 Ciprofloxacine, Metronidazole; 4 Albendazole, Mebendazole

* Student's t test on cluster level summaries & accounting for the stepped wedge design

Table 16: Availability of essential medicines and equipment

	Baseline (N = 158)		Control arm (N = 292)		Intervention arm (N = 168)	
	N	%	N	%	N	%
Essential equipment (availability observed or reported & equipment functional)						
Source of electricity	158	**91.1**	292	**98.6**	168	**100.0**
Electricity without any power cut in the last 7 days	155	**41.9**	198	**33.3**	254	**66.7**
Baby weighing scale (graduation 100 grams)	157	**100.0**	291	**99.3**	168	**100.0**
Children weighing scale (graduation 250 grams)	157	**100.0**	291	**99.3**	168	**100.0**
Measuring rod	157	**100.0**	291	**99.3**	168	**100.0**
Mid-upper arm circumference tape	157	**100.0**	290	**99.7**	168	**100.0**
Thermometer	157	**100.0**	256	**99.6**	166	**99.4**
Rapid Diagnostic Test	157	**89.8**	291	**94.9**	167	**98.2**
Source of clean water	158	**91.8**	292	**96.2**	163	**97.0**
Spoons, cups and jugs to mix and administer ORS	158	**21.5**	289	**32.9**	168	**85.1**
Kit for intravenous injection	157	**94.3**	292	**64.7**	166	**31.3**
Single-use syringes with disposable needles	157	**100.0**	292	**99.0**	167	**99.4**
Refrigerator	152	**99.3**	287	**99.3**	168	**99.4**
Availability of all essential equipment (13 items)	158	**7.0**	290	**10.0**	166	**19.9**
Availability index of essential equipment (13 items)	158	**86.9**	292	**87.1**	161	**90.6**
Essential medicine (availability observed with at least one unexpired)						
Albendazole	158	**94.3**	290	**93.5**	166	**79.5**
Amoxicilline	158	**97.5**	291	**89.7**	166	**73.5**
Artesunate + Amodiaquine or Artemether/ Lumefantrine (ACT)	158	**99.4**	291	**99.3**	166	**97.6**
Ciprofloxacine	158	**99.4**	291	**97.3**	166	**94.6**
Cotrimoxazole	158	**99.4**	291	**99.3**	166	**98.2**
Iron and folic acid	157	**98.7**	291	**98.6**	165	**94.6**
Mebendazole	158	**98.1**	291	**97.6**	166	**89.2**
Metronidazole	158	**100.0**	290	**99.7**	166	**97.6**
Multivitamins	158	**95.6**	290	**75.9**	166	**68.1**
ORS	158	**94.3**	291	**93.1**	166	**85.5**
Ready to use therapeutic food (RUTF)	158	**96.2**	289	**92.0**	166	**91.0**
Zinc	158	**95.6**	288	**93.1**	165	**87.3**
Vitamin A	158	**100.0**	290	**98.6**	164	**97.0**
Availability of all of essential oral medicines (13 items)	158	**80.4**	284	**52.5**	165	**28.5**
Availability index of essential oral medicines (13 items)	158	**97.6**	291	**94.4**	166	**88.7**

Table 17: Comparison of HCWs' performance with and without use of IMCI paper-based forms in the control arm

Adherence to IMCI's clinical assessment	Without paper-based IMCI form			With paper-based IMCI form		
	N	%	95%CI	N	%	95%CI
Overall adherence (33 tasks)	307	**57.1**	53.5　60.7	916	**50.2**	44.8　55.6
Adherence to danger signs' assessment (3 tasks)	307	**45.1**	33.1　57.1	916	**22.2**	11.6　32.8

Identification of at least one danger sign (out of 4): Proportion of children correctly identified with at least one danger sign	Without paper-based IMCI form			With paper-based IMCI form		
	N†	%	95%CI	N†	%	95%CI
	6	**66.7**	45.0　83.0	18	**50.0**	22.2　77.8
†Number of children identified, by the validation nurse, with a given danger sign						

Overall correct classification: Proportion of children correctly classified with x given classifications	Without paper-based IMCI form			With paper-based IMCI form		
	N†	%	95%CI	N†	%	95%CI
Accounting for the severity of classifications	240	**71.7**	60.0　81.0	703	**67.4**	63.4　71.2
Ignoring the severity of the classifications	240	**74.6**	64.4　82.7	703	**71.0**	65.8　75.7
† Number of children classified, by the validation nurse, with x given classification						

Overall correct prescription: Proportion of children who were prescribed the correct treatments	Without paper-based IMCI form			With paper-based IMCI form		
	N†	%	95%CI	N†	%	95%CI
According to the HCWs' classifications	238	**77.7**	60.5　88.8	733	**77.5**	73.5　81.0
According to the validation nurses' classifications	240	**67.5**	51.7　80.1	703	**63.9**	60.3　67.3
†Number of children classified, by the HCW or by the validation nurse, with a given classification						

Overall correct referral/hospitalisation: Proportion of children in need of referral/hospitalisation who were actually referred or hospitalised	Without paper-based IMCI form			With paper-based IMCI form		
	N†	%	95%CI	N†	%	95%CI
According to the HCWs' classifications	8	**62.5**	32.1　85.5	27	**55.6**	19.2　86.8
According to the validation nurses' classifications	6	**50.0**	23.3　76.7	25	**52.0**	33.9　69.6
†Number of children identified, by the HCW or the validation nurse, with at least one danger sign or a classification requiring referral/hospitalisation						

Overall correct treatment counselling: Proportion of child's caretakers who received information on the prescription for treating the child at home	Without paper-based IMCI form			With paper-based IMCI form		
	N†	%	95%CI	N†	%	95%CI
	255	**87.5**	81.0　91.9	779	**92.8**	91.0　94.3
† Number of children who were prescribed, by the HCW, a given treatment (regardless of the classification)						

Table 18a: Child's measurements agreement between HCWs and validation nurses

	Baseline				Control arm				Intervention arm			
	N	mean (SD)	Range	RMSE	N	mean (SD)	Range	RMSE	N	mean (SD)	Range	RMSE
Difference in weight (kg)	676	0.02 (0.70)	-9, 6.3	0.70	1,320	0.08 (0.75)	-10, 6	0.76	687	0.01 (0.45)	-7, 4	0.45
Difference in height (cm)	580	0.12 (2.43)	-30, 20	2.43	1,213	0.07 (2.78)	-31, 30	2.78	692	0.34 (2.81)	-30, 20	2.83
Difference in MUAC (mm)	544	-0.25 (5.62)	-25, 39	5.62	1,087	-0.77 (4.69)	-30, 50	4.75	600	-0.21 (3.87)	-19, 30	3.87
Difference in temperature (°C)	669	-0.03 (0.53)	-3, 4	0.53	1,203	-0.09 (0.52)	-10, 2	0.53	646	-0.06 (0.54)	-3, 9	0.55
Difference in respiratory count	169	0.18 (9.51)	-28, 29	9.48	226	-0.47 (9.51)	-34, 37	9.50	285	0.51 (8.66)	-35, 29	8.66

Table 18b: Actual agreement and Cohen's Kappa coefficients between HCWs and validation nurses RDT results

	Actual agreement (%)	Kappa coef.
Baseline	97.0	0.90
Control arm	96.9	0.93
Intervention arm	96.2	0.92