

1 **The effect of community dialogues and sensitization on patient reporting of adverse**
2 **events in rural Uganda: uncontrolled before-after study**

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18 **Abstract**

19 **Background:** The patients that experience adverse events are in the best position to report
20 them, only if they were empowered to do so. Systematic community engagement and support
21 to patients in a rural setting to monitor any potential harm from medicines should provide
22 evidence for patient safety.

23

24 **Methods:** This paper describes an uncontrolled before and after study aimed at assessing the
25 effect of a community engagement strategy, the Community Dialogues and Sensitization
26 (CDS) intervention between January and April 2017, on the knowledge, attitude and practice
27 of reporting adverse drug events by community members in the two eastern Ugandan districts.

28 A representative cross-sectional baseline household survey was done prior to the intervention
29 in September 2016 (n=1034) and the end-line survey (n=827) in July 2017.

30 **Results:** After implementation of the CDS intervention, there was an overall 20% (95% CI=16-
31 25) increase in awareness about adverse drug events in the community. The young people (15-
32 24 years) demonstrated a 41% (95% CI =31-52) increase and the un-educated showed a 50%
33 (95% CI=37-63) increase in awareness about adverse drug events. The attitudes towards
34 reporting increased overall by 5% in response to whether there was a need to report ADEs
35 (95% CI =3-7). An overall 115% (95% CI =137-217) increase in the population that had ever
36 experienced ADEs was also reported.

37 **Conclusion:** Our evaluation shows that the CDS intervention increases knowledge, improves
38 attitudes by catalyzing discussions among community members and health workers on health
39 issues and monitoring safety of medicines.

40 **Key words:**

41 **Patient adverse drug event reporting, community dialogue and sensitization, rural health**
42 **setting**

44 **Background**

45

46 Globally, adverse drug reactions account for up to 18% of hospital deaths 1-5. An adverse
47 event is defined as any untoward medical occurrence in a patient administered a medicinal
48 product and which does not necessarily have to have a causal relationship with the treatment,
49 including worsening of the clinical condition⁶. Like many resource- limited countries, Uganda
50 uses spontaneous reporting of suspected adverse drug events (ADE) predominantly by health
51 workers to monitor the safety of medicines⁷. However, one of the biggest inherent limitations
52 of this method is under-reporting. In as much as the Ugandan pharmacovigilance regulations
53 of 2014 require healthcare professionals to report adverse drug events, the grossly under-
54 resourced health sector makes it hard for health workers to report them⁸. A recent study
55 reported an incidence of 25% of hospital-acquired suspected ADEs among Uganda inpatients⁹.
56 Antibiotics and anti-malarials have been the most commonly implicated drugs in community-
57 acquired ADEs in surveys of healthcare professionals¹⁰. With increased access and use of
58 medicines in the community, it is becoming increasingly important to collect more safety
59 information by involving the patients directly. However, healthcare professionals become less
60 involved in patient treatment thus minimizing their role in healthcare delivery. The Ugandan
61 National Pharmacovigilance Centre (NPC) has its main goal of promoting patient safety by
62 monitoring adverse drug reactions. It intends to implement a program of a dialogue-based
63 intervention aimed at encouraging community members to report and possibly contribute to
64 prevention of adverse drug events and any drug-related issues in the community.

65 The Community Dialogue and Sensitization (CDS) approach was a hybrid modification of the
66 community dialogue (CD) previously used to stimulate community support and engagement in
67 the context of integrated community case management (iCCM) of childhood diarrhoea,
68 pneumonia and malaria by Malaria Consortium in Zambia, Mozambique and Uganda¹¹. The

69 CDS model added a sensitization campaign using radio messages, posters and brochures to
70 raise drug-safety awareness encourage dialogue and involve the community in designing
71 solutions to pertinent issues. This approach involved a participatory communication process
72 of sharing information through existing community-based structures and aimed to enable
73 communities make informed choices and to take individual and collective action.

74 The CDS model assumed that the respondents knew the common diseases that affected the
75 population across different ages and the treatment they often received. We assumed that the
76 respondents knew the different common points of care in the community. Another assumption
77 made was that the community members were familiar with the adverse events that they
78 commonly experienced as well as the reporting channels in the community for the different
79 service providers. This model assumed that respondents did not know that it was their right to
80 report ADEs and their obligation to give feedback on ADEs to the national medicine
81 regulatory authority to improve drug safety in the country. Some community members
82 therefore had misconception about reporting ADEs and some patients accessed drugs through
83 the most convenient avenues to them.

84 The messages developed for this study focused on informing communities that any drug was
85 capable of causing ADEs and monitoring them was essential in improving drug safety. This
86 paper describes an uncontrolled before and after study aimed at assessing the effect of a
87 community engagement strategy, the Community Dialogues and Sensitization between
88 January and April 2017, on the knowledge, attitude and practice of reporting ADEs by
89 community members in the two eastern Ugandan districts

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92 **Materials and methods**

93 **Context**

94 The CDS intervention was implemented in two predominantly rural districts of Iganga and
95 Mayuge in Eastern Uganda. This area hosts a health and demographic surveillance site that
96 works closely with the communities, health facilities and the district health office. The
97 Iganga-Mayuge health and demographic surveillance site (IMHDSS) is run by Makerere
98 University Centre for Health and Population Research (MUCHAP). The population here is a
99 very young. About half is under 15 years and a total birth rate of five children. The IMHDSS
100 population is largely homogeneous with 83% being from a single tribal-group, the Basoga. At
101 the IMHDSS, there is bi-annual update of individual and household data conducted between
102 February-May and August-November in the 65 villages. The updates contain information on
103 pregnancy registrations and outcomes, in and out-migrations, births and deaths. Prior to each
104 round, an information officer from each village gives feedback from the previous round and
105 identifies the 35 data collectors for a 2-day training.

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107 **The Intervention: Community Dialogue and Sensitization**

108 The implementation team conducted a preliminary audience evaluation to understand the
109 community needs and interests, gauge reactions to different communication strategies and
110 identify preferences for various prototype materials. The National Pharmacovigilance Centre
111 and MUCHAP jointly developed the CDS toolkit. The toolkit included a facilitators' guide-
112 book with ten repeatable steps- key talking points, pictorial posters, and a monitoring and
113 feedback tool. Tools and images were pre-tested with the target audience before finalizing the
114 toolkit The CDS intervention included several components (See table 1) conducted between
115 December 2016 and April 2017. The CDS meetings began after the official launch of the
116 project. The goal of the community dialogue meetings was to improve the knowledge of the
117 community members, about ADEs, improve attitude towards reporting ADEs and to
118 minimize barriers to reporting ADEs. The primary target audience were the primary
119 household member in charge of health care decisions, private health care providers, health

120 workers at different levels, drug shop operators, pharmacies, district policy makers where
121 possible, and patients.

122

123 After a courtesy visit to the district health office, the team explained the planned activities to
124 the district health officer, district drug inspector and the district health educator. The teams
125 went out in pairs composed of a community health worker and a note-taker from MUCHAP.
126 The team enlisted the help of the local council heads to introduce them to the community to
127 gain the acceptance of community members. Mobilization took the form of public
128 announcements in churches, mosques, village meetings and women groups, a day before the
129 CDS meeting. Announcement messages included the purpose, day, time and venue of the
130 meeting. Teams emphasized to community members that the meeting would contain
131 information that is important to their health and well-being.

132

133 During the community dialogue, a local leader or elder opened the session and introduced the
134 team. The team leader then explained the purpose of the meeting and stimulated the dialogue
135 into the ten-step process of the CDS toolkit and the talking points around ADEs. Community
136 dialogues provided communities with the opportunity to discuss extensively within their
137 villages, newly available healthcare services like patient ADE reporting. In addition, the
138 members discussed how they could best benefit from the CDS approach and support it. In
139 each village as far as possible, there were separate men and women's meetings.

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145 **Table 1: Multiple interventions used to improve patient reporting**

Intervention Components	Description	Beneficiaries		Deliverers
		Individual	Others	
Community dialogue meetings	<p>Mobilization: The team of the CHW & MUCHAP information officer enlisted support of district health office and the local council leaders. The LC provided access to the community. Public announcements about the CDS were made in churches, mosques, village meetings & women groups a day prior to the meeting.</p> <p>Intervention activities: The CHW & MUCHAP information officer conducted the CDS using the CDS toolkit containing the Facilitator's 10-step process, ADE pictorial posters and brochures in the local language, Lusoga. Forty CDSs were conducted January to April 2017</p> <p>Reach: 658 participants (139 men, 519 women).</p>	Primary household member in charge of health care decisions,	Community members Community leaders	CHW MUCHAP information officer
Radio messages	<p>Radio spot messages aimed at raising community awareness were aired 3 times a day (8am, 1pm & 9pm) for three days in a week (Monday, Wednesday & Friday).</p> <p>Period of airing: January to April 2017</p> <p>The messages were developed by NDA & MUCHAP</p>	Patients and care-givers in the community	Community members, district, religious & village leaders, private & public health service providers	3 radio stations NBS FM, R FM & Safari FM covering Iganga and Mayuge districts
Focus Group discussions	FGDs in Public health facilities and FGDs which included health workers and some community members.	Community members	Private & public health care providers,	MUCHAP information officer
Brochures	Distributed 2000 Lusoga brochures to participants in their households and communities with information about ADEs and encouraging reporting of the suspected ADEs during the HDSS routine data collection by Field assistants	Household members	Community members	MUCHAP field assistants
ADE posters	Distributed 500 posters to private and public health facilities encouraging ADE reporting with some guidelines of how and where to report them	Health workers	Community members Private & public health facilities	MUCHAP staff
ADE reporting forms	Distribution of 70 booklets of 25 ADE carbonated reporting forms was accompanied by sensitization of the health workers about	Health workers in Iganga & Mayuge	Health workers beyond	MUCHAP staff NDA staff

	pharmacovigilance		implementation districts	
Advocacy	An official launch of the CDS approach to create more awareness about the well-being of the community and the importance of ADE reporting. Posters and brochures were also distributed, 16 th December 2016 Courtesy call to the district health office by NDA officials	Not applicable	District health authorities Community leaders	NDA staff MUCHAP staff Journalists

146 CHW=Community Health Worker, MUCHAP= Makerere University Centre for Health and Population Research, ADE=Adverse Drug Event, NDA=National Drug Authority,
147 CDS= Community Dialogue and Sensitization, LC=Local Council

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149 **Study design, respondents and sampling**

150 This uncontrolled before and after study was conducted between September 2016 and August

151 2017 in the Iganga/Mayuge Health Demographic Surveillance Site (IDMSS). Prior to the

152 CDS intervention in September 2016 and the end-line survey in July 2017, we conducted a

153 representative cross-sectional-baseline household survey. The entire adult population of the

154 study area was considered as the sampling domain, where all households were eligible for

155 selection. The total sample size of 778 for each survey was calculated in order to allow for a

156 comparison of proportions between two groups, i.e. baseline and end-line respondents.

157 Assuming a baseline proportion with an acceptable level ρ of 0.5, and testing at the 0.05

158 level, a sample size of 389 for each survey was determined to give 80 per cent power to

159 detect a change of at least ten per cent of the primary outcome. To allow adjustment for

160 confounders, non-response and design effect, we doubled the sample size, to obtain the

161 required sample size. Sampling involved a single-stage household sampling. In each of the 65

162 villages in the IMHDSS surveillance area, the study team sampled an equal number of

163 households using a simple random sampling approach with the help of community leaders.

164 For the purpose of the surveys, a household was defined as a group of people who routinely

165 lived and ate together. One person per selected household was interviewed. The target for

166 interviews was the person best placed to answer questions about the household's health in the

167 community members' questionnaire (Additional file # 1). All community based health

168 facilities in the intervention area were included in the survey. At least two healthcare workers

169 from each health facility were randomly selected and interviewed using a specific healthcare

170 provider questionnaire (Additional file # 2). The facilities considered were both private and

171 public owned and these included hospitals, health centre VI-II, pharmacies, drug shops and

172 shops that sell drugs with other merchandise.

173

174 **Data collection**

175 A quantitative assessment of target communities' knowledge, attitudes and practices of
176 patient ADE reporting was done using identical questions before and after the CDS
177 intervention.

178

179 Interviews were carried out by local field researchers, using a pre-tested structured and
180 validated questionnaire translated in the local language (Lusoga). The field researchers were
181 instructed to read out the survey questions exactly as rendered on the questionnaire.

182 Instructions for field researchers with regard to whether the question required a single
183 response or whether multiple responses were possible and answer options were provided in
184 the questionnaire in English. Answer options were not read out aloud and field researchers
185 were instructed not to suggest answers to the respondent. An 'other' category was provided
186 for most questions and field researchers were instructed to note down respondents' answers if
187 they could not clearly assign the answer to an existing answer category.

188

189 All field team members had previous experience of conducting or supervising field research.
190 Field researchers and supervisors attended a two-day training course covering data collection
191 tools, field procedures and interview techniques. Field supervisors received an additional
192 days' training focusing on supervision of field teams as well as the sampling process.

193 Following the pre-test, a half-day training session was conducted to discuss challenges
194 identified during the pre-test. The training materials were prepared by MUCHAP and NDA
195 and the training was conducted by MUCHAP, who were responsible for coordination and
196 supervision during the field work. Field supervisors were tasked with monitoring the quality
197 of the data collected and seeking clarification from the field researchers where necessary. At
198 the end of each day, they were responsible for conducting a feedback meeting with their
199 team, giving researchers the opportunity to discuss and resolve challenges and providing

200 feedback and training to the team as appropriate. They reported to the study coordinator
201 daily, summarizing progress made, challenges encountered and discussing field work to be
202 completed on the following day.

203

204 **Data entry and analysis**

205 Data entry was done using EpiData 3.1 (EpiData Association) software by ten trained data
206 entry officers. All records were double entered to ensure accuracy. First and second entries
207 were done by different data entry officers for each village. Where differences between first and
208 second entry were detected, data were verified by checking the record against the paper
209 questionnaire. If in doubt, data entry officers were instructed to log their query and discuss it
210 with the study coordinator. The data was transferred to STATA Version 12 (StataCorp LP) for
211 further consistency checks and preparation for analysis. All percentages reported are
212 population average estimates which have been adjusted to take into account the clustering of
213 the study design. Responses recorded under ‘other’ by field researchers were reviewed and
214 either re-assigned to an existing answer category, assigned to a new answer category or left in
215 the ‘other’ category. All comparisons were done at 5% level of significance and 95%
216 confidence intervals for the mean difference were constructed to test the significance of the
217 difference before and after the intervention.

218

219 **Outcome measures**

220 The primary outcomes measured comprised of the percentage differences between the
221 knowledge, attitudes and practice of reporting before and after the CDS intervention.
222 Knowledge was measured by the responses from the question “Do drugs “cause” negative or
223 side effects?” For the respondents who answered “yes”, to the above question, their attitude
224 towards reporting adverse drug effects was measured by asking if they considered it necessary
225 to report an adverse drug effect. To understand the respondents’ practices, we asked them if

226 they would report any ADE if encountered. The secondary outcome of this study was to
227 establish the best ways to engage the community and this was included as part of the
228 questionnaire during the surveys.

229

230 **Results**

231 **Description of Survey respondents**

232 There were 1034 respondents that participated in the baseline survey (before implementation
233 of the CDS model) and 827 participated in the end-line survey. These were house-hold adult
234 members who consented to our interview. All the participants that were recruited in the study
235 consented to participate. There was a big positive difference in knowledge, attitudes and
236 practices of respondents regarding reporting ADE between the baseline and end-line surveys.
237 This is true though the number in baseline were more than those in end-line survey. Table 2
238 summarizes survey respondents' profile in terms of age, education, religion and occupation.

239

240 **Table 2: Community member description by social demographic characteristics**

	Baseline n (%) N=1034	End line n (%) N=827
Age group		
15-24	163 (15.8)	137(16.6)
25-34	304 (29.4)	224(27.1)
35-44	243 (23.5)	200(24.2)
45-54	145 (14.0)	138(16.7)
55-64	105 (10.2)	54(6.5)
65+	74 (7.2)	74(9.0)
Education		
None	147 (14.2)	90(10.9)
Primary	532 (51.5)	422(51.0)
Secondary	310 (29.9)	265(32.0)
Tertiary	23 (2.2)	27(3.3)
University	22 (2.1)	23(2.8)
Religion		
Anglican	246 (23.8)	251(30.4)
Roman catholic	93 (9.0)	82(9.9)
Pentecostal	103 (10.0)	103(12.5)
Muslim	573 (55.4)	380(46.0)
Other	19 (1.8)	10(1.2)
Occupation		
Professional	29 (2.8)	42(5.1)
Self employed	562 (54.4)	203(24.6)
Student	24 (2.3)	16(1.9)
Peasant	175 (16.9)	342(41.4)
Domestic work	241 (23.3)	127(15.4)
Other	3 (0.3)	96(11.6)

241

242 **Knowledge about adverse drug reactions**

243 After implementation of community dialogues about adverse drug events and reporting, there

244 was an overall 20% increase in knowledge about ADEs in the community. Disaggregating

245 knowledge of ADEs by background characteristics, revealed an even distribution positive

246 change but higher (41.1%, 95% CI =31-52) among young people (15-24years), those with no
247 education (50%, 95% CI=37-63) as shown in table 3.

249 *Table 3: Knowledge of ADEs by respondent demographic characteristics before and after the CDS intervention*

Do drugs “cause” negative or side effects?												
	Yes				No				DK			
	Before	After	% age diff.	95% CI	Before	After	% age diff.	95% CI	Before	After	% age diff.	95% CI
Age category												
15-24	86 (52.8)	102 (74.5)	41.1	0.31-0.52	63 (38.7)	33(24.1)	-37.73	-0.57--0.19	14(8.6)	2(1.5)	-82.56	-1.22--0.43
25-34	173 (56.9)	151 (67.4)	18.5	0.10-0.27	110(36.2)	67(29.9)	-17.40	-0.32--0.03	21(6.9)	6(2.7)	-60.87	-0.82--0.39
35-44	145 (59.7)	137 (68.5)	14.7	0.06-0.24	84(34.6)	55(27.5)	-20.52	-0.36--0.05	14(5.8)	8(4)	-31.03	-0.50--0.12
45-54	79 (54.5)	87 (63.5)	16.5	0.05-0.28	51(35.2)	43(31.4)	-10.80	-0.30-0.08	15(10.3)	7(5.1)	-50.49	-0.76--0.25
55-64	54 (51.4)	37 (68.5)	33.3	0.18-0.49	37(35.2)	13(24.1)	-31.53	-0.59--0.04	14(13.3)	4(7.4)	-44.36	-0.80--0.08
65+	45 (60.8)	46 (62.2)	2.3	-0.13-0.18	26(35.1)	25(33.8)	-3.70	-0.30-0.22	3(4.1)	3(4.1)	0.00	-0.32-0.32
Education												0.00-0.00
None	50 (34.0)	46 (51.1)	50.3	0.37-0.63	79(53.7)	37(41.1)	-23.46	-0.43--0.04	18 (12.2)	7(7.8)	-36.07	-0.63--0.09
Primary	294 (55.3)	273 (64.8)	17.2	0.11-0.23	191(35.9)	132(31.4)	-12.53	-0.23--0.02	47(8.8)	16(3.8)	-56.82	-0.72--0.42
Secondary	199 (64.2)	193 (72.8)	13.4	0.06-0.21	95(30.6)	65(24.5)	-19.93	-0.34--0.06	16(5.2)	7(2.6)	-50.00	-0.68--0.32
Tertiary	19 (82.6)	25 (92.6)	12.1	-0.06-0.30	4(17.4)	2(7.4)	-57.47	-1.09--0.06	0(0)	0(0)	0.00	0.00-0.00
University	20 (90.9)	23 (100)	10.0	-0.02-0.22	2(9.1)	0(0)	-100.00	-1.40--0.60	0(0)	0(0)	0.00	0.00-0.00
Religion												0.00-0.00
Anglican	140 (56.9)	174 (69.3)	21.8	0.13-0.3	91(37)	69(27.5)	-25.68	-0.40--0.11	15(6.1)	8(3.2)	-47.54	-0.66--0.29
Roman Catholic	59 (63.4)	56 (68.3)	7.7	-0.06-0.22	29(31.2)	23(28)	-10.26	-0.35-0.15	5(5.4)	3(3.7)	-31.48	-0.62--0.01
Pentecostal	65 (63.1)	77 (74.8)	18.5	0.06-0.31	30(29.1)	25(24.3)	-16.49	-0.40-0.07	8(7.8)	1(1.0)	-87.18	-1.40--0.34
Muslim	308 (53.8)	244 (64.2)	19.3	0.13-0.26	217(37.9)	118(31.1)	-17.94	-0.28--0.07	48(8.4)	18(4.7)	-44.05	-0.58--0.30
Other	10 (52.6)	9 (90)	71.1	0.42-1.00	4(21.1)	1(10)	-52.61	-1.24-0.19	5(26.3)	0(0)	-100.00	0.00-0.00
Overall	582 (56.3)	560 (67.8)	20.4	0.16-0.25	371(35.9)	236(28.57)	-0.20	-0.28--0.13	81(7.8)	30(3.63)	-0.53	-0.64--0.43

250 ADE=Adverse Drug Event, DK=Don't Know, CI=Confidence Interval

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253 **Attitudes about reporting adverse drug effects**

254 In response to whether there it was necessary to report the adverse drug effects, there was an

255 overall increase of 4.6% after the implementation of the CDS intervention. The difference in

256 attitude after the intervention is presented in table 4 by social demographic characteristics of

257 age, education and religion.

258 *Table 4: Necessity to report adverse drug events by social demographic characteristics before and after the CDS intervention*

	Yes				No				DK			
	Before	After	% age diff.	95% CI	Before	After	% age diff.	95% CI	Before	After	% age diff.	95% CI
Age category												
15-24	144 (88.3)	133 (97.1)	9.97	4-16	12 (7.4)	4 (2.9)	-60.81	-88--33	7 (4.3)	0 (0)	-100.00	0
25-34	288 (94.7)	214 (95.5)	0.84	-3-5	8 (2.6)	8 (3.6)	38.46	21-55	8 (2.6)	2 (0.9)	-65.38	-88--42
35-44	227 (93.4)	192 (96.0)	2.78	-1-7	10 (4.1)	7 (3.5)	-14.63	-33-4	6 (2.5)	1 (0.5)	-80.00	-111--49
45-54	133 (91.7)	134 (97.8)	6.65	2-12	7 (4.8)	1 (0.7)	-85.42	-128--43	5 (3.4)	2 (1.5)	-55.88	-83--29
55-64	95 (90.5)	52 (96.3)	6.41	-1-14	4 (3.8)	1 (1.9)	-50.00	-90--10	6 (5.7)	1 (1.9)	-66.67	-113--20
65+	67 (90.5)	73 (98.6)	8.95	2-16	5 (6.8)	0 (0)	-100.00	-	2 (2.7)	1 (1.4)	-48.15	0
Education												
None	127 (86.4)	80 (88.9)	2.89	-6-11	12 (8.2)	7 (7.8)	-4.88	-30-20	8 (5.4)	3 (3.3)	-38.89	-0.67--0.10
Primary	488 (91.7)	410 (97.4)	6.22	3-9	22 (4.1)	7 (1.7)	-58.54	-74--43	22(4.1)	4 (1)	-75.61	-0.95--0.56
Secondary	294 (94.8)	259 (97.7)	3.06	0-6	12 (3.9)	6 (2.3)	-41.03	-59-0.00	4 (1.3)	0 (0)	-100.00	0
Tertiary	23 (100)	27 (100)	0.00	0	0 (0)	0 (0)	0.00	-	0 (0)	0 (0)	0.00	-
University	22 (100)	22 (95.7)	-4.30	-13-4	0 (0)	1 (4.3)	0.00	-	0 (0)	0 (0)	0.00	-
Religion							0.00	-				
Anglican	225 (91.5)	248 (98.8)	7.98	4-12	12 (4.9)	2 (0.8)	-83.67	-114--53	9 (3.7)	1 (0.4)	-89.19	-126--52
Roman Catholic	90 (96.8)	80 (97.6)	0.83	-4-6	1 (1.1)	2 (2.4)	118.18	-	2 (2.2)	0 (0)	-100.00	0
Pentecostal	97 (94.2)	98 (95.1)	0.96	-5-7	3 (2.9)	3 (2.9)	0.00	-27-27	3 (2.9)	2 (1.9)	-34.48	-62--7
Muslim	525 (91.6)	362 (95.3)	4.04	1-7	30 (5.2)	14 (3.7)	-28.85	-42--15	18 (3.1)	4 (1.1)	-64.52	-82--47
Other	17 (89.5)	10 (100)	11.73	-2-26	0 (0)	0 (0)	0.00	-	2 (10.5)	0 (0)	0.00	-
Overall	954(92.3)	798(96.6)	4.6	3-7	46(4.4)	21(2.5)	-43.18	-53--33	33(3.3)	7(0.8)	-75.76	-89--62

259

260 **Reporting ADEs by the respondents**

261 While at baseline only 21% mentioned that they had experienced an ADE, this proportion more
262 than doubled to 44% after the CDS intervention. However, there are variations in the different
263 demographic groups, for instance, there was a reduction among those who had attained tertiary
264 education level, as shown in table 5.

265

266

267 *Table 5: Reporting of ADEs by social demographic characteristics before and after the CDS intervention*

268

	Yes				No				DK			
	Before	After	% age diff.	95% CI	Before	After	% age diff.	95% CI	Before	After	% age diff.	95% CI
Age category												
15-24	51(31.3)	43(43)	37.38	18-57	108(66.3)	57(57)	-14.03	-29-1	4(2.5)	0(0)	-100.00	0
25-34	109(35.9)	61(42.1)	17.27	2-32	183(60.2)	84(57.9)	-3.82	-16-9	12(3.9)	0(0)	-100.00	0
35-44	80(32.9)	61(47.3)	43.77	28-60	159(65.4)	67(51.9)	-20.64	-34--7	4(1.6)	1(0.8)	-50.00	-76--24
45-54	47(32.4)	43(46.7)	44.14	24-64	96(66.2)	47(51.1)	-22.81	-40--6	2(1.4)	2(2.2)	57.14	31-83
55-64	36(34.3)	13(35.1)	2.33	-28-32	68(64.8)	24(64.9)	0.15	-22-22	1(1.0)	0(0)	-100.00	0
65+	26(35.1)	16(36.4)	3.70	-26-34	46(62.2)	28(63.6)	2.25	-20-25	2(2.7)	0(0)	-100.00	0
Education												
Primary	180(33.8)	120(42.4)	25.44	14-37	340(63.9)	161(56.9)	-10.95	-20--2	12(2.3)	2(0.7)	-69.57	-91--48
Secondary	109(35.2)	73(40.1)	13.92	0-28	194(62.6)	109(59.9)	-4.31	-16-7	7(2.3)	0(0)	-100.00	0
Tertiary	12(52.2)	8(40)	-23.37	-68-21	10(43.5)	12(60)	-86.21	-118--55	1(4.3)	0(0)	-100.00	0
University	10(45.5)	13(65)	42.86	16-70	12(54.5)	7(35)	-35.78	-73-1	0(0)	0(0)	0.00	-
Religion												
Anglican	89(36.2)	66(38.6)	6.63	-9-22	152(61.8)	104(60.8)	-1.62	-14-11	5(2.0)	1(0.6)	-70.00	-98--42
Roman Catholic	23(24.7)	20(41.7)	68.83	41-96	69(74.2)	28(58.3)	-21.43	-41--1	1(1.1)	0(0)	-100.00	0
Pentecostal	45(43.7)	32(46.4)	6.18	-16-29	55(53.4)	37(53.6)	0.37	-20-21	3(2.9)	0(0)	-100.00	0
Muslim	189(33)	115(45.6)	38.18	27-49	369(64.4)	135(53.6)	-16.77	-26--7	15(2.6)	2(0.8)	-69.23	-92--47
Other	3(15.8)	4(57.1)	261.39	195-328	15(78.9)	3(42.9)	-45.63	-98-7	1(5.3)	0(0)	-100.00	0
Overall	349(20.5)	237(44)	114.6%	137-217	660(63.8)	307(29.7)	-53.5%	-84--3	25(2.4)	3(0.29)	-87.9%	-50-21

270

271 **Commonly reported adverse events**

272 After the CDS intervention, there was an increase of more than 10% in the population who
273 would consider reporting serious reactions (19%, 95% CI =16-21%), reactions to newly
274 introduced drugs (15%, 95% CI = 11-18%), unexpected reactions (16%, 95% CI = 13-19%)
275 and reactions due to herbal and conventional medicines taken together (20%, 95% CI= 16-
276 24%) as shown in table 6. Regarding the top most five ADE types that the respondents would
277 report, it was found that serious reactions became more important after the CDS intervention.
278 The rest of the order of importance for reactions to be reported largely remained unchanged
279 from uncertain reactions to those of newly introduced drugs on the market, followed by
280 unexpected reactions and reactions to drugs that have been on the market for long in descending
281 order.

282 **Table 6: A comparison of the type of adverse events that the respondents would report before and after the CDS intervention**

	Yes/Agree n (%)				No/Disagree n (%)				Don't know n (%)			
	Baseline	End-line	%change	95% CI	Baseline	End-line	%change	95% CI	Baseline	End-line	%change	95% CI
Uncertain or suspected ADEs	807 (78.0)	721 (87.3)	11.92	9-15	133 (12.9)	84 (10.2)	-20.93	-28--14	94 (9.1)	21 (2.5)	-72.53	-80--65
Certain negative ADEs	697 (67.4)	634 (76.7)	13.80	10-18	235 (22.7)	168 (20.3)	-10.57	-17--4	102 (9.9)	24 (2.9)	-70.71	-78--63
Serious reactions	797 (77.1)	756 (91.5)	18.68	16-21	143 (13.8)	57 (6.9)	-50.00	-57--43	94 (9.1)	13 (1.6)	-82.42	-90--75
Mild reactions	728 (70.4)	573 (69.4)	-1.42	-6-3	243 (23.5)	246 (29.8)	26.81	20-33	63 (6.1)	7 (0.9)	-85.25	-93--78
Reactions to drugs which have been on market for a long period	718 (69.4)	649 (78.6)	13.26	10-17	223 (21.6)	146 (17.7)	-18.06	-24--12	93 (9.0)	31 (3.7)	-58.89	-65--52
Reactions to newly introduced drugs	770 (74.5)	706 (85.5)	14.77	11-18	147 (14.2)	73(8.8)	-38.03	-46--31	117 (11.3)	47 (5.7)	-49.56	-57--42
Common or well-known reactions	639 (61.8)	483 (58.5)	-5.34	-10--1	285 (27.6)	315 (38.1)	38.04	32-44	110 (10.6)	28 (3.4)	-67.92	-75--61
Unexpected reactions	737 (71.3)	683 (82.7)	15.99	13-19	186 (18.0)	107 (12.9)	-28.33	-35--21	111 (10.7)	36 (4.4)	-58.88	-66--52
Possible interaction with other drugs	660 (63.8)	582 (70.5)	10.50	6-15	231 (22.3)	179 (21.7)	-2.69	-9-4	143 (13.8)	65 (7.9)	-42.75	-50--35
Reaction due to herbal medicine	573 (55.4)	520 (62.9)	13.54	9-18	370 (35.8)	279 (33.8)	-5.59	-11-0.00	91 (8.8)	27 (3.3)	-62.50	-70--55
Reactions due to herbal & conventional medicine taken together	643 (62.2)	616 (74.6)	19.94	16-24	301 (29.1)	179 (21.7)	-25.43	-31--19	90 (8.7)	31 (3.7)	-57.47	-64--51

283 ADEs = adverse drug events

284

285 **Best way to engage the community**

286 The radio was reported as the best way to deliver the messages sensitizing the community
287 members about ADE reporting among the respondents, whereas community meetings was
288 regarded the best by health providers as shown in figure 1. The health-worker and the health
289 facility was found to increasingly play a vital role of ADE sensitization among health workers
290 and respondents. Residents of the community across the board were happy with the community
291 dialogue meetings as a way of raising their awareness and as the best way to engage the
292 community on ADE matters.

293 *Fig 1: Comparison of options for reaching the community members with the ADE message*
294 *between the community respondents and health providers.*

295

296

297 **DISCUSSION**

298 Our results suggest that the community dialogues and sensitization intervention increases
299 knowledge, attitudes and reporting practices of adverse drug events across all demographic
300 parameters in the rural communities. The population that reported having ever experienced an
301 ADE more than doubled during the time of the CDS intervention. We also found that the
302 intervention was widely acceptable through the focus group discussions and community
303 meetings that we held. The local leaders were involved in mobilization and the local healthcare
304 providers strengthened the messages on health consciousness and ADE awareness by the
305 community. This study took advantage of the MUCHAP data collectors who were familiar
306 with the community as they routinely collected data for the IMHDSS household surveys. The
307 extent that such facilitated community meetings influence the quality of health care lies in the
308 social capital that they raise. They provide an opportunity for networking and critical practical
309 and emotional support, often leading to formulation of positive action plans and solidarity to

310 action them¹³. A number of community dialogues and similar interventions have been
311 implemented in similar settings but there is a paucity of data evaluating such interventions in
312 the published literature. In line with results from our study, published evaluation data show
313 positive effects of similar community-level interventions to improve awareness and attitude
314 change regarding health issues¹³⁻¹⁵.

315

316 The results of this study indicated that, while the public is inclined to acquire information about
317 ADEs and realize the benefits of reporting ADEs, their understanding of their essential role in
318 reporting ADEs was insufficient. To increase awareness about ADEs, health workers reported
319 that community meetings was the best method of raising their awareness and as the best way
320 to engage the community on ADE matters while consumers suggested media campaigns on
321 radios as the best way to deliver the messages sensitizing the community members about ADE
322 reporting. One of the underlying assumption of the CDS intervention model was that individual
323 exposure to the concept of monitoring and reporting ADEs would affect cognitions that
324 continue to affect the behaviour of actual reporting of the events over a short term. Other
325 studies have also reported the importance of media in raising community awareness and
326 increase the likelihood of achieving new behaviour^{15, 16}. This indicates that a combination of
327 community dialogues and use of media campaigns on radios to sensitize people could increase
328 reporting of ADEs in line with suggestions from other studies¹⁵⁻¹⁸. The present study
329 demonstrated that the effect of CDS interventions would help improve ADE reporting.
330 However, community interventions are time bound and hence continuous public educational
331 programs on pharmacovigilance are essential to enhance reporting in the end. The long-term
332 effect of especially the sensitization part of the model may operate through social and
333 institutional pathways in addition to the individual learning that will require sustained levels
334 of exposure through multiple channels over longer periods. Such effects tend to accumulate

335 detectable change on certain sections of the audience over time and therefore should be
336 assessed over time for a complete picture.

337

338 We found a significant improvement in attitudes of respondents towards reporting of ADEs.
339 For example, in regard to whether it was necessary to report the adverse drug effects, there was
340 an overall increase of 5% (95%CI =3-7%) after the implementation of the CDS intervention.
341 There was an increase in the population who would consider reporting serious reactions,
342 reactions to newly introduced drugs, unexpected reactions and reactions due to herbal and
343 conventional medicines taken together. This showed that more than 15% of this community
344 gained information about the negative effects of drugs in the short time of study. Similar results
345 were found by other studies assessing educational interventions to improve attitudes of
346 healthcare professionals and the adverse drug reaction-reporting rate in return^{19, 20}.

347

348 Health providers and consumers' willingness to report was reflected by an increase in the
349 number of ADE reports submitted after the intervention. In regard to reporting practices, there
350 was a change in respondents' willingness to report serious reactions, reactions to newly
351 introduced drugs, unexpected reactions and reactions due to herbal and conventional medicines
352 taken together after the CDS intervention. The increase in willingness of health providers to
353 report ADEs after community intervention was also reported by other studies²¹⁻²³. However,
354 the actual reporting could not be measured immediately since it's an impact measure and
355 therefore could not be ascertained immediately after the CDS intervention. The study results
356 are still very informative for a policy on patient ADE reporting.

357

358 In Uganda, patients and consumers report adverse drug events either indirectly through their
359 healthcare provider or directly through the newly established online reporting system²⁴. In the

360 rural setting, the capacity of patients to report was assessed by a proxy variable seeking to find
361 out if the respondents had ever experienced or reported an ADE both before and after the CDS
362 intervention. The 115% (95%CI =137-217) increase in recognition and reporting the ADE to
363 the researchers is evidence that a separate system needs to be established for direct patient or
364 consumer reporting. The launch of this system should be accompanied by a lot of sensitization
365 delivered through multiple channels and with reporting tools that are tailored to the level of
366 literacy and understanding of the rural community. There was no resistance to the intervention
367 both at the community level and among the health workers. The increased reporting rate from
368 this study and the wide acceptability of the CDS intervention in these two districts are
369 ingredients for success of such a model of patient ADE reporting that can possibly be replicated
370 in other limited resource settings. However, this successful implementation of the intervention
371 in the study area could be because the respondents are used to research activities in the health
372 demographic surveillance site and makes it hard to decline it. This means that, for a successful
373 implementation of the same intervention in other settings, there is need for vigorous
374 sensitization to prepare the communities and increase awareness.

375

376 Despite the initial increase of respondents' and healthcare providers' knowledge and attitudes
377 towards ADE reporting following the CDS intervention, the influence of this intervention on
378 the practice of ADEs reporting was not studied, which presents a major limitation in this study.
379 The effect of the CDS intervention that was studied shortly after implementation, may not
380 reflect the actual effect in the long term. Additionally, this study was conducted among
381 healthcare providers and consumers from the rural settings from one region. Hence, the results
382 of this study may be cautiously generalizable to rural settings in other regions.

383

384 The baseline and end-line surveys had limitations as to the CDS intervention model's
385 contribution to the changes in knowledge, perceptions and practice of patient ADE reporting
386 given that randomly selected participants (before and after CDS) may, or may not have been
387 beneficiaries of the project. There are also limits of the extent to which we can track direct
388 changes to knowledge, practice and attitudes at an individual level given we did not track the
389 same individuals throughout the life of the project.

390

391 There was no balance in samples selected at the baseline and at the end line surveys. This
392 brought about overlap in frequencies and percentages by some demographic characteristics,
393 for example in the gender and occupation variables. This could best be avoided by using exactly
394 the same individuals before and after the intervention.

395

396 **CONCLUSION**

397 In conclusion, the results of the current study showed that community dialogues and
398 sensitization as a community intervention can increase knowledge, attitude and practices for
399 reporting of ADEs, and that the respondents were able to apply the knowledge they gained
400 from dialogues into their everyday life leading to increased reporting. Following the CDS
401 intervention, the knowledge and attitude toward the ADE reporting seem to have improved.
402 Hence, to improve ADE reporting among health-care professionals, there is a need to conduct
403 periodic workshops and continued medical education frequently to sensitize them.

404

405 Despite having some fair knowledge that medicines have a potential to cause harm, the
406 community shows signs of willingness to report the occurrence of adverse events through the
407 preferred community channels, as well as to their healthcare providers. Some community
408 members have experienced and reported ADEs to their healthcare providers. Further studies

409 may be necessary to evaluate the impact of community interventions in the long-term effect
410 after implementing the intervention. In its current state, the CDS intervention model is highly
411 beneficial and can be adapted for consumer reporting in limited resource settings.

412

413 **DECLARATIONS**

414 **Ethics approval and consent to participate**

415 The study protocol was approved by the Mildmay Uganda research and ethics committee

416 (REC REF 0604-2017) and Uganda National council of Science and Technology (HS 2247),

417 the institution responsible for national research clearance in accordance with the World

418 Medical Association Helsinki Declaration. Permission to conduct the study in the area was

419 also obtained from NDA, the local administration of Iganga and Mayuge Districts, IMHDSS

420 and MUCHAP. Written informed consent was obtained from the participants

421 **Consent for publication**

422 Not applicable

423

424 **Availability of data and material**

425 The datasets generated and analyzed during the current study are not publicly available but

426 are available from the corresponding author on reasonable request.

427

428 **Author's Contribution**

429 HBN and DK designed the study. DAK made substantial contributions to conception,

430 design of the study and acquisition of the data. LM, DK and HBN analysed and

431 interpreted the data. LM was a major contributor in writing the manuscript. SO, AS and NS

432 made substantial contributions during the review of the manuscript. All authors read and

433 approved the final manuscript.

434

435

436 **Competing interests**

437 Helen Byomire Ndagije, Leonard Manirakiza, Dan Kajungu, Edward Galiwango, Donna
438 Asiimwe Kusemererwa, Sten Olsson, Anne Spinewine, Niko Speybroeck have no conflicts of
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542

543

544

545 ***Additional Files***

546

547 Additional file # 1: Household survey questionnaire.doc

548 Title of data:

549 Knowledge Attitudes and Practice (KAP) study on adverse drug reactions – Household
550 questionnaire

551

552 Description of data

553 This was the questionnaire used to collect data about the households involved in the baseline
554 and end-line surveys conducted before and after implementation of the community dialogues
555 and sensitization.

556

557 Additional file # 2: Healthcare provider survey questionnaire.doc

558

559 Title of data:

560 Knowledge Attitudes and Practice (KAP) study on adverse drug reactions – Provider

561 questionnaire

562

563 Description of data

564 This questionnaire was used to collect data about the healthcare providers in the community-

565 based health facilities involved in the baseline and end-line surveys. At least two healthcare

566 workers from each health facility were randomly-selected.

