1   **Supplementary File One**

2   **Sample size calculation**

3

4    $$N = \frac{Z^2 \; P \; (1-P)}{d^2} \quad (1)$$

5

6   N = sample size

7   D = 0.05 (level of accuracy)

8   Z = 1.96 (critical value of specified confidence interval)

9   P = Expected proportion of caregivers of 3–5-year-old children with correct practice on
10   reconstitution of oral antibiotic suspension. A study conducted in Palestine revealed that
11   knowledge on preparation and storage of antibiotic suspensions for paediatrics was around 75 per
12   cent (2). A similar study conducted in Taiwan among paediatric caregivers revealed good
13   knowledge ranging from 46 per cent to 98 per cent depending on the specific aspect of preparation
14   (3). Similar findings were exhibited in a few studies conducted in India with knowledge on
15   preparation, storage and disposal ranging from 50 per cent to 90 per cent. However, Indian studies
16   were mainly focused on adult medications with few questions on accessibility by children (4-6).
17   However, no studies were done to specifically assess the knowledge on preparation, storage and
18   disposal of oral paediatric medicinal drugs of caregivers. Thus, it was decided to use 50 per cent
19   as P.

20   In primary caregivers of 3-5 year old children, correct practice on reconstitution of paediatric oral
21   antibiotic medications were taken as P_p= 50 per cent, P_s= 50 per cent and P_d= 50 per cent,
22   respectively.

23

24   $$N = \frac{1.96^2 \times 0.50 \times (1-0.50)}{0.05^2}$$

25

26   N= 384.16 ≈ 385 primary caregivers of 3–5-year-old children

27

28 **Definition of a cluster**

29 A cluster was defined as a single clinic session of a Child Welfare Clinic (CWC) geographically

30 located within boundaries of Ratnapura district.

31

32 Rationale behind the decision for selecting a clinic session rather than a Child Welfare clinic was

33 that each clinic session would consists of non-repetitive study units. As care givers of 3-5 years

34 old children was attending Child Welfare clinics for the 3 years MMR (Measles Mumps and

35 Rubella) vaccination and 5-year OPV (Oral Polio vaccine) & DT (Diphtheria and Tetanus)

36 vaccination, there would not be a repetition or overlapping of study units. The cluster was based

37 on vaccination session of a given clinic center and not on geographical area which the clinic center

38 was situated.

39

40 On rare occasions, children might be referred to CWC sessions to be assessed by the Medical

41 Officer of Health regarding their nutrition status including children aged 3 to 5 years though

42 Family Health Bureau have instructed to conduct a separate Nutrition clinic for such children. In

43 such instances, they too were included in the study provided that they did not attended a CWC for

44 3 years vaccination during the period of data collection.

45

46 As cluster sampling method was used in this study, correction to the homogeneity within the cluster

47 was added (7).

48 N= Design effect x n

49 Design effect = $1 + \delta(\beta - 1)$

50 β= cluster size; taken as 10 (as expected average number of caregivers of 3–5-year-old

51 children attending a single child welfare session in Ratnapura District was between 10-

52 15, the cluster size was decided as 10)

53

54 δ = rho; in the absence of previous studies, as mentioned by the Bennett and others estimated value

55 of rho was taken as 0.1 (8). The study population was caregivers of 3-5-year-old   children. In a

56 given cluster, families of different socio-economic and cultural backgrounds reside. Hence, there

57 was adequate heterogeneity within clusters that justifies the use of 0.1 as the rho.

58

59

60   Design effect = 1+ 0.1 (10-1) =1.9

61   Therefore, the required sample size= 384.16 x 1.9 = 729.9

62   ≈ 730 primary caregivers of 3–5-year-old children

63

64   After adding 10% for non-response,

65   730 /0.9 = 812

66

67   **Sample size was also calculated to accommodate potential associated factors.**

68

69   **Table S1- Prevalence of Poor Health Literacy According to Identified Associated Factors**

70   **among School Teachers in 2017, Colombo District**

Identified condition / associated factor	P1	P2	OR	Sample size
Age above 45	27.3%	36.7%	1.6	
Good knowledge on health	26.4%	35.7%	1.5	502
Mass media mode as printed media (newspaper, magazines) accessed to obtain health related information	28.7%	40.7%	1.7	

71

72   Above sample in Table one, consisted of schoolteachers in Colombo District of Sri Lanka.

73   Therefore, limited/ poor health literacy among general population in Ratnapura District most

74   probably should be more than the percentages reported as in Table 3.7. Therefore, the P1, limited

75   or poor health literacy among the population with the condition or positive for the associated factor

76   was taken as 35 per cent. P2, limited or poor health literacy among the population without the

77   condition or negative for the associated factor was taken as 45 per cent (9).

$$N = \frac{[z_\alpha \sqrt{P(1-P)(1/q_1 + 1/q_2)} + z_\beta \sqrt{P_1(1-P_1)(1/q_1) + P_2(1-P_2)(1/q_2)}]^2}{(P_1 - P_2)^2}$$

78   (10)

79   P1= 35 per cent

80   P2= 45 per cent

81 Z_α = Confidence level -95% - 1.96

82 Z_B =Power of 0.8- 0.84

83 q1= proportion of subjects in group 1- 0.5

84 q2= proportion of subjects in group 2- 0.5

85 P= q1P1 + q2P2

86 N=750.283

87 N=751

88

89 The required total sample size =751; 10% non-response rate= 835

90

91 Therefore, the final sample size was taken as 835.

92

93 Sample was selected from 10 Medical Officer of Health areas (out of 19 MOH areas) in Ratnapura

94 District. As stated above the cluster size was decided as 10.

95

96 The data collection was carried out during the period of 4 months. Usually, 3- to 5-year-old

97 children attend the CWCs to receive vaccination at 3 years (MMR) and 5 years (OPV and DT

98 booster) according to the Expanded Programme of Immunization, Sri Lanka. And their growth

99 monitoring programme is conducted in weighting centres and not in CWCs. Therefore, a child

100 aged 3 to 5 years attending CWCs multiple times in a span of 4 months was highly unlikely. Thus,

101 selecting the clinic session instead of clinic centre is justifiable. Usually, clinic sessions in a given

102 clinic centre was held once a fortnight. However, in some clinic centres sessions are held weekly

103 and in others, centres, once a month.

104

105 Number of clusters needed, 835/10 – 84

106 ***The approximate number of clusters available during a single selected month (No. of CWC***

107 ***sessions)***

108

109 Number of clinic centres which cater 3–5-year-old children in Ratnapura District - 273

110 Number of clinic centres which conduct clinics for 3–5-year-old children four times a month - 19

111 Number of clinic centres which conduct clinics for 3-5 year -old children twice a month - 155

112   Number of clinic centres which conduct clinics for 3–5-year-old children once a month - 89

113

114   **Total number of clinic sessions which cater to 3- 5-year-old children in Ratnapura District**

115   **(per month)- (19×4) + (155 × 2) + 89 = 475 per month**

116

117   Number of clinic sessions for 3 -5 year old children during the period of data collection (4 months)

118   in Ratnapura District- (475×4) = 1900

119

120   As we selected only 10 Medical Officer of Health (MOH) areas out of a possible 19 MOH areas,

121   on average, the estimated clinic sessions for the selected MOH areas for the period of data

122   collection (273×4) = 1092 sessions

123   However, there was the risk of clinic attendance of 3–5-year-old children of less than 10 per

124   session. Therefore additional 10 per cent clusters (9 clusters) were randomly selected as back-up

125   if the desired number was not fulfilled by the initial 84 clusters during the planning stage (total of

126   93 clinic sessions form 950 clinic sessions).

127

128   **Sampling frame**

129   A list of all CWCs in Ratnapura District was obtained from the Regional Director of Health

130   Services Office. Number of total clusters in the study population would depend on number of clinic

131   sessions per each Child Welfare clinic during the period of data collection which was first 4 months

132   of the year 2021 (January to April).

133

134   **Sampling technique**

135   Two stage cluster sampling method was used.

136

137   No of clusters required= 84

138   However, due to low attendance of children due to the COVID 19 situation in Ratnapura District,

139   in some MOH areas up-to 10 additional clusters were selected randomly (Final number of clusters-

140   128) (In some days, Ratnapura reported the highest number of daily cases out of all districts in Sri

141   Lanka). (Tables S2 & S3).

142

143

144

First stage

A list of all MOH areas was prepared. Each MOH area in the list was coded. The list was scrambled, and 10 MOH areas were randomly selected from the list with MS Excel.

1. Ratnapura MC
2. Weligepola
3. Udawalawe (Embilipitiya North)
4. Kuruwita
5. Kiriella
6. Pelmadulla
7. Nivithigala
8. Elapatha
9. Godakawela
10. Kahawatta

Second stage

Number of clusters per each selected Medical Officer of Health (MOH) area was determined by the proportion of 3-to-5-year-old children estimated to be in each selected MOH area for the year 2020 using probability proportionate sampling. A list containing number of 3-to-5-year-old children under care, per each selected MOH area for the year 2020 was created for this purpose. Above list was prepared by data obtained from Medical Officer of Maternal & Child Heath, Ratnapura. Following the allocation of number of clusters per each MOH area, selection of clusters within each MOH area was carried out by simple random sampling technique. In each cluster, first ten caregivers that were registered by Public Health Midwives in Clinic Register who meet eligibility criteria was selected for the study.

169

170

171

172

173

174 *Table S2- Sample Size Allocated to Each MOH Area in Ratnapura District*

	MOH area	3-5yr Children Under Care	Number Planned to Select from each MOH	Number Selected from each MOH
1	Elapatha	1482	51	56
2	Embilipitiya North (Udawalawe)	2629	89	81
3	Godakawela	3469	118	118
4	Kahawatta	2012	69	85*
5	Kiriella	1278	43	41
6	Kuruwita	4105	140	159*
7	Nivithigala	2313	79	62*
8	Pelmadulla	3551	121	89*
9	Ratnapura MC	2239	77	90*
10	Weligepola	1420	48	39
	Total	**24498**	**835**	**820**

175 *Due to the COVID 19 pandemic and the lack of human resources (no permanent MOH) and logistic issues, the
176 desired number of respondents were not recruited from Pelmadulla and Nivithigala MOH areas. Therefore, to
177 compensate for the reduced number, a slightly higher number of respondents were recruited from three adjacent MOH
178 areas, namely Ratnapura MC, Kuruwita and Kahawatta.

179

180

181

182

183

184

185

186

187

188

189

190   *Table S3- Number of Clusters Selected in Each MOH Area in Ratnapura District*

191

	MOH area	Number of Clinic Sessions Clusters Initially Recruited	Number of Clusters Selected from each MOH
1	Elapatha	6	12
2	Embilipitiya North (Udawalawe)	9	15
3	Godakawela	12	18
4	Kahawatta	7	9
5	Kiriella	5	8
6	Kuruwita	14	25
7	Nivithigala	8	8
8	Pelmadulla	13	16
9	Ratnapura MC	8	11
10	Weligepola	5	6
	Total	**87**	**128**

192

193   **References**

194   1.   Lwanga SK, Lemeshow S. Sample Size Determination in Health Studies; A Practical
195   Manual. Geneva: World Health Organization; 1991.
196   2.   Al-Ramahi RJ, Zaid AAN, Anabousi H. Problems associated with reconstitution,
197   administration, and storage of antibiotic suspensions for pediatrics: a cross-sectional study in
198   Nablus city, Palestine. BMC Research Notes. 2015;8(1).
199   3.   Hu H, Wu F-LL, Hu F-C, Yang H-Y, Lin S-W, Shen L-J. Effectiveness of Education
200   Programs About Oral Antibiotic Suspensions in Pediatric Outpatient Services. Pediatrics &
201   Neonatology. 2013;54(1):34-42.
202   4.   Sivasankaran P, Mohammed EB, Ganesan N, Durai R. Storage and Safe Disposal of
203   Unwanted/Unused and Expired Medicines: A Descriptive Cross-Sectional Survey among Indian
204   Rural Population. Journal of Young Pharmacists. 2018;11(1):97-100.
205   5.   Sil A, Sengupta C, Das AK, Sil PD, Datta S, Hazra A. A study of knowledge, attitude and
206   practice regarding administration of pediatric dosage forms and allied health literacy of
207   caregivers for children. Journal of Family Medicine and Primary Care. 2017;6(3):636-42.
208   6.   Patel DP, Sneha C, Bhatt SP, S. DS. Storage and Disposal of Medicines In Home Among
209   Students. Journal of Pharmacy Research. 2016;10(6):343-50.
210   7.   Abramson J, Abramson ZH. Research methods in community medicine : surveys,
211   epidemiological research, programme evaluation, clinical trials. 6 ed. New York: Wiley; 2008.

212   8.   Bennett S, Woods T, Liyanage WM, Smith DL. A Simplified general method for cluster-
213   sample surveys of health in developing countries. World Health Statistics Quarterly.
214   1991;44(3):98-106.
215   9.   Denuwara HMBH, Gunawardena NS. Level of health literacy and factors associated with
216   it among school teachers in an education zone in Colombo, Sri Lanka. BMC Public Health.
217   2017;17(1).
218   10.   Hulley SB, Cummins SR, Browner WS, Grady DG, Newman TB. Designing Clinical
219   Research. 3 ed: Lippincott Williams & Wilkins; 2007.

220