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Opportunities and barriers in paediatric pulse oximetry for pneumonia in low-resource clinical settings: a qualitative evaluation from Malawi and Bangladesh

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Complete List of Authors:	King, C.; University College London Institute for Global Health, Boyd, Nicholas; Great Ormond Street Hospital For Children NHS Trust, UCL Institute of Child Health Walker, Isabeau; Great Ormond Street Hospital For Children NHS Trust, UCL Institute of Child Health Zadutsa, Beatiwel; Parent and Child Health Initiative Baqui, Abdullah; Johns Hopkins University Bloomberg School of Public Health, International Center for Maternal and Newborn Health Ahmed, Salahuddin; Johns Hopkins University Bloomberg School of Public Health, International Center for Maternal and Newborn Health Islam, Mazharul; Shahjalal University of Science and Technology, Department of Anthropology Kainja, Esther; Parent and Child Health Initiative Nambiar, Bejoy; Institute for Global Health Wilson, Iain; Lifebox Foundation McCollum, Eric ; Johns Hopkins School of Medicine, Eudowood Division of Paediatric Respiratory Diseases; Johns Hopkins University Bloomberg School of Public Health, Department of International Health
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	1	Title: Opportunities and barriers in paediatric pulse oximetry for pneumonia in low-resource clinical
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	4	Authors: Carina King ^{1*} , Nicholas Boyd ² , Isabeau Walker ² , Beatiwel Zadutsa ³ , Abdullah H. Baqui ⁴ ,
	5	Salahuddin Ahmed ⁴ , Mazharul Islam ⁵ , Esther Kainja ³ , Bejoy Nambiar ¹ , Iain Wilson ⁶ , Eric D.
	6	McCollum ^{7,8}
	7	
	8	Affiliations:
	9	1. Institute for Global Health, University College London, London, UK
	10	2. Great Ormond Street Hospital NHS Foundation Trust, UCL Institute of Child Health, London,
	11	UK
:	12	3. Parent and Child Health Initiative, Lilongwe, Malawi
:	13	4. International Center for Maternal and Newborn Health, Johns Hopkins Bloomberg School of
	14	Public Health, Baltimore, USA
:	15	5. Department of Anthropology, Shahjalal University of Science and Technology, Sylhet,
:	16	Bangladesh
:	17	6. Lifebox Foundation, London, UK
:	18	7. Eudowood Division of Pediatric Respiratory Diseases, Johns Hopkins School of Medicine,
:	19	Baltimore, USA
:	20	8. Department of International Health, Johns Hopkins Bloomberg School of Public Health,
:	21	Baltimore, USA
:	22	
:	23	*Corresponding author:
:	24	Address: Institute for Global Health, 30 Guilford Street, London, WC1N 1EH; Email: c.king@ucl.ac.uk;
:	25	telephone: +44 (0) 2076797619
:	26	
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30 Abstract

Objective: To gain an understanding of what challenges pulse oximetry for paediatric pneumonia

32 management poses, how it has changed service provision and what would improve this device for

33 use across paediatric clinical settings in low-income countries.

Design: Focus group discussions (FGDs), with purposive sampling and thematic analysis using a
 framework approach.

Setting: Community, front line outpatient and hospital outpatient and inpatient settings in Malawi
 and Bangladesh, which provide paediatric pneumonia care.

38 Participants: Healthcare providers (HCPs) from Malawi and Bangladesh who had received training in

39 pulse oximetry and had been using oximeters in routine paediatric care, including community

40 healthcare workers, non-physician clinicians or medical assistants, and hospital-based nurses and
41 doctors.

Results: We conducted six FGDs, with 23 participants from Bangladesh and 26 from Malawi. We identified five emergent themes: trust; value; user-related experience; sustainability and design. HCPs discussed the confidence gained through using oximeters, resulting in improved trust from caregivers and valuing the device; although there were conflicts between the weight given to clinical judgement versus oximeter results. HCPs reported the ease of using oximeters, but identified movement and physically smaller children as measurement challenges. Challenges in sustainability related to battery durability and replacement parts, however many HCPs had used the same device longer than four years demonstrating robustness within these settings. Desirable features included back-up power banks and integrated respiratory rate and thermometer capability.

Conclusions: Pulse oximetry was generally deemed valuable by HCPs for use as a spot-check device

52 in a range of paediatric low-income clinical settings. Areas highlighted as challenges by HCPs, and

53 therefore opportunities for re-design, included battery charging and durability, probe fit and

54 sensitivity in paediatric populations.

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3 4	55	Strengths and Limitations
5 6	56	• This is the first study to report on end-user perceptions of opportunities, challenges and
7	57	desirable design features of pulse oximeters used for paediatric pneumonia management in
8 9	58	low-resource settings, including community and outpatient providers.
10	59	• Pulse oximeters were valued by healthcare providers, but challenges were highlighted with
11 12	60	use in smaller and moving children. Desirable features to improve pulse oximeters for low-
13 14	61	resource paediatric settings included improved battery life, integrated respiratory rate and
15	62	temperature, and quicker results.
16 17	63	• A key strength was the wide range of healthcare provider perspectives included, from
18	64	community to referral hospital settings in South Asia and sub-Saharan Africa.
19 20	65	• The study was limited to participant's experience of using specific pulse oximeters and
21 22	66	
23	67	settings.
24 25	68	
26 27		therefore may lack generalizability to other paediatric pulse oximeters not used in these settings.
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69 Introduction

Several interventions, such as Pneumococcal conjugate vaccine (PCV) and standardised guidelines for diagnosis and treatment, have led to reductions in pneumonia morbidity and mortality over the last twenty years ¹². However, in spite of these gains, pneumonia remains the leading cause of infectious mortality amongst children globally, with the vast majority of the burden falling in sub-Saharan Africa and south Asia ³. To accelerate reductions in pneumonia mortality, further refinement of diagnosis and treatment pathways are needed, including correct referral and access to oxygen treatment ⁴.

Pulse oximetry non-invasively measures peripheral arterial oxyhemoglobin saturation (SpO_2) . Hypoxemia (defined as an $SpO_2 < 90\%$) is included in the World Health Organization (WHO) guidelines as a pneumonia danger sign ⁵, and is associated with increased mortality from pneumonia, as well as other illnesses like malaria ⁶⁻⁸. Recent evidence from Malawi has also indicated that a $SpO_2 90-92\%$ is predictive of mortality amongst children hospitalized with pneumonia ⁸.

While some studies have attempted to predict hypoxemia in children with pneumonia using a combination of clinical signs, there has been mixed success ⁹⁻¹¹. Clinical signs alone fail to identify a proportion of hypoxemic children based on the current WHO guidelines, which results in a missed opportunity for referral and appropriate treatment ^{12 13}. In addition, the subjectivity of clinical signs can lead to variation in care – especially among community healthcare workers (CHWs), who often lack ongoing supervision.

Pulse oximeters have been successfully used in low-resource paediatric settings, but are yet to be
widely adopted, particularly during outpatient care ^{14 15}. The Ethiopian Ministry of Health has
demonstrated leadership in this area, setting up an initiative in 2016 to ensure oximetry and oxygen

- si demonstrated leddership in this dread setting up an initiative in 2010 to ensure shined y and skyger
- 92 therapy are available nationally across the healthcare system ¹⁶. However, Ethiopia is an exception,
- 93 with implementation of oximetry in other developing countries continuing to be slow.

94 Implementation barriers cited include cost, lack of appropriately designed, robust oximeters and

95 universal paediatric probes and issues with training and supervision ¹⁷.

In order to better understand current barriers to use of pulse oximetry by healthcare providers
(HCPs) in a range of healthcare settings, and explore opportunities that this technology provides,
input from end-users is needed ¹⁸. With the ultimate goal of designing a universal paediatric probe
for all levels of healthcare services in resource-poor settings, we aimed to gain an understanding of
the challenges of pulse oximetry, how its use has changed service provision and how current devices

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101	could be improved for these settings. This end-user perspective is currently limited in the literature
102	and is essential to ensure investment in pulse oximetry is sustainable and effective.

104 Methods

We conducted a qualitative study with HCPs from different levels of the healthcare system in Malawi
 (Mchinji district, central region) and Bangladesh (Sylhet district, northeast region) from May – July
 2016, as part of a wider programme of work aiming to design a universal paediatric oximeter probe.

108 <u>Setting:</u>

In Malawi there are three levels of government provided healthcare: CHWs (locally known as Health Surveillance Assistants), health centres and district hospitals. CHWs conduct weekly or bi-weekly village clinics and home visits providing basic integrated community case management (iCCM) for paediatric infections¹⁹²⁰. Health centres are outpatient facilities run by nurses, clinical officers or medical assistants, and District Hospitals have inpatient facilities with capacity for oxygen treatment. In Bangladesh, the study was conducted at Projahnmo, a research consortium comprised of Johns Hopkins University and several local non-governmental organizations in partnership with the Bangladesh Ministry of Family Health and Welfare. Current Projahnmo activities are integrated within three government-operated sub-district hospitals, called Upazila Health Complexes (UHCs), and the referral government hospital in Sylhet city (Osmani Medical College), all of which are staffed by physicians and nurses. The UHCs operate outpatient clinics for children under five and provide basic inpatient paediatric care, including oxygen. The majority of government provided inpatient care is provided at Osmani Medical College. Female CHWs employed by Projahnmo conduct bimonthly household surveillance, with a subset of CHWs providing weekly surveillance as a part of a PCV effectiveness study. Projahnmo CHWs conduct basic clinical assessments and refer ill children for care at the UHCs; they do not administer medicines themselves.

Currently pulse oximetry is not part of standard care in the community or health centre setting in
either Malawi or Bangladesh. In Mchinji, pulse oximetry was successfully introduced into all three
healthcare settings in 2012 as part of a PCV research project, using the Acare Technology AH-MX
manufactured Lifebox[®] oximeter and universal adult clip probe¹². Since 2015, a National Institutes of
Health-funded study (K01TW009988) trained and supplied all Projahnmo clinical staff in Bangladesh,
including CHWs, with pulse oximeters to screen children for hypoxemia, using the Masimo Rad5[®]
oximeter and the LNCS[®] Y-I Multisite wrap probe (Figure 1).

132 Design:

 We conducted focus group discussions (FGDs). We planned three FGDs in each country, aiming to recruit between 6 and 10 people for each FGD (up to 60 participants in total). The groups were planned to be CHWs, health centre or UHC staff, and referral hospital staff separately. Conducting separate FGDs for the different types of healthcare workers was to allow context-specific discussions and encourage participants with varying training backgrounds to feel confident about raising challenges relevant to their specific setting.

139 Sampling:

HCPs were purposefully sampled from sites where pulse oximetry had been introduced, and the
participants had received some form of training or mentorship in oximetry. Participants were
identified by local researchers (BZ in Malawi and SA in Bangladesh) to be a representative sample of
HCPs from their setting (e.g. small and large health centres, inpatient wards and outpatient
departments in the hospital), and contacted directly by phone. All HCPs contacted participated.
Participants were reimbursed for their travel costs and provided with refreshments.

146 <u>Procedure:</u>

FGDs were led by local researchers with experience in conducting qualitative research, with support from a facilitator with knowledge of pulse oximeters. The FGDs were divided into two sections, the first addressing the participants' personal experience with using pulse oximeters. The topic guide included: positive and negative experiences, and possible improvements and challenges (Web appendix 1). During the second part of the discussion, the participants were presented with different probe designs and given an opportunity to use them for an hour. Following this, the discussion addressed positive and negative aspects of the different designs to encourage critical thinking of possible design solutions to the current limitations of a universal paediatric probe.

The FGDs were audio recorded and then transcribed. The participants were told to answer in English
or their native tongue (Chichewa, Bangla or Sylheti), depending on their preference and ease of
expressing concepts. Recordings were transcribed and translated where necessary. Translations for
Malawi were done by BZ and EK together until final transcripts were agreed, and by an independent
professional service for Bangladesh.

160 <u>Analysis:</u>

We analysed the data thematically using a framework approach, as an appropriate method for a
multi-disciplinary team conducting health research ²¹. This process involves five steps:

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163 familiarisation, identifying a thematic framework, indexing, mapping and interpretation ²². The 164 transcripts and notes from the FGDs were printed and coded on paper, with the coding matrix 165 created in Microsoft Excel. CK and KF independently familiarised themselves and indexed the data, 166 and the emergent themes were discussed until a consensus was reached on the mapping and 167 interpretation of the data. This interpretation was shared with the local researchers (BZ and EK in 168 Malawi; EDM and MI in Bangladesh) for further discussion until all were in agreement.

169 <u>Ethics:</u>

Written informed consent was obtained from all FGD participants. This study was reviewed and
approved by the University College London research ethics committee (8075/003), Johns Hopkins
Medicine Institutional Review Board (IRB00047406), the Malawi National Health Sciences Research
Committee (16/4/1570) and Bangladesh Medical Research Council (BMRC/NREC/2013-2016/1272).

175 Results

We conducted six FGDs, with 23 participants from Bangladesh and 26 from Malawi (Table 1). We
identified five emergent themes: trust; value; user-related experience; sustainability and design.

178 <u>Trust</u>

Trust emerged as a theme both in terms of how the HCPs interpret the oximetry results, and how
caregivers interact with HCPs and the pulse oximeter. We found that all cadres of HCPs in both sites
had an awareness of the fallibility of the oximetry readings, specifically relating to lower SpO₂ values.
For SpO₂ levels which were deemed abnormal, <90% up to <95% according to different participants,
HCPs stated that they would often re-check the result before making a referral or treatment
decision:

"if we see it is 89% we change the probe or change the finger" (Hospital, Bangladesh)

However, questioning the validity of these lower SpO₂ results in the context of a child's clinical
condition was only discussed by the HCPs who worked in the hospital setting. This difference in the
trust placed in the SpO₂ results by different types of HCPs suggests that more in-depth clinical
training and understanding of the technology may result in different clinical applications:

"sometimes the pulse oximeter can give readings which you are not comfortable with according to

191 the presentation of the child [...] most of the time when it happens like that, we just use our

192 judgement" (Hospital, Malawi)

An outcome of using pulse oximeters for pneumonia diagnosis was a change in parental and community understanding and perceptions of care, with HCPs discussing increased trust in their referral and treatment decisions. This worked in two ways, firstly with the oximeter acting as a direct feedback and education tool: "if the mother is able to read you can show the exact figure and she will accept the treatment of oxygen, [before] it was very difficult to explain the role or the importance of the oxygen machine and some mothers refused" (Hospital, Malawi) Secondly, in Malawi HCPs projected that the oximeters had improved clinical care, and therefore outcomes, which led caregivers to be more inclined to accept the referral or treatment being recommended, especially in the case of oxygen: "[previously] in the village they were saying that when a child is put on the oxygen machine it facilitates death, therefore it was making problems, but this time because children are put on oxygen earlier they survive, it's because we knew the saturation" (Health centre, Malawi) Value The theme of value relates to the inherent value of improved decision making, HCPs perceived self-value (i.e. confidence) in their clinical work, and the physical value placed on maintaining a working pulse oximeter. As pneumonia is classified using a range of non-specific and often subjective clinical signs, HCPs discussed the positive addition of this more objective measure: "...by looking at this we can understand how much respiratory distress is in there. Of course this helps us a lot." (Health Centre, Bangladesh) In both sites HCPs from frontline settings (CHWs, health centres and UHCs) stated that the pulse oximeters had changed the way they work and given them confidence in making referral decisions. Interestingly however, in the referral hospital setting in Bangladesh where staff training is higher, very little value was placed on the pulse oximeter for improving their clinical performance, with the ability to conduct chest x-rays, lung ultra-sound and their clinical judgement valued more highly:

218 "...its sensitivity and specificity is very negligible to be taken as a diagnostic tool." (Hospital,

219 Bangladesh)

- 220 In Bangladesh the CHWs reported pride in using the oximeters. In Malawi, the CHWs (who
- 221 individually own the oximeters) placed a physical value on the oximeters and discussed the personal
- 222 effort, such as paying out of pocket for charging, they put in to maintaining a working device:

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2 3	223	we have been trying all that is humanly possible to take care of these things, but it only becomes a
4 5 6	224	problem when it comes to the issue of charging." (CHW, Malawi)
7	225	This was also reflected at the health centre, where not all facilities have electricity and one or two
8 9	226	staff are responsible for assessing children; at the referral hospital however this was not discussed,
10	227	with oximeters belonging to the ward, which has a more consistent power supply. Ward-based
11 12	228	ownership was discussed as a challenge by hospital staff, suggesting individual ownership could
13 14 15	229	result in improved care and maintenance.
16	230	"some of the clinicians do not take care of them, so when the machine is not working it means the
17 18 19	231	whole department is affected" (Hospital, Malawi)
20 21	232	User-related experience
22 23	233	HCPs at all levels discussed their experiences of using pulse oximeters in children under 5-years,
24 25	234	presenting challenges, their solutions and perceptions of usability. The time taken to get a
25 26	235	measurement ranged widely, with CHWs in Bangladesh agreeing measurements took less than 1
27 28	236	minute but in Malawi that it could take up to 20 minutes. The factors that increased the time taken
29	237	to get a measurement were consistently cited as movement and physically smaller children, and in
30 31 32	238	Malawi dirty toes making measurements difficult:
33 34	239	"Getting readings from irritable babies is a bit tough and it takes time." (Health centre, Bangladesh)
35 36	240	"using it on a child up to six months of age, sometimes it has been a problem because these
37	241	children have got small fingers, so although we use toes sometimes they are also small and the child
38 39	242	is afraid so they start crying. So we have got other things we can give a child to play with but it is a
40 41	243	little bit of a problem, but at the end we get the results." (CHW, Malawi)
42 43	244	Solutions to these challenging children included asking caregivers to breastfeed, giving them a toy to
44 45	245	distract them, and simply waiting. The term used frequently to describe challenging children was
46	246	'fear', with the HCPs stating that children are afraid of having the measurements taken and even
47 48	247	that the sensors' red light caused this fear. Despite these issues in small and agitated infants, the
49 50	248	oximeters were considered easy to use:
51 52	249	"it's not complicated, it doesn't need complicated education for a healthcare worker to use, with a
53 54 55 56 57	250	good explanation from a colleague or friend you are able to use it." (Hospital, Malawi)
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251 There was also the acknowledgement that time to reading was not as important as getting the

correct measurement; for some respondents, the reason some measurements take longer is the

253 desire to get a reliable reading. This included cleaning the child's digits or repositioning the probe:

254 *"…taking longer does not mean that one doesn't know the procedure, but sometime it's because you*255 *want to give the correct reading."* (CHW, Malawi)

256 A key challenge reported by frontline HCPs in Malawi was around keeping the oximeter charged; this

257 was not considered a significant challenge in Bangladesh. However, here they had issues with

258 ensuring the oximeter remained dry and protected during rains and being fully waterproof was

259 desirable. Depending on usage, battery life was reported as 1 week – 2 months. In Malawi, none of

260 the CHWs and only some of the health centres have access to electricity for charging the re-usable

261 batteries, and therefore they reported travelling to use commercial charging services:

262 *"Most of the times we take the pulse oximeter to the trading centre and charge it, then we pay for*

that only to make sure that we are working, but sometimes you also feel you become bankrupt."

264 (Health centre, Malawi)

265 <u>Sustainability</u>

266 Sustainability was discussed in terms of the device's durability, and the need for continued

267 professional development. Generally the pulse oximeters were thought of as robust and durable,

268 with some of the HCPs having used their device for over four years without replacements. However,

the battery was highlighted as the least durable part of the device, and there was a perception that

270 when the battery was worn down the readings became less reliable.

271 *"There is a matter with the battery too, if the battery is not enough the reading takes a long time to*272 *appear. It sometimes gives false negative readings."* (Hospital, Bangladesh)

273 This related to the HCPs suggestion of having on-going maintenance support rather than wanting

274 replacement devices. HCPs described the need for on-going training and support, but also expressed

a desire for more in-depth education on how oximetry works which goes beyond the basic training

to take a reliable measurement:

277 "A person gets used to what they are doing once they have been oriented. I think sometimes it's also

278 good for you and your team to orient us on how this thing works [...] the way this thing works, we

279 *don't know*" (Health centre, Malawi)

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280	In terms of keeping the devices clean, we found conflicting opinions between Malawi and
281	Bangladesh. Malawi deemed the probes easy to clean and store securely, although the light colour
282	and materials of the device was thought to show dirt easily. However, in Bangladesh cleaning was
283	described as burdensome; this likely reflects the different devices and therefore methods needed for
284	cleaning, or different perceptions of the importance and frequency of cleaning.
	"It is hard work to clean it with hexsol and cotton after coming back from the field every day. If we
	could get something else to clean it with so that we can clean once a week, I don't like cleaning it
287	every day." (CHW, Bangladesh)
288	Design
289	The key challenges mentioned repeatedly across sites and HCP cadres were the battery, sensitivity of
290	the probe in relation to movement or low perfusion, and the probe fit in younger children. Box 1
291	summarises the design features requested or suggested to improve the pulse oximeters for use in
292	these low-resource settings.
	The oximeters which HCPs used were designed for continuous monitoring; therefore oxygen
	saturation is not a single static result. This was seen as a negative, with HCPs in both sites wanting
295	the ability to stop at a result and even store measurements (e.g. a blood glucose monitor):
296	"Readings would fluctuate if the baby moves. We don't want that. After getting the actual reading it
297	should stay fixed." (CHW, Bangladesh)
298	In Bangladesh specifically, the CHWs stated a preference for numbers or bars to indicate
299	measurement quality, rather than a dynamic waveform display. This opinion was not reflected in
300	Malawi, which could be a result of using different devices or different training. A specific challenge
301	presented by CHWs in Malawi was the use of the oximeter in direct sunlight; CHWs often hold clinics
302	outside and they faced the combined challenges of bright sunlight and dust, both of which they
303	reported as challenges in taking measurements.
304	"it returns the correct results when you are in the shade, but while you are in sunlight it fails to
305	determine good results." (CHW, Malawi)
306	Positive design features included the portability of devices, the ease of using them and perceived
307	durability, with little direct criticism of the oximeters that the HCPs had been using:
308	of the things I like most about using the pulse oximeter, the first one is the portability, because I
309	can use it anywhere." (Hospital, Malawi)
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311	Discussion
312	We investigated end-user experiences of using pulse oximeters by a range of different HCPs across
313	clinical settings in Malawi and Bangladesh. The FGDs highlighted similarities in experience, such as
314	challenges in battery durability, the difficulty of small and agitated children and the positive impact
315	of oximeters on clinical practice. However, there were key differences between Malawi and
316	Bangladesh and between HCP cadres.
317	Of note was the difference in perceived ease of cleaning, which was seen as more burdensome in
318	Bangladesh. This is likely associated with the Y-shaped wrap probe design, compared to the more
319	easily cleaned clip design used in Malawi (Figure 1). Interestingly though, most critiques were similar
320	between sites, highlighting some of the major challenges of using pulse oximetry in children –
321	namely movement, low perfusion and small digits. This consistency between sites suggests these
322	challenges are not device dependent and therefore a specifically designed re-usable device for
323	universal paediatric use in low-resource settings is needed.
324	We identified differences in the sense of value placed on the oximeters by HCPs, with the higher
325	trained HCPs attributing less value to the results than the HCPs with more limited training. Those
326	with more training valued their clinical judgement more and were more willing to question the
327	accuracy of SpO $_2$ results. This poses interesting lessons for scaling-up implementation and training,
328	as despite perceptions that obtaining a SpO $_2$ measurement is generally easy, the interpretation of
329	the result is more nuanced. Sustained mentorship and more in-depth training were desired by the
330	HCPs, and this needs to be considered as part of any implementation programme.
331	As the oximeters were used as spot-check devices rather than continuous monitors, as would
332	generally be found in operating theatres or high-dependency care in high-income settings, many of
333	the suggested design changes related to improving the devices for this process. One example of this
334	was the need for improved battery-life and charging, with HCPs highlighting their limited ability to
335	easily access charging points, unlike high-income inpatient settings. Consistently, the desire for
336	quicker, static results and a movement tolerant probe with improved fit on younger infants was
337	important. Unexpected issues, such as usability in direct sunlight, emphasize the importance of end-
338	user engagement in product development as clinical devices designed for high-income settings
339	would not need to be robust to outdoor use.
340	The idea of a pulse oximeter being able to improve trust between a caregiver and healthcare
341	provider poses potentially exciting opportunities for improving referral and treatment for paediatric

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pneumonia. Early diagnosis and treatment as downstream in the health system as possible, ideally to the level of CHWs, are key strategies for improving pneumonia outcomes and therefore reducing morbidity and mortality burden ²³. Therefore, an objective and simple clinical tool with in-built decision support, e.g. auditory or visual alarms when the SpO_2 is outside of normal range, presents an opportunity for caregiver education and empowerment in the referral decision-making process. Recent data from Malawi supports this notion. Frontline Malawian HCPs using pulse oximeters during routine outpatient care demonstrated that among children with pneumonia who were clinically eligible for referral, children with a SpO₂ <90% were more than twice as likely to have been correctly referred compared to those with a SpO₂ \geq 90% ¹². Interestingly, this has not necessarily been the case with other more objective diagnostic tools, with examples of rapid diagnostic malaria tests leading to provider-caregiver tensions around treatments ^{24 25}.

This study was potentially subject to social-desirability bias, with healthcare workers expressing opinions which they thought the facilitators wanted to hear. The purpose of the study was explained to the participants during the consent process, and was highlighted as an opportunity for them to contribute to the design of a revised paediatric oximeter and probe. To mitigate this potential bias, the facilitators encouraged the participants to be critical throughout, and the FGDs were conducted amongst peers, rather than between different HCP cadres with different educational backgrounds and social dynamics. Both positive and negative views were given in both Malawi and Bangladesh, and by different types of HCPs, therefore we do not feel this bias is likely to have impacted our findings.

Overall pulse oximeters were valued by HCPs, despite challenges with charging, maintenance and speed of achieving accurate readings in moving or smaller children. This implies that making improvements to currently available oximeters and probes could further facilitate successful implementation of this technology at the community through to the hospital level for routine paediatric care. Based on these data, we recommend that efforts to re-design a pulse oximeter for paediatric spot-checks focus on improvements to battery durability, better fit for smaller digits and the speed at which readings are obtained; these were all important challenges which did not necessarily have local solutions presented. More substantive design changes could focus on alternative power and charging systems (e.g. solar charging) and '3-in-1' devices which include respiratory rate and temperature measurements.

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383	Authors declare no conflicts of interest.
384	
385	Author contributions
386	The qualitative study was designed and topic guides developed by IWi, IWa, CK and EDM, and the
387	field manual written by CK. In Malawi, BZ and EK arranged, conducted, transcribed and translated
388	the FGDs. In Bangladesh SA and MI arranged and conducted the FGDs. The data was coded and
389	analysed by CK and KF. The manuscript was written by CK, with considerable input from KF and ED
390	All authors read, commented and approved the manuscript.
391	
392	Data Sharing Statement
393	Anonymised transcripts can be shared, following the signing of a data sharing agreement, subject
394	approval from the relevant National ethics committees. For further information please contact Dr.
	Carina King: c.king@ucl.ac.uk.

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worker (8)Medical officer (3)Associate professor ICU staff (1) Anaesthesiologist		Community level	Health centre or Upazila Health Complex	Hospital
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Total participants989Job titlesCommunity healthcare worker (8) Vital signs assistant (1)Medical assistant (7) Medical technician (1)Clinical officer (3) Nurse midwife (3) Medical assistant (3) 8.3 years (3 - 23)Years' work experience (mean)10.6 years (5 - 20)8.3 years (3 - 23)8.1 years (4 - 13)	(mean, range)	1.7 years (0.6 – 4)	2.3 years (1 – 6)	14.7 years (0.5 – 32)
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experience (mean)		worker (8) Vital signs assistant (1)	Medical technician (1)	Nurse midwife (3) Medical assistant (3)
		10.6 years (5 – 20)	8.3 years (3 – 23)	8.1 years (4 – 13)
	experience (mean)			

Panel 1: Suggestions of desirable features or improvements

Challenge:	Design suggestion:
Probe fit	Supplied with multiple sizes of probes for different ages A single cable with multiple probes that can be changed (e.g. clipped into the cable) Softer material for a more comfortable fit
	Softer material for a more connortable int
Probe placement	Probe made of transparent material so sensor placement on the nail can be seen
Cleaning	Alcohol wipes provided for easier cleaning Different colour probe to make it easier to see the dirt, but does not look dirty quickly
Power	Solar powered charger with rechargeable batteries Back-up power bank Supplied with a spare battery
Agitated children	Toy feature in the device to distract the child Improve the sensitivity of the device to be quicker Improve the sensitivity of the device to tolerate movement
Integrated spot-check device	Store results in a memory that can later be accessed Static oxygen saturation result display '3-in-1' device which includes temperature and respiratory rate measurements as well Shorter cable length for easier portability

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2 3 4	465	Figure 1: Pulse oximeters and probe used by healthcare providers in routine clinical care
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22 23 24 25 26 27 28 29 30 31 32 33 34	470	1 st July 2017 from: www.pacificmedicalsupply.com)
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Web Appendix 1 – Topic Guide

- What is your experience of using pulse oximeters in children?
- What have been the main issues you've encountered when using pulse oximeters?
- What have been the things you like most about using the pulse oximeters?
- What type of probes have you used? Have any been better than others? Why?
- Thinking about the probes, we would like to hear your feedback about some aspects of using them: ease of putting and keeping the probe on the child, durability, ease of taking a reading, ease of keeping it clean and storage
- Thinking about the oximeter, we would like to hear your feedback about some aspects of using them: ease of reading the display, durability, battery life and charging, time taken to get a reading
- What things would make the probe and pulse oximeter easier to use?
- tings wour What things would make the probe and pulse oximeter harder to use?

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Opportunities and barriers in paediatric pulse oximetry for pneumonia in low-resource clinical settings: a qualitative evaluation from Malawi and Bangladesh

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SCHOLARONE[™] Manuscripts

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1	Title: Opportunities and barriers in paediatric pulse oximetry for pneumonia in low-resource clinical		
2	settings: a qualitative evaluation from Malawi and Bangladesh		
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4	Authors: Carina King ^{1*} , Nicholas Boyd ² , Isabeau Walker ² , Beatiwel Zadutsa ³ , Abdullah H. Baqui ⁴ ,		
5	Salahuddin Ahmed ⁴ , Mazharul Islam ⁵ , Esther Kainja ³ , Bejoy Nambiar ¹ , Iain Wilson ⁶ , Eric D.		
6	McCollum ^{7,8}		
7			
8	Affiliations:		
9	1. Institute for Global Health, University College London, London, UK		
10	2. Great Ormond Street Hospital NHS Foundation Trust, UCL Institute of Child Health, London,		
11	UK		
12	3. Parent and Child Health Initiative, Lilongwe, Malawi		
13	4. International Center for Maternal and Newborn Health, Johns Hopkins Bloomberg School of		
14	Public Health, Baltimore, USA		
15	5. Department of Anthropology, Shahjalal University of Science and Technology, Sylhet,		
16	Bangladesh		
17	6. Lifebox Foundation, London, UK		
18	7. Eudowood Division of Pediatric Respiratory Diseases, Johns Hopkins School of Medicine,		
19	Baltimore, USA		
20	8. Department of International Health, Johns Hopkins Bloomberg School of Public Health,		
21	Baltimore, USA		
22			
23	*Corresponding author:		
24	Address: Institute for Global Health, 30 Guilford Street, London, WC1N 1EH; Email: <u>c.king@ucl.ac.uk</u> ;		
25	telephone: +44 (0) 2076797619		
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30 Abstract

Objective: To gain an understanding of what challenges pulse oximetry for paediatric pneumonia

32 management poses, how it has changed service provision and what would improve this device for

33 use across paediatric clinical settings in low-income countries.

Design: Focus group discussions (FGDs), with purposive sampling and thematic analysis using a
 framework approach.

Setting: Community, front line outpatient and hospital outpatient and inpatient settings in Malawi
 and Bangladesh, which provide paediatric pneumonia care.

38 Participants: Healthcare providers (HCPs) from Malawi and Bangladesh who had received training in

39 pulse oximetry and had been using oximeters in routine paediatric care, including community

40 healthcare workers, non-physician clinicians or medical assistants, and hospital-based nurses and
41 doctors.

Results: We conducted six FGDs, with 23 participants from Bangladesh and 26 from Malawi. We identified five emergent themes: trust; value; user-related experience; sustainability; and design. HCPs discussed the confidence gained through using oximeters, resulting in improved trust from caregivers and valuing the device; although there were conflicts between the weight given to clinical judgement versus oximeter results. HCPs reported the ease of using oximeters, but identified movement and physically smaller children as measurement challenges. Challenges in sustainability related to battery durability and replacement parts were reported, however many HCPs had used the same device longer than four years demonstrating robustness within these settings. Desirable features included back-up power banks and integrated respiratory rate and thermometer capability. Conclusions: Pulse oximetry was generally deemed valuable by HCPs for use as a spot-check device in a range of paediatric low-income clinical settings. Areas highlighted as challenges by HCPs, and

53 therefore opportunities for re-design, included battery charging and durability, probe fit and

54 sensitivity in paediatric populations.

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3	55	Strengths and Limitations
4 5	56	• This is the first study to report on end-user perceptions of opportunities, challenges and
6	57	desirable design features of pulse oximeters used for paediatric pneumonia management in
7 8	58	low-resource settings, including community and outpatient providers.
9 10		
11	59 60	• A key strength was the wide range of healthcare provider perspectives included, from
12 13	60	community to referral hospital settings in South Asia and sub-Saharan Africa.
14	61	• The study was limited to participant's experience of using specific pulse oximeters and
15 16	62	therefore may lack generalizability to other paediatric pulse oximeters not used in these settings.
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65 Introduction

Several interventions, such as Pneumococcal conjugate vaccine (PCV) and standardised guidelines for diagnosis and treatment, have led to reductions in pneumonia morbidity and mortality over the last twenty years ¹². However, in spite of these gains, pneumonia remains the leading cause of infectious mortality amongst children globally, with the vast majority of the burden falling in sub-Saharan Africa and south Asia ³. To accelerate reductions in pneumonia mortality, further refinement of diagnosis and treatment pathways are needed, including correct referral and access to oxygen treatment ⁴.

Pulse oximetry non-invasively measures peripheral arterial oxyhemoglobin saturation (SpO₂).
Hypoxemia (defined as an SpO₂ <90%) is included in the World Health Organization (WHO)
guidelines as a pneumonia danger sign ⁵, and is associated with increased mortality from
pneumonia, as well as other illnesses like malaria ⁶⁻⁸. Recent evidence from Malawi has also
indicated that a SpO₂ 90-92% is predictive of mortality amongst children hospitalized with
pneumonia ⁸.

While some studies have attempted to predict hypoxemia in children with pneumonia using a combination of clinical signs, there has been mixed success ⁹⁻¹¹. Clinical signs alone fail to identify a proportion of hypoxemic children based on the current WHO guidelines, which results in a missed opportunity for referral and appropriate treatment ^{12 13}. In addition, the subjectivity of clinical signs can lead to variation in care – especially among community healthcare workers (CHWs), who often lack ongoing supervision.

Pulse oximeters have been successfully used in low-resource paediatric settings, but are yet to be
widely adopted, particularly during outpatient care ^{14 15}. The Ethiopian Ministry of Health has
demonstrated leadership in this area, setting up an initiative in 2016 to ensure oximetry and oxygen
therapy are available nationally across the healthcare system ¹⁶. However, Ethiopia is an exception,
with implementation of oximetry in other developing countries continuing to be slow.
Implementation barriers cited include cost, lack of appropriately designed, robust oximeters and

91 universal paediatric probes and issues with training and supervision ¹⁷.

92 In order to better understand current barriers to use of pulse oximetry by healthcare providers
93 (HCPs) in a range of healthcare settings, and explore opportunities that this technology provides,
94 input from end-users is needed ¹⁸. With the ultimate goal of designing a universal paediatric probe
95 for all levels of healthcare services in resource-poor settings, we aimed to gain an understanding of
96 the challenges of pulse oximetry, how its use has changed service provision and how current devices

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could be improved for these settings. This end-user perspective is currently limited in the literature and is essential to ensure investment in pulse oximetry is sustainable and effective.

Methods

We conducted a qualitative study with HCPs from different levels of the healthcare system in from one site in Malawi (Mchinji district, central region) and one in Bangladesh (Sylhet district, northeast region) from May – July 2016, as part of a wider programme of work aiming to design a universal paediatric oximeter probe.

Setting:

In Malawi there are three levels of government provided healthcare: CHWs (locally known as Health Surveillance Assistants), health centres and district hospitals. CHWs conduct weekly or bi-weekly village clinics and home visits providing basic integrated community case management (iCCM) for paediatric infections^{19 20}. Health centres are outpatient facilities run by nurses, clinical officers or medical assistants, and District Hospitals have inpatient facilities with capacity for oxygen treatment. In Mchinji, pulse oximetry was successfully introduced into all three healthcare settings in 2012 as part of a PCV research project, using the Acare Technology AH-MX manufactured Lifebox® oximeter and universal adult clip probe (Figure 1a)¹².

In Bangladesh, the study was conducted at Projahnmo, a research consortium comprised of Johns Hopkins University and several local non-governmental organizations in partnership with the Bangladesh Ministry of Family Health and Welfare. Current Projahnmo activities are integrated within three government-operated sub-district hospitals, called Upazila Health Complexes (UHCs), and the referral government hospital in Sylhet city (Osmani Medical College), all of which are staffed by physicians and nurses. The UHCs operate outpatient clinics for children under five and provide basic inpatient paediatric care, including oxygen. The majority of government provided inpatient care is provided at Osmani Medical College. Female CHWs employed by Projahnmo conduct bimonthly household surveillance, with a subset of CHWs providing weekly surveillance as a part of a PCV effectiveness study. Projahnmo CHWs conduct basic clinical assessments and refer ill children for care at the UHCs; they do not administer medicines themselves. Since 2015, a National Institutes of Health-funded study (K01TW009988) trained and supplied all Projahnmo clinical staff in Bangladesh, including CHWs, with pulse oximeters to screen children for hypoxemia, using the Masimo Rad5[®] oximeter and the LNCS[®] Y-I Multisite wrap probe (Figure 1b).

In Malawi, CHWs individually own the oximeters, and facilities were given a device for each clinic or ward, while in Bangladesh, Projahnmo owns the oximeters and individual healthcare providers are responsible for routine care and maintenance of the devices. Oximetry was not included in the Malawi paediatric guidelines, and Bangladesh did not have national paediatric pneumonia guidelines

132 at the time of the study.

133 <u>Design:</u>

 We conducted focus group discussions (FGDs). We planned three FGDs in each country, aiming to recruit between 6 and 10 people for each FGD (up to 60 participants in total). This number of groups was agreed upon before data collection began, driven by practical considerations given few healthcare workers in either setting have experience using pulse oximeters with children. The groups were planned to be CHWs, health centre or UHC staff, and referral hospital staff separately. Conducting separate FGDs for the different types of healthcare workers was to allow context-specific discussions and encourage participants with varying training backgrounds to feel confident about raising challenges relevant to their specific setting.

142 <u>Sampling:</u>

HCPs were purposefully sampled from sites where pulse oximetry had been introduced, and the
participants had received some form of training or mentorship in oximetry. Participants were
identified by local researchers (BZ in Malawi and SA in Bangladesh) to be a representative sample of
HCPs from their setting (e.g. small and large health centres, inpatient wards and outpatient
departments in the hospital), and contacted directly by phone. All HCPs contacted participated.
Participants were reimbursed for their travel costs to the local healthcare facility and provided with
refreshments.

150 <u>Procedure:</u>

FGDs were led by local researchers with experience in conducting qualitative research, with support from a facilitator with knowledge of pulse oximeters. The FGDs were divided into two sections, the first addressing the participants' personal experience with using pulse oximeters. The topic guide included: positive and negative experiences, and possible improvements and challenges (Web appendix 1). During the second part of the discussion, the participants were presented with different probe designs and given an opportunity to use them for an hour (Web appendix 2). Following this, the discussion addressed positive and negative aspects of the different designs to encourage critical thinking of possible design solutions to the current limitations of a universal paediatric probe.

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The FGDs were audio recorded and then transcribed, along with the facilitators notes. Questions
were asked in a mix of English and local dialects depending on understanding and ease of expression
(Chichewa, Bangla or Sylheti) and participants were told to answer in their preferred language.
Responses were clarified by facilitators if there was an issue with language and understanding
between participants. Recordings were transcribed and translated where necessary. Translations for
Malawi were done by BZ and EK together until final transcripts were agreed, and by an independent
professional service for Bangladesh.

166 <u>Analysis:</u>

167 We analysed the data thematically using a framework approach, as an appropriate method for a 168 multi-disciplinary team conducting health research ²¹. This process involves five steps: familiarisation, identifying a thematic framework, indexing, mapping and interpretation²². The 169 170 transcripts and notes from the FGDs were printed and coded on paper, with the coding matrix 171 created in Microsoft Excel. CK and KF independently familiarised themselves and indexed the data, 172 and the emergent themes were discussed until a consensus was reached on the mapping and 173 interpretation of the data. This interpretation was shared with the local researchers (BZ and EK in 174 Malawi; EDM and MI in Bangladesh) for further discussion until all were in agreement.

175 <u>Ethics:</u>

Written informed consent was obtained from all FGD participants. This study was reviewed and
approved by the University College London research ethics committee (8075/003), Johns Hopkins
Medicine Institutional Review Board (IRB00047406), the Malawi National Health Sciences Research
Committee (16/4/1570) and Bangladesh Medical Research Council (BMRC/NREC/2013-2016/1272).

180

181 Results

182 We conducted six FGDs, with 23 participants from Bangladesh and 26 from Malawi (Table 1). We

183 identified five emergent themes: trust; value; user-related experience; sustainability; and design.

184 <u>Trust</u>

Trust emerged as a theme both in terms of how the HCPs interpret the oximetry results, and how
caregivers interact with HCPs and the pulse oximeter. We found that all cadres of HCPs in both sites
had an awareness of the fallibility of the oximetry readings, specifically relating to lower SpO₂ values.
For SpO₂ levels which were deemed abnormal, <90% up to <95% according to different participants,

189	HCPs stated that they would often re-check the result before making a referral or treatment
190	decision:
191	"if we see it is 89% we change the probe or change the finger" (Hospital, Bangladesh)
192	However, questioning the validity of these lower ${\sf SpO}_2$ results in the context of a child's clinical
193	condition was only discussed by the HCPs who worked in the hospital setting. This difference in the
194	trust placed in the SpO $_2$ results by different types of HCPs suggests that more in-depth clinical
195	training and understanding of the technology may result in different clinical applications:
196	sometimes the pulse oximeter can give readings which you are not comfortable with according to
197	the presentation of th <mark>e child</mark> [] most of the time when it happens like that, we just use our
198	judgement" (Hospital, Malawi)
199	An outcome of using pulse oximeters for pneumonia diagnosis was a change in parental and
200	community understanding and perceptions of care, with HCPs discussing increased trust in their
201	referral and treatment decisions. This worked in two ways, firstly with the oximeter acting as a direct
202	feedback and education tool:
203	"if the mother is able to read you can show the exact figure and she will accept the treatment of
204	oxygen, [before] it was very difficult to explain the role or the importance of the oxygen machine and
205	some mothers refused" (Hospital, Malawi)
206	Secondly, in Malawi HCPs projected that the oximeters had improved clinical care, and therefore
207	outcomes, which led caregivers to be more inclined to accept the referral or treatment being
208	recommended, especially in the case of oxygen:
209	"[previously] in the village they were saying that when a child is put on the oxygen machine it
210	facilitates death, therefore it was making problems, but this time because children are put on oxygen
211	earlier they survive, it's because we knew the saturation" (Health centre, Malawi)
212	Value
213	The theme of value relates to the inherent value of improved decision making, HCPs perceived self-
214	value (i.e. confidence) in their clinical work, and the physical value placed on maintaining a working
215	pulse oximeter. As pneumonia is classified using a range of non-specific and often subjective clinical
216	signs, HCPs discussed the positive addition of this more objective measure:
217	"by looking at this we can understand how much respiratory distress is in there. Of course this helps
218	us a lot." (Health Centre, Bangladesh)
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2 3	219	In both sites HCPs from frontline settings (CHWs, health centres and UHCs) stated that the pulse
4	220	oximeters had changed the way they work and given them confidence in making referral decisions.
5 6	220	Interestingly however, in the referral hospital setting in Bangladesh where staff training is higher,
7	221	very little value was placed on the pulse oximeter for improving their clinical performance, with the
8 9		
10	223	ability to conduct chest x-rays, lung ultra-sound and their clinical judgement valued more highly:
11 12	224	"its sensitivity and specificity is very negligible to be taken as a diagnostic tool." (Hospital,
13 14	225	Bangladesh)
15 16	226	In Bangladesh the CHWs reported pride in using the oximeters. In Malawi, the CHWs placed a
17	227	physical value on the oximeters and discussed the personal effort, such as paying out of pocket to
18 19 20	228	travel commercial charging services, they put in to maintaining a working device:
21	229	we have been trying all that is humanly possible to take care of these things, but it only becomes a
22 23 24	230	problem when it comes to the issue of charging." (CHW, Malawi)
25	231	This was also reflected at the health centre, where not all facilities have electricity and one or two
26 27	232	staff are responsible for assessing children. At the referral hospital however this was not discussed,
28	233	with oximeters belonging to the ward, which has a more consistent power supply. Ward-based
29 30	234	ownership was discussed as a challenge, suggesting individual ownership could result in improved
31	235	care and maintenance as having a device in working order would not be dependent on the
32 33 34	236	performance of others.
35	237	"some of the clinicians do not take care of them, so when the machine is not working it means the
36 37 38	238	whole department is affected" (Hospital, Malawi)
39 40	239	User-related experience
41 42	240	HCPs at all levels discussed their experiences of using pulse oximeters in children under 5-years,
43	241	presenting challenges, their solutions and perceptions of usability. The time taken to get a
44 45	242	measurement ranged widely, with CHWs in Bangladesh agreeing measurements took less than 1
46 47	243	minute but in Malawi that it could take up to 20 minutes. The factors that increased the time taken
48	244	to get a measurement were consistently cited as movement and physically smaller children, and in
49 50 51	245	Malawi dirty toes making measurements difficult:
52 53	246	"Getting readings from irritable babies is a bit tough and it takes time." (Health centre, Bangladesh)
54	247	using it on a child up to six months of age, sometimes it has been a problem because these
55 56 57 58	248	children have got small fingers, so although we use toes sometimes they are also small and the child
58		

2		
3	249	is afraid so they start crying. So we have got other things we can give a child to play with but it is a
4 5	250	little bit of a problem, but at the end we get the results." (CHW, Malawi)
6	254	
7 8	251	Solutions to these challenging children included asking caregivers to breastfeed, giving them a toy to
9	252	distract them, and simply waiting. The term used frequently to describe challenging children was
10 11	253	'fear', with the HCPs stating that children are afraid of having the measurements taken. This fear was
12	254	associated with the sensors' red light which frightened children, the anticipation of pain, or just
13 14	255	being an unknown. All of these could result in the child being agitated, crying and uncooperative.
15	256	Despite these issues in small and agitated infants, the oximeters were considered easy to use:
16 17	257	"it's not complicated, it doesn't need complicated education for a healthcare worker to use, with a
18 19 20	258	good explanation from a colleague or friend you are able to use it." (Hospital, Malawi)
21	259	There was also the acknowledgement that time to reading was not as important as getting the
22 23	260	correct measurement; for some respondents, the reason some measurements take longer is the
24 25	261	desire to get a reliable reading. This included cleaning the child's digits or repositioning the probe:
26 27	262	"taking longer does not mean that one doesn't know the procedure, but sometime it's because you
28 29	263	want to give the correct reading." (CHW, Malawi)
30 31	264	A key challenge reported by frontline HCPs in Malawi was around keeping the oximeter charged; this
32	265	was not considered a significant challenge in Bangladesh. However, here they had issues with
33 34	266	ensuring the oximeter remained dry and protected during rains and being fully waterproof was
35 36	267	desirable. Depending on usage, battery life was reported as 1 week – 2 months.
37 38	268	Sustainability
39 40	269	Sustainability was discussed in terms of the device's durability, and the need for continued
41 42	270	professional development. Generally the pulse oximeters were thought of as robust and durable,
43	271	with some of the HCPs having used their device for over four years without replacements. However,
44 45	272	the battery was highlighted as the least durable part of the device, and there was a perception that
46 47	273	when the battery was worn down the readings became less reliable.
48 49	274	"There is a matter with the battery too, if the battery is not enough the reading takes a long time to
50 51	275	appear. It sometimes gives false negative readings." (Hospital, Bangladesh)
52 53	276	This related to the HCPs suggestion of having on-going maintenance support rather than wanting
54 55 56 57	277	replacement devices. HCPs described the need for on-going training and support, but also expressed
58		10

1		
2 3	278	a desire for more in-depth education on how oximetry works which goes beyond the basic training
4 5	279	to take a reliable measurement:
6 7	280	"A person gets used to what they are doing once they have been oriented. I think sometimes it's also
8	281	good for you and your team to orient us on how this thing works [] the way this thing works, we
9 10	282	don't know" (Health centre, Malawi)
11		
12 13	283	In terms of keeping the devices clean and properly stored, an important factor for prolonging shelf-
14 15	284	life, we found conflicting opinions between Malawi and Bangladesh. Malawi deemed the probes
15 16	285	easy to clean and store securely, although the light colour and materials of the device was thought
17 18	286	to show dirt easily. However, in Bangladesh cleaning was described as burdensome; this likely
18 19	287	reflects the different devices and therefore methods needed for cleaning, or different perceptions of
20 21	288	the importance and frequency of cleaning.
22	289	"It is hard work to clean it with hexsol and cotton after coming back from the field every day. If we
23 24	205	could get something else to clean it with so that we can clean once a week, I don't like cleaning it
25		No.
26 27	291	every day." (CHW, Bangladesh)
28	292	Design
29 30	293	The key challenges mentioned repeatedly across sites and HCP cadres were the battery, sensitivity of
31 32		
33	294	the probe in relation to movement or low perfusion, and the probe fit in younger children. Panel 1
34 35	295	summarises the design features requested or suggested to improve the pulse oximeters for use in
35 36	296	these low-resource settings. Suggestions covered the probe, such as having detachable probes of
37	297	different sizes, charging and battery life, such as additional power packs and solar charging, and
38 39	298	features to help with agitated children.
40 41	299	The oximeters which HCPs used were designed for continuous monitoring; therefore oxygen
42	300	saturation is not a single static result. This was seen as a negative, with HCPs in both sites wanting
43 44	301	the ability to stop at a result and even store measurements (e.g. a blood glucose monitor):
45		
46 47	302	"Readings would fluctuate if the baby moves. We don't want that. After getting the actual reading it
48	303	should stay fixed." (CHW, Bangladesh)
49 50	304	In Bangladesh specifically, the CHWs stated a preference for numbers or bars to indicate
51 52	305	measurement quality, rather than a dynamic waveform display. This opinion was not reflected in
52 53	306	Malawi, which could be a result of using different devices or different training. A specific challenge
54 55	307	presented by CHWs in Malawi was the use of the oximeter in direct sunlight; CHWs often hold clinics
55 56	507	presented by errors in malawi was the use of the oximeter in anect sunlight, errors often noid tillings
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58 59		11
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308 outside and they faced the combined challenges of bright sunlight and dust, both of which they309 reported as challenges in taking measurements.

*"…it returns the correct results when you are in the shade, but while you are in sunlight it fails to*311 *determine good results."* (CHW, Malawi)

312 Positive design features included the portability of devices, the ease of using them and perceived

313 durability, with little direct criticism of the oximeters that the HCPs had been using:

314 "...of the things I like most about using the pulse oximeter, the first one is the portability, because I
315 can use it anywhere." (Hospital, Malawi)

317 Discussion

We investigated end-user experiences of using pulse oximeters by a range of different HCPs across clinical settings in Malawi and Bangladesh. The FGDs highlighted similarities in experience, such as challenges in battery durability, the difficulty of small and agitated children and the positive impact of oximeters on clinical practice. However, there were key differences between the providers' experiences in Malawi and Bangladesh and between HCP cadres.

323 Of note was the difference in perceived ease of cleaning, which was seen as more burdensome in

Bangladesh. This is likely associated with the Y-shaped wrap probe design, compared to the more
easily cleaned clip design used in Malawi (Figure 1). Interestingly though, most critiques were similar
between sites, highlighting some of the major challenges of using pulse oximetry in children –
namely movement, low perfusion and small digits. This consistency between our sampled HCPs from
each site suggests these challenges are not device dependent and therefore a specifically designed

329 re-usable device for universal paediatric use in low-resource settings is needed.

We identified differences in the sense of value placed on the oximeters by the HCPs, with the higher trained HCPs attributing less value to the results than the HCPs with more limited training. Those with more training valued their clinical judgement more and were more willing to question the accuracy of SpO₂ results. This poses interesting lessons for scaling-up implementation and training, as despite perceptions that obtaining a SpO₂ measurement is generally easy, the interpretation of the result is more nuanced. Sustained mentorship and more in-depth training were desired by the HCPs, and this needs to be considered as part of any implementation programme.

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337 As the oximeters were used as spot-check devices rather than continuous monitors, as would 338 generally be found in operating theatres or high-dependency care in high-income settings, many of 339 the suggested design changes related to improving the devices for this process. One example of this 340 was the need for improved battery-life and charging, with HCPs highlighting their limited ability to 341 easily access charging points, unlike high-income inpatient settings. Consistently, the desire for 342 quicker, static results and a movement tolerant probe with improved fit on younger infants was 343 important. Unexpected issues, such as usability in direct sunlight, emphasize the importance of end-344 user engagement in product development as clinical devices designed for high-income settings 345 would not need to be robust to outdoor use.

346 The idea of a pulse oximeter being able to improve trust between a caregiver and healthcare 347 provider poses potentially exciting opportunities for improving referral and treatment for paediatric 348 pneumonia. Early diagnosis and treatment as downstream in the health system as possible, ideally to 349 the level of CHWs, are key strategies for improving pneumonia outcomes and therefore reducing morbidity and mortality burden²³. Therefore, an objective and simple clinical tool with in-built 350 351 decision support, e.g. auditory or visual alarms when the SpO_2 is outside of normal range, presents 352 an opportunity for caregiver education and empowerment in the referral decision-making process. 353 Recent data from Malawi supports the potential for oximetry to improve referral decision-making in 354 frontline settings, with HCPs more than twice as likely to correctly refer children with a $SpO_2 < 90\%$ 355 compared to those with a SpO₂ \geq 90% when using an oximeter during routine outpatient care ¹². 356 Interestingly, this has not necessarily been the case with other more objective diagnostic tools, with 357 examples of rapid diagnostic malaria tests leading to provider-caregiver tensions around treatments 24 25 358

359 This study was potentially subject to social-desirability bias, with healthcare workers expressing 360 opinions which they thought the facilitators wanted to hear. The purpose of the study was explained 361 to the participants during the consent process, and was highlighted as an opportunity for them to 362 contribute to the design of a revised paediatric oximeter and probe. In addition, the groups in some 363 cases were mixed in terms of gender and job titles, possibly influencing participant's confidence in 364 expressing their views and experiences. To mitigate these potential biases, the facilitators 365 encouraged the all participants to contribute to the discussions and to be critical throughout. Both 366 positive and negative views were given in both Malawi and Bangladesh, and by different types of 367 HCPs, therefore we do not feel these biases detract from our findings. Finally, we were limited by the number of groups we conducted; additional groups or a different sampling approach may have 368

369 led to alternative perspectives being included, as the number was not driven by saturation.

370 Therefore the conclusions we draw need to be interpreted accordingly.

Overall pulse oximeters were valued by the HCPs we sampled for this study, despite challenges with charging, maintenance and speed of achieving accurate readings in moving or smaller children. This implies that making improvements to currently available oximeters and probes could further facilitate successful implementation of this technology at the community through to the hospital level for routine paediatric care in these two settings. Based on these providers varied experiences, we recommend that efforts to re-design a pulse oximeter for paediatric spot-checks focus on improvements to battery durability, better fit for smaller digits and the speed at which readings are obtained; these were all important challenges which did not necessarily have local solutions presented. More substantive design changes could focus on alternative power and charging systems (e.g. solar charging) and '3-in-1' devices which include respiratory rate and temperature anu s... measurements.

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23 24	392	Conflict of Interest
25 26	393	Authors declare no conflicts of interest.
27		
28 29	394	
30 31 32	395	Author contributions
33	396	The qualitative study was designed and topic guides developed by IWi, IWa, CK and EDM, and the
34 35	397	field manual written by CK. Oversight of the study was conducted by CK, BN and BZ in Malawi and
36	398	EDM, AB and MI in Bangladesh. In Malawi, BZ and EK arranged, conducted, transcribed and
37 38	399	translated the FGDs. In Bangladesh SA and MI arranged and conducted the FGDs. The data was
39 40	400	coded and analysed by CK. The manuscript was written by CK, with considerable input from EDM.
41 42	401	IWi, IWa, EDM, BZ, EK, SA, MI, NB, AB and BN read, commented and approved the manuscript.
43 44	402	
45 46	403	Data Sharing Statement
47 48	404	Anonymised transcripts can be shared, following the signing of a data sharing agreement, subject to
49 50	405	approval from the relevant National ethics committees. For further information please contact Dr.
50 51 52	406	Carina King: c.king@ucl.ac.uk.
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	Community level	Health centre or Upazila	Hospital
	,	Health Complex	
BANGLADESH		'	
Total participants	8	7	8
Job titles (number)	Community healthcare worker (8)	Physician (4) Medical officer (3)	Senior staff nurse (1) Associate professor (2) ICU staff (1) Anaesthesiologist (1) Assistant registrar (1) Intern medical officer
Work experience (mean, range)	1.7 years (0.6 – 4)	2.3 years (1 – 6)	14.7 years (0.5 – 32)
MALAWI			
Total participants	9	8	9
Job titles	Community healthcare worker (8) Vital signs assistant (1)	Medical assistant (7) Medical technician (1)	Clinical officer (3) Nurse midwife (3) Medical assistant (3)
Years' work experience (mean)	10.6 years (5 – 20)	8.3 years (3 – 23)	8.1 years (4 – 13)

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Supplied with multiple sizes of probes for different ages A single cable with multiple probes that can be changed (e.g.

Probe made of transparent material so sensor placement on the

Different colour probe to make it easier to see the dirt, but does

Softer material for a more comfortable fit

Alcohol wipes provided for easier cleaning

Solar powered charger with rechargeable batteries

Improve the sensitivity of the device to tolerate movement

'3-in-1' device which includes temperature and respiratory rate

Store results in a memory that can later be accessed

Toy feature in the device to distract the child Improve the sensitivity of the device to be quicker

Static oxygen saturation result display

Shorter cable length for easier portability

2 3 4	474	Panel 1: Suggestions of desira
5		Challenge:
6 7 8		Probe fit
9 10 11 12		Probe placement
13 14		
15 16 17		Cleaning
18 19 20 21		Power
22 23 24 25		Agitated children
26 27 28 29		Integrated spot-check device
30 31 22		
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4 **Panel 1:** Suggestions of desirable features or improvements given by healthcare providers

Design suggestion:

clipped into the cable)

nail can be seen

not look dirty quickly

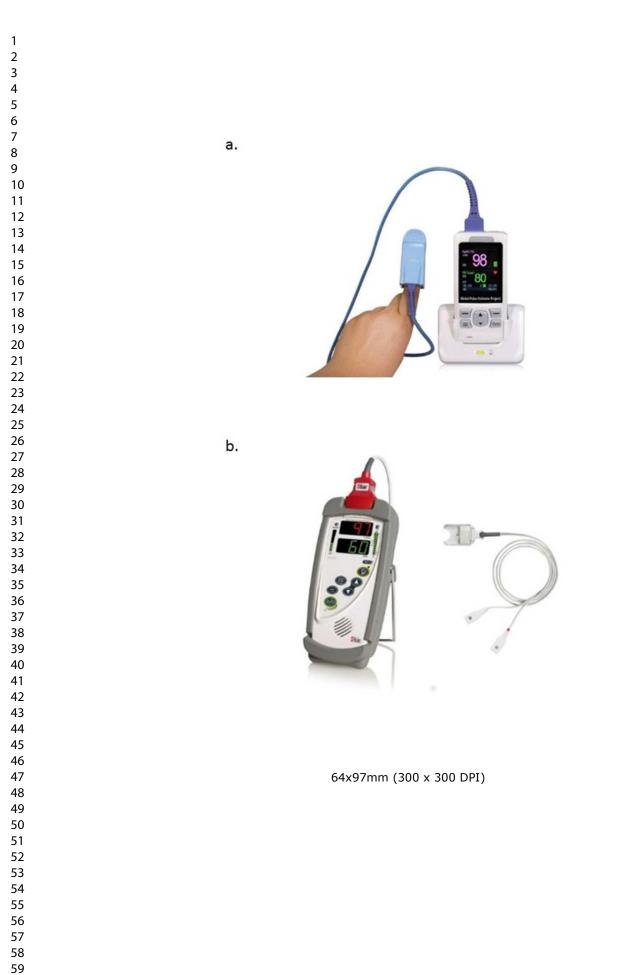
Back-up power bank

measurements as well

Supplied with a spare battery

Figure legends:

- Figure 1: Pulse oximeters and probe used by healthcare providers in routine clinical care
- a. Lifebox[®] oximeter and adult universal clip probe used in Malawi (accessed on 1st July 2017
- from: www.lifebox.org)
- <text> b. Masimo Rad5[®] oximeter and LNCS[®] Y-I Multisite wrap probe used in Bangladesh (accessed on



Web Appendix 1 – Topic Guide

- What is your experience of using pulse oximeters in children?
- What have been the main issues you've encountered when using pulse oximeters?
- What have been the things you like most about using the pulse oximeters?
- What type of probes have you used? Have any been better than others? Why?
- Thinking about the probes, we would like to hear your feedback about some aspects of using them: ease of putting and keeping the probe on the child, durability, ease of taking a reading, ease of keeping it clean and storage
- Thinking about the oximeter, we would like to hear your feedback about some aspects of using them: ease of reading the display, durability, battery life and charging, time taken to get a reading
- What things would make the probe and pulse oximeter easier to use?
- What things would make the probe and pulse oximeter harder to use?

Appendix 2: Summary of pulse oximeter probes presented during focus group discussions with healthcare providers

Probe type	Figure	Product code
Neonatal wrap		Acare ASYNR-D1
Adult clip		Acare ASANR-D1
Paediatric clip		Acare ASPNR-D1
Ear clip		Nellcor U401-2HL
Adult boot		Acare ASSNR-D1
Paediatric boot	1 Martin	Nellcor U401-2EL

COREQ Checklist

No	ltem	Guide questions/description	Page / evidence			
Domain 1: Research team and reflexivity						
Personal Characteristics						
1.	Interviewer/ facilitator	Which author/s conducted the interview or focus group?	Pg 15, Author contributions			
2.	Credentials	What were the researcher's credentials? <i>E.g. PhD, MD</i>	A mix of diploma BSc, MSc and PhI			
3.	Occupation	What was their occupation at the time of the study?	Pg 6, Methods: procedure			
4.	Gender	Was the researcher male or female?	Both			
5.	Experience and training	What experience or training did the researcher have?	Pg 6, 'Methods: Procedure'			
Re	lationship with participa	ints 2				
6.	Relationship established	Was a relationship established prior to study commencement?	No			
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Pg 15, Discussior			
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. <i>Bias, assumptions, reasons and interests in the research topic</i>	Pg 15, Discussior			
Domain 2: study design						
Theoretical framework						

No	ltem	Guide questions/description	Page / evidence
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? <i>e.g. grounded theory, discourse</i> <i>analysis, ethnography, phenomenology, content</i> <i>analysis</i>	Pg 7, Methods: Analysis
Ра	rticipant selection		
10.	Sampling	How were participants selected? <i>e.g. purposive, convenience, consecutive, snowball</i>	Pg 6, Methods: Sampling
11.	Method of approach	How were participants approached? e.g. face-to- face, telephone, mail, email	Pg 6, Sampling
12.	Sample size	How many participants were in the study?	Pg 7, Results an Table 1
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	Pg 6, Sampling
Se	tting	2.	
14.	Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Pg 6, Sampling
15.	Presence of non- participants	Was anyone else present besides the participants and researchers?	Pg 6, Methods: Procedure
16.	Description of sample	What are the important characteristics of the sample? <i>e.g. demographic data, date</i>	Table 1
Da	ta collection		
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Appendix 1
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	Not applicable

No	ltem	Guide questions/description	Page / evidence
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	Pg 7, Methods: Procedure
20.	Field notes	Were field notes made during and/or after the interview or focus group?	Pg 7, Methods: Procedure
21.	Duration	What was the duration of the interviews or focus group?	Between 1 and 2 hours
22.	Data saturation	Was data saturation discussed?	Pg 14, Discussion
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	This was not possible due to language potentia barriers
Do	main 3: analysis and fin	dings	
	main 3: analysis and fin ta analysis	dings	
		dings How many data coders coded the data?	Pg 7, Methods: Analysis
Da	ta analysis Number of data		-
Da 24.	ta analysis Number of data coders Description of the	How many data coders coded the data? Did authors provide a description of the coding	Analysis Pg 7, Methods:
Da 24. 25.	ta analysis Number of data coders Description of the coding tree Derivation of	How many data coders coded the data? Did authors provide a description of the coding tree? Were themes identified in advance or derived from	Analysis Pg 7, Methods: Analysis

No	ltem	Guide questions/description	Page / evidence
Re	eporting		
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Throughout results section (pg 7 – 12)
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	Throughout results section (pg 7 – 12)
31.	Clarity of major themes	Were major themes clearly presented in the findings?	Pg 7, Results
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Throughout results section (pg 7 – 12)

of minor une.

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Opportunities and barriers in paediatric pulse oximetry for pneumonia in low-resource clinical settings: a qualitative evaluation from Malawi and Bangladesh

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Complete List of Authors:	King, C.; University College London Institute for Global Health, Boyd, Nicholas; Great Ormond Street Hospital For Children NHS Trust, UCL Institute of Child Health Walker, Isabeau; Great Ormond Street Hospital For Children NHS Trust, UCL Institute of Child Health Zadutsa, Beatiwel; Parent and Child Health Initiative Baqui, Abdullah; Johns Hopkins University Bloomberg School of Public Health, International Center for Maternal and Newborn Health Ahmed, Salahuddin; Johns Hopkins University Bloomberg School of Public Health, International Center for Maternal and Newborn Health Islam, Mazharul; Shahjalal University of Science and Technology, Department of Anthropology Kainja, Esther; Parent and Child Health Initiative Nambiar, Bejoy; Institute for Global Health Wilson, Iain; Lifebox Foundation McCollum, Eric ; Johns Hopkins School of Medicine, Eudowood Division of Paediatric Respiratory Diseases; Johns Hopkins University Bloomberg School of Public Health, Department of International Health
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1	Title: Opportunities and barriers in paediatric pulse oximetry for pneumonia in low-resource clinical
2	settings: a qualitative evaluation from Malawi and Bangladesh
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4	Authors: Carina King ^{1*} , Nicholas Boyd ² , Isabeau Walker ² , Beatiwel Zadutsa ³ , Abdullah H. Baqui ⁴ ,
5	Salahuddin Ahmed ⁴ , Mazharul Islam ⁵ , Esther Kainja ³ , Bejoy Nambiar ¹ , Iain Wilson ⁶ , Eric D.
6	McCollum ^{7,8}
7	
8	Affiliations:
9	1. Institute for Global Health, University College London, London, UK
10	2. Great Ormond Street Hospital NHS Foundation Trust, UCL Institute of Child Health, London,
11	UK
12	3. Parent and Child Health Initiative, Lilongwe, Malawi
13	4. International Center for Maternal and Newborn Health, Johns Hopkins Bloomberg School of
14	Public Health, Baltimore, USA
15	5. Department of Anthropology, Shahjalal University of Science and Technology, Sylhet,
16	Bangladesh
17	6. Lifebox Foundation, London, UK
18	7. Eudowood Division of Pediatric Respiratory Diseases, Johns Hopkins School of Medicine,
19	Baltimore, USA 8. Department of International Health, Johns Hopkins Bloomberg School of Public Health,
20 21	 Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, USA
21	Baitmore, USA
22	
23	*Corresponding author:
24	Dr. Carina King; Email: c.king@ucl.ac.uk; Address: Institute for Global Health, 30 Guilford Street,
25	London, WC1N 1EH; Telephone: +44 (0) 2076797619
26	
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30 Abstract

Objective: To gain an understanding of what challenges pulse oximetry for paediatric pneumonia

32 management poses, how it has changed service provision and what would improve this device for

33 use across paediatric clinical settings in low-income countries.

Design: Focus group discussions (FGDs), with purposive sampling and thematic analysis using a
 framework approach.

Setting: Community, front line outpatient and hospital outpatient and inpatient settings in Malawi
 and Bangladesh, which provide paediatric pneumonia care.

38 Participants: Healthcare providers (HCPs) from Malawi and Bangladesh who had received training in

39 pulse oximetry and had been using oximeters in routine paediatric care, including community

40 healthcare workers, non-physician clinicians or medical assistants, and hospital-based nurses and
41 doctors.

Results: We conducted six FGDs, with 23 participants from Bangladesh and 26 from Malawi. We identified five emergent themes: trust; value; user-related experience; sustainability; and design. HCPs discussed the confidence gained through using oximeters, resulting in improved trust from caregivers and valuing the device; although there were conflicts between the weight given to clinical judgement versus oximeter results. HCPs reported the ease of using oximeters, but identified movement and physically smaller children as measurement challenges. Challenges in sustainability related to battery durability and replacement parts were reported, however many HCPs had used the same device longer than four years demonstrating robustness within these settings. Desirable features included back-up power banks and integrated respiratory rate and thermometer capability. Conclusions: Pulse oximetry was generally deemed valuable by HCPs for use as a spot-check device in a range of paediatric low-income clinical settings. Areas highlighted as challenges by HCPs, and

53 therefore opportunities for re-design, included battery charging and durability, probe fit and

54 sensitivity in paediatric populations.

1 2		
3	55	Strengths and Limitations
4 5	56	• This is the first study to report on end-user perceptions of opportunities, challenges and
6	57	desirable design features of pulse oximeters used for paediatric pneumonia management in
7 8	58	low-resource settings, including community and outpatient providers.
9 10		
11	59	A key strength was the wide range of healthcare provider perspectives included, from
12 13	60	community to referral hospital settings in South Asia and sub-Saharan Africa.
14	61	• The study was limited to participant's experience of using specific pulse oximeters and
15 16	62	therefore may lack generalizability to other paediatric pulse oximeters not used in these settings.
17	63	settings.
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65 Introduction

Several interventions, such as Pneumococcal conjugate vaccine (PCV) and standardised guidelines for diagnosis and treatment, have led to reductions in pneumonia morbidity and mortality over the last twenty years ¹². However, in spite of these gains, pneumonia remains the leading cause of infectious mortality amongst children globally, with the vast majority of the burden falling in sub-Saharan Africa and south Asia ³. To accelerate reductions in pneumonia mortality, further refinement of diagnosis and treatment pathways are needed, including correct referral and access to oxygen treatment ⁴.

Pulse oximetry non-invasively measures peripheral arterial oxyhemoglobin saturation (SpO₂).
Hypoxemia (defined as an SpO₂ <90%) is included in the World Health Organization (WHO)
guidelines as a pneumonia danger sign ⁵, and is associated with increased mortality from
pneumonia, as well as other illnesses like malaria ⁶⁻⁸. Recent evidence from Malawi has also
indicated that a SpO₂ 90-92% is predictive of mortality amongst children hospitalized with
pneumonia ⁸.

While some studies have attempted to predict hypoxemia in children with pneumonia using a combination of clinical signs, there has been mixed success ⁹⁻¹¹. Clinical signs alone fail to identify a proportion of hypoxemic children based on the current WHO guidelines, which results in a missed opportunity for referral and appropriate treatment ^{12 13}. In addition, the subjectivity of clinical signs can lead to variation in care – especially among community healthcare workers (CHWs), who often lack ongoing supervision.

Pulse oximeters have been successfully used in low-resource paediatric settings, but are yet to be widely adopted, particularly during outpatient care ¹⁴¹⁵. The Ethiopian Ministry of Health has demonstrated leadership in this area, setting up an initiative in 2016 to ensure oximetry and oxygen therapy are available nationally across the healthcare system ¹⁶. However, Ethiopia is an exception. with implementation of oximetry in other developing countries continuing to be slow. Implementation barriers cited include cost, issues with training and supervision and the lack of appropriately designed, robust oximeters and universal paediatric probes, although there are several initiatives to develop devices for low-income settings (e.g. Lifebox[®] and the Phone OximeterTM)¹⁷⁻¹⁹.

94 In order to better understand current barriers to use of pulse oximetry by healthcare providers
95 (HCPs) in a range of healthcare settings, and explore opportunities that this technology provides,
96 input from end-users is needed ²⁰. With the ultimate goal of designing a universal paediatric probe

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97 for all levels of healthcare services in resource-poor settings, we aimed to gain an understanding of

98 the challenges of pulse oximetry, how its use has changed service provision and how current devices

99 could be improved for these settings. This end-user perspective is currently limited in the literature

and is essential to ensure investment in pulse oximetry is sustainable and effective.

102 Methods

103 We conducted a qualitative study with HCPs from different levels of the healthcare system in from 104 one site in Malawi (Mchinji district, central region) and one in Bangladesh (Sylhet district, northeast 105 region) from May – July 2016, as part of a wider programme of work aiming to design a universal 106 paediatric oximeter probe.

107 <u>Setting:</u>

In Malawi there are three levels of government provided healthcare: CHWs (locally known as Health Surveillance Assistants), health centres and district hospitals. CHWs conduct weekly or bi-weekly village clinics and home visits providing basic integrated community case management (iCCM) for paediatric infections ^{21 22}. Health centres are outpatient facilities run by nurses, clinical officers or medical assistants, and District Hospitals have inpatient facilities with capacity for oxygen treatment. In Mchinji, pulse oximetry was successfully introduced into all three healthcare settings in 2012 as part of a PCV research project, using the Acare Technology AH-MX manufactured Lifebox® oximeter and universal adult clip probe (Figure 1a)¹².

In Bangladesh, the study was conducted at Projahnmo, a research consortium comprised of Johns Hopkins University and several local non-governmental organizations in partnership with the Bangladesh Ministry of Family Health and Welfare. Current Projahnmo activities are integrated within three government-operated sub-district hospitals, called Upazila Health Complexes (UHCs), and the referral government hospital in Sylhet city (Osmani Medical College), all of which are staffed by physicians and nurses. The UHCs operate outpatient clinics for children under five and provide basic inpatient paediatric care, including oxygen. The majority of government provided inpatient care is provided at Osmani Medical College. Female CHWs employed by Projahnmo conduct bimonthly household surveillance, with a subset of CHWs providing weekly surveillance as a part of a PCV effectiveness study. Projahnmo CHWs conduct basic clinical assessments and refer ill children for care at the UHCs; they do not administer medicines themselves. Since 2015, a National Institutes of Health-funded study (K01TW009988) trained and supplied all Projahnmo clinical staff in

Bangladesh, including CHWs, with pulse oximeters to screen children for hypoxemia, using the
Masimo Rad5[®] oximeter and the LNCS[®] Y-I Multisite wrap probe (Figure 1b).

In Malawi, CHWs individually own the oximeters, and facilities were given a device for each clinic or ward, while in Bangladesh, Projahnmo owns the oximeters and individual healthcare providers are responsible for routine care and maintenance of the devices. Oximetry was not included in the Malawi paediatric guidelines, and Bangladesh did not have national paediatric pneumonia guidelines at the time of the study.

135 <u>Design:</u>

We conducted focus group discussions (FGDs). We planned three FGDs in each country, aiming to
recruit between 6 and 10 people for each FGD (up to 60 participants in total). This number of groups
was agreed upon before data collection began, driven by practical considerations given few
healthcare workers in either setting have experience using pulse oximeters with children. The groups

140 were planned to be CHWs, health centre or UHC staff, and referral hospital staff separately.

141 Conducting separate FGDs for the different types of healthcare workers was to allow context-specific

discussions and encourage participants with varying training backgrounds to feel confident about

143 raising challenges relevant to their specific setting.

144 <u>Sampling:</u>

145 HCPs were purposefully sampled from sites where pulse oximetry had been introduced, and the

146 participants had received some form of training or mentorship in oximetry. Participants were

147 identified by local researchers (BZ in Malawi and SA in Bangladesh) to be a representative sample of

148 HCPs from their setting (e.g. small and large health centres, inpatient wards and outpatient

149 departments in the hospital), and contacted directly by phone. All HCPs contacted participated.

150 Participants were reimbursed for their travel costs to the local healthcare facility and provided with

151 refreshments.

152 <u>Procedure:</u>

FGDs were led by local researchers with experience in conducting qualitative research, with support from a facilitator with knowledge of pulse oximeters. The FGDs were divided into two sections, the first addressing the participants' personal experience with using pulse oximeters. The topic guide included: positive and negative experiences, and possible improvements and challenges (Web appendix 1). During the second part of the discussion, the participants were presented with different probe designs and given an opportunity to use them for an hour (Web appendix 2). Following this,

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159 the discussion addressed positive and negative aspects of the different designs to encourage critical 160 thinking of possible design solutions to the current limitations of a universal paediatric probe. 161 The FGDs were audio recorded and then transcribed, along with the facilitators notes. Questions 162 were asked in a mix of English and local dialects depending on understanding and ease of expression 163 (Chichewa, Bangla or Sylheti) and participants were told to answer in their preferred language. 164 Responses were clarified by facilitators if there was an issue with language and understanding 165 between participants. Recordings were transcribed and translated where necessary. Translations for 166 Malawi were done by BZ and EK together until final transcripts were agreed, and by an independent 167 professional service for Bangladesh.

168 Analysis:

169 We analysed the data thematically using a framework approach, as an appropriate method for a multi-disciplinary team conducting health research ²³. This process involves five steps: 170 familiarisation, identifying a thematic framework, indexing, mapping and interpretation ²⁴. The 171 172 transcripts and notes from the FGDs were printed and coded on paper, with the coding matrix 173 created in Microsoft Excel. CK and KF independently familiarised themselves and indexed the data, 174 and the emergent themes were discussed until a consensus was reached on the mapping and 175 interpretation of the data. This interpretation was shared with the local researchers (BZ and EK in 176 Malawi; EDM and MI in Bangladesh) for further discussion until all were in agreement.

177 Ethics:

Written informed consent was obtained from all FGD participants. This study was reviewed and
approved by the University College London research ethics committee (8075/003), Johns Hopkins
Medicine Institutional Review Board (IRB00047406), the Malawi National Health Sciences Research
Committee (16/4/1570) and Bangladesh Medical Research Council (BMRC/NREC/2013-2016/1272).

182

183 Results

We conducted six FGDs, with 23 participants from Bangladesh and 26 from Malawi (Table 1). We
 identified five emergent themes: trust; value; user-related experience; sustainability; and design.

186 Trust

187 Trust emerged as a theme both in terms of how the HCPs interpret the oximetry results, and how188 caregivers interact with HCPs and the pulse oximeter. We found that all cadres of HCPs in both sites

had an awareness of the fallibility of the oximetry readings, specifically relating to lower SpO_2 values. For SpO₂ levels which were deemed abnormal, <90% up to <95% according to different participants, HCPs stated that they would often re-check the result before making a referral or treatment decision: "if we see it is 89% we change the probe or change the finger" (Hospital, Bangladesh) However, questioning the validity of these lower SpO₂ results in the context of a child's clinical condition was only discussed by the HCPs who worked in the hospital setting. This difference in the trust placed in the SpO₂ results by different types of HCPs suggests that more in-depth clinical training and understanding of the technology may result in different clinical applications: "sometimes the pulse oximeter can give readings which you are not comfortable with according to the presentation of the child [...] most of the time when it happens like that, we just use our judgement" (Hospital, Malawi) An outcome of using pulse oximeters for pneumonia diagnosis was a change in parental and community understanding and perceptions of care, with HCPs discussing increased trust in their referral and treatment decisions. This worked in two ways, firstly with the oximeter acting as a direct feedback and education tool: "if the mother is able to read you can show the exact figure and she will accept the treatment of oxygen, [before] it was very difficult to explain the role or the importance of the oxygen machine and *some mothers refused*" (Hospital, Malawi) Secondly, in Malawi HCPs projected that the oximeters had improved clinical care, and therefore outcomes, which led caregivers to be more inclined to accept the referral or treatment being recommended, especially in the case of oxygen: "[previously] in the village they were saying that when a child is put on the oxygen machine it facilitates death, therefore it was making problems, but this time because children are put on oxygen earlier they survive, it's because we knew the saturation" (Health centre, Malawi) Value The theme of value relates to the inherent value of improved decision making, HCPs perceived self-value (i.e. confidence) in their clinical work, and the physical value placed on maintaining a working pulse oximeter. As pneumonia is classified using a range of non-specific and often subjective clinical signs, HCPs discussed the positive addition of this more objective measure:

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2 3	219	by looking at this we can understand how much respiratory distress is in there. Of course this helps
4 5	220	us a lot." (Health Centre, Bangladesh)
6 7	221	In both sites HCPs from frontline settings (CHWs, health centres and UHCs) stated that the pulse
8	222	oximeters had changed the way they work and given them confidence in making referral decisions.
9 10	223	Interestingly however, in the referral hospital setting in Bangladesh where staff training is higher,
11 12	224	very little value was placed on the pulse oximeter for improving their clinical performance, with the
12 13	225	ability to conduct chest x-rays, lung ultra-sound and their clinical judgement valued more highly:
14 15	220	" its consitivity and enalificity is your positivity to be taken as a discussion to al "Ulassital
16 17	226	"its sensitivity and specificity is very negligible to be taken as a diagnostic tool." (Hospital,
17 18	227	Bangladesh)
19 20	228	In Bangladesh the CHWs reported pride in using the oximeters. In Malawi, the CHWs placed a
20	229	physical value on the oximeters and discussed the personal effort, such as paying out of pocket to
22 23	230	travel commercial charging services, they put in to maintaining a working device:
24	224	
25 26	231	"we have been trying all that is humanly possible to take care of these things, but it only becomes a
27 28	232	problem when it comes to the issue of charging." (CHW, Malawi)
29	233	This was also reflected at the health centre, where not all facilities have electricity and one or two
30 31	234	staff are responsible for assessing children. At the referral hospital however this was not discussed,
32	235	with oximeters belonging to the ward, which has a more consistent power supply. Ward-based
33 34	236	ownership was discussed as a challenge, suggesting individual ownership could result in improved
35	237	care and maintenance as having a device in working order would not be dependent on the
36 37	238	performance of others.
38 39	239	"some of the clinicians do not take care of them, so when the machine is not working it means the
40 41	240	whole department is affected" (Hospital, Malawi)
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43 44	241	User-related experience
45 46	242	HCPs at all levels discussed their experiences of using pulse oximeters in children under 5-years,
47	243	presenting challenges, their solutions and perceptions of usability. The time taken to get a
48 49	244	measurement ranged widely, with CHWs in Bangladesh agreeing measurements took less than 1
50	245	minute but in Malawi that it could take up to 20 minutes. The factors that increased the time taken
51 52	246	to get a measurement were consistently cited as movement and physically smaller children, and in
53 54	247	Malawi dirty toes making measurements difficult:
55 56 57	248	"Getting readings from irritable babies is a bit tough and it takes time." (Health centre, Bangladesh)
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....using it on a child up to six months of age, sometimes it has been a problem because these children have got small fingers, so although we use toes sometimes they are also small and the child is afraid so they start crying. So we have got other things we can give a child to play with but it is a little bit of a problem, but at the end we get the results." (CHW, Malawi) Solutions to these challenging children included asking caregivers to breastfeed, giving them a toy to distract them, and simply waiting. The term used frequently to describe challenging children was 'fear', with the HCPs stating that children are afraid of having the measurements taken. This fear was associated with the sensors' red light which frightened children, the anticipation of pain, or just being an unknown. All of these could result in the child being agitated, crying and uncooperative. Despite these issues in small and agitated infants, the oximeters were considered easy to use: "...it's not complicated, it doesn't need complicated education for a healthcare worker to use, with a good explanation from a colleague or friend you are able to use it." (Hospital, Malawi) There was also the acknowledgement that time to reading was not as important as getting the correct measurement; for some respondents, the reason some measurements take longer is the desire to get a reliable reading. This included cleaning the child's digits or repositioning the probe: "...taking longer does not mean that one doesn't know the procedure, but sometime it's because you want to give the correct reading." (CHW, Malawi) A key challenge reported by frontline HCPs in Malawi was around keeping the oximeter charged; this was not considered a significant challenge in Bangladesh. However, here they had issues with ensuring the oximeter remained dry and protected during rains and being fully waterproof was desirable. Depending on usage, battery life was reported as 1 week – 2 months. Sustainability Sustainability was discussed in terms of the device's durability, and the need for continued professional development. Generally the pulse oximeters were thought of as robust and durable, with some of the HCPs having used their device for over four years without replacements. However, the battery was highlighted as the least durable part of the device, and there was a perception that when the battery was worn down the readings became less reliable. "There is a matter with the battery too, if the battery is not enough the reading takes a long time to appear. It sometimes gives false negative readings." (Hospital, Bangladesh)

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2 3	278	This related to the HCPs suggestion of having on-going maintenance support rather than wanting
4 5	279	replacement devices. HCPs described the need for on-going training and support, but also expressed
6	280	a desire for more in-depth education on how oximetry works which goes beyond the basic training
7 8 9	281	to take a reliable measurement:
10	282	"A person gets used to what they are doing once they have been oriented. I think sometimes it's also
11 12	283	good for you and your team to orient us on how this thing works [] the way this thing works, we
13 14	284	don't know" (Health centre, Malawi)
15 16	285	In terms of keeping the devices clean and properly stored, an important factor for prolonging shelf-
17	286	life, we found conflicting opinions between Malawi and Bangladesh. Malawi deemed the probes
18 19	287	easy to clean and store securely, although the light colour and materials of the device was thought
20	288	to show dirt easily. However, in Bangladesh cleaning was described as burdensome; this likely
21 22	289	reflects the different devices and therefore methods needed for cleaning, or different perceptions of
23 24 25	290	the importance and frequency of cleaning.
25 26	291	"It is hard work to clean it with hexsol and cotton after coming back from the field every day. If we
27 28	292	could get something else to clean it with so that we can clean once a week, I don't like cleaning it
29 30	293	every day." (CHW, Bangladesh)
31 32	294	every day." (CHW, Bangladesh) Design
33 34	295	The key challenges mentioned repeatedly across sites and HCP cadres were the battery, sensitivity of
35	296	the probe in relation to movement or low perfusion, and the probe fit in younger children. Table 2
36 37	297	summarises the design features requested or suggested to improve the pulse oximeters for use in
38 39	298	these low-resource settings. Suggestions covered the probe, such as having detachable probes of
40	299	different sizes, charging and battery life, such as additional power packs and solar charging, and
41 42	300	features to help with agitated children.
43 44	301	The oximeters which HCPs used were designed for continuous monitoring; therefore oxygen
45	302	saturation is not a single static result. This was seen as a negative, with HCPs in both sites wanting
46 47 48	303	the ability to stop at a result and even store measurements (e.g. a blood glucose monitor):
49 50	304	"Readings would fluctuate if the baby moves. We don't want that. After getting the actual reading it
51 52	305	should stay fixed." (CHW, Bangladesh)
53 54	306	In Bangladesh specifically, the CHWs stated a preference for numbers or bars to indicate
55	307	measurement quality, rather than a dynamic waveform display. This opinion was not reflected in
56 57	308	Malawi, which could be a result of using different devices or different training. A specific challenge
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309 presented by CHWs in Malawi was the use of the oximeter in direct sunlight; CHWs often hold clinics

310 outside and they faced the combined challenges of bright sunlight and dust, both of which they

311 reported as challenges in taking measurements.

"...it returns the correct results when you are in the shade, but while you are in sunlight it fails to
determine good results." (CHW, Malawi)

Positive design features included the portability of devices, the ease of using them and perceived
durability, with little direct criticism of the oximeters that the HCPs had been using:

316 "...of the things I like most about using the pulse oximeter, the first one is the portability, because I
317 can use it anywhere." (Hospital, Malawi)

318

319 Discussion

We investigated end-user experiences of using pulse oximeters by a range of different HCPs across clinical settings in Malawi and Bangladesh. The FGDs highlighted similarities in experience, such as challenges in battery durability, the difficulty of small and agitated children and the positive impact of oximeters on clinical practice. However, there were key differences between the providers'

324 experiences in Malawi and Bangladesh and between HCP cadres.

Of note was the difference in perceived ease of cleaning, which was seen as more burdensome in Bangladesh. This is likely associated with the Y-shaped wrap probe design, compared to the more easily cleaned clip design used in Malawi (Figure 1). Interestingly though, most critiques were similar between sites, highlighting some of the major challenges of using pulse oximetry in children – namely movement, low perfusion and small digits. This consistency between our sampled HCPs from each site suggests these challenges are not device dependent and therefore a specifically designed re-usable device for universal paediatric use in low-resource settings is needed.

We identified differences in the sense of value placed on the oximeters by the HCPs, with the higher trained HCPs attributing less value to the results than the HCPs with more limited training. Those with more training valued their clinical judgement more and were more willing to question the accuracy of SpO₂ results. This poses interesting lessons for scaling-up implementation and training, as despite perceptions that obtaining a SpO₂ measurement is generally easy, the interpretation of the result is more nuanced. Sustained mentorship and more in-depth training were desired by the HCPs, and this needs to be considered as part of any implementation programme.

As the oximeters were used as spot-check devices rather than continuous monitors, as would generally be found in operating theatres or high-dependency care in high-income settings, many of the suggested design changes related to improving the devices for this process. One example of this was the need for improved battery-life and charging, with HCPs highlighting their limited ability to easily access charging points, unlike high-income inpatient settings. Consistently, the desire for quicker, static results and a movement tolerant probe with improved fit on younger infants was important. Unexpected issues, such as usability in direct sunlight, emphasize the importance of end-user engagement in product development as clinical devices designed for high-income settings would not need to be robust to outdoor use.

The idea of a pulse oximeter being able to improve trust between a caregiver and healthcare provider poses potentially exciting opportunities for improving referral and treatment for paediatric pneumonia. Early diagnosis and treatment as downstream in the health system as possible, ideally to the level of CHWs, are key strategies for improving pneumonia outcomes and therefore reducing morbidity and mortality burden²⁵. Therefore, an objective and simple clinical tool with in-built decision support, e.g. auditory or visual alarms when the SpO_2 is outside of normal range, presents an opportunity for caregiver education and empowerment in the referral decision-making process. Recent data from Malawi supports the potential for oximetry to improve referrals, with HCPs from frontline settings more than twice as likely to correctly refer clinically-eligible children with a SpO₂ <90% compared to those with a SpO₂ \geq 90% during routine outpatient care ¹². Interestingly, this has not necessarily been the case with other more objective diagnostic tools, with examples of rapid diagnostic malaria tests leading to provider-caregiver tensions around treatments ^{26 27}.

This study was potentially subject to social-desirability bias, with healthcare workers expressing opinions which they thought the facilitators wanted to hear. The purpose of the study was explained to the participants during the consent process, and was highlighted as an opportunity for them to contribute to the design of a revised paediatric oximeter and probe. In addition, the groups in some cases were mixed in terms of gender and job titles, possibly influencing participant's confidence in expressing their views and experiences. To mitigate these potential biases, the facilitators encouraged the all participants to contribute to the discussions and to be critical throughout. Both positive and negative views were given in both Malawi and Bangladesh, and by different types of HCPs, therefore we do not feel these biases detract from our findings. Finally, we were limited by the number of groups we conducted; additional groups or a different sampling approach may have led to alternative perspectives being included, as the number was not driven by saturation. Therefore the conclusions we draw need to be interpreted accordingly.

Overall pulse oximeters were valued by the HCPs we sampled for this study, despite challenges with charging, maintenance and speed of achieving accurate readings in moving or smaller children. This implies that making improvements to currently available oximeters and probes could further facilitate successful implementation of this technology at the community through to the hospital level for routine paediatric care in these two settings. Based on these providers varied experiences, pulse, ter fit for sn challenges which d. sign changes could focus. 1-1' devices which include respin we recommend that efforts to re-design a pulse oximeter for paediatric spot-checks focus on improvements to battery durability, better fit for smaller digits and the speed at which readings are obtained; these were all important challenges which did not necessarily have local solutions presented. More substantive design changes could focus on alternative power and charging systems (e.g. solar charging) and '3-in-1' devices which include respiratory rate and temperature measurements.

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	Community level	Health centre or Upazila	Hospital
		Health Complex	
BANGLADESH			
Total participants	8	7	8
Job titles (number)	Community healthcare worker (8)	Physician (4) Medical officer (3)	Senior staff nurse (Associate professor ICU staff (1) Anaesthesiologist (Assistant registrar (Intern medical offic
Work experience (mean, range)	1.7 years (0.6 – 4)	2.3 years (1 – 6)	14.7 years (0.5 – 32
MALAWI			
Total participants	9	8	9
Job titles	Community healthcare worker (8) Vital signs assistant (1)	Medical assistant (7) Medical technician (1)	Clinical officer (3) Nurse midwife (3) Medical assistant (3)
Years' work	10.6 years (5 – 20)	8.3 years (3 – 23)	8.1 years (4 – 13)
experience (mean)			

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481 **Table 2:** Suggestions of desirable features or improvements given by healthcare providers

Challenge:	Design suggestion:
Probe fit	Supplied with multiple sizes of probes for different ages A single cable with multiple probes that can be changed (e.g. clipped into the cable) Softer material for a more comfortable fit
Probe placement	Probe made of transparent material so sensor placement on the nail can be seen
Cleaning	Alcohol wipes provided for easier cleaning Different colour probe to make it easier to see the dirt, but does not look dirty quickly
Power	Solar powered charger with rechargeable batteries Back-up power bank Supplied with a spare battery
Agitated children	Toy feature in the device to distract the child Improve the sensitivity of the device to be quicker Improve the sensitivity of the device to tolerate movement
Integrated spot-check device	Store results in a memory that can later be accessed Static oxygen saturation result display '3-in-1' device which includes temperature and respiratory rate measurements as well Shorter cable length for easier portability

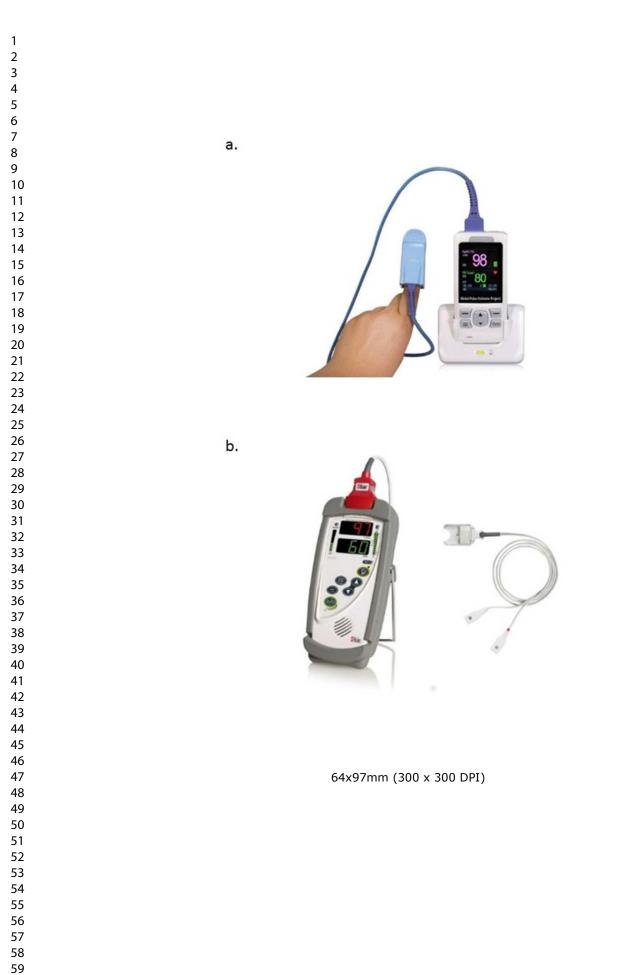
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Figure legends:

Figure 1: Pulse oximeters and probe used by healthcare providers in routine clinical care

- a. Lifebox[®] oximeter and adult universal clip probe used in Malawi (accessed on 1st July 2017
- from: www.lifebox.org)
- b. Masimo Rad5[®] oximeter and LNCS[®] Y-I Multisite wrap probe used in Bangladesh (accessed on

<text>



Web Appendix 1 – Topic Guide

- What is your experience of using pulse oximeters in children?
- What have been the main issues you've encountered when using pulse oximeters?
- What have been the things you like most about using the pulse oximeters?
- What type of probes have you used? Have any been better than others? Why?
- Thinking about the probes, we would like to hear your feedback about some aspects of using them: ease of putting and keeping the probe on the child, durability, ease of taking a reading, ease of keeping it clean and storage
- Thinking about the oximeter, we would like to hear your feedback about some aspects of using them: ease of reading the display, durability, battery life and charging, time taken to get a reading
- What things would make the probe and pulse oximeter easier to use?
- What things would make the probe and pulse oximeter harder to use?

Appendix 2: Summary of pulse oximeter probes presented during focus group discussions with healthcare providers

Probe type	Figure	Product code
Neonatal wrap		Acare ASYNR-D1
Adult clip		Acare ASANR-D1
Paediatric clip		Acare ASPNR-D1
Ear clip		Nellcor U401-2HL
Adult boot		Acare ASSNR-D1
Paediatric boot	100 March 100 Ma	Nellcor U401-2EL

COREQ Checklist

No	ltem	Guide questions/description	Page / evidence			
Do	Domain 1: Research team and reflexivity					
Pei	Personal Characteristics					
1.	Interviewer/ facilitator	Which author/s conducted the interview or focus group?	Pg 15, Author contributions			
2.	Credentials	What were the researcher's credentials? <i>E.g. PhD, MD</i>	A mix of diploma BSc, MSc and PhI			
3.	Occupation	What was their occupation at the time of the study?	Pg 6, Methods: procedure			
4.	Gender	Was the researcher male or female?	Both			
5.	Experience and training	What experience or training did the researcher have?	Pg 6, 'Methods: Procedure'			
Re	lationship with participa	ints 2				
6.	Relationship established	Was a relationship established prior to study commencement?	No			
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Pg 15, Discussior			
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. <i>Bias, assumptions, reasons and interests in the research topic</i>	Pg 15, Discussior			
Do	main 2: study design		1			
The	eoretical framework					

No	ltem	Guide questions/description	Page / evidence
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? <i>e.g. grounded theory, discourse</i> <i>analysis, ethnography, phenomenology, content</i> <i>analysis</i>	Pg 7, Methods: Analysis
Pa	rticipant selection		
10.	Sampling	How were participants selected? <i>e.g. purposive, convenience, consecutive, snowball</i>	Pg 6, Methods: Sampling
11.	Method of approach	How were participants approached? e.g. face-to- face, telephone, mail, email	Pg 6, Sampling
12.	Sample size	How many participants were in the study?	Pg 7, Results an Table 1
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	Pg 6, Sampling
Se	tting	2.	
14.	Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Pg 6, Sampling
15.	Presence of non- participants	Was anyone else present besides the participants and researchers?	Pg 6, Methods: Procedure
16.	Description of sample	What are the important characteristics of the sample? <i>e.g. demographic data, date</i>	Table 1
Da	ta collection		
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Appendix 1
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	Not applicable

No	ltem	Guide questions/description	Page / evidence
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	Pg 7, Methods: Procedure
20.	Field notes	Were field notes made during and/or after the interview or focus group?	Pg 7, Methods: Procedure
21.	Duration	What was the duration of the interviews or focus group?	Between 1 and 2 hours
22.	Data saturation	Was data saturation discussed?	Pg 14, Discussion
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	This was not possible due to language potentia barriers
Do	main 3: analysis and fin	dings	
	main 3: analysis and fin	dings	
		dings How many data coders coded the data?	Pg 7, Methods: Analysis
Da	ta analysis Number of data		-
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Da 24. 25.	ta analysis Number of data coders Description of the coding tree Derivation of	How many data coders coded the data? Did authors provide a description of the coding tree? Were themes identified in advance or derived from	Analysis Pg 7, Methods: Analysis

No	Item	Guide questions/description	Page / evidence	
Re	Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Throughout results section (pg 7 – 12)	
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	Throughout results section (pg 7 – 12)	
31.	Clarity of major themes	Were major themes clearly presented in the findings?	Pg 7, Results	
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Throughout results section (pg 7 – 12)	

of minor une.

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